IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA AB,	)	
Plaintiff,	)	
	)	C.A. No. 23-931
v.	)	
XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,	)	
Defendants.	)	

Wednesday, January 31, 2024
9:10 a.m.
Oral Argument

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE COLM F. CONNOLLY
United States District Court Judge

APPEARANCES:

MCCARTER & ENGLISH
BY: DANIEL M. SILVER, ESQ.

-and-

APPEARANCES CONTINUED:

HOGAN LOVELLS US LLP
BY: CATHERINE E. STETSON, ESQ.
BY: SUSAN M. COOK, ESQ.

Counsel for the Plaintiff

UNITED STATES ATTORNEY'S OFFICE
BY: JACOB LAKSIN, ESQ.

-and-

DEPARTMENT OF JUSTICE
BY: BRIAN NETTER, , ESQ.
BY: CASSANDRA SNYDER, ESQ.

Counsel for the Defendants

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P R O C E E D I N G S

(Proceedings commenced in the courtroom beginning at 9:10 a.m.)

THE COURT: All right. Please be seated. Before we get started, I understand there are a bunch of attorneys from D.C. who were precluded from coming in because they don't have bar cards but have electronic

equipment.

Does anybody know anything about the state of that? We tried to call down to the lobby to see if arrangements could be made to let those people --

MR. SILVER: Your Honor, Dan Silver for AstraZeneca. Our team, some of whom are from Washington, D.C., got in with no problem because they have bar cards. I don't know anything about the issue downstairs.

THE COURT: Does anybody else know? No. All right.

Why don't we have introductions.

Mr. Silver, do you want to start.

MR. SILVER: Thank you, Your Honor.

Good morning. Dan Silver from McCarter & English on behalf of AstraZeneca. And I'm joined by Catharine Stetson and Susan Cook from Hogan Lovells in D.C. And also with us today in the gallery, Your Honor, are Mariam Koohdary, "D.C.," Danelco Moxey, from AstraZeneca.

THE COURT: All right. Thank you. Good morning.

And Mr. Laksin.

MR. LAKSIN: Good morning, Your Honor. Jacob Laksin from the U.S. Attorney's Office. And with me at counsel's table is Mr. Brian Netter, Cassandra Snyder,

and Christine Coogle, all from the Department of Justice Civil Division and Matthew Campbell right behind them, from the Department of Health and Human Services, Your Honor.

THE COURT: All right.

Who's going to go first. Have you all figured that out?

Two things. So one, I just had my knee replaced relatively recently, Mr. Silver knows that, so I have to -- I can't sit for too long, so I might stand during argument. Just keep talking. Just ignore the fact that I'm standing.

And then, secondly, just give me a chance to get into the transcript for a second, please.

MS. STETSON: Certainly. While we are doing that, Your Honor, we have a small briefing book.

May I approach and hand that up? I have two copies.

THE COURT: Okay. That would be great. Go ahead.

Okay, great. Go ahead.

MS. STETSON: Good morning, Your Honor. May it please the Court, my name is Cate Stetson. I represent AstraZeneca.

We are here in a challenge to the Inflation

Reduction Act's Drug Price Negotiation Program and the guidance that CMS put in place to implement it.

We've made three claims. The first is, the statute provides that CMS may not select drug products for this negotiation process called qualifying single source drugs unless they have been on the market for a period of years. The guidance that CMS implemented lumps different drugs approved at different times together as one qualifying single source drug or QSSD subject to one price.

Second claim. The CMS -- the statute also prohibits CMS from approving a drug or continuing it in the price program if a generic of that drug has been approved and marketed. But CMS took that statutory directive and in the guidance implemented another requirement, which is that the marketing be, quote, robust and meaningful.

Third claim is of a constitutional valence. We say that the Inflation Reduction Act's combination of no comment on the front end to the guidance, no meaningful negotiation in the middle, and no judicial review on the back end combines to produce a due process violation for AstraZeneca.

So those are our three claims. The reason that we're here today --

THE COURT: Can I ask you on that last claim, so then you agree then the statute precludes judicial review?

MS. STETSON: I think the statute, as the Government interprets it, precludes judicial review. And I think in those circumstances, that would lead to our due process problem.

THE COURT: So I guess what I'm getting at, is it your position then, you only get to Claim 3 if I rule against you on Claims 1 and 2?

MS. STETSON: I think there is an independent basis for Claim 3. But I think it's narrower.

The independent basis for Claim 3 is that, even if you accept our argument that the judicial review preclusion only goes to the selection of the drug or to the determination of what drug qualifies, there's still a barrier to judicial review on even those -- on even those components. But our point is, the way the government is interpreting this, there --

THE COURT: But at that point, if I accepted that, then I presumably would have had to accept you have Article 3 standing, and so, then, you are not harmed, right, because if I accepted that argument, you're good to go.

MS. STETSON: I think if you accepted that

argument, then the guidance certainly would fail -- fall because our contention is that the guidance, as written, extends well beyond what the statutory mandate says.

So I think in those circumstances -- and the reason -- that's the reason we put our Constitutional argument last, to be candid. We think that --

THE COURT: So then, you do agree. I only get to Claim 3 for you if I find that you lose on Claims 1 and 2 because of the absence of judicial review.

MS. STETSON: I think I can agree to that with one caveat, if I could, which is the reason that there's a due process valence in this case is because of that combination of factors that we're talking about.

Our challenges on the administrative procedure side are targeted and narrow, but they don't really get at the other failings, process failings of the program.

So with that caveat, I agree that if you rule for us on the administrative procedure claims, our problems with respect to this particular drug, Farxiga, that we're talking about, would be resolved.

THE COURT: Okay.

MS. STETSON: So the reason that we're here today -- and we thank you for your accommodation to the Government's and our expedited briefing and argument schedule -- is because we are on the clock.

The Government is due tomorrow to make its initial price offer for Farxiga, the drug that we're here to talk about. We have 30 days. AstraZeneca has 30 days after that point to make its counteroffer.

That's the reason that we put in place and you've accepted the expedited briefing schedule. It's the reason we are arguing at this point, rather than at some point later this spring, because that counteroffer is what supplies the basis for our standing.

A lot of the Government's brief has to do with whether or not AstraZeneca has standing to challenge the guidance that so plainly violates the text of the statute.

The answer is, of course, it does. You know, AstraZeneca, in order to make a counteroffer to the Government's price offer coming in tomorrow, AstraZeneca needs to know what is the value of this product that we have.

The value of that product, among other things, depends on a couple of key components. One of them is, what is coming down the pipeline, as our declarant says, that might, under the Government's construction of the guidance, be treated as the exact same drug and shunted into the same price? That's going to affect our valuation of the product right now, this product,

Farxiga.

The exact same calculus comes into play with respect to our other merits APA argument, which is the bona fide marketing requirement. If this drug, as should be, is taken back out of the price negotiation after generics come on the market, which 17 of them are poised to do as our declarant points out, that affects our valuation of the drug right now because we will understand that, in the world of the statute, this drug should be taken back out of the price program after a year.

But because the CMS has chosen to interpret the statute in two very faulty ways, we are not able to make that kind of valuation. We have no idea whether the value will be higher or lower because we don't know the impact of CMS's flawed guidance on our ability to negotiate.

So we, essentially, have to walk in over the next 30 days to this counteroffer, based on a flawed definition that affects our ability to value our product. That is the reason that we have standing.

THE COURT: All right. So I'm trying to figure out the timeline here, and so the way the statute is set up, as I understand it, is you're all to engage in this back and forth, the identification of the drugs, the

negotiation, the setting of the price, and that will be completed when? The setting of the price for January 1, 2026 is completed -- is it in March of 2025?

MS. STETSON: No. I think -- let me turn -- I have some notes on the timeline, and I want to make sure I get it right.

THE COURT: Actually, is it September 1 of 2024? That's when the final price offer is made?

MS. STETSON: Yes, that's the deadline for the secretary to publish the prices.

THE COURT: So at that point --

MS. STETSON: And then my notes have March of 2025 as the deadline for the explanation of the prices.

THE COURT: Right.

MS. STETSON: So I --

THE COURT: I like that you get five months to explain your --

MS. STETSON: Explain themselves.

THE COURT: -- your decision. I should employ that more often.

But is it correct that that's it? I mean, as of 9/1/24 the price is set? Is that your understanding?

MS. STETSON: Oh, yes. And not only that, the price is set for three years. There is no further discussion --

THE COURT: When you say that it's set for three years, what three-year period?

MS. STETSON: '26, '27, '28. And then after that three-year period, there's an opportunity to renegotiate. But as you can imagine, the circumstances in which CMS will renegotiate the price are very limited indeed.

THE COURT: Right. But it's set -- just for a second. It's set for '26 and '27, but if a generic entered the market -- and just assume for argument's sake under the guidance, the revised guidance, and it was a bona fide marketing by the generic, as of, let's say January 2, 2026.

MS. STETSON: Uh-huh.

THE COURT: A generic entered the market. I guess there's no adverb for bona fide, but, you know, more than de minimis, right?

MS. STETSON: Right.

THE COURT: Such that it satisfied the revised guidance definition of marketing. And it does that on January 2nd. Then, am I correct that what happens is, you, basically, are stuck for a year plus whatever time it takes for CMS to do all its data analysis? Or is it, no, there's a bona fide marketing and there's some timeline by which that is adjudicated or determined by

CMS that we now have a bona fide --

MS. STETSON: It's --

THE COURT: And -- let me just finish up.

MS. STETSON: Sure.

THE COURT: And when is the next price that's affected by that? In other words, the way I understand this is, come September 1, 2024, you are stuck for sure with the price for 2026.

MS. STETSON: Correct.

THE COURT: And I'm going to ask the Government that too, but that's my understanding. But where I lose track of things is, what happens for what the price will be come January 1, 2027?

MS. STETSON: Yes. So let me -- the answer to your question is you asked if it was either one or the other. It's the former. It's the first part of your question, which was, when, if a drug, generic, comes on the market bona fidely in January of 2026, under our interpretation, we should be relieved from the program's price controls for 2027.

The cutoff for the generic determination is March 31 of that relevant year. So as long as CMS made a determination by March 31st of 2026, we'd be relieved from the program for 2027. If you remain in the program on April 1st, 2026, you are in it for 2027.

So the problem here is what you alluded to, which is CMS in its guidance had said we're going to look at robust and meaningful marketing, and we're going to look at 12 months of data in order to determine whether the marketing has been robust and meaningful. That data in itself takes, as you can imagine with the Government, a quarter to catch up.

THE COURT: Right.

MS. STETSON: So we're already --

THE COURT: Can I just interrupt?

And I'm going to let you go really -- I mean, we're here -- we're definitely here until 12:30 if you all want. I need to --

I'm not as up to speed as I would love to be just because I just concluded a trial last week and just our docket and whatnot.

MS. STETSON: Understood.

THE COURT: Because of the expedited nature, I want to try to give you all an opportunity to fully flesh out your arguments. But let me just interrupt though.

So given what you just said, it sounds like you're stuck at a minimum for the price for '26 and '27 because a determination -- when it comes to bona fide. The bona fide marketing determination, you would say, well, look, it can't be made until the completion of

12 months of data, right? Can't be.

MS. STETSON: That's -- yes. That's the way the CMS has gone about this in its guidance, yes.

THE COURT: Right. And then on top of that, you have to the 12 months be concluded, then you have to have some period of time for CMS to make its determination.

MS. STETSON: Right.

THE COURT: Right. And then if you, AstraZeneca, remain in the market and it comes April 1 of 2027, you are stuck for calendar year '27 as well.

MS. STETSON: We're stuck for calendar year '28.

THE COURT: Oh, '28 if it's April 1.

MS. STETSON: Yes. That's the kicker.

THE COURT: But if they make their determination -- so, if, under my hypothetical, on January 22, 2026, generic enters the market it's bona fide marketing, the worst case for you would be for two years, for '26 and '27, you pay the price that was determined or that was set as of September 1st, 2024.

MS. STETSON: I'm not sure that's the worst case. The only reason I'm thinking through the timelines here that we've been talking about --

THE COURT: When I say "worst case," assuming

CMS agreed with you. Like I said, assume as a matter of fact, it was bona fide marketing, right?

MS. STETSON: Yes.

THE COURT: So it's either going to be, again, January 2, right, right after you enter.

MS. STETSON: Uh-huh.

THE COURT: The day after, you have a bona fide entry by a generic.

MS. STETSON: Right.

THE COURT: Price is already set for 2006, so you're paying whatever was set in September 2024.

MS. STETSON: Correct.

THE COURT: Okay. Twelve months elapse. CMS, they're just the most diligent government bureaucrats that exist. They come January 3, 2027, they say this was a bona fide entry. Then the price doesn't change, or does it, for 2027 at that point?

MS. STETSON: It does not change for 2027.

THE COURT: Right.

MS. STETSON: That's the -- the relevant date is the previous April 1st.

THE COURT: Right.

MS. STETSON: So that's --

THE COURT: Maybe I should have phrased it "best," case. But come January 1, 2028, you are no

longer subject to being part of this program, right?

MS. STETSON: If CMS makes its determination after that 12 months of data, by January 2, 2027, that's before the April 1st cutoff. So we would be relieved, as in 2028. But, you know, harkening back to the timeline we were talking about earlier, let's say that CMS decides it's going to take five months to explain itself.

THE COURT: Right. Then you could --

MS. STETSON: Now, we're talking --

THE COURT: Now you're talking three years.

MS. STETSON: Exactly. Yes.

THE COURT: Right. Okay. But you're talking three years, and I take it the regs don't provide any requirement that CMS issue its decision about bona fide marketing under any timeline; is that right?

MS. STETSON: Oh, no, yeah. I mean, in fact, the opposite.

I think CMS went out of its way in the final guidance, I think it's Section 70 of the final guidance, to say what constitutes bona fide marketing is going to change. We're going to look at, you know, maybe we'll look at this particular type of data, maybe it's this data that matters. But they're not even willing to commit to a process that is categorical or uniform across the board.

And there's certainly no commitment to saying if something comes on the market on January 1st of 2026, in 90 days, we're going to give you our decision. There's no such commitment.

THE COURT: Okay. All right. Sorry I diverted you. Go ahead and pick up wherever you'd like.

MS. STETSON: Sure. I want to touch on the other threshold issues that the Government mentions because it spends so much of its brief talking about it.

And I just want to take maybe a couple minutes and lay out the array of cases on the preclusion of judicial review point because there's a lot of --

THE COURT: The statutory you're talking about.

MS. STETSON: Statutory preclusion on judicial review.

THE COURT: Okay.

MS. STETSON: There's a lot of back-and-forth in the briefs about, you know, these cases say X, these cases say Y. And I want to make one overarching point.

If you look at your briefing book at Page 12, you will see the judicial --

THE COURT: Now, this briefing book, this is like a supplemental brief you're giving me?

MS. STETSON: No, no. This is a collection of

the relevant statutory language. It's essentially the old-fashioned form of the PowerPoint that the Government will have. It's not a supplemental brief.

So on Page 12, you see at the top of the page, the statutory preclusion that we're talking about.

THE COURT: Hold on. I don't have a Page 12. Yes, I do. Oh, the Ader declaration starts, I see. Okay. Yes. On Page 12. Okay.

MS. STETSON: So you should have Page 12, limitation on administrative and judicial review. So this is not part of the Ader declaration. Right?

THE COURT: Right.

MS. STETSON: Okay. So at the top of that page, you see the statutory preclusion that we're talking about. No administrative or judicial review of the selection of drugs, the determination of negotiation-eligible drugs, a determination of qualifying single source drugs.

I want to start by comparing that to a relatively recent Third Circuit case containing a much different standard of review. This is the *United States v. Dohou* case that's just underneath that.

This has to do with an immigration statute. You can see here, notwithstanding any other provision of law, et cetera, et cetera, no clause or claim arising

from or relating to the implementation or operation of an order of removal, that is the language of the broad statutory preclusion provision.

What we are dealing with are understandably targeted statutory preclusion provisions. And I want to take a minute, just because of all of the cases that the parties have both cited, to try to break down, if it would be helpful, the cases that preclude judicial review and those that allow it because I think the distinction is really important here.

There are --

THE COURT: I will let you do it, but before you do, can you just -- I want to make sure you don't -- are you going to come back to standing jurisdiction?

MS. STETSON: I'm sorry?

THE COURT: Are you going to come back to the Article 3 standing or you just want to go right into --

MS. STETSON: I'm happy to take your lead, Your Honor.

THE COURT: Well, no. I think you should, at some point.

But let me just ask you a threshold question. So if you're me and you're really busy, you like to try to figure out the most efficient way to resolve things, do I get to Article 3 jurisdiction if I just conclude,

right off the bat, the statute precludes judicial review?

In other words, under Third Circuit law, do you think I have to address first Article 3 or can I go right to the statute?

MS. STETSON: I think it's *Trichy Steel Company* kind of question about which has to go first. I think because the statute purports to strip the Court of jurisdiction, that under *Steel Company*, would be considered equally on par with the Article 3 jurisdictional issue.

So I don't think you need to favor one over the other in those circumstances.

THE COURT: Okay. All right.

MS. STETSON: But briefly on judicial review, and then I'm happy to turn back to standing.

If you break down the cases into, you know, the list of the cases that preclude review and the cases that don't, the cases that preclude review all share something in common, and they -- almost all of these, if not all of them, come up in the Medicare reimbursement context because this is where a lot of those statutory preclusions are hiding.

They all have to do with challenges to the numbers. You used the wrong data to calculate my reimbursement rate. You should have looked at this

particular set of disproportionate share data, not the 2011 set of disproportionate share date.

The cases that find or allow judicial review ask different questions. They say, for example, in *American Clinical Laboratories Association,* your definition of laboratory, HHS, doesn't comport with what the statute tells you to do.

That's the kind of signal difference between the set of cases that preclude review and the set of cases that allow it.

Our case is, of course, in that latter category. We're not challenging, you know, you should have looked at this particular price data to choose Farxiga as your negotiation drug. You should have looked at this particular data. That's not our challenge.

Our challenge is, you have interpreted the statute in a way that is outside of your authority. And for the narrow preclusion of judicial review that we're talking about to bar that kind of basic legal definitional challenge, I think the statutory preclusion would have to look a lot more like the preclusion statute in *Dohou* than the narrow targeted preclusion we have here.

So circling back to standing, if there are no questions on judicial review, I think the --

THE COURT: I did have one.

MS. STETSON: Sure.

THE COURT: I just want to ask you one question. Let me get the briefs. Hold on a second. It's in your opposition brief, D.I. 58.

So can I just also say -- well, let me just ask you this question. So it's on Page 19 of the hard copy. So that's Page 27 of the electronic.

And you see at the top of the page there, it references Section 1192(d) and, then it says 1192(e). I'm assuming, like, that is from the original public law. I just want to make sure that's referring to 1320f-1(d). Right? It is, right?

MS. STETSON: Yes.

THE COURT: Okay.

MS. STETSON: That's -- a constant problem in this particular statute is that there's references to sections, and they don't translate into the actual code.

THE COURT: But in this one they do, right? This translate into 1192(d) does translate into 1320f-1(d), right?

MS. STETSON: I believe that's correct. Yes.

THE COURT: And then the same thing, 1192(e), that is 1320f-1(e), right?

MS. STETSON: Yes.

THE COURT: I have to tell you, both sides, the briefing was just, it was outstanding. It was really, really good briefing. It's the best briefing I've read as a judge on both sides in five years.

Anyway, I thought that was the case, so I'm going to treat it that way. All right.

All right. Now, you want to address, then, Article 3 that had to do with the statutes. I want to go back now -- you want to address Article 3 standing; is that right, next?

MS. STETSON: Yes.

THE COURT: Okay. Go ahead.

MS. STETSON: Yes.

I think in addition to the point that I started with, which is the need for AstraZeneca to understand the value of the product that it has, right now, for its negotiation process for Farxiga, depends on a couple critical inputs. One of those inputs is what else is in development for this drug that we might value very highly, were it not for the Government's overreaching definition?

The other is, what generics are poised to come on the market that might actually temper our price offer if it weren't for the fact that this was going to stay on the market?

THE COURT: I mean, doesn't that open up just an incredible can of worms? You know, defense company wants to contract with the Government to sell it some product, sell the Government some product three years from now. And, clearly, if the defense company, the defense contractor, wants to figure out the value of what that product is three years from now, there's all sorts of things it would like to understand about different defense systems that the Government might be interested in the future, what's the state of the world affairs three years from now.

I mean, that just seems to me to be -- I can't even imagine where it would lead to. It would make everything a potential injury. I'd love to understand the value of my product in the future.

I guess -- and that's not really in your brief, right? I mean, I didn't get that theme from your brief, that that was the injury. I thought your injury was the loss of economic incentive.

MS. STETSON: I think that's definitely a component of it. I wanted to start with what I think of as the nearest term harm, which is we've got to make up our minds in the next month.

We have to decide, you know, among other things whether to even engage in this process. If the

Government is to be believed, this is a process. We're going to engage in that in good faith. And one of the things we need to figure out is what's the value of this product.

But I take your point that if you were to strip out some of the factual particulars here, and just talk about this in terms of, you know, I'm a regulated entity. I have a product. I'd love to forecast how the Government is going to regulate this in five years. That would be hugely problematic, I think, for standing.

But here, there's a couple of anchors that I think help. One of them is, we are talking about a particular drug, Farxiga.

The second is, with respect to drug development in particular, as Your Honor well knows, drug development is on a long fuse. And so there are in this industry, as our declarant points out, decisions that are made now that are designed to have impact a couple years from now.

So I don't think that you could take this to some other, you know, regulated industry and say, I'm going to forecast the Government's reaction in five years; and, therefore, I have standing now. There is some concrete decisions that have to be made now, including the negotiation process, including the

investment that you talked about, including whether to negotiate at all.

THE COURT: All right. But the Government would say, look, the guidelines could change between now and '26 or '27, '28, generics could come on the market. You know, they are also operating in the blind you could argue. In fact -- and, actually, I don't want to forget; I want to ask you about this, because I don't think this is in the briefs.

There was ANDA litigation over this drug, correct, with Judge Andrews?

MS. STETSON: I don't know the answer to that, but I'm happy to find out.

THE COURT: Well, I know the answer to that because there was a published decision. I think Mr. Silver participated in that case, right?

MR. SILVER: Correct, Your Honor.

THE COURT: Yeah. And I think there what was an appeal, and it was dismissed on appeal after Judge Andrews upheld on validity of the patent, right?

MR. SILVER: Yes, Your Honor.

THE COURT: So that would strike me that there must have been some settlement reached with at least one of the generics. Was there?

MS. STETSON: I don't know the answer to that,

Your Honor.

THE COURT: So isn't that really, really critical for us to know right now?

In other words, you are telling me that it's not mere speculation that generics will enter the market at the end of '25 and early '26, right?

MS. STETSON: That's correct. There are 17 of them to be clear.

THE COURT: Is that right?

MS. STETSON: Yeah.

THE COURT: And my guess is, just because we see a lot of ANDA cases here, that, because it looks like there's at least one settlement, that you might -- your client might actually have an agreement with at least one of those generics about when it enters the market. Do you?

MS. STETSON: Your Honor, I don't know the answer to that, but I think -- and the reason that I'm pausing is because I'm searching to figure out whether or how it's relevant to the timing question that we talked about earlier.

THE COURT: Well, here's why it's relevant. Because the Government is saying, look, one of the purposes of this statute is to avoid that situation. And, actually, I should say, especially one of the

purposes of the revised guidance and its definition of marketing is to avoid the situation where some kind of agreement is reached between the brand and the generic to allow for purely de minimis marketing, which would pull the -- under AstraZeneca's definition, pull AstraZeneca off the ten drug list, but not allow for true competition; and, therefore, cause Medicare to have to pay an exorbitant price for the drug.

And you should know, I have two -- do you know what *Actavis* is, the case? Yeah. I have two antitrust cases involving *Actavis* theories, right, where the allegation is precisely this.

MS. STETSON: Pay for delay.

THE COURT: And since you are saying on one hand, I'm to accept as a matter of fact, and it's not speculation, that 17 generics will enter the market at the end of '25 and in '26, why shouldn't we all have, you know, know as well, well, what are the terms of the agreements, if any, that you all have such that you can make that statement but not necessarily disclose what are the terms of those agreements?

Now, Mr. Silver is standing.

MR. SILVER: Your Honor, I apologize for interrupting, but it may be helpful to put some concrete structure around this. There is no settlement agreement.

THE COURT: Okay.

MR. SILVER: It was a compound patent case. Judge Andrews found that they failed to establish obviousness.

THE COURT: Right.

MR. SILVER: It went up on appeal. It was a very strong decision by Judge Andrews that they weren't even close, and then the appeal was dropped.

THE COURT: Without a settlement?

MR. SILVER: Without a settlement.

THE COURT: In that case?

MR. SILVER: In that case.

THE COURT: But, and, look, I don't mean that you have to answer this, but since you're standing. And I don't know that we can just accept an attorney proffer, but is it a fact, do you know, that there have been no settlement agreements reached with any generics?

MR. SILVER: I don't know that, Your Honor. What I do believe is that the other 16 generics did not challenge the compound patent.

THE COURT: And so, then, it's not going to expire until -- well, actually, when does the compound patent expire?

MR. SILVER: I don't know that offhand. But I think what we alluded to in the brief is when we expect

the generics to enter.

I don't want to get too far over my skis.

THE COURT: No, no. That's fair. And I appreciate that, Mr. Silver.

MS. STETSON: Thank you.

THE COURT: Go ahead.

MS. STETSON: So, Judge Connolly, maybe I can make one point here that I think is important based on what you mentioned a couple minutes ago.

As you pointed out, it's the Government's guidance that suggests that this concept exists. Of course, the statute just talks about approved and marketed.

But the other thing I want to point out --

THE COURT: But you can see, incidentally, look, let me -- I mean, we're getting into the merits here, right?

But what's "marketed"? Would AstraZeneca take the position that, you know, somebody sold ten pills, and now you're off the list?

MS. STETSON: I'm going to say, yes, but it doesn't matter. And the reason it doesn't matter here is that, remember, the guidance doesn't talk about sham marketing or de minimis marketing.

The guidance talks about robust and meaningful

marketing. "Is the generic" -- and this is the guidance at Page 68 -- "regularly and consistently available for purchase through the pharmaceutical supply chain, available in sufficient quantities at community retail pharmacies?" There is a lot of meat around the idea of marketing.

If CMS had put out guidance that said, we are going to be on the lookout for sham marketing, ten pills nationwide and that's it, that might be a different story. But that's not how CMS chose to interpret marketing.

And the other thing I would point out, just to return back to the statute is, there are circumstances where CMS has or where Congress in the statute has put some similar kind of guardrails around the idea of marketing. And we mentioned them in our brief.

The common understanding of marketing, including CMS's common understanding of marketing, is that when a generic goes on the market, it is marketed, full stop.

But the other problem, I think, with what CMS has done here isn't just that it's imposed this threshold that nobody knows when it's hid until they hid it, I suppose, but it's the conversation you and I had several minutes ago, which is, even under the best of

circumstances where generics come on the market, they are marketed robustly, there is robust uptake regardless of marketing -- I guess that's the real issue, are people buying this drug? -- we still have to wait 12 months for CMS to release us from these price commitments, so it's that it's almost a one, two punch.

THE COURT: And that's why I kind of asked you to walk me through the guideline.

Let's just assume as a given that you set the price September 1, 2024 for calendar year 2026, right?

MS. STETSON: Yes.

THE COURT: And it's set, and there's nothing that can change it; even though, if the facts existed, as you say they will in 2026, you would never have qualified for the QS -- what's that acronym you used?

MS. STETSON: QSSD.

THE COURT: QSSD. Right. So, but that happens all time with Government contracting, right? We set -- and private companies do the same thing. We set a price that is going to be in effect three years from now. And we just do that. And then, yeah, events change, circumstances change, and guess what? A year and a half from now, it turns out you wouldn't have qualified for the designation such that, come 2027 or 2028, we'll have a different price. And that happens all the time.

MS. STETSON: I think what's different here, and just to be clear, we are already in the CMS tractor beam.

THE COURT: Um-hmm.

MS. STETSON: You know, Farxiga was selected for negotiation. What we're talking about is how and whether we are able to negotiate understanding what the limits of CMS's authority are on how Farxiga and its relevant, you know, active moieties, which is the Government's phrase, are going to be treated down the road.

THE COURT: I get that. I mean, that sounds like an advisory opinion. You want to know how we are going to interpret down road, this guidance --

MS. STETSON: No, I --

THE COURT: -- to guide your decisions now.

MS. STETSON: I don't think that's accurate, Your Honor, for this reason: If we were just -- if we were able freely to price our product over the next several years, and we wanted to -- we came in to you, and we said, you know, we're curious about this new government regulation that's going to hit several years down the road where, you know, we would like you to just quickly eyeball what it means for us now, that's a different story. We have to make a price counteroffer

within the next month.

THE COURT: Yeah, but you still are -- the words you used -- I wrote them down -- "freely to price our product." When are you not free to price your product?

MS. STETSON: We are not free to price our product because we are deprived of a couple key inputs because of the way the Government has gone about interpreting the statute. We're essentially working on some guidance that is, I think, flatly, textually unlawful.

THE COURT: But you're still free to price it. In fact, you're free to sell it, right? In fact, that's like a big point I'm having a hard time with and if you can show me a case, I'd love to see it.

How is any of this involuntary? You're free to do what you want. You may not make as much money --

MS. STETSON: Right.

THE COURT: -- but you're free.

MS. STETSON: Sure. I'm happy to switch --

THE COURT: Yeah, go ahead.

MS. STETSON: -- over to the voluntariness issues.

THE COURT: Well, to me, they're the same issue. You just said, you know, when you just said you

are, you said, "Freely to price our product," and I'm trying to understand. You may not have all the information you want about what's going to happen in the future and what the Government's position will be. I get that.

MS. STETSON: I think there's a difference between not having -- not being omniscient and Farxiga and its development as our declarant says, subject to unlawful guidelines that impact our decision-making now, including the counteroffer, including our future investment. You know, there's sort of a tale of injury that starts now and extends into the future.

But on the voluntariness point, I want to make two observations. The first is, the Government has not made a voluntariness argument as I read their brief, when it comes to these administrative procedure, statutory authority arguments.

The voluntariness argument has to do with that due process argument. And I will say a couple of quick things on that. The first is, we point out in our reply brief, it is a tell, I think, that the Government's voluntariness cases all come from the takings world. And that makes some sense as a practical matter. If you're about to complain that the government should be paying you for something and you voluntarily engaged in what

you're giving the Government, you shouldn't expect payment for it.

But if you look at the Government's -- one of the Government's cases that it cites, that Supreme Court case long time ago, *Bowles v. Willingham*, 321 U.S. 503, the Government cites that case for the proposition that you can't claim a taking if you have voluntarily engaged in something. So in that circumstance, it was a landlord, and Court said, for takings purposes, the fact that the landlord voluntarily chose to make his property available for rent means it can't be subject to a takings claim.

And then you should look at Page 519, because what the Court went on to do was to make a due process analysis separate from the taking claim that had nothing to do with voluntariness.

So our point here is, to the extent that this is voluntary -- and there's a lot of, you know, discussion that we can have on that -- it is not relevant to a straight due process claim.

The only case that the Government cites for that purpose is that *Chamber, Dayton Chamber* case from the Ohio District Court, but the Government in that case, if you look at its briefing, explains that what the *Dayton Chamber* was doing there is really a takings claim

in due process clothing.

So really, on that side of the ledger, all they have is takings claims. On our side of the ledger, first, it's the dog that didn't bark; there's no due process case that talks about voluntariness.

And second, in the Government's own cases, *Bowles v. Willingham* shows that difference. Voluntariness is pertinent to a takings claim; it has no relevance whatsoever to a due process Claim.

THE COURT: Well, what's the property interest for due process? You need a property interest, right?

MS. STETSON: Yes.

THE COURT: Okay.

MS. STETSON: Yeah.

THE COURT: So what's the property interest? And you need a deprivation of the property interest, right?

MS. STETSON: We do.

THE COURT: So how does that differ from a takings issue, and then can you show me a -- can you just cite me a Supreme Court case or a Third Circuit case that addresses that?

MS. STETSON: Sure. So the Third Circuit case, I think I'd cite you to, I believe it's *Fein*, F-E-I-N. It's in our brief. But it stands for the

proposition that there is, you know, before the \depravation\deprivation of any property interest, you need a notice and a meaningful opportunity to be heard, so basic principles.

As far as our property interest, we cite Supreme Court cases going back 100 years for the proposition that a patent held in a particular product, a drug product, is a property interest.

And I would pause here and say that one of the gaps in the Government's briefing is that, by putting all of its eggs in the voluntariness basket, it really didn't contest that there was a property interest, that this quasi negotiation process deprives AstraZeneca of the opportunity to sell this particular patented drug product at a price that it would get in the market.

So those -- the interest and the \depravation\deprivation are all things that the government glossed over in favor of this overarching voluntariness theory.

THE COURT: All right. Let me ask you, then, I do see, to be candid, a bit of a moving target.

What's the property interest that you allege AstraZeneca is being deprived of without process?

MS. STETSON: It is the -- it's two parts. It's the interest in our patented product being sold on a

fair market at a price that the product would command.

THE COURT: Doesn't the patent expire in 2026? I mean, didn't you just say that? Didn't Mr. Silver -- he didn't say an exact date, but don't your briefs effectively say that?

MS. STETSON: I think there are patents and exclusivities that expire in 2026, yes. But we're here talking about a patented product now in 2024.

If I could make one other point on due process and voluntariness, just because I don't want the voluntariness issue to get lost completely. To the extent that voluntariness plays any role in the due process inquiry, which for all the reasons and for *Bowles* and everything else, it doesn't. If it does, I would like to ask the Court to consider what I think of as the immense disproportionality between what AstraZeneca is being asked to do here and the consequences if it walks away.

So, you know, unlike a situation where a doctor can say, I choose not to treat Medicare patients, this is the situation where we can't just say, I choose not to offer Farxiga into this program. If we walk away, all of our products nationally come with it. We cannot participate in either Medicare or Medicaid with respect to any AstraZeneca drug products. And it's that seismic

disproportionality that I think makes this coercive.

You know, there's a difference between engaging in a negotiation with the Government where, you know, the government is pinching your arm a little bit; this is breaking your arm. And if you look at the Government's briefing in the Supreme Court, in the *NFIB* case on the Medicaid issue -- because there's lots of briefing in the Supreme Court in that case.

The Government's response brief on the Medicaid issue makes exactly the same arguments that it's making here. Medicaid is voluntary. A state can choose to walk away from it. The fact that it might hurt a little bit is really irrelevant because Medicaid is a voluntary program.

And what the Supreme Court majority said was, there's voluntariness, and then there's coercion. And where you have a Government hammer that is going to, essentially, deprive AstraZeneca, as our declarant says, of a vast percentage of its drug consumers -- to their detriment as well I might add -- that is coercion. That is not a voluntary --

THE COURT: Coercion happens all the time. Taxes are coercion, right? We have sin taxes; they're not unconstitutional. I mean, that's coercion.

MS. STETSON: I'm trying to think about a

quick analogy to that. So let's suppose that you have a sin tax. I go and buy a bottle of bourbon. The bourbon costs $10. The tax is $100,000. That's coercive.

THE COURT: Yeah.

MS. STETSON: That's what we're talking about here. If you have a circumstance where we can pull our drug from this negotiation only at --

THE COURT: Is there any case that says, that has held that a tax violates due process because it's too high?

MS. STETSON: I don't know the answer to that exact question, whether a tax violates a due process because it's too high. I think the analogy here is to *NFIB* because what we're talking about is a coercive Government program that essentially hammers a participant if it attempts to exit the program.

And what the Supreme Court in *NFIB* said was that is over the line. Wherever the line is, this is past it I think is how the majority put it. And I think it's telling that the Government, in its *NFIB* brief, makes the same flavor of arguments that it makes here.

Now, Mr. Netter is going to stand up, and he's going to say *NFIB* is different. That involved a state, this involved a private entity. That's nowhere in the Supreme Court's decision.

The Supreme Court didn't say, this is a special coercion rule only available to states. Coercion is coercion when you're dealing with the Government. So on that due process point, I think the two takeaways are voluntariness isn't relevant to due process and even if it is, this is not voluntary. This is coercive.

THE COURT: All right. Can you go back, you know, I'm still at -- the property interest -- I think I've got -- I'll go back and look at the transcript.

Did you want to say anything else about what the property interest is of AstraZeneca? At the beginning, you were talking -- you led off, really, saying that the injury, which I think is essentially the same thing as the property interest, right, that you are talking about?

MS. STETSON: Uh-huh.

THE COURT: -- is the inability to assess the value of the products to make a counteroffer.

MS. STETSON: Yeah. That's the nearest term injury. You know, then there's the injury you mentioned as well.

THE COURT: I think you should give me the universe. Because, like I said, you know, I came away from the briefs that the first injury was this loss of economic incentive to develop the product. And,

basically, you know, for other uses. But am I wrong on that?

MS. STETSON: No. I think there is an allegation of that injury as well. You know, I had a mentor who used to say, Nothing sharpens the mind like argument preparation.

THE COURT: Right.

MS. STETSON: The thing that struck me about the nearest term injury is this need for AstraZeneca to understand the value of what it is holding right now in order to negotiate right now.

But you're absolutely right. There is, as I think of it, a longer tail injury, and that is how are we going to make investment decisions, including in products, as our declarant says, that we are currently developing, with the same active moiety as Farxiga if we understand -- why would we invest if we understand at the end of the day, if that product makes it all the way through the gauntlet, subject to a separate NDA, it immediately gets shunted into the maximum fair price program.

THE COURT: And how is that not pure speculation and -- maybe not even speculation, but not tied to current reality?

I mean, this is what your witness, Mr. Ader --

is that how you pronounce it?

MS. STETSON: Yes, I believe so.

THE COURT: Right.

He says in Paragraph 23, "While clinical trials are currently focused on combination product therapies that would not be impacted by the agency's definition of qualifying single source drug, there are other ongoing drug development efforts involving the same active moiety as Farxiga, where one development pathway could result in the product being treated as the same QSSD as Farxiga, under CMS's position."

I mean, the second part of that sentence, I would -- my take on it is there's some possibility, you know, it could result. That's speculation.

MS. STETSON: Right.

THE COURT: But the killer for you, I think, is the first part, which says the clinical trials current, the current ones, wouldn't be impacted. What you're developing right now, currently, would not be impacted by the agency's definition.

Not only are you, basically, as I understand your theory you are articulating this morning, which is, we want to be able to value the product, your current plans for the product aren't going to be impacted at all by the agency's current guidelines.

MS. STETSON: I don't think that's entirely accurate.

THE COURT: All right.

MS. STETSON: This is something the Government fastens in on that I don't think is relevant.

The first part of that sentence talks about clinical trials. Second talks about other ongoing development efforts.

So what we're talking about are two things that are both currently going on. One is just further down the pike than the other.

THE COURT: But you said "could result." And, incidentally, should I hold it against you?

I mean, you don't -- it's a very vague sentence. Quote, "ongoing drug development efforts involving the same active moiety." Right, so that's vague. And then, quote, "could result in the product being treated," unquote.

I mean, I'm supposed to say that's a concrete harm that gives rise to jurisdiction?

MS. STETSON: I hear you on the "could," but let me make this observation.

The declarant, of course, is not a lawyer. From the declarant's perspective, you know, the declarant is not able to point out what we can point out, which is

a drug involving the same active moiety as Farxiga is, under the Government's guidance, going to be treated as the same QSSD. The fact that Mr. Ader couldn't make that legal determination is understandable.

THE COURT: Am I supposed to accept that he's not a lawyer and that's probative? I mean, my personal experience as a lawyer and as a judge is, would suggest there's a good chance a lawyer drafted or certainly participated in the drafting of his declaration.

I mean, should I infer any facts about that, that he's not a lawyer? I mean, doesn't say he's not a lawyer either.

It's summary judgment, right? You're asking me to make some kind of -- I'm supposed to assume the facts are not in dispute. I don't know. I mean, should I really place any value, to use your word, on the fact that you just said he's not a lawyer?

MS. STETSON: No. I don't want you to over -- you don't need to overemphasize that. My point was that could result in those circumstances is not some kind of a weaselly hedge word.

But, you know, for our purposes, and for AstraZeneca's purposes valuing Farxiga right now, the takeaway from that Paragraph 23 is that there are development efforts underway. Even if we take the

"could," that could result in this being treated as the same qualifying single source drug, and that affects our decision right now to negotiate, to negotiate offering a particular price, and to accept that price. That's the immediate harm.

And then the longer term harm, as you mentioned earlier, is the idea that, depending on the Government -- whether the Government's unlawful definition sticks, we are forced to make investment choices now about what products to pursue, what indications to pursue, in what order, all because the Government has taken it upon itself to interpret drug, not through the pathway that the statute directs in terms of definition, but to introduce a brand-new phrase that you will look in vain through the statute to find, which is this idea that the active moiety controls, regardless of how many NDAs get lumped in together. That is a complete aberration when it comes to what the statute directs.

THE COURT: But the statute does refer to plural approvals, right?

MS. STETSON: It does, but I -- short answer is yes. But it refers to plural approvals. But, of course, approvals can also be an approval of an SNDA, a supplemental NDA, as the Court knows.

THE COURT: But the particular passage in question doesn't refer to supplemental. It just says "approvals," right? I mean, it's -- let me see if I can find it.

So I'm looking at 1320f-3(e)(1)(D).

And so the manufacturing-specific data that's supposed to be submitted for consideration includes, quote, "data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications, plural, and approvals, plural, under Section 355(c) of Title 21 or Section 262(a) of this title." Right? Now, that could include supplemental NDAs. That's your point, right?

MS. STETSON: It's one of my points.

THE COURT: Yeah.

MS. STETSON: The other one is, and you'll see this, this is a harbinger of Slide 14 in the Government's presentation.

That provision that you just read begins with, "The following data with respect to such selected drug," singular.

And what it ends with, right after it says "under Section 355(c) or 262(a) of this title for the drug."

So what the Government is doing is essentially

moving the lens away from how do we define the drug, and looking at everything after that. There's --

THE COURT: Actually, drug -- Sorry.

MS. STETSON: -- approvals?

THE COURT: Sorry. Go ahead.

MS. STETSON: No. Please.

THE COURT: Is drug defined in the statute?

MS. STETSON: Yes.

THE COURT: Okay. And what does it say?

MS. STETSON: So if you look at our briefing book, we -- this is a classic congressional navigational exercise, but Page 3 of your briefing book, Qualifying Single Source Drugs. This is 42 U.S.C. 1320f-1(e).

For purposes of this part, the term "qualifying single source drug" means, with respect to an additional price applicability ear subject ... a covered Part D drug as defined in Section 1395w-102(e) of this title.

THE COURT: Right.

MS. STETSON: So turn the page.

Page 4. Covered Part D drug defined. The term "Covered Part D drug," means a drug that may be dispensed only upon a prescription. And that's described in subparagraph (A) (i), (ii), or (iii). Turn the page to Page 5.

"Covered outpatient drug means," it lists a number of drugs. And then turn to Page 6, Single source drug, which, of course, is part of qualifying single source drug, means a covered outpatient drug, already defined.

And then if you look about five lines down, "which is produced or distributed under a new drug application approved by the FDA."

So that's perhaps not as long a path as some congressional paths, but what you get to the -- when you get to the end of that, the takeaway is --

THE COURT: Wait. Actually, hold on. Hold on.

Where is it limited to a single new drug application? Can you show me that?

MS. STETSON: If you look at Page 6 of the briefing book, it's subprovision 7(A)(iv), single source drug. Four lines down a covered outpatient drug, which is produced or districted under a new drug application.

THE COURT: This is a definition -- hold on -- for a single source drug.

MS. STETSON: Correct.

THE COURT: Okay. But I asked if there was a definition of "drug."

MS. STETSON: So the definition of drug is

everything that we discussed preceding that. It reduces down to covered outpatient drug and --

THE COURT: Right. So how does it get from covered outpatient drug to single source drug?

MS. STETSON: I think it gets to single source drug by way of what -- of course what we're talking here is only single source drugs. Those are the only things that qualify.

So we first define "drug," and then we look at single source drug. And let me make, maybe, a more important point.

THE COURT: No. No. Actually, I want you to make the point about drug.

Because here's the thing, again, we do ANDA cases here all the time. The reality is people refer to "drug" in multiple ways. And a lot of times, everybody knows what people are talking about when they refer to "drug," both for legal and for medical reasons, it means the active moiety. And so that's why I actually would like to see the definition of drug.

I think your best argument is, and I'll wait for the Government, but I'm really trying just to explore this to learn, but where is the definition of "drug" anywhere in the statute or in a reg, that limits it to a product covered by a single NDA?

MS. STETSON: I think the best I can show you for the textual analysis is what we just walked through.

THE COURT: All right.

MS. STETSON: So Pages 3 through 6 of that briefing book. The qualifying single source drug is defined with reference to another statute, which is defined with reference to another. And that drug product, when you're talking about single source drug, means an NDA.

But let me make two other points on this, if I could. The first is, that's not the only textual clue that we have in the Inflation Reduction Act about how this is supposed to read.

THE COURT: Right.

MS. STETSON: Right? One of the other provisions -- this is 42 U.S.C. 1320f-1(e)(1)(B).

Statute talks about if FDA approves a new drug under Section 355(c) and at least 7 years have elapsed since the date of such approval, or with respect to a BLA, such licensure.

THE COURT: Right. This is (1)(A), incidentally. This is not (1)(B). Right? (1)(B) is biological product.

MS. STETSON: Oh, that might be --

THE COURT: But I think this is your best

argument, right? It's talking about the date, singular, of such approval.

MS. STETSON: Yes.

THE COURT: So we're talking about one approval.

MS. STETSON: We're talking about one approval, the date, such approval, the drug.

THE COURT: Right.

MS. STETSON: What the Government is doing, I think -- there's a couple of different things at work.

Remember first, that the guidance is talking all about active moieties. However you choose to pick your way through those provisions that we just talked about, the words "active" and "moiety" appear nowhere in those statutes. So that's problem Number 1.

Problem Number 2 is when the Government tries to make a textual argument, what they're doing, as I alluded to before, is looking at things that are happening after the selection of the drug. The drug subject to such approval. They're looking at, you know, what are the drugs -- the drugs approvals, what are, you know, the forms and dosages of the drug. But all of that depends on the question about what's the drug that you're talking about.

And our point here is when you line up the

statute against the guidance, which you also have a few pages further in your briefing book, there's simply kind of an undeniable cognitive dissonance between talking about the drug, such approval, and talking about active moiety regardless of the number of NDAs and so on and so forth.

The whole idea behind this, of course, is to try to lump in as many different products as possible under that maximum fair price. But that's not the way that Congress chose to write this.

There is, as you've mentioned, a role for active moiety in some certain drug product discussions and when that occurs, the FDA's statutes talk about active moiety having a role. But here, the way that the IRA, Inflation Reduction Act, chose to go about it, the Inflation Reduction Act puts its emphasis on "the drug" and "such approval." That's what creates that statutory overreach that we're arguing about.

THE COURT: All right. So here's your last chance, I just want to make sure. Give me the universe of the property interests that you say is at issue such that AstraZeneca has a cognizable harm that gives rise to subject matter jurisdiction.

MS. STETSON: It is our property interest in our patented drug Farxiga.

THE COURT: And when do the patents expire for Farxiga?

MS. STETSON: I think the patents and exclusivities expire two years hence, if I remember correctly.

THE COURT: All right. And then, you know, you all decided to present this to me in this procedural posture of competing summary judgment motions. And as I understand the stipulation, it was to forego preliminary injunction litigation. Is that a fair summary?

MS. STETSON: That is fair. Yes.

THE COURT: Now, if we were in a preliminary injunction posture and you asked specifically for preliminary injunctive relief in your complaint, I would be looking, among other things, at irreparable harm, or alleged irreparable harm, and I would think in such situation, I'd probably have affidavits that told me how much money AstraZeneca is spending to these -- in furtherance of these, quote, "ongoing development efforts." There's none of that.

I mean, there's no -- the harm you're pointing to is, it's broadly, if not vaguely, stated. It's conclusorarily stated. And I'm almost tempted to, you know, question, well, why that lack of supporting fact that I would expect to see in a preliminary injunction

proceeding isn't enough just to say, yeah, where's the harm? And did you meet your burden to establish a harm?

MS. STETSON: Two responses, Your Honor. The first is, we and the Government, with thanks to the Government, agreed not to light your busy docket on fire a few months ago. And we were able to negotiate and agree on this expedited posture precisely to avoid having to go through the rigmarole, for you and for us, of a preliminary injunction hearing.

So that's why we don't talk about it in terms of irreparable harm anymore. It was in our complaint, of course, because that was the first thing we filed. But we're past that juncture.

THE COURT: Wait, wait. We're past prelim- -- You're still seeking permanent injunctive relief.

MS. STETSON: Yes.

THE COURT: Okay. So I still have to address irreparable harm under that, right?

MS. STETSON: Yes. So as to harm, I think what I would point you to, again, is the Ader declaration. We are, you know, it is difficult for us on a public record to talk about, you know, the amount of investment in a particular product, but our point is, our choices about investment are being damaged by the Government's statutory overreaches here.

And irreparable harm, you know -- or let's say, "harm," since we are past irreparable, it doesn't have to be for standing purposes much. It just has to be something.

So for these purposes, to the extent we're going to look at the monetary investment side, we shouldn't have to come in and say, you know, we're investigating X hundreds of millions of dollars in a particular line of research.

It should be enough to say we are making these choices because we are forced to make them based on the Government's statutory overreach.

THE COURT: Right. But the order that you've submitted me to sign calls for you -- calls for a permanent injunction.

It says, "The Court further orders that defendants and their officers, agents, servants, employees, and attorneys, and other persons who are in active concert or participation with the foregoing persons are permanently enjoined from implementing or enforcing the Drug Price Negotiation Program."

So, you know, you're asking for a permanent injunction, but nobody is telling me or offering me any ability to address a specific element of what you need to have to get a permanent injunction, which would be

irreparable harm.

MS. STETSON: So that is one form of the relief that we are seeking; you are right. And that's the broadest form of the relief that we're seeking.

And that, in a way, circles all the way back to the beginning of our conversation, which is, you know, if we are at the point where you are considering enjoining the implementation of the entire Drug Price Negotiation Program, we are at the point where we have registered a constitutional harm. And that is the harm that we would be talking about in that injunctive circumstance.

The other relief that we seek in that same proposed order is vacate the guidelines; vacate the guidelines, declare this interpretation of qualifying single source drug as beyond the statute, just as a plain legal matter. Declare the interpretation of "marketing" as bona fide --

THE COURT: Hold on. Sorry. I think you said the relief is I vacate the guidelines, but that's not the relief you've asked for. It's you want -- so you've got a declaratory judgment.

MS. STETSON: Yes.

THE COURT: Which is I would declare it unconstitutional, or I would declare the regulations to

be in violation of the APA. I get that, okay. And that is part of what the complaint seeks as relief. And I get how these summary judgment briefs tee up those issues. I get that. And I think there's enough for me to make some determinations about those and whether there's jurisdiction, right?

MS. STETSON: Right.

THE COURT: Okay. And from the Government's point of view, it would be -- I don't have the order in front of me, but I'd dismiss for lack of jurisdiction the whole complaint, right?

I assume is that what you're asking for? Is that in your order, sir?

MR. NETTER: It is, Your Honor, except we are asking for dismissal only on the APA claims.

THE COURT: And, actually, that's true. So it would be a partial dismissal. I would just get rid of Counts 1 and 2. So I just want to figure out the procedural posture of the case.

Because I think you all are assuming I'm going to rule and this is going up to the Third Circuit right away. But I don't know that you'd have a final order to go to the Third Circuit, even if I granted your side of the ledger is what I'm getting at. Because you are seeking an injunction, and I don't think you've really

teed that up issue up for me. And if you think otherwise, let me know.

I see where you've teed up the declaratory judgments that you are asking for. And so if I only ruled on the declaratory judgment action, assuming I ruled your way, so what then?

I mean, is the case still ongoing on the injunction, the injunction relief you've asked for? I mean, where does it stand procedurally?

MS. STETSON: I think there's probably a few different combinations and permutations --

THE COURT: Right.

MS. STETSON: -- of the answer. If you were to rule in our favor on -- meaning you would grant us summary judgment on our APA claims, but decline --

THE COURT: You keep saying that. So granting summary judgment, what do you mean, right? Summary judgment on what? I mean, summary judgment on a declaratory judgment? Summary judgment on a permanent injunction?

MS. STETSON: Summary judgment on a declaratory judgment with respect to the APA claims.

THE COURT: Okay. So let's say I issued an order, and I said that the APA -- or rather the QSSND is -- well, A, I would have to say I have jurisdiction;

B, the statute doesn't preclude judicial review; and, C, you prevail on Claim 1 insofar as it seeks a declaratory judgment.

All right. Let's say I stop there. What next?

MS. STETSON: If we prevail on Claim 1, insofar as it seeks a declaratory judgment, and you find that we haven't established sufficient harm to warrant an injunction --

THE COURT: Well, you haven't even -- where is any briefing on an irreparable harm?

MS. STETSON: I think the Ader declaration contains the best factual averments as to that. Because we, in terms of harm, what we are alleging is harm to our investment decisions. We are not meaning to quantify it in that respect.

THE COURT: Okay. So it goes back to unquantified investment decisions?

MS. STETSON: Yes.

THE COURT: Okay. But they're unquantified; you admit that?

MS. STETSON: I do, yes.

THE COURT: All right.

All right. Let's hear from the other side.

THE COURT: Actually, does the court reporter

want a break?

Let's take a break. We will come back in about eight minutes or so.

(Whereupon, a recess was taken.)

THE COURT: Please be seated. Before you start, I just want to do a follow-up question.

So the property interest is the patented product, right?

MS. STETSON: Correct, yes.

THE COURT: The patents, according to the declarations, expire '25, late '25 or 26; is that right?

MS. STETSON: The patents expire, yes. And I think --

THE COURT: So your property interest -- is it fair to say, then, as I understand your position, your property interest goes away when those patents expire sometime in '25, '26. Is that what you are saying?

MS. STETSON: I'm not going to go so far as to say that for two reasons, if I could.

The first is, you know, that puts us really between a rock and a hard place, because one of the things that the Government is saying is that we don't yet have standing to complain about our property interest being compromised.

And the second is, it's the patented product,

it's the drug product that we own. We're still going to own the product even if the patent goes away. And --

THE COURT: Well, then why did you say, "patented" if it's just the drug product.

MS. STETSON: Well, because, I think for -- as I mentioned, for a hundred years, the Supreme Court has said the patent, in particular, is also a separate property interest.

But I think it's -- if you think of it as the typical bundle, it's a bundle of interests. It's the patent. It's the product. It's the patented product.

If I could while I'm here.

THE COURT: Well, hold up. But see, now, there's an Orange Book, right, and there are lots of patents that are listed for this drug in the Orange Book that don't expire until way after 2026, right?

MS. STETSON: Yes, I believe that's correct.

THE COURT: And isn't the real property interest, it's the -- or what you are hoping will be a property interest is that you would be able to develop further exclusivity through new NDAs that would extend, or that would extend your exclusivity, and, in fact, as part of that, it's because you've -- right now you've said the only two patents or the patents at issue expire in '25, '26. What you are hoping to do is to develop new

uses of drug that might be covered by other patents in the Orange Book that would extend your exclusivity beyond 2026.

MS. STETSON: I don't think that's an argument that we've made with respect to our property interest.

THE COURT: Well, isn't -- see, that's what confuses me, because I, again, I didn't hear, I didn't see in your briefs the argument you made at the outset about the property interest is, the value to negotiate this month or in the coming 30 days. I thought it was loss of economic incentive. And the loss of economic incentive is to go out and develop further exclusivity for the drug, isn't it?

MS. STETSON: I see. I see. So I think there are two different concepts. And if you think about them like a Venn diagram as I often do, maybe they overlap a little bit. When we talk about standing and we talk about harm, our harm is that set of circumstances we've talked about: \depravation\deprivation of information we need to negotiate right now. \depravation\deprivation of our incentive to further invest.

The property interest -- for purposes of our due process argument, our property interest is in the drug product, the drug product that we hold right now.

So it should not matter to this, you know,

property interest due process discussion whether or not there's going to be some point way down the road where we have a different bundle of property interests in Farxiga than what we hold right now. So standing and property interest, I think, are two slightly different concepts.

If I could make one more point just where we left off on the injunction issue, I want to make sure we're clear here. If you look at the end of our complaint, we ask for a declaration that the interpretation of "qualifying single source drug" is unlawful. We ask for a declaration that the interpretation of "bona fide marketing" is unlawful. We ask for -- and that's Sub C, I think, of our remedies -- we ask for vacatur of the --

THE COURT: You ask for that in your complaint. You don't ask for that in your order for summary judgment, I don't believe, did you?

MS. STETSON: I think we do in the proposed order.

THE COURT: All right. Let me look at it because I didn't see it, so hold on. Oh, okay, "the guidance documents be set aside and vacated." Okay.

MS. STETSON: Yes. And that pertains to our administrative procedure claims. Then the injunction comes into play only if you declare the IRA

unconstitutional for due process reasons. And that injunction, just in an APA case, the injunction involves from that declaration of unlawfulness. There's no separate inquiry that has to occur. The injunction, as an administrative procedure matter, follows from that declaration. So that's what makes it a somewhat different animal, I think. But on the last point, I just wanted to tie that up in a knot before we left off.

THE COURT: I'm not sure that helps me understand things. The complaint seeks preliminary injunctive and permanent injunctive relief barring defendants from applying the drug pricing provisions of the IRA to AstraZeneca.

So, for instance, even if I agree with you on Claim 1 and Claim 2, but I disagree with you on Claim 3 -- well, wait.

MS. STETSON: Then we --

THE COURT: They're not moving to dismiss -- see, they're not moving to dismiss Claim 3.

MS. STETSON: Correct, yes.

THE COURT: So --

MS. STETSON: So if you -- I'm sorry to interrupt.

THE COURT: No.

MS. STETSON: If you agree with us on Claim 1

and 2, that would mean that you would grant summary judgment for us on the administrative procedure claims. And the remedy that follows from that is the vacatur of the guidance.

THE COURT: Okay.

MS. STETSON: If you disagree with us on the due process argument --

THE COURT: Hold up. But I think you've already said if I agree with you on Claims 1 and Claim 2, you're saying I don't get to Claim 3.

MS. STETSON: I don't think you need to get to Claim 3. I think -- I think --

THE COURT: Okay.

MS. STETSON: I think then -- the work that the due process argument is doing -- this is what I was trying to articulate before -- there is almost an overarching constitutional violation here, that we get no comment on the front end, as I said, no discussion in the middle, no challenge on the back. But in our -- the way that we have narrowly targeted this case, that due process violation is pertinent to AstraZeneca right now because of what AstraZeneca is being asked to do right now.

So if you agree with us that the guidance is unlawful and should be vacated, I don't think you need to

reach that constitutional question. That's why we ordered it in the way that we did.

I think it's relevant to your thinking about this case to understand the highly unusual nature of it, but I don't think you need to get to it. And even if you do, at the end of the day, the only reason that injunction would come into play is actually if you agree with us that there's a due process violation.

So that's the permutation I mentioned earlier. You would have to disagree with us on both administrative procedure counts, agree with us on due process, declare the IRA unlawful because it does not permit sufficient process to the regulated entity, and then the injunction would flow from that. And I'm sorry to sidetrack us back again, but it felt like we left off on an unfinished note.

THE COURT: It's not finished in my mind, at least, even with this. So I give you the declaratory judgment you're seeking in Counts 1 and Count 2, I order the guidance documents to be set aside and vacated, and I don't address Count 3. All right.

MS. STETSON: Yes.

THE COURT: Because under your theory, I don't have to. And the Government is not moving to dismiss Count 3.

So you're saying I only issue an injunction if I get to Count 3. That's what you're saying?

MS. STETSON: Correct.

And I think what Mr. Netter would say if he were here is that they're not moving to dismiss Count 3, but they're moving for summary judgment on Count 3. They're not moving to dismiss on standing grounds, but they are moving for summary judgment. They have filed a cross-motion that seeks to dispose of all of the claims, two of them on standing or judicial preclusion grounds, one of them on its merits, the constitutional ground on its merits.

THE COURT: All right. So then your proposed order, you would actually revise it. I would just delete the paragraph that says, "The Court further orders that the defendants and their officers are permanently enjoined."

You would say, don't do that, if I agree with you and would sign the order of the first four paragraphs. Is that what you're saying?

MS. STETSON: I think you could, yes.

THE COURT: What do you mean I could? Of course, I could.

What do you want me to do?

MS. STETSON: I'm hedging. I'm hedging only

because of what I mentioned earlier.

For AstraZeneca's purposes, the due process, the immediacy of this entire procedure is what constitutes the due process violation. We, of course, had no opportunity to comment on this unlawful guidance. We're in the, as I said earlier, the tractor beam of this negotiation process.

THE COURT: So let me just ask you, if I set aside the guidelines, what happens next?

Do they need guidelines to -- do they have to have guidelines before they pick these ten drugs?

MS. STETSON: Yes.

THE COURT: They do.

MS. STETSON: The statute requires them to issue guidelines to implement the drug price negotiation process.

THE COURT: They cannot issue without guidelines. Okay. And then the guideline period, the review period is how long? Is that in the statute?

MS. STETSON: No. There's no review period, I think, set forth in the statute.

THE COURT: So they could issue guidelines an hour after I ruled that these guidelines are vacated?

MS. STETSON: They could, yes. And if the guidelines hued to the statute, we would have more of a

problem.

THE COURT: Okay. And let's say they issued the guidelines, and they said, oh -- because there's no other NDA for Farxiga, right?

MS. STETSON: There's no other NDA for Farxiga right now, yes.

THE COURT: Well, you've got the only clinical trials that you have that are ongoing according to the Ader declaration wouldn't impact the guidelines, right? It wouldn't have any impact on this case?

MS. STETSON: I think that's that distinction we were talking about earlier between focusing on the clinical trial stage and focusing on the development stage.

THE COURT: But let's focus on the clinical. The clinical trial is the last stage of a development, right?

MS. STETSON: Correct.

THE COURT: So if you've got no ongoing clinical trials and I were to vacate the guidelines tomorrow, all right, and an hour later after I issued my opinion, they tweaked something about the guidelines. And let's say they said, oh, yeah, the drug has to be limited to a single NDA. You win Claim 1. Let's say they said it.

MS. STETSON: Right.

THE COURT: All right. Farxiga falls under that; they only have one NDA. So you could be picked an hour after I issue my ruling.

MS. STETSON: That would be the Government's argument, yes.

THE COURT: Well --

MS. STETSON: The Government's argument is Farxiga is already in there.

THE COURT: Actually, can you disagree with that argument?

MS. STETSON: If we're in this counter-factual world where the guidance hues to the statute, then I don't think I could disagree with the argument. The reason we're --

THE COURT: Well, okay. And don't you admit that -- I mean, under your reading of the statute, the drug has to be limited to a single NDA, right?

MS. STETSON: Yes.

THE COURT: Okay. And Farxiga, undisputedly, is limited to a single NDA, right?

MS. STETSON: Yes.

THE COURT: All right. So I issue my order tomorrow. AstraZeneca, that Stetson, she's amazing, she persuaded me, I'm good. For claim 1, she wins, DJ on

that count. I'm going to vacate the guidance on that part of it.

And an hour later, they switch the guidance to say, yep, it's got to be a single NDA; Farxiga you are still on the list. Right?

MS. STETSON: I think that would be a rare thing, indeed, for the Government --

THE COURT: To move that quick.

MS. STETSON: -- to issue guidance the following day.

THE COURT: But they could. So doesn't that show you're not harmed? There's no harm for Claim 1 for you.

MS. STETSON: I don't think that's accurate. I think the fact that harm could be remedied at some point after the fact is a completely different issue. But we are harmed right now because of the unlawful interpretation right now.

If the Government were to do that, and let's, you know, put aside the fact that, you know, as you and I talked about a while ago, the Government is taking five months even to explain why it set the prices where it is. But let's assume the government comes back the day after tomorrow and says, here's new guidance that's completely in concert with the law. There's nothing to see here.

If we were to come back at that point and file another lawsuit making the same allegations, we wouldn't have standing because, for these purposes, the statute, you know, we fit the statute, and the statute, you know, the guidance doesn't go beyond the statute.

But that's a -- I mean, talk about speculation. That's a future-looking set of circumstances that might diminish some future allegation of harm. It has no bearing on the current set of circumstances. It's the -- I don't want to say, as lawyers often do, that's just a hypothetical, but, you know, our present circumstances are that the guidance is unlawful in two different ways for the same reason, they go outside the statute.

THE COURT: Right.

MS. STETSON: And Farxiga is subject to that unlawful interpretation because of all of that work that we need to do around value and investment that we've talked about.

THE COURT: Okay. Thank you.

MS. STETSON: Thank you, Your Honor.

THE COURT: Let me hear from the other side.

Good morning.

MR. NETTER: It is still the morning. Good morning, Your Honor. May it please the Court, my name is

Brian Netter. I am counsel for the defendants in this case.

We have a slide deck that we have put on the screen. I have hard copies here if I may approach.

THE COURT: Please. Thank you.

Go ahead.

MR. NETTER: Your Honor, Congress adopted the negotiation program as part of the Inflation Reduction Act, to curb runaway spending caused by a small number of drugs reimbursed by Medicare. Under the terms of statute, ten drugs were selected as part of initial price applicability, year 2026. And all ten of those drugs are involved in one way or another in a pending lawsuit seeking to upend the implementation of this program.

THE COURT: Can you tell me what the status of the cases are?

Like, in other words, the timing you expect of decisions. Has anybody else had an early summary judgment motion like this teed up before them?

MR. NETTER: So there are other case that have fully briefed summary judgment motions. This is the first hearing in a summary judgment case.

THE COURT: Does anybody else have a target date like I do, that the parties asked for a target date?

MR. NETTER: I don't believe that there is a

target date as soon as this Court's target date.

THE COURT: Why was it set in this case?

MR. NETTER: Excuse me, Your Honor?

THE COURT: Why this case?

MR. NETTER: I think that that's probably a better question directed to the plaintiffs, in terms of why they think an answer needs to be given within the next month. We don't share that assessment.

THE COURT: I got that. But I don't know who -- it was presented to me as a stipulation from both sides, so I don't know how it got there how and how it ended up or what began the discussions that led to it.

So, I guess I can ask them. But you're telling me that none of the other cases have a target date of March 1st?

MR. NETTER: That's correct, Your Honor.

THE COURT: Let me just ask you this, just procedurally, too.

I assume you all had discussions back and forth to figure out how to frame this for summary judgment; is that right?

MR. NETTER: Discussions with --

THE COURT: With the other side, AstraZeneca.

MR. NETTER: Yes, Your Honor.

THE COURT: All right. Did you guys talk

about standing before the briefing started?

MR. NETTER: Your Honor, I was not involved in such conversations. I don't believe that we had substantive conversations about the arguments the parties would be making.

The nature of the discussions was to decide to do this in a cross-motion format with four briefs.

THE COURT: Okay. All right. Go ahead.

MR. NETTER: So as the Court is well aware, the issues that have been laid before the parties here are standing, the statutory bar on judicial review, and the merits issues, and we have slides that walk us through these issues. Of course happy to jump around, should the Court prefer.

But to begin with standing, I think the critical point, which the Court was just alluding to, is that AstraZeneca's claims here have no bearing on Farxiga's status as a selected drug for price applicability year 2026. Even were they to prevail on their legal theories as to the definition of a qualifying single source drug or as to the rule pertaining to when a generic is going to result in a drug being deselected, they still would be part of the program now. All of the facts are potentially future facts that we would deem to be speculative.

And that's critical because we're here at summary judgment and, as the Court knows under *Lujan*, the plaintiff's burden to establish standing rises with the level of the case, and at summary judgment, they need to come forward with actual facts, not mere allegations, not mere speculation, actual concrete facts. And the facts that have been presented in the Ader declaration and are, in our view, far too thin and far to speculative to support an exercise of this Court's jurisdiction as to the APA claims that the plaintiffs have presented before the Court.

Now, in your colloquy with counsel for the plaintiffs, I think you already looked here at Paragraph 23, where AstraZeneca acknowledges that there are no clinical trials currently involving the same active moiety as Farxiga. And that's notable, not just because they acknowledge here that, at most, there are ongoing drug development efforts that are in a preclinical phase, but in Paragraph 7 of this same declaration, Mr. Ader acknowledges that the likelihood that a drug in preclinical testing or a product in preclinical testing is actually going to result in an approved drug product is 1 in 5000.

So speaking from a standpoint of speculation, if there is a 1 in 5000 chance that a product in

preclinical investigation is actually going to be approved, that can't be the basis for the Court to enter imminently a ruling on whether these rules are actually applicable.

Now, the governing standard here comes from *Clapper v. Amnesty International,* and that was a case in which the plaintiffs came to the Court and said, We anticipate that in the future we're going to withstand an injury, and as a result of that future expectation, we're going to take prophylactic steps now. We're going to introduce antisurveillance protocols that are going to cost us money now because we think in the future we're going to be surveilled under this program.

The Court rejected -- the Supreme Court rejected that theory of standing, finding that it was not certainly impending that Amnesty International would actually be subject to the surveillance that it feared and that, as a result, any cost that they incurred in the present day were simply self-inflicted wounds. And that, in our view, is the circumstance here, too. That in order for AstraZeneca to be able to say to the Court that they're experiencing injury now as a result of their expectation of how the guidance might be applied in the future, and I should pause to note that the guidance that we're here discussing is only the guidance for this first

year of the program. There's going to be new guidance issued for the subsequent, the ensuing two years, that aren't presently before the Court. But even with respect to --

THE COURT: But this guidance applies for a three-year period.

MR. NETTER: No. This guidance -- well, insofar as it covers through 2026, yes.

THE COURT: Well, but -- so you disagree that it also sets the price for '27 and '28?

MR. NETTER: It sets the price, Your Honor, yes, but there will be new guidance for initial price applicability year 2027.

THE COURT: And you're saying that that guidance could address things like what happens if a generic emerges on the market January 2, 2026?

MR. NETTER: Yes, Your Honor.

In terms of the time, I should note also that many of the timing considerations about when a determination has to be made by the agency and when that determination has an effect on the price for the drug, those are baked into the statute. So those -- you can't have an APA claim as to the nature on the statute, obviously.

So the fact that there is an eight-month delay

or nine-month delay, between when the agency makes a determination that there is a bona fide marketing of a generic, and when that actually affects the pricing, that's baked into the statute. That's not a matter of --

THE COURT: Right. But is there anything baked in the statute that would -- and I think the answer is no -- but that would require you to address, within a certain amount of time after January 2, 2026, the fact that there's a generic on the market?

MR. NETTER: So I don't believe that's in the statute, Your Honor, but there is a provision in the revised guidance, I think I flagged here, that indicates that the agency is going to review the market data on a monthly basis. So the suggestion that we don't know how often they're going to look at the data or what the cycle that's going to be, is inaccurate.

THE COURT: So your point -- go ahead and look for it and give it to us. But while you're looking for it.

So are you saying, then, that if, in fact, on January 2, 2026, the generics came on the market with more than de minimis market, they met the bona fide definition, right, that -- are you saying within one month of that you would have to do the 12-month retrospective data analysis is that what you're saying?

MR. NETTER: Yes, Your Honor.

THE COURT: Okay.

MR. NETTER: The 12-month period, that's just identifying the window of data that --

THE COURT: Right.

MR. NETTER: -- CMS is going to look at. Right? It doesn't say you need to wait for a year. And I think that that is to the benefit of the drug companies. Right?

THE COURT: Because your point would be it doesn't have to include times when the generics were on the market.

MR. NETTER: Correct.

THE COURT: In fact, if -- within 30 days, is it, you say you have to conduct this analysis?

MR. NETTER: That's Page 165 of the revised guidance.

THE COURT: All right. So is this a factual dispute that would preclude summary judgment?

MR. NETTER: I don't think so, Your Honor. I don't believe there is any other factual information in the record as to the cycle on which the data are going to be reviewed. But in any event --

THE COURT: Hold on. I want to make this clear.

So to the extent you all differ -- because, for instance, there is some differences on, you know, the length of time that will pass, right, before a remedy. I think there's one instance where I think you say 30 days, they say 11 months. Maybe it's this issue in your briefing, where you address this.

But you would say that's not a factual dispute; that's interpreting the guidance, which is a legal dispute I can make. Is that right?

MR. NETTER: That's right, Your Honor. And I would refer the Court to Page 166 of the revised guidance, which has a pretty helpful chart about when, you know, various determinations would have the real world effect in terms of deselection or the price, the negotiated price no longer applying as to a specific drug.

THE COURT: Okay.

MR. NETTER: But I don't want to get us too far off target with respect to the core standing question, which is whether there is a certainly impending injury that stems from what exists right now, the facts that are in the record right now.

And with respect to the definition of "qualifying single source drug," all that AstraZeneca has put into the record is the possibility there's some

unidentified ongoing drug development efforts that they don't even say that drug development efforts would result in a different NDA. They say only that it could result in the product being treated as the same QSSD as Farxiga, which, now, it would also be the case if their investigation resulted in a product that were approved under the existing NDA.

So from our standpoint, the factual record here is so sparse that it can't support an exercise of the Court's jurisdiction under the summary judgment standard.

Likewise, with respect to "bona fide marketing." The Ader declaration identifies that there are 17 generic versions of Farxiga that have received tentative approval, and that, in AstraZeneca's views, are poised to enter the market.

Now, in order for AstraZeneca to be able to obtain standing on the basis, they would have to establish that the bona fide marketing standard wouldn't matter. And if are 17 generic versions sitting on the sidelines waiting for the exclusivity periods to end, then AstraZeneca has to establish that the delta, that there's some difference in the pricing of Farxiga that is going to result from the bona fide marketing standard.

So what I think that means is that, of these

17 generics, they would have to establish that at least one of them is going to make it to market, but that all 17 of them are not going to be on the market and marketed in a bona fide manner such that the difference between whether their drug is selected or not hinges on the interpretation of the bona fide marketing standard that has been adopted in the revised guidance.

There certainly doesn't seem to be any facts in the record to establish that that standard is met. And as the Court acknowledged, it's AstraZeneca that has all the factual information about any agreements that they may have with the generic companies, any agreements they may have to delay market entry, to partition the market in some way. Such agreement may or may not be appropriate or lawful under the antitrust laws. But insofar as the thrust of claim here, is that AstraZeneca is seeking this Court's preapproval for what I think we would call "gamesmanship" to engage in some sort of an agreement with a generic manufacturer so that it would be nominally marketed, but not marked in a bona fide sense.

Any facts that they would like to put before the Court, those are in AstraZeneca's possession. The facts they introduced here, the existence of 17 generic versions, does not suggest that the bona fide marketing standard is going to be implicated.

Now, the plaintiffs in their brief say, well, this established that the bona fide marketing standard certified going to be applied. On Page 8 of their opposition reply brief, they say they, "soon will be subject to the unlawful bona fide marketing test."

But the standard for standing is not whether a party is subject to the law; it's whether it's injured by the law. And that's where there is the absence of evidence here.

Now, it didn't come up in Ms. Stetson's presentation, but there are a few paragraphs in the Ader declaration that speak to other drugs too. There's a drug other than Calquence that's mentioned in the briefs. It may only being Calquence that's mentioned here in the Ader declaration.

We think all the questions, all the issues with this being speculative, not knowing whether a drug is going to be selected, not knowing whether there's going to be this issue with multiple NDA, they haven't established the factual predicate for any of this. And as a result, we think the easiest way for the Court to resolve the APA claims is just to identify the lack of factual support as a basis for granting summary judgment under the standing.

THE COURT: All right. So let me ask you

that, you know, I asked this to Ms. Stetson.

So you think the easy way is Article 3, not the statutory provisions that address judicial review?

MR. NETTER: So, Your Honor, I said that, and I immediately regretted it because I do think that the bar on statutory reviews is an extremely straightforward way to resolve the case, and I don't want to suggest otherwise.

It so happens here that we think the factual record is so sparse that an opinion could be written quite easily to say it's the plaintiffs burden. They haven't identified why these issues need a decision right now such that this would be, effectively, an advisory opinion.

I agree with Ms. Stetson's answer that the Court could, in its discretion, decide either of these threshold issue first because they are both of a judicial character.

THE COURT: Okay. And then, let's just -- I want you to go to the statutory argument, but before you do, I want to just flesh this out. I try to be practical about things, and let's just say.

So let's say I went either under Article 3 or under the statute and said, I don't have jurisdiction under Claims 1 and 2, so they are dismissed, right?

MR. NETTER: Yes, Your Honor.

THE COURT: And then you are not moving to dismiss Claim 3?

MR. NETTER: That's correct, Your Honor. We don't have standing or jurisdictional bar arguments as to Claim 3.

THE COURT: Right. Are you asking for summary judgment, though, on Claim 3?

MR. NETTER: We are.

THE COURT: Right. And so you do anticipate that there will be a final judgment.

I mean, isn't that -- because what I'm getting at is, you guys reached this stipulation.

Was it your expectation that I would issue a judgment that would be final? Because, in other words, your thought is, if I dispose of this either in favor of AstraZeneca or in favor of you, or even if I, I don't know, come up with some partial thing, there will be a final judgment that will be subject to appeal? Is that your understanding?

MR. NETTER: That is our expectation, Your Honor. There's always the theoretical possibility that the Court could find that we are in this middle space where a trial needs to be held on some factual issues. I don't think we are in a place where there is an actual

dispute of material fact such that there can't be a determination.

THE COURT: Well, I mean, you go -- you made this point. I mean, it's summary judgment. The burden is on them to put forth facts that would be sufficient to establish harm that would give rise to jurisdiction. Right?

MR. NETTER: That's right, Your Honor.

THE COURT: Yeah. So, I mean, they had their chance. So I'm not going to allow for -- you're saying we don't need further opportunity to -- we don't need a trial on that.

MR. NETTER: Right. The only reason that we would need a trial was if we disputed Mr. Ader's assertion that there are drugs in the predevelopment phase that use the same active moiety as Farxiga. That's a matter that could require a trial. But we're not disputing those facts.

So the question is whether the factual record that the plaintiffs have introduced, whether that's sufficient to invoke the Court's jurisdiction.

THE COURT: All right. And then what do you do with all this injunctive -- the fact that they've asked for, though, an injunction in their order. What does that -- what do you think about that?

MR. NETTER: So we certainly agree, Your Honor, that an injunction is a remedy that invokes the Court's equitable authority. And in order to invoke that authority, the party seeking the injunction has an obligation to demonstrate that the equities are in their favor. And the lack of factual support for those equities is rather telling. Now, we don't --

THE COURT: Factual support. There's no legal argument from either of you, right? I mean, nobody says here are the four prongs of an injunction and weigh the public interest or engage in this. I don't think. Was that in the briefs?

MR. NETTER: It wasn't, Your Honor. And I think, in part, that's because as strategic matter or however, most of the briefing in this case focuses on the APA claims.

Sometimes claims end up at the end of the brief, and they don't get the same amount of development as a result of -- there are strategic reasons why things end up at the end of the brief.

We certainly think, though, that the Court, as an exercise of its authority, would have an obligation to consider the equities before entering an injunction, certainly in a public law context like this.

THE COURT: All right. But what I take from

your comments is that both sides want and expect a final judgment to be issued by me that would be subject to an immediate appeal, correct?

MR. NETTER: That's correct, Your Honor. I think we differ as to how urgent we think the Court needs to rule, but insofar as this being the end of the case, we both agree with that.

THE COURT: Okay. So, just to flesh that out, in other words, the only one who's asked for the March 1 target date is AstraZeneca?

MR. NETTER: Right. We agreed to brief the case so as to facilitate that schedule. We're not asking for a March 1 date.

THE COURT: Right. Okay. Is everybody else; i.e., the other -- I don't know if there's nine pharmaceutical companies. But for the other nine drugs, that those pharmaceutical companies, they're all involved in litigation with you right now; is that right?

MR. NETTER: So either the pharmaceutical companies, themselves, are involved in litigation or, as was the case in the *Dayton area Chamber* case, there's a case brought by Pharma, the industry group also. They are claiming, as members, the other manufacturers and relying upon injuries to the drugs for their assertions of standing.

THE COURT: Okay. And is the timing exactly the same for all of the other pharmaceutical companies? In other words, their counteroffer is due March 1st; is that right?

MR. NETTER: Yes. The schedule is the same for all ten drugs.

THE COURT: But nobody else is asking a Court to issue an opinion before March 1st?

MR. NETTER: I'll look at my team here again.

MS. SNYDER: No. We had one PI in one of the other cases, but otherwise, no.

THE COURT: Was that the Ohio case, the PI?

MS. SNYDER: Yes.

THE COURT: Right.

MS. SNYDER: And the PI was denied --

THE COURT: Right. Okay.

MR. NETTER: Right. We'll talk about that later. That was limited to the due process issue. And in that case, the chamber asked for a ruling before the negotiation process would even begin, before the negotiation agreements would need to be signed.

But this seems as good a time as any for us to move on to the statutory bar on judicial review.

So I put the statute up here. This is codified at 1320f-7, and the critical language here in

subsection 2 says that "There shall be no be administrative or judicial review as to the selection of drugs under F1B, the determination of negotiation eligible drugs under F1D, and the determination of qualifying single source drugs under F1E."

Now, the plaintiffs seem to take it for granted that the definition of the words "selection" and "determination" are so narrow that they are only referring to the things selected or what is determined. So I just wanted to start by quickly putting on the screen actual dictionary definitions. And I'll zoom in on the critical part here. This is the American Heritage dictionary, but the Oxford English dictionary has the equivalent definition.

So "determination" means either the ascertaining or the result of the ascertaining, either the act of making and arriving at the decision or the decision that's reached. Same thing for "selection."

"Selection" means either the act of selecting something or what is actually selected.

So if we put the statutory bar on judicial review back up here, the determination, the act of identifying the qualifying single source drugs under Section 1320f-1(e), that's precisely what the plaintiffs are seeking to challenge here.

Now, Ms. Stetson discussed with the Court the Third Circuit's decision in the *Dohou* case. I think she said, "Dohou," so I'll go with her pronunciation. It's D-O-H-O-U. That's a 2020 decision. And they included in their little booklet here, one of the statutes that was at issue in that case.

That's 8 U.S.C. Section 1252(a)(2)(A). So I think it's important to put that case into context. So in the immigration world, there are various circumstances in which, when the relevant agency makes a determination that a noncitizen is subject to removal and enters a removal order, sometimes that's immediately reviewable and sometimes it isn't immediately reviewable.

And the issue before the Court in *Dohou* was whether a removal that was within the category of 8 U.S.C. Section 1252(a)(2)(C) was subject to a collateral attack in a subsequent criminal prosecution for an individual who failed to willfully -- who willfully failed to depart after being subject to an immigration removal order.

So what's important here is that 8 U.S.C. Section 1252(b)(7) says expressly that you haven't had a chance to challenge your removal order already, you can file a motion in the criminal case that collaterally attacks the removal order as part of the explanation for

why you shouldn't be criminally liable for willfully failing to depart the country.

So the Court was comparing two different subprovisions of 8 U.S.C. 1252(a)(2). Now, the one that Ms. Stetson put in the book here says, "No Court shall have jurisdiction to review or to entertain any other cause or claim arising from or relating to the implementation or operation of an order of removal that is subject to" the conditions set forth there.

By contrast, the provision that was an issue in *Dohou* said only, "No Court shall have jurisdiction to review any final order of removal."

So what the Third Circuit said in *Dohou* was, Congress has told us that you can't have immediate judicial review of the order of removal under the circumstances, but they haven't said that you can't have a collateral attack on the order of removal when the noncitizen is subsequently prosecuted for willful failure to depart.

And the distinction between two subsections, between 1252(a)(2)(C) and 1252(a)(2)(A) is so stark that it identifies the fact that 1252(a)(2)(A) was intended to bar, not just initial judicial review, but any future claim that could be based on the fact of that removal order.

So the dichotomy between (a)(2)(C) and (a)(2)(A) is what was at issue there. There's obviously nothing similar to that here.

Rather, I want to mention, also, one of the other cases that the plaintiffs invoked. And this was the decision of D.C. Circuit in *American Clinical Laboratory Association versus Azar* from 2019. This was a case that the plaintiffs described as perhaps most closely resembling the claims that they raise here.

And in the *American Clinical Laboratory Association* case, the Court did indeed find that a judicial preclusion bar did not cover the claims in that case. There was a judicial preclusion bar that covered pricing, like the actual amount that was being determined by the agency, and the lawsuit was challenging data collection.

And in order to find that data collection was not part of pricing, the Court noted that the data collection procedures were laid out in a totally different part of the law from the pricing, and the data collection procedures themselves were subject to their own notice and comment procedure that was particular only to the data collection proceedings, and that a specific notice and comment procedure is suggestive of their being judicial review, because that's ordinarily why notice and

comment would be required.

That's obviously not the case here. All of the text that we are looking at is within f-1(c), (d) and (e). They're the provisions that -- sorry -- f-1(b), (d) and (e), the provisions that Congress has identified as being part of the judicial bar.

THE COURT: What's left to review by the courts as far as the implementation of this program under your reading of 1320f-7?

MR. NETTER: So I don't think we can survey the scene, but the answer may be not much. And I think that that's fine because Congress has the authority to determine the jurisdiction of Federal District Courts with respect to statutory claims. And there's good reason when Congress --

THE COURT: Well, when you say, "district courts," what about just Federal? I mean, this is not limited to district courts, right? This is judicial review, period, right?

MR. NETTER: Oh, absolutely. I was just trying to separate off --

THE COURT: Well, listen. Do they have the authority to preclude the Supreme Court?

MR. NETTER: Yes, with respect to statutory claims, certainly.

THE COURT: Okay.

MR. NETTER: And, you know, Congress -- it's sensible for Congress to have precluded judicial review as to key aspects of this program, because, otherwise, it would be very difficult for the program to launch. And we see that from the existence of all these lawsuits filed trying to challenge every aspect of program.

THE COURT: Right. But, you know, let's say you have an agency that promulgated guidance, which is just absolutely clearly inconsistent and contradicts, not just inconsistent, contradicts the explicit statutory text. All right?

For argument's sake, let's say I agree on the merits with the first claim. All right? That the language referring to the date of approval makes clear that you can only have a drug qualify as a QSSND --is that right? Yeah. QSS --

MR. NETTER: No N.

THE COURT: No N. QSSD. Can only qualify if there's a single NDA. All right?

So CMS comes along, promulgates this guidance, and when can that possibly be reviewed?

MR. NETTER: Well, it wouldn't be, Your Honor, and that is Congress's determination, that the frame of analysis here is not to determine whether the agency has

made a mistake and then to figure out some way to review it. Right?

The first question is, does Congress permit the Court to review this question.

THE COURT: Right.

MR. NETTER: Now, there may be circumstances where the ultra vires standard comes into play if an agency is doing something that is so far beyond the scope of the statute.

THE COURT: Let's say this is. I read the statute. It's clear as a bell. I'm not saying it is clear as a bell by any stretch. But there's language, though, clearly in 1320f-1(e)(1)(A) which refers to the date of such approval. So it's singular date, singular approval. That says to me, there's a single approval. There's one. And it's talking about a drug. Right? That's defining a drug that would -- or the drug products that would be subject to this.

So let's just say I agree with AstraZeneca on that. When would a drug company be able to challenge your designation of its blockbuster product? Let's say it only makes one product. When can it do that?

MR. NETTER: So it wouldn't be able to, Your Honor.

THE COURT: Ever?

MR. NETTER: Ever? Well, unless they could try to convince Congress to change the statutory bar. But it's Congress' prerogative.

THE COURT: That doesn't bother you, that you could have -- again, imagine it was, again, that there was no other ambiguity in the statute to shed doubt on AstraZeneca's interpretation.

So you're saying that an agency can come along and can issue a regulation that absolutely contradicts the explicit statutory text of Congress? And here -- and you're saying, tough noogies, there's no review?

MR. NETTER: That is the outcome of the standard analysis on judicial bars. Now, were it the case that the judicial preclusion bar were implicit, that's where the ultra vires discussion could take place. But here, it is explicit that Congress didn't want there to be review of the determination of what constitutes a qualifying single source drug.

And if the agency is interpreting it wrong, well, Congress had the authority to give the agency this power and Congress has the authority to wrest that power back. And I --

THE COURT: I guess -- I thought you might tell me that, well, there's going to be in the future some period to review it, but you're not going there.

MR. NETTER: No. This is not a judicial review provision.

THE COURT: For instance, maybe if AstraZeneca decided, you know what, we're going to take the risk. We will go get a second NDA.

Would they be able to challenge it if they had two NDAs that covered this drug?

MR. NETTER: Well, that would take away the standing issue; that would not remove the bar on judicial review.

THE COURT: It would not.

MR. NETTER: That also would arise in the subsequent period where there could be different governing guidance. That certainly wouldn't be --

THE COURT: No, I agree.

MR. NETTER: Right.

THE COURT: I just want to make sure, your point, so what you're saying is if they did decide if they didn't have Ader's declaration and they had another declaration which said, you know, we've got these clinical trials, we're ready to go, we're about to go seek a new NDA, but your point would be, no, doesn't matter, you can get the second NDA; you can never challenge this in the courts. That's right, right?

MR. NETTER: That's correct, Your Honor. And

I would refer the Court to the Second Circuit's recent decision in *Yale New Haven Hospital versus Becerra*. Because that was a situation in which the Court thought that the -- what was being challenged was a few steps removed from what was covered in the statute.

The plaintiffs were trying to challenge the rule-making procedures that would set the policies that would result in an estimate. And the statute said there was a bar on judicial review of any estimate.

And the court's conclusion was it didn't matter that this was, you know, a procedural challenge as to the mode of administrative process, and it didn't matter that it was as to the procedure, even though the procedure was going to lead to the estimate.

They described the distinction as nearly metaphysical as between these two steps. And I think that's the case here, that if this judicial preclusion provision were interpreted so as not to cover plaintiff's challenges, then it would convert the judicial bar, the judicial review bar into a creative or artful pleading standard. Whereas all of the precedents in this space say that both the plain language, which we think plainly covers their claims here as to Claims 1 and 2, also, steps that are inextricably linked with the plain text here. And at a very minimum, the process for

determining, you know, how one counts drugs or what marketed means, that is all bound up in the ultimate determinations of what constitutes a qualifying single source drug.

THE COURT: All right. Give me a second.

MR. NETTER: Your Honor, while we are transitioning to the merits of this case, my colleagues just noted that the plaintiffs in the *Chamber* case in Ohio did ask for an order by a specific date on dispositive motions, but the Court denied that request.

THE COURT: Clearly a smarter judge than I, I'll say that.

Just give me a second.

Okay. Now, your motion, your proposed order says, "Upon consideration of the parties' cross-motions, it is hereby ordered plaintiff's Motion for Summary Judgment is denied, and it's further ordered that defendant's cross-motion for Summary Judgment is granted."

And in your motion, you just say, "We move for summary judgment on all claims."

So what's the judgment you're seeking on Claim 3? How would the judgment read on Claim 3?

MR. NETTER: We're just seeking judgment on the merits. So we are seeking a determination that

plaintiff's claim fails as a matter of law. We don't think there are any facts that play into that decision.

And the conclusion section of our brief probably describes the relief that we are seeking more precisely.

THE COURT: Where is it? So which brief, the opening brief? The memorandum of law and support?

MR. NETTER: I think that's what I'm referring to.

THE COURT: D.I. 22?

MR. NETTER: Memorandum Support is ECF 21-1.

THE COURT: Yeah. So you dismiss -- you say you want to enter judgment for defendants on Count 3.

MR. NETTER: Right.

THE COURT: All right. So then -- but, you know, so they're seeking a declaration that the IRA's drug price control program is, therefore, unconstitutional under the Fifth Amendment, should be enjoined.

All right. Now, is it as applied? I mean, what am I supposed to declare? That's what I'm trying to understand, and what judgment am I entering? I'm supposed to say that the law is constitutional?

I mean, I think, generally, we don't issue judgments like that. You know, we say that the plaintiff

failed to establish that the law was unconstitutional, right? What's the judgment you're looking for?

MR. NETTER: So, Your Honor, we think of this as a facial challenge to which *Salerno* would apply. And the plaintiffs burden has established that there's no set of circumstances in which the law would be kept constitutional. Because there isn't a price at the end of day, they don't know what the price is going to be, such that the procedural claims are, in a sense, unripe.

So the judgment that we would ask the Court to enter would say that the plaintiffs have not met their burden to establish a facial constitutional violation, and as a result the defendants are entitled to judgment as a matter of law.

I would note also --

THE COURT: Give me a second.

MR. NETTER: Sorry, Your Honor.

THE COURT: All right. So you just think the order should say, judgment entered in your favor on Count 3.

MR. NETTER: Yes, Your Honor.

THE COURT: And by the way, why don't you address this. Well, what do you think the -- what's your -- and I know I'm putting you kind of in their shoes, but what do you understand their property interest

to be?

MR. NETTER: We struggled with this question also, Your Honor. It sounds to us like they are saying they have a right to enter into contracts to sell their products to the Government on the terms that they want. That is the thrust of their claim. The suggestion that they have a patent interest doesn't make sense, because we aren't seizing the patent. We aren't demanding they sell products to us under the patent. This is a voluntary program. They get to choose whether they want to sell Farxiga to Medicare beneficiaries or they don't.

So, you know, we think what they are trying to say is that they want this commercial relationship to occur under terms that they think are suitable for them, but that's not a basis on which any Court, to our knowledge, has ever found there to be a protected property interest.

And so long as we are discussing due process, the --

THE COURT: Wait. Hold on. And then, you know, you do have a lot of takings cases. What's your response to, oh, well, they're not due process cases; they're takings cases?

MR. NETTER: So this issue came up in the *Chamber* case also. And what we said there and what I'll

say here is that the due process clause and the takings clause are adjacent in the Fifth Amendment, and they both have the same predicate, which is the government can't deprive an individual of a protected property interest unless certain steps are followed.

So the cases about due process and the cases about takings, they refer to each other. For these purposes, right, there are places where the clauses diverge. For purposes of determining whether there is a protected -- a property interest that has constitutional protection, those standards are coextensive and have been understood as such by the case law.

THE COURT: All right. Go ahead. You want to address something?

MR. NETTER: So I was going to note before we move on that I just don't want to leave the impression with the Court that we think that any review of anything happening under this program is barred by the judicial preclusion provision.

THE COURT: Oh, so you're going to change your answer, then, is what you're saying?

MR. NETTER: No, I'm not. I'm not. It's just that the statutory claims are precluded. And that means that, of all the cases we have been briefing in this space, there have been two cases where we've raised a

statutory bar defense. A lot of other cases raise other constitutional claims as part of their challenges, and those aren't circumstances where we think the constitutional claims are barred.

THE COURT: Those other two cases are part of the ten, of the nine or ten?

MR. NETTER: Right, yes. So most of cases don't have --

THE COURT: Well, that's weird because I thought -- we'll go back. I'll have to look at the transcript.

I thought I kind of invited you to tell me when you would have judicial review, and I thought you said, "There is none."

MR. NETTER: As to statutory claims. So the claims that are being raised in the other cases are things like excessive fines, Eighth Amendment claims, the due process claim that exists here.

So the constitutional challenges can proceed, but the challenges to the mechanics of the statutory operation, that's what Congress barred from review.

THE COURT: Okay.

MR. NETTER: So let's move on to the merits, the definition of "qualifying single source drug."

Now, Ms. Stetson already walked through the

how the statutes connect, but there's one point that I want to clarify. So we start here with 1320f-1(e)(1), which incorporates the definition of a covered Part D drug in 1395w-102. And the definition of a covered Part D drug under 1395w-102 says, "A drug that may be dispensed only upon a prescription and that is described in Subparagraph (a)(1), (a)(2), or (a)(3) of Section 1396r-8(k)(2) of this title."

And I am specifically focusing on the text that applies to drugs as opposed biologics; it's all parallel ,though.

So then she led you to r-8(k)(2), which says that the drug has to be dispensed only upon prescription, and that it has to be approved for safety and effectiveness.

But then after that, she read a different provision of r-8(k); it was r-8(k)(7). That was a definition for single source drug under the Medicaid statute.

THE COURT: Yeah, I lost her. My questions, I think, pointed out I kind of lost that connection.

MR. NETTER: Precisely. Congress didn't incorporate that definition into the IRA. So even if that, you know, leant some clarity to the question of what constitutes a drug for the purposes of the

definition of qualifying single source drug, Congress did not incorporate r-8(k)(7). So if any inference is to be drawn from r-8(k)(7), it's that Congress did not want that to be a part of the IRA.

Instead, we think there are a couple of other statutory provisions that are a part of the IRA that are probative here. The first one the Court referenced, that -- and identifying the data the agency is supposed to consider, it refers to applications and approvals, plural, pertaining to a drug, singular.

THE COURT: Go back on that.

MR. NETTER: Yeah.

THE COURT: You know that they've got an explanation for this; it's supplemental. Supplemental applications, which the code allows for, right?

MR. NETTER: The code does allow for supplemental applications.

THE COURT: And they're different than new drug applications?

MR. NETTER: They are. Right. I don't want to suggest that this provision in and of itself is completely dispositive and airtight. I think, if anything, the next provision I'm going to put on the screen explains more as to why we think that the definition adopted by the agency is appropriate here.

THE COURT: Right.

MR. NETTER: And that's f-1(d)(3)(B), which says that, "In identifying the data, the secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug."

Now, this is significant because there is long-standing agency guidance -- this is dated December 2004. And the guidance for industry says that different dosage forms should be submitted in separate original applications unless the products are identical, in the case of drugs, in a quantitative and qualitative composition.

THE COURT: Right, but that happens all the time.

MR. NETTER: So I don't think that it happens with respect to, for example, you know, necessarily. You know, our understanding is that it is commonplace, that commonly, immediate and extended-release formulations are submitted in distinct applications because they wouldn't satisfy the standard of being identical and quantitative and qualitative compositions.

THE COURT: Wait, wait. What did you just say? Sorry?

MR. NETTER: So what I said is that extended

and immediate-release formulations are commonly submitted in distinct applications. So they have separate NDAs.

THE COURT: Okay. So they're commonly, but aren't there NDA that cover multiple dosages? I think I see them all the time.

MR. NETTER: They could cover multiple dosages. That's not uncommon.

THE COURT: Okay.

MR. NETTER: What we're talking about are different formulations, one of which has immediate release, and one of which is extended release.

THE COURT: But this is not -- the language you are focusing on is not limited to different formulations. And it's not so limited, in fact, that the clause that follows that's not highlighted, "including new formulations," and "such as an extended-release formulation" would suggest that they're -- this is much broader.

MR. NETTER: So here's how we interpret this, Your Honor. You know, because this says the secretary has to aggregate data across dosage forms and strengths, including across an extended-release formulation, and given that extended-release formulations are commonly submitted in different NDAs --

THE COURT: But they're commonly; they're not

required to be, right?

MR. NETTER: Well, I'm not sure that's correct. And I don't want to stand up hearing offering chemical -- or pharmacological expertise. But the long-standing guidance is that dosage forms should be submitted in separate original applications unless the products are identical in quantitative and qualitative composition.

And just intuitively, the way that a drug product, you know, has a release period that extended as opposed to immediate is, there necessarily has to be some difference there. Right? So we identified in Footnote 7 of our opening brief circumstances in which the extended-release formulations are submitted in distinct NDAs. The record doesn't contain any counter-example.

So if it is the case, which we think it is, that extended-release formulations are commonly -- and there are no counter-examples that we have before the Court -- submitted in separate NDAs, then Congress's directive to aggregate data, including extended-release formulations, necessarily means that Congress anticipated aggregating across -- excuse me -- across NDAs, so long as the same active moiety is involved.

THE COURT: Does this raise a factual issue? Because they dispute it. They say, you know, they don't

agree with you on this.

MR. NETTER: Well, they don't agree with the legal interpretation. They didn't introduce any facts.

THE COURT: Well, no, but you said "commonly." This is commonly done before the FDA. That sounds like a fact, factual assertion.

MR. NETTER: So the legal source here, Your Honor, which I think we can presume that Congress is aware of, is this requirement that different dosage forms be submitted in separate original applications unless they're identical.

THE COURT: So I've got to tell you, I've had ANDA cases where experts dispute what guidance means. It's guidance. It's not mandatory.

Is this really a legal determination for me to make?

MR. NETTER: So I don't think it's a legal determination, Your Honor. I think that the Court can draw the inference that because of the common industry practice --

THE COURT: But, again, that's a fact, isn't it? What the common industry practice is, is a fact. And it sounds like you guys disagree about it.

Is this something that is a material fact that precludes summary judgment?

MR. NETTER: So I don't understand there to be any evidence in the record from the plaintiffs as to whether it's commonplace for extended-release formulations to be introduced under the same new drug application.

THE COURT: Well, there's none from you either.

MR. NETTER: No, we do -- we do cite, in footnote 7, the examples, and we offered into the record also this guidance for industry.

In any event, the relevance of this is the inference that it wouldn't have been sensible for Congress to direct the secretary to aggregate across dosage forms, including extended release formulations, if those extended release formulations arise under a different new drug application.

And I think, also, if we take a step back and look to the purpose of the statute more broadly, that a lot of the record here is concerns about product hopping, about the gamesmanship that results in periods of exclusivity stretching out and having unchecked prices being paid by Medicare as a result. And provisions like this are responsive to that concern.

Adopting an interpretation of the statute that requires -- that would effectively turn the drug maker's

decision on whether to submit something as a separate new drug application is having consequences for pricing, I think that would be surprisingly inconsistent with the nature of the statute.

And I wanted to move on, also, because the plaintiffs suggested in their briefing that the government previously had a different interpretation as to the relationship between the meaning of "drug" and the existence of multiple new drugs applications. And they cited a D.C., district court, decision in a case called *Ipsen Biopharmaceuticals*.

Now we, in our final brief in this sequence, indicated that we thought that they were misinterpreting what happened in that case. But I wanted to put up on the screen here -- this is from the joint appendix in that case, which is part of the record. This is what CMS actually said. They said, while Section 1927(k)(2) -- that's 1396r-8(k)(2) in the codified version -- while that defines a covered outpatient drug based on FDA approval, we find no indication that Congress intended that FDA approval status be used for determining whether a drug qualifies as a new drug for purposes -- for the Medicaid pricing purposes that were at issue in that case.

So the interpretation that the agency

adopted -- let's see -- this stamped 2017. I think the letter is actually 2016. You know, before the Inflation Reduction Act was adopted, it's entirely consistent with the agency's approach here, which we certainly think is significant.

I do want to address, also, the part of the statute that the Court questioned Ms. Stetson about.

THE COURT: The date, right?

MR. NETTER: Right.

THE COURT: Yeah.

MR. NETTER: And the date of approval is addressed in the revised guidance in Section 30.1. And the way that the agency has construed the statute is the date of approval means the date at which the drug, as a unit, encompassing all of its products, was approved, the first date at which it was approved.

Now, the counterargument, I suppose, is, well, there could be multiple dates. But there could be multiple dates if there are grants of a supplemental NDA also. So in any circumstance, there has to be a relevant date. And the date of approval, the date that the drug was approved is the first date that a drug containing that active moiety was approved. And that seems to us perfectly sensible and consistent with the other provisions of the statute.

Unless the Court has further questions on that issue, I would move on to the bona fide marketing standard. So I'll throw the text up here. This says that a drug that is not the listed drug for any drug that is approved and marketed under Section 355J of such title -- that's referring to the ANDA process.

So I alluded to this earlier, and I think we should be clear on what effectively is being asked of the Court here. The plaintiffs are asking for what we would describe as an advisory opinion that they can engage in transactions with the generic manufacturers that will result in a drug being offered in some de minimis capacity such that it's nominally available for sale somewhere, but not truly marketed as the way that anybody would understand that concept in the real world.

They say that if Congress had intended to mean real marketing, they would have added that qualifier. I think that that instinct, that intuition is inconsistent with the way the law ordinarily functions. There are plenty of circumstancing in which courts will disregard transactions that have no bona fide purpose. The sham transaction doctrine in the tax context. Here in Delaware, there's a whole body of law as to when one can breach the corporate veil because there is, effectively, a sham relationship between a parent and a subsidiary.

There's also the sham affidavit rule that applies with respect to summary judgment.

Now, I think that Ms. Stetson -- I think I heard her say that she would have been more comforted if the words "de minimis" applied in the guidance. So I do want to highlight --

THE COURT: They're both, you know, italicized, de minimis, bona fide. I don't find that argument compelling. I mean, just for what it's worth, I just don't. But go ahead.

I mean, I do want to be a little bit mindful of time, so -- but go ahead.

MR. NETTER: Of course, Your Honor. I just wanted to refer to the fact --

THE COURT: Not your argument. I meant I don't find their argument compelling. In other words, what I'm trying to say is if you put the words in de minimis, you put as opposed to bona fide, I mean, you know, they're qualifiers of what marketing means, to bring clarity to what is meant by "marketed."

MR. NETTER: Right. Entirely agreed, Your Honor. And I would just refer the Court to Page 72 of the revised guidance, which says that the alternative, the opposite of having a bona fide marketing standard is permitting, quote, "a token or de minimis amount of

generic drug to be allowed."

THE COURT: Right. All right. Thank you. So it's actually in there is what you're saying.

MR. NETTER: Exactly.

THE COURT: Gotcha.

MR. NETTER: So I think that leaves only the due process claim, which we touched on briefly. I would put up here just this quote from the Supreme Court in *American Manufacturers Mutual Insurance Company v. Sullivan*, that the first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in property or liberty.

Our reading of their arguments is that they're basically skipping that step. They are assuming that there's been this \depravation\deprivation and then are complaining about the processes that are required once there has been a \depravation\deprivation of a protected property interest.

Because we don't believe that to be the case, we find that to be dispositive of their due process.

THE COURT: I mean, it's somewhat funny, right? I mean, on one level you can say, well, really they're arguing a liberty interest, their freedom to contract. But they want total freedom, where they have all information, including information in the future.

MR. NETTER: Yes, Your Honor.

And your Honor alluded earlier to defense contractors, and that feels like an apt comparison here because there are plenty of defense contractors who would like to have greater control about the military products that they're selling to the United States Government. And one can only imagine the chaos that would result from applying a due process standard there instead of treating these as market transactions where the parties can decide either they want to transact with the United States in this commercial manner or that they don't.

Now, the plaintiffs try to suggest that this isn't just an ordinary market transaction because Medicare and the United States is such a big player in the market, but --

THE COURT: They are the only player in the defense market.

MR. NETTER: Only player in the defense market. Absolutely.

But there are plenty of cases out there that say that Medicare and Medicaid are voluntary, despite the fact that these programs are so essential. There are Eighth Circuit cases that talk about both nursing homes, which are obviously dependent on Medicare and Medicaid, and hospice facilities, which are obviously dependent on

Medicare and Medicaid.

In those contexts, the courts have said this is still a voluntary program for purposes of the law. And that's why, in the Chamber case, the Court said the law established in the Sixth Circuit and beyond is clear. Participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice.

The plaintiffs tried to invoke the NFIB decision, and I think that Ms. Stetson anticipated what our response to that would be, which is, *NFIB*, by its terms, is speaking to the relationship among counterparts' soverance, not about commercial transactions in which one party can say yes or say no. There is such a robust body of case law establishing the voluntariness of Medicare and Medicaid that that seems to us entirely dispositive.

THE COURT: None of the penalties that they deem coercive affect the price that they can sell to a private citizen or anybody other than Medicare, right?

MR. NETTER: That's correct, Your Honor. They are not obligated to sell to Medicare. They can withdraw, they can divest the drug. There are things that they can do. And they can always sell to private parties on whatever terms they want.

THE COURT: Or foreign governments.

MR. NETTER: Or foreign governments. I don't want to speak to --

THE COURT: Although the price might be lower if they sell to a foreign government.

Let me ask you a couple of things. There's a disagreement, it appears, between how quick you can withdraw, whether it's 30 months or 11 months. Can you -- and you guys, the Government, says it's one month.

Can you just direct me to where -- what's the support for that position.

MR. NETTER: So that position is within the revised guidance. And maybe one of my colleagues can find the page number in the revised guidance that says that.

THE COURT: While they're looking for that, let me give you another question I have.

You know, you brought up this idea of product hopping, right?

Is there anything that you can point me to in the statute or -- I don't generally resort to legislative history, but in the legislative history -- suggesting or indicating or confirming that Congress was aware of that and that that's part of what it was trying to accomplish here in restraining such agreements?

MR. NETTER: Your Honor, this isn't a

circumstance in which all the purposes of the statute are laid out in the statutory provision.

THE COURT: Right.

MR. NETTER: So I think that it would require a resort to the legislative process.

THE COURT: Okay.

MR. NETTER: But, also, just the -- what is in the ether. The public discussion about the need for this law.

THE COURT: Right. And you both resort to that. You both do this, you refer me to websites and whatnot that talk about various things to support your policy positions. All right?

When does CMS, when will it release guidance for 2027?

MR. NETTER: That's a fair question, Your Honor. I don't recall -- my colleague from HHS may have the precise date over there.

THE COURT: It's required to release the guidance by a date certain, is that right under the statute or not?

MR. NETTER: So the statute requires the agency to operate by program guidance for the first three years of the program. So we do construe that as obligating the agency to issue guidance prior to the

start of the next negotiation cycle.

As to what the precise date certain is for issuance of that guidance, I don't have that offhand.

THE COURT: But your understanding is the requirement is that the guidance must be issued prior to the beginning of the negotiation cycle.

So you would say the 2027 guidance has to be issued before the negotiation period for that year, 2027, not when the year begins, but rather when the negotiation for that period begins.

MR. NETTER: Right. Right. That would be the guidance that will govern that initial price applicability, Your Honor.

So that guidance has to be issued prior to when the drugs are selected because the guidance, as before the Court right now, dictates the rules that the agency's going to follow to identify which drugs get selected.

THE COURT: All right.

MR. NETTER: Your Honor, we may not have identified where the 30-day period exists. We could make a supplemental filing that directs the Court to the particular cite.

I think the thrust of that dispute is that the statute says that the secretary can -- direct withdraw

within 30 days upon good cause shown. And the revised guidance defines "good cause shown" to say, well, if you want to get out of this program because you don't want to participate in the negotiation, that's good cause shown.

The plaintiffs are effectively saying, at this more generous interpretation that the agency has adopted, that it wouldn't be their interpretation. As a result, it isn't governing. But I don't think that they have standing to say that the Government has done something that is too much in their favor.

Just like that, here it is. I believe this is going to be on Page 34 of the revised guidance.

THE COURT: Page 34 of the revised guidance?

MR. NETTER: Yes.

THE COURT: Okay. Now, do you dispute whether AstraZeneca would be harmed if, on January 2, 2026, generics enter the market?

MR. NETTER: We would dispute that because their challenge is as to the bona fide marketing standard. So they would have to demonstrate not just that the generics entered the market, but that the presence of the bona fide marketing standard dictated whether Farxiga remained a selected drug that was subject to the maximum fair price. Right? So it's one step further from that.

THE COURT: I guess what I'm getting at is, well, let's assume it was bona fide. Let's assume, as a factual matter, on January 2, 2026, 17 generics began bona fide marketing of generic drug products. Do you dispute that for the remainder of that year they would be harmed? "They" being AstraZeneca. Excuse me. That it would be harmed.

MR. NETTER: Yes, Your Honor, we do dispute that. Because the harm that they would suffer there would be harm coming from the statute.

THE COURT: That's my point is, you don't dispute that they'd be harmed in the sense that, yeah, they'd have competition, but the point is, it's not attributable to the statute is what you would say.

MR. NETTER: Right. So their legal claim, they wouldn't have injury that is traceable to their legal claim.

THE COURT: Right.

MR. NETTER: They would be objecting to the statute, but that's not one of the claims they have.

THE COURT: Right. But they would be having to sell to Medicaid at a price that private people wouldn't tolerate on the market for the remainder of that year, right?

MR. NETTER: Potentially.

THE COURT: Right. And your point would be, goes back to my point, I think, earlier on, is, Government contracts all the time, agree way ahead in advance to certain prices in the future. So I'm a defense contractor. I agree to build certain planes. I'm going to sell them to you five years from now -- takes a long time to build these planes -- at a certain price. Titanium goes up a hundred percent the next year, tough luck for the defense contractor. It's not going to make as much money as it anticipated it would have when it sells, consummates a sale five years from day.

MR. NETTER: Correct.

THE COURT: I kind of think in Joe 6-pack-type terms, right. I mean, that's, when you really boil it down to it, isn't that their position, is, I mean -- or it's not their position, but it's the reality is that folks contract with the Government all the time for a future price.

MR. NETTER: Yes. And in this context, that's perfectly sensible because insurance plans are going to be contracting with drug formularies. And all of the contracts that depend on the pricing of particular drug products that are downstream, those can't be updated on a day-to-day basis is either. So it's perfectly sensible for the price to be fixed for one price applicability

year, and then, you know, potentially to be changed in the subsequent year.

THE COURT: All right. Anything else?

MR. NETTER: No, Your Honor.

THE COURT: All right. Thank you.

All right. Briefly here, AstraZeneca. Just very brief. Just rebuttal. Go ahead.

MS. STETSON: Thank you, Your Honor. I am mindful of the 12:30.

THE COURT: Well, don't. You don't have 25 minutes. No.

MS. STETSON: I understand.

THE COURT: You need to go. I said that was the absolute latest.

MS. STETSON: I won't need it. I have one point, essentially, on each of the points of discussion.

The first thing is on standing. I actually would encourage you to look closely at *Clapper* if you haven't already. So that was a circumstance where the plaintiffs were coming in and saying, we might talk to people who might be wiretapped pursuant to one of several programs, and that particular wiretapping program we had problems with.

The Court found that that kind of cascade of possibilities was simply too remote to establish

standing. Here, we have a drug that has been selected for this program, that the piano has already falling on us. This is not a piano might fall someday. We have a drug that has been selected for this program. We have to operate, you know -- unlike your government contractor example where the government contractor wasn't having to operate with legally flawed definitions that governed its ability to negotiate, we have having to value something right now, taking into account the fact that the Government has way overstepped its legal authority with respect to the guidance. That kind of immediacy is what grounds the standing here.

I want to make one more point that the bona fide marketing standing in particular, I thought I heard Mr. Netter say that there was something in the guidance that suggested that the Government would take care of the question about whether something was bona fide marketed within 30 days. The guidance, it's Page 165, of the revised guidance, and I think Page 62 of the initial guidance. The guidance says, every 30 days CMS will take a look at bona fide marketing, but remember what you and I talked about earlier. It is going to be looking at 12 months of data. And unless Mr. Netter is prepared to say that the 12 months of data proceeding an entry of generic on the market is going to suffice for their determination

about whether a generic would be robustly and meaningfully marketed, that delay is what is causing the harm.

This is not an advisory opinion about whether something is or is not going to be subjected to de minimis marketing. This is the delay that is occasioned by the Government saying we're going to look at 12 months of data about this marketing and then decide whether to let you out of the program.

Point three. The judicial review ban. The fact that Mr. Netter put those competing dictionary definitions -- it could mean -- selection could mean this; it could mean this -- I think, is exactly the problem with their argument. You begin, when you talk about a preclusion of judicial review, with the strong presumption, as the Supreme Court has said, that there is judicial review.

And what the Supreme Court has also said in the *Gutierrez de Martinez* case, 510 US at 434. This is cited in the *American Clinical Laboratories* case. If the judicial review provision is reasonably susceptible to two competing interpretations, then you rule in favor of the traditional understanding that administrative actions are subject to judicial review. And as you pointed out, this is not --

THE COURT: Well, wait. Let's do this.

MS. STETSON: Sure.

THE COURT: Let's assume you're right about that. Let's take "selection." Go under either definition of "selection." How would it make a difference in this case?

MS. STETSON: I think it would make a difference in this case, because we're not -- as I mentioned earlier, we are not contesting the selection of Farxiga for negotiation. We're not saying, oh, we shouldn't have been in the top ten list because our revenues are actually X versus Y.

What we are contesting is the definition of "qualifying single source drug," which is -- and I encourage you to look at the cases that provide against judicial review. That is a completely different animal than the cases that hold against judicial review, including *American Clinical Laboratories Association*, which turns on the question of the definition of "laboratory."

THE COURT: All right. Well, let's hold on. How would the determination of qualifying single source drugs go under either determination definition that was put up on the screen?

MS. STETSON: That would be my point.

THE COURT: Explain the two. Like why that difference? Which determination, first of all, do you want? Which definition that he gave?

MS. STETSON: We would like the definition of qualifying single source drug --

THE COURT: No, no, the definition of "determination."

MS. STETSON: Oh, determination.

THE COURT: Isn't that what you just said? You said that's what -- that's what he was pointing out. That's what you took issue with. So which definition of "determination" does AstraZeneca want me to use for the statute?

MS. STETSON: I'm going to answer that in two -- I'm going to answer your question and then explain.

We want the narrower definition.

THE COURT: Which is what?

MS. STETSON: Which is the act of decision, the deciding. We want --

THE COURT: The determining?

MS. STETSON: Determining. Yes, the determination.

THE COURT: The determining.

MS. STETSON: Yes. The determination.

THE COURT: All right. We'll using use "the determining." So you're saying that it's not the fact that Farxiga was determined. You are saying it was the determination, the process of determining Farxiga. How does that make a difference in this case? Whether I use either one, I don't understand how it makes a difference.

MS. STETSON: I think that's my point, though.

THE COURT: Well, just explain it to me if you want to make it your point.

MS. STETSON: Sure. The reason that that is a point in our favor is because of that *Gutierrez de Martinez* language that I just said. If you have --

THE COURT: Well, wait a second. Before you even get there, you said, "that was a point." What do you mean by "that"? So that's why I go back to, how did -- let's just do this. Let's start with the language of the statute: "The determination of qualifying single source drugs."

All right. What does determination mean in that statute, in that sentence, that clause from the statute?

MS. STETSON: The identification of a drug. The determination of a qualifying single source drug.

THE COURT: I don't think he disputes that. Where is the dispute?

MS. STETSON: I think he does. I don't want to speak for Mr. Netter either, but my point with respect to judicial review is that what you didn't hear Mr. Netter say was that, when you begin that inquiry -- do I or do I not have the power to look at this unlawful guidance? -- that you begin with the strong presumption in favor of review. If, as Mr. Netter demonstrated with those two competing definitions: Determination could mean this; it could mean this.

If it's competing definitions like that, that means that it's reasonably susceptible to an interpretation where we get judicial review of this predicate definition that we're talking about. That's the point of construing judicial review provisions narrowly. That was the point I wanted to make on how and whether to construe this judicial review provision to preclude us, or, apparently, anyone, from ever making a statutory challenge to us. That's not the way that the presumption works.

THE COURT: All right. To try to flesh this out, the determination of qualifying single source drug in this case was already done, correct?

MS. STETSON: Correct.

THE COURT: You're challenging the manner in which the determination was made, or are you challenging

the fact that it was made?

MS. STETSON: We are challenging the manner in which it was made, and we are challenging the definition that kind of sits behind it. So like the *Baxter* case --

THE COURT: The definition of qualifying --

MS. STETSON: Of qualifying --

THE COURT: -- single source drug.

MS. STETSON: -- single source drug. Yes.

THE COURT: Okay.

MS. STETSON: Not the determination of a particular drug. We're not saying you shouldn't have chosen Farxiga. That would walk us right into the judicial review bar. What we are saying is, there is a definition that you are using of "qualifying single source drug" that impacts our ability to figure out how to value Farxiga. Because if you, Government, are right, that despite what the statute says, qualifying single source drug actually sweeps in anything with the same active moiety, no matter when or how it's proved, that affects our ability to value our product --

THE COURT: All right. Now you're back to "affecting our ability to value our product," which I didn't see in your brief at all. But I'm not saying that matters, and the argument is very good, and I'll go back and look.

I mean, do you think "determination of value" is anywhere in the brief?

MS. STETSON: I want to say at Page 12 of our reply brief in particular, we talk about needing to make decisions now that impact our ability to negotiate later. And that's, of course, why we're here. You mentioned the March 1st deadline.

THE COURT: That's what I do want to spend the remainder of the argument on, why you're here. You know, I just signed the stipulation. I knew this was an important act. And I've got the Government and the lawyers on this case, who come with a lot of credibility to the Court and say, stipulation, hey, let's take it up. I'm going to do it.

I have to say as I sit here, I'm thinking why did I ever agree to this? I probably should have had you all brief it. I mean, but the Government agreed to do it. And, frankly, I thought at the time it was because it was in the Government's interest as well.

In other words, it was both parties, it was in both of your interests to get this decided here, get it to the Court of Appeals, and get it decided. And you avoid a preliminary injunction, and that's attractive to me, so I was like, sure, I'll sign the stipulation. And you avoided a preliminary injunction proceeding and

briefing and that kind of thing.

But I'm even just thinking, so I issue my decision by March 1. You say your response is due March 2; is that right?

MS. STETSON: That's correct.

THE COURT: So how is my decision going to influence anything you do between now and March 2, and now the biggest -- what you are saying today, which was not in your briefs, that you need a decision now so you can get involved or -- and you can meaningfully give a counter-proposal.

You're not going to get it. Even if I get you a decision by March 1, you're not going to get it in time to accomplish what you need.

MS. STETSON: Oh --

THE COURT: I agreed to get it by March 1; I didn't agree to get it before.

MS. STETSON: Understood. I think there are a couple of different answers.

The first is, the reason that we asked for March 1st and none of the other cases did, to my recollection, is because, as Mr. Netter mentioned, all of those other cases with one distinguishable exception, are making constitutional claims. There's one other case that is bringing a procedural --

THE COURT: You are making a constitutional claim.

MS. STETSON: They are, but they're not bringing APA claims. And for these purposes, the APA claims are what are driving the decision-making here for all the reasons we've talked about, the need to understand whether we are operating under lawful or unlawful guidance.

At the very least, if you are able to render a decision by March 1st, we will at least have a judicial imprimatur of whether or not in your view this is lawful or this is unlawful. That's helpful information to us.

THE COURT: That's an advisory opinion.

MS. STETSON: No, it is not. It is not because it's what we are intending to do with valuing our product under the negotiation that we are compelled to enter into.

If I could make two more quick points.

THE COURT: Just give me one second.

Okay.

MS. STETSON: So the first is on qualifying single source drug. I want to point out a couple of things that Mr. Netter said. When we, he and I both, walked through the definition, Mr. Netter concluded his definition by adding the phrase -- and I wrote this

down -- "so long as the same active moiety is involved." And that, of course, is the problem. That appears nowhere in the statutory definition.

I want to point out what Mr. Netter put up on the screen with --

THE COURT: Hold on, hold on.

Go ahead.

MS. STETSON: What Mr. Netter put up on the screen with respect to the *Ipsen* joint appendix, I'd encourage the Court to look at that entire document. Because I think is, unfortunately, one of those things what happens when you look at the 23 words that are good for you and not for the rest. That letter has to do with Ipsen's request in that case for a different price based on a supplemental NDA approval. That was what that language was about.

So the fact that the Government is reaching that far to pull 23 words from a completely inapposite letter suggests that maybe what we should be doing is looking at the statute for the definition.

Last thing I'll say is what you didn't hear Mr. Netter say on the due process arguments. You didn't hear a response to my point about *Bowles*, which is that *Bowles* said you don't get a taking claim because your participation is voluntary, but we're going to look at

due process.

You didn't hear a response with respect to the coercion, the absolutely -- "seismically" was my word -- disproportionate penalty that comes from us having to withdraw all of our drugs from the program based on withdrawing one drug from negotiation.

THE COURT: You don't have a case that says it's -- you don't have a case that talks about the withdrawal from Medicaid being a due process violation, do you?

MS. STETSON: No, but I have *NFIB* that says when the penalty is so disproportionate to the withdrawal, that is coercive. And, you know, I did anticipate Mr. Netter's response, which is that involved a state.

THE COURT: But it does, and that's a pretty big thing.

MS. STETSON: But the Court's ruling did not say, we're finding this coercive because it involves a state; they said, we are finding this coercive because the penalty for withdrawal is so harsh.

One last point on due process if I could, you and I and you and Mr. Netter spent some time today talking about the property interest. I'd encourage to you to go back and look at the government's briefs,

opening brief and reply brief. What the Government argued today about the property interest is nowhere in its briefing.

The Government's brief on due process begins and ends with the argument that our participation is voluntary. It is not voluntary for both of the reasons that we've already talk about. It either doesn't --

THE COURT: Not voluntary? You're going to have to -- how is it not voluntary?

MS. STETSON: I, actually. Let me --

THE COURT: And that seems a brand-new argument at 12:22.

You're saying your participation in Medicare is involuntary?

MS. STETSON: No, no. Let me bite that back.

What I meant is the only argument the Government made in its brief was that our participation was voluntary.

THE COURT: Correct. And because it's voluntary, you don't have a property interest. It's not your property interest, I mean, that you're being deprived of. You said your property interest is the patented products.

MS. STETSON: My point was the Government didn't make a separate argument that we didn't have a

property interest, even if you included either, as we've argued, that the voluntariness inquiry has no relevance to the due process question, or that this actually isn't voluntary.

So the Government is now arguing that, you know, setting aside the voluntariness, there's no property interest. That is not in their briefing. Their brief rises and falls on this argument that there's no due process violation because our participation is voluntary, not relevant to due process and, in any event, not voluntary. Those are our two arguments.

THE COURT: So are you saying they've waived their argument that you don't have a property interest?

MS. STETSON: Yes, I am. We're here on summary judgment, as you pointed out. And what they have argued, in its entirety, if you look at the header of the brief, is no due process because it's voluntary.

THE COURT: Have you waived ultra vires, then, your argument?

MS. STETSON: No. There's the third Circuit case we cite in our brief, the name of which escapes me, it begins with a B, but it talks about how ultra vires means contrary to statutory command under the APA.

THE COURT: Okay. Interesting.

MS. STETSON: There are no further questions.

THE COURT: All right. Thank you very much.

I enjoyed the argument very much. It's very, very helpful. I am a little taken aback by the March 1 deadline now.

You're not going to be able to get an appeal in time, it seems to me, to affect any of the ongoing negotiation over this price.

I mean, you know, the Third Circuit, on an expedited basis, just realistically, wouldn't have an opinion for you before September 1 of 2024. And even if they did, at that point, your counterproposal is already given. So why the March 1 deadline?

MS. STETSON: I think the March --

THE COURT: I mean, in other words, why didn't you come to me and say, hey, we need this decided by December 1? Nobody did that. You didn't bring a preliminary injunction.

MS. STETSON: I think we were trying to give -- two things. We were trying to give you as much time as possible, and the second is --

THE COURT: But as much time as possible -- hold on. And I appreciate any time somebody gives me as much time as possible. But to issue an opinion on a deadline that would be ineffectual. What advantage does it serve to get the opinion out?

In other words, why didn't you bring a preliminary injunction to me in the fall? It would have been -- it's always difficult to address preliminary injunctions, but I do. I am a little, as I say, taken aback.

MS. STETSON: I think what we were -- what we were thinking about is this. March 2nd is our counteroffer deadline. Depends on whether -- March 2 is a Saturday, so I'm hesitating only because maybe it's March 4 -- the March 1st deadline was designed to give you as much time as possible and us at least some time to take a judicial decision into account.

We understand that neither side is going to be able to sort of run the complete gauntlet before March 1st or March 2nd. This at least gives us some further certainty about what we're negotiating for and why. That's the line we were trying to navigate.

THE COURT: All right. Well, and I suppose in your favor, you could argue -- well, plus, if you won, you don't have to submit a bid, at least potentially. Depends how an order would be framed.

MS. STETSON: True also.

THE COURT: But that would be an issue.

MS. STETSON: Yes.

THE COURT: All right. Yeah. I can see that.

Okay.

MS. STETSON: Thank you, Your Honor.

THE COURT: Thank you. Maybe I'm not as taken aback as much as I thought I was.

Okay. All right. Thank you very much.

I will say one other thing. It's possible, as I write this, I may have follow-up questions. I did not get to prepare for this, given my trial last week, you know, and given the complexity of the issues, you could spend weeks and days. And I'm sure some Court of Appeals will one day.

So as I write and formulate further questions, I make issue oral orders asking for immediate responses. And because you've put me on a clock, I'm going to put you on one.

Just be ready. You have a lot of lawyers. I can see issuing an order saying, you know, you have 24 hours to let me know what the answer to X is. Okay?

MS. STETSON: Understood.

THE COURT: And if I ever do something like that, it would be -- I will give both -- even if it's directed to one party, both parties will have the same time frame to respond to whatever question I have. I may not have any questions, but just be ready for that. All right?

Thank you. Take care.

(The proceedings concluded at 12:26 p.m.)

CERTIFICATE OF COURT REPORTER

I hereby certify that the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

/s/ Bonnie R. Archer
Bonnie R. Archer
Official Court Reporter
U.S. District Court