

1 IN THE SUPREME COURT OF THE UNITED STATES

3 SANDOZ INC., :

4 Petitioner : No. 15-1039

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6  AMGEN INC., ET AL.,                               :
7  Respondents.                                       :

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9      AND

11 AMGEN INC., ET AL., :

12 Petitioners : No. 15-1195

14 SANDOZ INC., :

15 Respondent. :

17 Washington, D.C.

19

1 APPEARANCES:

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3 the Petitioner in No. 15-1039.

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9 the Petitioners in No. 15-1195.

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1	C O N T E N T S	
2	ORAL ARGUMENT OF	PAGE
3	DEANNE E. MAYNARD, ESQ.	
4	On behalf of the Petitioner in No. 15-1039	4
5	ORAL ARGUMENT OF	
6	ANTHONY A. YANG, ESQ.	
7	For United States, as amicus curiae,	
8	supporting the Petitioner in No. 15-1039	23
9	ORAL ARGUMENT OF	
10	SETH P. WAXMAN, ESQ.	
11	On behalf of the Petitioners in No. 15-1195	34
12	REBUTTAL ARGUMENT OF	
13	DEANNE E. MAYNARD, ESQ.	
14	On behalf of the Petitioner in No. 15-1039	60
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

1 P R O C E E D I N G S

2 (10:05 a.m.)

3 CHIEF JUSTICE ROBERTS: We'll hear argument  
4 first this morning in Case 15-1039, Sandoz v. Amgen.

5 Before we get started, Ms. Maynard,  
6 Ms. Maynard and Mr. Waxman, the Court has decided to  
7 give each of you five extra minutes, and you can  
8 proceed, Ms. Maynard, when you're ready.

9 MS. MAYNARD: Thank you, Your Honor.

10 ORAL ARGUMENT OF DEANNE E. MAYNARD

11 ON BEHALF OF THE PETITIONER IN 15-1039

12 MS. MAYNARD: Mr. Chief Justice, and may it  
13 please the Court:

14 The Biosimilars Act created a comprehensive  
15 and self-contained scheme for the early resolution of  
16 patent disputes. Regardless of the actions an applicant  
17 or sponsor take along the way, the end result is the  
18 same, patent litigation. Courts should apply that  
19 comprehensive scheme as written. They shouldn't look  
20 elsewhere for consequences.

21 I'd like to start with the issue in Sandoz's  
22 petition, our petition, the notice of commercial  
23 marketing issue, and then turn to the issue in Amgen's  
24 petition, the -- the information exchange.

25 The Federal Circuit misread the notice of

1 commercial marketing provision to provide sponsors a  
2 180-day automatic stay that's nowhere in the statute.  
3 That ruling will wrongly delay the marketing of every  
4 biosimilar, even when there are no patent rights left to  
5 be --

6 JUSTICE KENNEDY: Could you tell me, suppose  
7 that in year 2 of the 12-year exclusive period, the  
8 application for the biosimilar is made. And then in  
9 year 4, there is eight more years to run, the  
10 commission -- the FDA decides that it's going to approve  
11 it. Is it licensed at that time?

12 MS. MAYNARD: Well --

13 JUSTICE KENNEDY: Or is it not licensed  
14 until the very end of the 12-day period.

15 MS. MAYNARD: The FDA cannot license a  
16 biosimilar until the end of the 12-year period. And --  
17 and actually, a sponsor can't apply for a biosimilar  
18 license until year 4, at the end of year 4. As a  
19 practical matter, though, Justice Kennedy, it takes  
20 eight to ten years to develop biosimilars, so it would  
21 be very rare.

22 JUSTICE KENNEDY: If it's done in -- if the  
23 approval is done in year 6 or year 7, is that announced  
24 publicly, that -- that the approval is done?

25 MS. MAYNARD: The statute prohibits the --

1 the -- the FDA from making an approval effective, and --  
2 and that's in -- in the statute, Your Honor, at (k)(7).  
3 It's the exclusivity provision that you're referring to.  
4 It prohibits the FDA from making the license effective  
5 until 12 years have run. That's the exclusivity period.

6 JUSTICE SOTOMAYOR: I'm sorry.

7 MS. MAYNARD: They --

8 JUSTICE SOTOMAYOR: Could you clarify? Does  
9 that mean that the FDA can't announce its intent to  
10 approve on year 12 plus 1 earlier than year 12, or --  
11 I'm not quite sure I understand.

12 How long does it take for the FDA to approve  
13 the biosimilar? Assuming you go through Phase I, and  
14 there is -- and Phase II has been finished. How long --  
15 those run independent of the FDA approval, correct?

16 MS. MAYNARD: That's right. The information  
17 exchange and the patent litigation process is completely  
18 separate and de-linked from the FDA process.

19 JUSTICE SOTOMAYOR: So how long -- I want  
20 you to go back to Justice Kennedy, but I just want to  
21 get a sense of timing. How long does it generally take  
22 for the FDA to say, this is okay effective 12 plus 1?

23 MS. MAYNARD: So two points about that,  
24 Justice Sotomayor. To answer your question, the FDA has  
25 said that it takes about -- they are aiming to try to

1 approve biosimilar applications within 10 months of  
2 application. But there's nothing in the -- this Act, in  
3 contrast to the Hatch-Waxman Act, that expressly allows  
4 the kind of tentative approval that I think both of you  
5 are asking about.

6 And I think you may be asking about the --  
7 the -- the fix that the Federal Circuit suggested for  
8 the problem they've created in the --

9 JUSTICE SOTOMAYOR: No, no.

10 MS. MAYNARD: No. Okay.

11 JUSTICE SOTOMAYOR: I'm trying to get the  
12 process down.

13 MS. MAYNARD: Okay.

14 JUSTICE SOTOMAYOR: It takes them 10 months.

15 MS. MAYNARD: Yes, Your Honor.

16 JUSTICE SOTOMAYOR: Let's assume you put in  
17 an application in year 4. Do they have to wait until  
18 when to announce that it's okay?

19 MS. MAYNARD: They can't -- under the  
20 statute, under (k) (7), they can't make it effective.  
21 They can't make the approval effective until year 12.

22 JUSTICE SOTOMAYOR: When do they tell you  
23 that they will?

24 MS. MAYNARD: Well, there -- there's nothing  
25 in the statute that calls for an approval before year

1 12.

2 JUSTICE KENNEDY: I mean, do they get a  
3 phone call? They say, hey, good news, we've got it  
4 approved, but in five years, we're going to be able to  
5 market. I mean, how does it work?

6 MS. MAYNARD: No, Your Honor.

7 JUSTICE KENNEDY: And then -- incidentally,  
8 when you're talking about (k), is this in -- can you  
9 give me the citation and the appendix to the --

10 MS. MAYNARD: Yes, Your Honor. So I'm  
11 looking at -- it's in the blue brief --

12 JUSTICE KENNEDY: Right.

13 MS. MAYNARD: -- at 24A.

14 JUSTICE KENNEDY: 24A. Thank you.

15 MS. MAYNARD: Exclusivity for reference  
16 from, and it says: Effective date of biosimilar  
17 application approval. The approval of an application  
18 under this subsection may not be made effective by the  
19 Secretary until the date that is 12 years after the date  
20 on which the referenced product was first licensed under  
21 subsection (a). That's the reference product,  
22 biological sponsor.

23 So the statute does not allow the FDA to  
24 approve the biosimilar until year 12, until the  
25 exclusivity period has run. The statute also does not



1 expressly allow any tentative approval, unlike the  
2 Hatch-Waxman Act, which does say you can call in advance  
3 and say you're -- you're tentatively approved.

4 But even in the Hatch-Waxman Act, the -- the  
5 -- the government doesn't consider it licensed, which is  
6 the word in the statute in the marketing provisions --

7 JUSTICE KENNEDY: I -- I have one more  
8 question --

9 MS. MAYNARD: Yes, Your Honor.

10 JUSTICE KENNEDY: -- and then I'll -- and  
11 then I'll subside. It seems to me that this process,  
12 this aspect of the process cuts against you insofar as  
13 the 180 days' notice.

14 MS. MAYNARD: I'm not sure I understand the  
15 premise of your question, Justice Kennedy.

16 JUSTICE KENNEDY: Well, if -- the -- the 180  
17 days has to run from some time, and it seems to me that  
18 it has to run from the time that it's licensed --

19 MS. MAYNARD: Well --

20 JUSTICE KENNEDY: -- based on what you're  
21 telling me.

22 MS. MAYNARD: No, Your Honor. So I'd like  
23 to turn to the text then of the Notice of Commercial  
24 Marketing Provision, because I think the text forecloses  
25 that reading. The text of the Commercial Marketing

1 Provision has one and only one timing element. It  
2 requires notice at least 180 days before the date of the  
3 first commercial marketing.

4 JUSTICE BREYER: Yes. But there is what you  
5 already noticed about. What does this notice say? And  
6 what it says is that you have to provide more -- no  
7 later than 180 days, is notice of -- maybe -- it doesn't  
8 even say this; it's not a complete sentence -- of the  
9 first commercial marketing of the biological product  
10 licensed.

11 Now, how could you do that if you don't know  
12 what the product licensed is?

13 MS. MAYNARD: Well --

14 JUSTICE BREYER: And I take it that they had  
15 in the agency -- this goes to an agency, doesn't it?  
16 And I have -- in the agency, they have the authority to  
17 say, we will license this provided it's made this way,  
18 but not that way; provided you do this kind of a check,  
19 but not that kind of a check. They have a lot of power  
20 over what is licensed.

21 So how can you provide notice -- by the way,  
22 maybe that isn't what notice means. Maybe it just means  
23 notice that you will commercially market X, or maybe it  
24 means some combination thereof. The reason that I point  
25 to that ambiguity -- which, to me, is a crucial

1     ambiguity -- and it has to do with both your arguments,  
2     indeed, all of them on both sides. There is an agency  
3     here, isn't there?

4                   MS. MAYNARD: The FDA. Yes, Your Honor.

5                   JUSTICE BREYER: All right. Now, we are  
6     being asked to interpret very technical provisions that  
7     I find somewhat ambiguous and am operating in a field I  
8     know nothing about. But it's going to have huge  
9     implications for the future. So why isn't the way to go  
10    about this case to ask the agency to issue some  
11    regulations? Then when we see their interpretation, you  
12    all will be able to argue that their interpretation  
13    exceeds the statutory delegation. And by doing that, we  
14    would have a better picture.

15                  MS. MAYNARD: Well, I think, Your Honor, to  
16    take the text, which is where I think the Court should  
17    look for the answer to this question --

18                  JUSTICE KENNEDY: Oh?

19                  MS. MAYNARD: -- on page 39A.

20                  JUSTICE BREYER: Yeah, I've got it.

21                  MS. MAYNARD: -- of the blue brief, is the  
22    Notice of Commercial Marketing Provision.

23                  JUSTICE KENNEDY: Yeah.

24                  MS. MAYNARD: And it says, as you read: The  
25    subsection (k) applicant shall provide notice to the

1 referenced product sponsor not later than -- so the --

2 JUSTICE BREYER: So --

3 MS. MAYNARD: -- not later than 180 days  
4 before the date of the first commercial marketing. But  
5 the 180 days, Justice Breyer, modifies the date of first  
6 commercial marketing.

7 JUSTICE BREYER: Yeah, yeah, that's true.

8 MS. MAYNARD: Because of that --

9 JUSTICE BREYER: Provide the what? What is  
10 it you're to provide notice of?

11 MS. MAYNARD: Of the biological product  
12 licensed under subsection (k). But this statute uses  
13 that phrasing to describe the biosimilar.

14 JUSTICE KENNEDY: But you just -- but you've  
15 just said in answer to my question that the license  
16 doesn't happen until 12 years plus 1.

17 MS. MAYNARD: Well, the license can't happen  
18 until 12 years plus 1, Justice Kennedy, but, like, right  
19 now and for years to come, the exclusively period has  
20 already run. And so when applications are made, as it  
21 was here, we expect it to be licensed within 10 months  
22 of application and were, in fact, licensed. So when  
23 Sandoz gave the notice here and said we expect to be  
24 licensed in the first quarter, second quarter of next  
25 year, Sandoz was licensed.

1                   So if the -- if your questions earlier,  
2 Justice Kennedy, were getting to does the applicant have  
3 an idea how its application is faring, does the  
4 applicant know when to expect it's going to get  
5 approved, the answer to that is yes. And Congress  
6 didn't show any concerns with litigation too early.

7                   So to your purpose question, Justice Breyer,  
8 the purpose of this statute is to allow early resolution  
9 of patent --

10                  CHIEF JUSTICE ROBERTS: But Justice Breyer's  
11 question was about agency regulations.

12                  JUSTICE BREYER: That's right. Thank you.

13                  MS. MAYNARD: Well, with -- with respect,  
14 Mr. Chief Justice, the United States is here explaining  
15 its reading of the statute and agrees with our reading.

16                  JUSTICE BREYER: Oddly enough, I -- I  
17 would -- I would find an explanation far more convincing  
18 as a layperson, if, in fact, there had been notice and  
19 comment proceedings before an expert agency, which, in  
20 fact, having heard all the different views on what that  
21 word "notice" means, and having figured out whether if  
22 we allow day one notice, what's going to happen is we're  
23 going to gut the possibility of people going in and  
24 making these exchanges, because everybody will be free  
25 under the 23 -- under whatever this is 9 -- 9(a), to go

1 and start bringing declaratory-judgment actions. And  
2 somebody will make that argument, somebody will make the  
3 opposite, and we'll know what we're doing.

4 So -- so that's the --

5 MS. MAYNARD: Well, we --

6 JUSTICE BREYER: -- same thing the Chief  
7 just said.

8 MS. MAYNARD: Well, we -- we know -- we know  
9 two things from the text of the statute, though, Your  
10 Honor. One is that the 12-year exclusivity period was  
11 set by the Congress and said the FDA can make a license  
12 effective at the 12-year point. If the Federal  
13 Circuit's reading is right, that license is not  
14 effective, not effective in any case, even when there  
15 are no patent rights until 12 1/2 years.

16 JUSTICE SOTOMAYOR: Can I go back to the  
17 beginning of Justice Breyer's question. He made an  
18 assumption that until the approval of the product, that  
19 the other side won't know exactly what it is that's  
20 going to be approved, particularly in a situation like  
21 this, where you -- you've kept your application from  
22 them so they don't have it.

23 Take -- address that issue. In your brief  
24 you say they can get it. They can get it from the  
25 industry, from the SEC filings, from -- from FDA talk,

1 all of that stuff. But that won't tell them exactly  
2 what it is that you're intending to market.

3 So -- or the other side -- how -- how would  
4 you know? If you start a declaratory-judgment action,  
5 as you're entitled to do, wouldn't you know then?  
6 Couldn't you get it in discovery?

7 MS. MAYNARD: Exactly, Your Honor. And  
8 that's our point. So -- so that's exactly the  
9 consequence Congress provided when someone failed to  
10 provide notice or doesn't provide the application.

11 So here, Sandoz didn't provide its  
12 application, as you note, and that allowed Amgen to sue.  
13 That -- there are two acts of artificial infringement  
14 created by the statute, both of which are key to  
15 understanding the whole point, which is to allow  
16 litigation based on the application. It's the  
17 application, just like in Hatch-Waxman, that  
18 crystallizes the controversy. And so in the  
19 situation -- and it provides two -- two acts of  
20 infringement.

21 And if I can just point to them, they are in  
22 E(2)(c) of 271, so that's on page 5A. One is in the  
23 instance where the parties engage in the information  
24 exchange, which applicants are highly incentivized to  
25 do. If -- if there's any fear of any patents that might

1 block their product, an applicant is going to go through  
2 the information exchange, because it gives --

3 JUSTICE SOTOMAYOR: Could it -- could the  
4 company with the product file a declaratory-judgment  
5 action when they don't know what you're going to do? Do  
6 they have a good-faith basis for believing you're going  
7 to infringe if they don't have the application to look  
8 at until they get discovery?

9 MS. MAYNARD: Yes, Your Honor. So --

10 JUSTICE SOTOMAYOR: Tell me how.

11 MS. MAYNARD: Okay. Well, first I want to  
12 say, Congress obviously thought they did, because it  
13 created, in the text, an artificial-infringement act for  
14 that very thing.

15 Two, and they're right. By definition, a  
16 biosimilar is highly similar to the reference-product  
17 sponsor's product. So a reference-product sponsor would  
18 have good-faith basis in that case to bring suit on any  
19 patent that covers its own product, or any patent that  
20 covers a use of its own product.

21 CHIEF JUSTICE ROBERTS: But it doesn't know  
22 the specifics of the biosimilar. I mean, by definition,  
23 the biosimilar is similar; it's not identical. And  
24 whether or not it infringes might have something to do  
25 with the ways in which it is different.



1 MS. MAYNARD: It might, Your Honor. But the  
2 question is whether or not you have a good-faith basis  
3 to sue. And given the standard of highly similarity and  
4 the kind of similarities there have to be, if the  
5 sponsor has any patent that covers its product, this  
6 product itself or any uses of the product, it would have  
7 a good-faith basis to sue, which is exactly what Amgen  
8 did here.

9 CHIEF JUSTICE ROBERTS: Well, you're suing  
10 saying, this thing infringes our patent. We don't even  
11 know what "this thing" is.

12 MS. MAYNARD: You know that -- that the  
13 applicant has submitted to the FDA using your data to  
14 produce a product that's highly similar to your product.

15 JUSTICE KAGAN: Is the way this statute  
16 works, Ms. Maynard, that if I have a valid patent, I  
17 sue?

18 MS. MAYNARD: Yes. Yes, exactly, Justice  
19 Kagan.

20 JUSTICE KAGAN: Is that it? I mean, I don't  
21 know. I'm asking.

22 MS. MAYNARD: Yes. So if --

23 JUSTICE KAGAN: But just, is the practice  
24 that given that these will all be similar, if I have a  
25 valid patent, I bring litigation?

1 MS. MAYNARD: Right. Exactly. And Congress  
2 provided for this exact situation in (e) (2) (C), which is  
3 on 5A of our blue brief, made an -- someone applying and  
4 not providing the application within 20 days made that  
5 precise act an act of infringement, and you would have a  
6 good-faith basis to sue, as they did here.

7 CHIEF JUSTICE ROBERTS: You would not -- I  
8 don't know if I agree with you on that. But you would  
9 have to sue. That's the problem; right? What would the  
10 patent litigation look like? I have this patent; you're  
11 bringing this biosimilar; I'm going to sue you. The  
12 litigation would decide whether the biosimilar infringes  
13 the patent, and that would have something to do with  
14 whether or not it's sufficiently -- whether it's too  
15 similar or whether it's certainly distinct.

16 And what your argument means is that if you  
17 have the patent Justice Kagan said, you have to sue.

18 MS. MAYNARD: No, Your Honor.

19 CHIEF JUSTICE ROBERTS: So this -- no?

20 MS. MAYNARD: No, Your Honor. You don't  
21 have to sue. I'm sorry if I misunderstood your  
22 question.

23 JUSTICE KAGAN: All I was asking as a matter  
24 of practice, that, in fact, that's the way people  
25 operate under this statute; that given the similarity of

1 these products, if I believe I have a valid patent, that  
2 the patent hasn't lapsed, I'm going to bring a suit.

3 MS. MAYNARD: That is exactly what Amgen did  
4 here. And I want to emphasize that in most situations,  
5 applicants will go through the process, because the  
6 information exchange and they have in those situations.  
7 So this is the only situation in which I'm aware  
8 where --

9 JUSTICE SOTOMAYOR: I'm sorry. If the  
10 biosimilar files a notice of intent to file the  
11 application and a copy of the application, if it  
12 complies with all of the steps in Phase 1, does it estop  
13 the bio -- the -- the licensed product holder from  
14 seeking a declaratory-judgment action?

15 MS. MAYNARD: Yes, Your Honor. And so if --  
16 for -- until you get to a certain point in the process;  
17 right? So if the -- the way that it works is if the  
18 applicant does provide, so does participate in the  
19 information exchange, then they go through a  
20 back-and-forth exchange.

21 During that period of time, the -- the  
22 (1)(9)(A) bar -- if you'd like me to walk you through  
23 it, I can explain why -- so but the (1)(9)(A) bar would  
24 bar anybody bringing declaratory action during that  
25 exchange.

1 JUSTICE SOTOMAYOR: Well, that's assuming  
2 good faith. And that's the next question, which is if  
3 you -- if the biosimilar doesn't comply, you're saying  
4 the other side can sue. But what happens if you do  
5 comply? Can the other side -- and the other side fails  
6 to, they -- they don't give you the notice that they're  
7 required to. They don't do something that's required on  
8 their part in that exchange process.

9 MS. MAYNARD: This --

10 JUSTICE SOTOMAYOR: What is your biosimilars  
11 remedy in that case?

12 MS. MAYNARD: The statute provides powerful  
13 incentives for the sponsors to continue through the  
14 process, Justice Sotomayor.

15 JUSTICE SOTOMAYOR: All incentives have a  
16 way of failing. Just look at our society.

17 MS. MAYNARD: If --

18 JUSTICE SOTOMAYOR: So --

19 (Laughter.)

20 MS. MAYNARD: Yes. And I -- but the  
21 consequence if they -- if -- to answer your question, if  
22 the -- if the sponsor doesn't follow through on the  
23 information exchange and then doesn't file the (1)(6)  
24 lawsuit, so (1) -- at stage (1)(6), it says the sponsor  
25 shall sue within a certain period of time. If the

1 sponsor doesn't bring that suit, it's limited in any  
2 future infringement suit to reasonable royalties.  
3 That's the provision in (e)(6)(A) of 271 on 8A.

4 And I think -- but this is one whole  
5 ecosystem. It's complicated to be sure, but Congress  
6 took into account all of these situations.

7 JUSTICE GINSBURG: Can you explain the  
8 difference -- there are two rounds of patent  
9 infringement; right? Round 1 and -- can you explain the  
10 difference between those two?

11 And with respect to Justice Breyer's  
12 question, you started out by saying all of this is about  
13 early resolution of patent litigation. So which would  
14 be the agency that's involved? Your answer was the Food  
15 and Drug Administration. What about Patent and  
16 Trademark Office?

17 MS. MAYNARD: Well, just to clarify to  
18 the -- Mr. Chief Justice's questions and Justice  
19 Breyer's questions, Justice Ginsburg, I don't believe  
20 FDA would have -- or the patent office has rule-making  
21 authority to interpret these provisions. So -- but  
22 in -- the -- so I don't think that will solve the  
23 problem. I think this is a statutory interpretation  
24 question. And I think the text answers --

25 JUSTICE BREYER: Yeah. But you don't

1     need -- you don't need explicit regulatory authority.  
2     There are many situations where you defer to an agency's  
3     determination that can have informal -- you know, you  
4     all know all that.  So -- so -- so I -- I would stick  
5     with the idea of the FDA doing this first, but maybe I  
6     can't get there.  And if I can't get there, I'm stuck.

7                     MS. MAYNARD:  I think the text answers these  
8     questions that I'm being asked.

9                     May I go back and answer Justice Ginsburg's  
10    question about the -- the way that the two phases work?  
11    First, Your Honor, there's not always two phases.  So  
12    even if the parties engage in the information exchange,  
13    it contemplates -- it gives the sponsor -- I mean, the  
14    applicant a great deal of control.  The applicant can  
15    put all of the patents on the lists into that  
16    litigation.  And if that happens, they -- there may  
17    never be a need for a second litigation if there are  
18    never any new patents.

19                    That's what happened in the Apotex case  
20    that's pending.  There are no patents left, yet Apotex  
21    is subjected to the 180-day bar of the notice of  
22    commercial marketing provision.

23                    So -- and the purpose of the notice of  
24    commercial marketing provision, Justice Ginsburg, is  
25    that it lifts the gate.  So once the parties go through

1 the information exchange, as Justice Sotomayor was  
2 suggesting, that creates a stay of any litigation except  
3 for the ones the parties agree to. The sponsor has  
4 great control over that first litigation.

5 The point of the notice is to allow the  
6 sponsor to litigate any other patents it might have  
7 before the exclusivity period runs out. And the notice  
8 does two things. It does two things. It lifts the gate  
9 to allow the sponsor to bring any declaratory-judgment  
10 actions. And it also says, if appropriate, the sponsor  
11 seek a preliminary injunction. But, of course, if you  
12 file an early-enough declaratory-judgment action, you  
13 don't need a preliminary injunction. It's a very  
14 powerful remedy that the statute has given to the  
15 sponsors.

16 Mr. Chief Justice, I see I -- I'm already  
17 into my -- am I into my extra rebuttal? If I --

18 CHIEF JUSTICE ROBERTS: Yes.

19 MS. MAYNARD: May I reserve the time?

20 CHIEF JUSTICE ROBERTS: Yes.

21 MS. MAYNARD: Thank you.

22 CHIEF JUSTICE ROBERTS: Mr. Yang.

23 ORAL ARGUMENT OF ANTHONY A. YANG

24 FOR UNITED STATES, AS AMICUS CURIAE,

25 SUPPORTING THE PETITIONER IN 15-1039

1                   MR. YANG: Mr. Chief Justice, and may it  
2 please the Court:

3                   The Congress enacted a detailed process for  
4 early resolution of patent disputes through patent  
5 infringement litigation while FDA is evaluating a  
6 biosimilar application. The statute expressly  
7 establishes a series of procedural steps, and then  
8 specifies the consequences for both the applicant and  
9 the sponsor if they fail to take the steps that would  
10 set you off the -- the (l) path. And all of those  
11 consequences address the timing and the scope of patent  
12 litigation.

13                  Those consequences, which are quite  
14 detailed -- we don't have the time to talk about all of  
15 them, but they're in the statute, they're in our  
16 brief -- are the exclusive consequences. It would be --  
17 it would muck up the statute for courts to come in and  
18 start policing each step of the (l) dance and then send  
19 the parties back. The whole idea of this --

20                  JUSTICE KENNEDY: But Justice Breyer's  
21 question and my question is the same. The FDA is  
22 involved in -- intimately, page 32A of the brief, the  
23 subsection (k) application information. Not later than  
24 20 days after the secretary notifies the applicant that  
25 the application has been accepted, the applicant shall



1 provide.

2                   Now, this -- this means that the agency  
3 gives the notice for 20 days. And it seems to me,  
4 certainly, it would be within its authority, or it would  
5 be a sensible thing for it to say -- and they have a  
6 regulation -- if you don't do that and we've told you to  
7 do that, we're going to delay the review process.

8                   MR. YANG: I actually think it's not so  
9 clear. If you compare this to the Hatch-Waxman Act --  
10 and I believe you had an opinion called Caraco about  
11 that not so long ago -- that actually embeds the FDA in  
12 the process of identifying patents. It has the orange  
13 book.

14                   This is quite a different process. The FDA  
15 is involved with the licensure, but Congress at this  
16 point separated FDA. FDA was actually petitioned to do  
17 some rule-making in this context and it declined to do  
18 so because of those differences. So we ultimately still  
19 are here --

20                   JUSTICE SOTOMAYOR: Mr. Yang, do --

21                   MR. YANG: -- about a statute. And the  
22 statute --

23                   JUSTICE SOTOMAYOR: Do we have your  
24 assurances that this is the FDA's position?

25                   MR. YANG: It is the FDA's position. It is

1 the PTO's position. We have --

2 JUSTICE SOTOMAYOR: Has it been a consistent  
3 position in other situations? I don't know if it gets  
4 --

5 MR. YANG: Yeah.

6 JUSTICE SOTOMAYOR: -- opinion letters or --  
7 or --

8 MR. YANG: Well, they've not issued opinions  
9 on how this works, so I don't know of anything that's  
10 inconsistent. I believe --

11 JUSTICE SOTOMAYOR: In any litigation, have  
12 they taken a different position?

13 MR. YANG: No, not that I know of.

14 JUSTICE GORSUCH: Mr. Yang, you -- you  
15 indicate that (1)(9) is the exclusive remedy for a  
16 (2)(A) violation.

17 MR. YANG: Close.

18 JUSTICE GORSUCH: All right. Well, let me  
19 know where I get it wrong, but -- or at least I  
20 understand that's the primary position of -- of your  
21 side. But Amgen sought relief under State law and --  
22 and I -- I didn't take -- take it that Petitioner argued  
23 preemption in any way, shape, or form. So where does  
24 that leave us? (1)(9) might otherwise be the exclusive  
25 -- or almost exclusive mechanism, but what happens when

1 we have a claim under State law that no one's argued is  
2 preempted?

3 MR. YANG: Well, I believe Sandoz argued, at  
4 least in the court of appeals, that it was preempted.  
5 But putting that to aside, the Federal Circuit in this  
6 case deemed the State law claim for the injunction to be  
7 moot. This is at page 24a and 25a of the Joint  
8 Appendix. It did so because it found a Federal  
9 injunction and imposed a Federal injunction to enforce  
10 the statute. That's precisely what the Federal Circuit  
11 made even more clear in the subsequent decision in  
12 Apotex, and so where we are now is only on the question  
13 of the Federal remedy, if there is one, for failing to  
14 give notice or failing to comply with the information  
15 exchange.

16 I will say that it --

17 JUSTICE GORSUCH: That's certainly not  
18 Amgen's position, so --

19 MR. YANG: I will say that there are -- I  
20 think there are strong arguments that this would be  
21 preempted. This is a highly detailed scheme. And if  
22 States were to start to interject different means of  
23 enforcing it on a State-by-State basis, that might wreak  
24 some havoc, but we've not taken a position on that.

25 JUSTICE GORSUCH: Exactly.

1 MR. YANG: Here we --

2 JUSTICE GORSUCH: I agree with you, but the  
3 absence of any argument on preemption is what makes it  
4 so curious.

5 MR. YANG: Well, the judgment below did not  
6 rest on the State law claim. Again, if you look at  
7 page 24 and 25 is where it says it's moot, it rests on a  
8 Federal law.

9 CHIEF JUSTICE ROBERTS: No, but it rests on  
10 a Federal law cause of action that also might not be  
11 there. And in terms of the preemption question, it  
12 seems to me that it's very hard to give a comprehensive  
13 answer to the questions presented without considering  
14 whether, well, thanks for your opinion on what Federal  
15 law does, but, in fact, State law, you can get the same  
16 injunction. It's really asking us to put together a  
17 puzzle where a big piece is missing.

18 MR. YANG: I don't think State law is a  
19 piece of the puzzle. Congress does not have the habit  
20 of enacting comprehensive statutes and then allowing  
21 States to fill it -- figure out --

22 CHIEF JUSTICE ROBERTS: Well, it becomes  
23 part -- so are you arguing the preemption question or --

24 MR. YANG: Well, we think there are strong  
25 arguments. Again, we've not taken a vetted position on

1     that because it's not been, as the case comes to the  
2     Court, what the case is about. The case is about --

3                 CHIEF JUSTICE ROBERTS: So you think that --  
4     do you think the statute can function in the way you're  
5     arguing, even if there are injunctions? Based on the  
6     State law provisions?

7                 MR. YANG: Can the statute work? I think it  
8     would mess up the scheme that Congress -- because if you  
9     were to look at "shall," you know, there's -- there are  
10    eight subsections, that's clauses of -- of subsection  
11    (1). If at each stage a court is policing and saying,  
12    no, no, no, you didn't give sufficient information, you  
13    didn't do that, you'd have a series of back and forth in  
14    the scheme. The whole idea is you go along a path, and  
15    at certain points, if you don't do something, boom, you  
16    bump out, you're in litigation. And --

17                JUSTICE SOTOMAYOR: So you're asking us,  
18    assuming, just an assumption for the sake of argument,  
19    that we rule in your favor and say, as you've asked us  
20    to say, that a declaratory judgment is the -- that --  
21    the only remedy available, and there is no Federal  
22    injunction that's possible here, do we vacate and remand  
23    for the court below to decide whether State law  
24    provides --

25                MR. YANG: No, I think the best -- the best

1 way for the Court to decide is what's required under the  
2 statute. The cause of action, if you do that, you'd  
3 leave open questions of State law and preemption. The  
4 cleanest way is just to resolve what the statute  
5 requires in the --

6 JUSTICE SOTOMAYOR: I'm sorry, so I say the  
7 statute says -- we say the statute says that.

8 MR. YANG: If the statute --

9 JUSTICE SOTOMAYOR: What are we doing?  
10 We're saying the State law is moot?

11 MR. YANG: No, because there's no State law  
12 claim. If you're complying with the Federal statute,  
13 there is no State law claim. The State law would  
14 piggyback on the Federal law.

15 I also want to address the question that the  
16 Court had earlier about no -- you know, you have to know  
17 what's licensed in order to -- to identify your claims.  
18 That's --

19 JUSTICE SOTOMAYOR: If it's not preempted,  
20 how would it be mooted?

21 MR. YANG: It would just fail, just like on  
22 (1)(2), the Federal Circuit said, you're complying with  
23 Federal law, therefore, you have no State law claim,  
24 because your State law claim is predicated on violating  
25 the Federal law. It would be the same for both.

1                   So the reason --

2                   JUSTICE SOTOMAYOR: But that begs the  
3 question on the question we're not looking at, but it  
4 begs the question on point 2 -- on the first point which  
5 is, is it a requirement that the biosimilar applicant  
6 give over the application. It is certainly a  
7 requirement of the statute, the remedy may be file a  
8 declaratory-judgment action.

9                   MR. YANG: And the exclusive remedy, and  
10 which would answer -- that would --

11                  JUSTICE SOTOMAYOR: That goes back to  
12 preemption.

13                  MR. YANG: Well, no, I think that would  
14 answer. You would say that this is the -- your  
15 complying with the statute is a mandatory condition  
16 precedent to continue on the path to take all of these  
17 steps, but if you don't, and the statute provides an  
18 off-ramp, you're not violating the statute. Congress  
19 contemplated that path.

20                  Now, on the question of licensure, remember,  
21 you have to identify at the very beginning what all the  
22 patents are at the (1)(3) stage. One of the  
23 consequences is, if the sponsor fails to identify the  
24 patents on the list, the sponsor can never bring an  
25 infringement action. Period. This is 271(e)(2) --

1 (e) (6) (A) and (B). And so the -- the consequence is  
2 that if you get at the end and you're like, oh,  
3 something is new, something I didn't think about,  
4 you're -- you have no artificial infringement action,  
5 because the list has been established before.

6 JUSTICE BREYER: That isn't the problem.  
7 The problem is you take her reading, there's language  
8 supporting it, but you can read that word notice, gee,  
9 if you read it, tough, you can't work it.

10 MR. YANG: Well, I think the --

11 JUSTICE BREYER: And now -- now, but that's  
12 the language.

13 Now, look at the next one. (B), okay, (A),  
14 or whatever that thing is. Hey, once they give the --  
15 the 2, the Section (2) notice --

16 MR. YANG: Right.

17 JUSTICE BREYER: -- no declaratory actions,  
18 they're all frozen. Ah, until you give the notice of  
19 marketing.

20 MR. YANG: Right.

21 JUSTICE BREYER: And so all we have to do  
22 is, number 1, day 1, they give the Section (2) notice,  
23 send them all the information. On day 2, they give the  
24 commercial notice, and all of a sudden everybody is free  
25 to give declaratory judgments.



1 MR. YANG: That's right.

2 JUSTICE BREYER: Yeah, that's right. And  
3 that's what it's supposed to be? That's what it's  
4 supposed to be?

5 MR. YANG: That -- that is --

6 JUSTICE BREYER: The system that was  
7 supposed to set up a -- a system, where you've put  
8 tremendous incentives on people to negotiate and to work  
9 it out in an orderly way, that you can just gut it by  
10 simply filing your commercial notice on day 2?

11 MR. YANG: There are strong incentives. For  
12 instance, if the applicant doesn't give the information  
13 in -- in the forefront, the (1)(2) information --

14 JUSTICE BREYER: Yeah, yeah.

15 MR. YANG: -- the applicant is for -- is  
16 barred.

17 JUSTICE BREYER: No, he'll give it. He'll  
18 give it.

19 MR. YANG: Well, if he gives the  
20 information, then they're only --

21 JUSTICE BREYER: Then all the declaratory  
22 courts come in and everybody jumps in on day 2. That's  
23 you're belief.

24 MR. YANG: No, you would -- you would  
25 have -- you would still go through the (1)(3) exchange.

1           In order to -- if -- if you look at this  
2   provision that you're talking about, which is  
3   (1) (9) (C) --

4           JUSTICE BREYER: Okay. I'll read the next  
5   paragraph, you can't do that in oral argument. I'm just  
6   illustrating to you one of the many things I don't  
7   understand, and why it seems to me this would work out a  
8   lot better if you could somehow get this to a rule  
9   making.

10          CHIEF JUSTICE ROBERTS: Thank you, counsel.

11          MR. YANG: Thank you, Mr. Chief Justice.

12          CHIEF JUSTICE ROBERTS: Mr. Waxman.

13          ORAL ARGUMENT OF SETH P. WAXMAN

14          ON BEHALF OF THE PETITIONERS IN 15-1195

15          MR. WAXMAN: Mr. Chief Justice, and may it  
16   please the Court:

17          Congress did not create detailed procedures  
18   for resolving biosimilar disputes and repeatedly use the  
19   word "shall" merely to have applicants who choose to  
20   take advantage of the statute's benefits and use the  
21   sponsor's information, then disregard those mandates.

22          I think -- I think I -- I'm inclined to be  
23   guided on what the -- which of the many complicated  
24   aspects of this statute to talk about by the Court's --  
25   by the Court's questions. It's -- it's tempting to

1 sit -- to just stand up and give a tutorial on this  
2 extremely complicated situation, but --

3 JUSTICE SOTOMAYOR: How -- I'll phrase a --  
4 I'll --

5 MR. WAXMAN: Okay.

6 JUSTICE SOTOMAYOR: I'll put a question  
7 before you, okay?

8 As I understand -- I got your position,  
9 which is that they have to give notice after the FDA  
10 approval, correct?

11 MR. WAXMAN: On the -- yes, on an (8) (A)  
12 issue, they have to give --

13 JUSTICE SOTOMAYOR: Wouldn't that stop Phase  
14 2 litigation from starting immediately? By your  
15 definition, they could go the biosimilar and the  
16 license --

17 MR. WAXMAN: Referenced product.

18 JUSTICE SOTOMAYOR: -- product could go all  
19 through round 1. They've now narrowed their dispute. I  
20 thought round 2 involved disputes about other patents,  
21 not the ones that they narrowed. And so wouldn't your  
22 reading always force round 2 into the post-license  
23 12-year period? I thought the whole purpose of the  
24 statute was to get round 1 and round 2 done and done  
25 before the 12-year period was finished.

1                   MR. WAXMAN: No. The whole -- the purpose  
2 of the statute, assuming that it's followed, that is,  
3 that there -- that (2)(A) is complied with and the  
4 information exchange occurs, is to have all patent  
5 litigation concluded before commercial launch. And that  
6 is, in fact, what was said over and over again.

7                   JUSTICE SOTOMAYOR: No, no, no. You still  
8 haven't answered my question.

9                   MR. WAXMAN: I'm -- I'm just getting warmed  
10 up.

11                  JUSTICE SOTOMAYOR: You're assuming --  
12 you're assuming commercial launch has to be 12 years  
13 plus 6.

14                  MR. WAXMAN: Well --

15                  JUSTICE SOTOMAYOR: I'm assuming that  
16 commercial launch should be 12 plus 1 --

17                  MR. WAXMAN: So let me --

18                  JUSTICE SOTOMAYOR: -- because you only have  
19 an exclusive license for 12 years.

20                  MR. WAXMAN: So let me address that, the 12  
21 years plus 6 months first, and then go to the point of  
22 why the notice of commercial licensing has to -- can  
23 only coherently be done once the FDA has announced what  
24 molecule has been approved for what therapeutic uses and  
25 by what manufacturing processes, which is the paramount

1 importance when you're talking about biosimilars.

2 So as to the 180 -- the 12 versus 12 and a  
3 half years, the FDA -- no one has yet applied for  
4 biosimilar licensure until long after the 12 years has  
5 ended. So we don't know when the FDA -- how the FDA  
6 will address a license application that is made during  
7 the 12-year period.

8 But two panels of the Federal Circuit have  
9 read the language of the statute that says -- and this  
10 is 262(k) (7) -- that FDA's approval of a biosimilar may  
11 not be made effective until 12 years -- until 12 years  
12 of data exclusivity has run. Two panels of the Federal  
13 Circuit have said that only means made effective. The  
14 FDA certainly could adjudicate a license and grant a  
15 license effective 12 years after, you know, the  
16 exclusivity period runs.

17 The reason --

18 JUSTICE SOTOMAYOR: That strengthens my  
19 argument.

20 MR. WAXMAN: Well --

21 JUSTICE SOTOMAYOR: Because if the FDA is  
22 taking that position, then it's basically kicking off  
23 the possibility of round 2 pretty early.

24 MR. WAXMAN: Yes. Now, the -- as -- as my  
25 friend on the other side pointed out, the notion that

1     there is going to be round 2 litigation very early in  
2     any event is unlikely for the following reasons.

3             Number one, as they've reported, it takes  
4     about 10 years, even for a biosimilar, to get developed.  
5     And, you know, Amgen is both a reference product maker  
6     and a biosimilar maker, and that's, in fact, consistent  
7     with our experience. So the notion that there's going  
8     to be, you know, an application filed in year 4 or year  
9     6 or year 8 is unlikely.

10            Another reason that it's unlikely is  
11     these -- these biosimilars -- you know, up until very,  
12     very recent advances in gene sequencing, biosimilars  
13     were -- the way they were defined was by the process  
14     under which they were made. You take a particular cell  
15     line and then you do the following 18 things at this  
16     atmospheric pressure.

17            And the FDA will not approve a biosimilar  
18     until it has inspected the manufacturing process and  
19     facilities, which, according to the record, take -- is  
20     about 100 or \$200 million. And the notion that a  
21     biosimilar is going to create a whole factory for the  
22     FDA to review and then leave it open for -- until year  
23     12 is quite unlikely.

24            The -- the issue here, even if the FDA took  
25     the position that, nope, even though the statute only

1 says that approval can't be made effective, we're not  
2 even going to tip our hand until 12 years is over, it  
3 still wouldn't defeat the manifest purpose of the  
4 statute.

5               This statute, like the Hatch-Waxman Act, has  
6 two relevant periods. There is a period of data  
7 exclusivity that is the period in which a competitor  
8 can't use the sponsor's data. That's not a period of  
9 market exclusivity. In fact, there is a competitor to  
10 the product at issue in this case that's been on the  
11 market for five years because Teva went through the  
12 regular 271(A) process. So we have, as in Hatch-Waxman,  
13 a period in which there's data exclusivity. And we then  
14 have a period, just like in Hatch-Waxman -- there it's  
15 30 months, here it's 180 days -- for the adjudication of  
16 any patent disputes.

17              Now, my friends on the other side say, well,  
18 this is different because in the Hatch-Waxman context,  
19 the FDA actually approves, and then the 30-month period  
20 for patent litigation occurs, whereas here, the FDA's  
21 approval leaves aside the question of when they can or  
22 can't approve it. If they don't approve it until  
23 sometime after the 12 years has run, there's an  
24 additional 180 days.

25              We don't know that because this has never

1 happened. But even if it did, the reason why  
2 Congress -- the reason why you have to have FDA -- the  
3 FDA say what's being approved, whereas in Hatch-Waxman  
4 you don't, is in Hatch-Waxman we are talking about a  
5 small molecule that has to be identical. It's made by  
6 chemical synthesis, so there's no question.

7           When -- when a generic asks for Hatch-Waxman  
8 approval, we know precisely what the molecule is. We  
9 know precisely for what therapeutic purposes it will be  
10 used because it has to be identical, and no one cares  
11 what the manufacturing process is because this is simply  
12 chemical synthesis of an identical molecule.

13           Whereas -- and this goes to Justice Breyer's  
14 question about notice -- until the FDA decides what it  
15 is, what is the compound that it is going to  
16 authorize -- which, by definition, won't be identical --  
17 and until it decides for what therapeutic purposes that  
18 will be used, and until it specifies what the  
19 manufacturing process in what location will be approved,  
20 you can't give notice of anything.

21           And, if -- in fact, if you look again, we're  
22 on the 180-day notice provision, subsection (a) of  
23 262(1)(8), which -- I'm sorry, I'm looking at my own  
24 appendix, but it's on page 31A of -- of my appendix.  
25 The -- (8)(a) says the Notice of Commercial Marketing.



1 Subsection (b), entitled Preliminary Injunction, tells  
2 you the most important consequence of (8)(a) -- and this  
3 does go again, I think, Justice Sotomayor, with respect  
4 to your question about how soon this can be done -- that  
5 (8)(a) notice, first and foremost, allows the sponsor,  
6 for the very first time, to seek a preliminary  
7 injunction against the commercial marketing of the  
8 product for the uses using the processes.

9                   And you cannot go to a Federal district  
10 court and ask for a preliminary injunction until you  
11 know, A, that there's an imminency that occurs. You  
12 can't go years in advance. B, you have to know what it  
13 is that you are seeking to enjoin. This notion that  
14 there's some artificial act of infringement that relates  
15 to whatever you may or may not know is in the original  
16 application for Article III purposes is irrelevant.

17                   I mean, once the FDA -- the -- the question  
18 is can you get an injunction against what is approved  
19 for what purposes using what processes. Until you know  
20 that, a court doesn't have a way of evaluating --

21                   CHIEF JUSTICE ROBERTS: How -- how many  
22 times --

23                   MR. WAXMAN: -- what it is that's being  
24 enjoined.

25                   CHIEF JUSTICE ROBERTS: How often is the

1     issue the validity of the patent rather than its  
2     infringement?

3                   MR. WAXMAN:  We don't have a sufficient data  
4     set to be able to evaluate it because, you know, in the  
5     seven years that this Act has been in place, the FDA has  
6     accepted for review only 14 of these applications and  
7     has only granted 5 of them, the last one being last  
8     Friday.

9                   And so in some of them, there have -- you  
10    know, for example, Amgen got approved -- biosimilar  
11    approval for its biosimilar to AbbVie's referenced drug  
12    Humira.  We got that last year.  We haven't given the  
13    180-day notice yet, and so we haven't started commercial  
14    marketing.  And it could be because some -- often, the  
15    biosimilar will wait until the expiration of the regular  
16    relevant patents.

17                   It also can be that there is this -- this  
18    litigation occurs, Phase I, Phase II, or whatever, and  
19    that there is then a settlement, which is, in fact, what  
20    happened between Amgen's referenced product in this  
21    case, and Teva's competitor.  We -- there was -- there  
22    was litigation and the litigation was settled.

23                   So -- but the -- the point here -- and if I  
24    can just -- maybe this -- this is a -- is a good point  
25    to shift to the (1) (2) (A) issue, which is the -- the

1 requirement that you provide that once the -- once the  
2 applicant decides not to go the regular route, that is,  
3 the A route, that is, to -- to do all the testing and  
4 prove that this is safe, potent, and pure, but instead  
5 to piggyback onto the referenced products, once that's  
6 done, the statute says -- not only in (2)(A), but also  
7 in (1)(A) -- says that you must -- once you make that  
8 choice, the consequence -- the consequence of using the  
9 referenced-product sponsor's data is, if I can just  
10 quote (1)(B), quote, "When a subsection (k) applicant  
11 submits an application under subsection (k), such  
12 applicant shall provide a copy of its application and  
13 information about its manufacturing process." And --

14 JUSTICE GORSUCH: Mr. Waxman, let's say --  
15 let's say I spot you that, okay, that (2)(A) "shall"  
16 means shall. All right?

17 MR. WAXMAN: Okay.

18 JUSTICE GORSUCH: But the question still  
19 remains under (1)(9) -- (9) -- (9)(C), rather,  
20 (1)(9)(C), what the remedy is. And we've heard from the  
21 other side that the exclusive remedy is a  
22 declaratory-judgment action. And how can we possibly  
23 decide what (2)(A) means without taking a peek at (9)(C)  
24 as to what remedies are permitted?

25 MR. WAXMAN: Well, what -- I mean, we agree

1 with the government that when (2) (A) says "shall," and  
2 when (1) (B) says "shall," that is a mandate.

3 JUSTICE GORSUCH: I'm spotting you that --

4 MR. WAXMAN: Okay.

5 JUSTICE GORSUCH: -- for purposes of this  
6 question.

7 MR. WAXMAN: I just want to make sure  
8 that --

9 JUSTICE GORSUCH: You can't -- it's hard to  
10 divorce a right from its remedy, isn't it, and to  
11 understand the contours of the right. And if (2) (A)  
12 gives you a certain right to information, we usually  
13 understand the right in the context of the remedy  
14 provided.

15 MR. WAXMAN: So --

16 JUSTICE GORSUCH: And here the remedy is  
17 (9) (C) .

18 MR. WAXMAN: So let me -- can I bookmark the  
19 State law cause of action, because I do want to get back  
20 and explain why --

21 JUSTICE GORSUCH: However -- however best  
22 you want to do it.

23 MR. WAXMAN: Our -- okay. Let me do State  
24 law first, which is what was at issue and was  
25 adjudicated here, and then go to the Federal law issue.

1                   So the litigation -- the complaint in this  
2     case asked for an order under the California statute.  
3     The California statute, like many other State statutes,  
4     including the one that was directly at issue in your  
5     decision in *Bates v. Dow Agrosience*, makes it a  
6     violation of State law to fail to comply with Federal  
7     mandates, including this one.

8                   JUSTICE GORSUCH: I -- I got that.

9                   MR. WAXMAN: Okay.

10                  JUSTICE GORSUCH: I'm sorry. My question is  
11     how can we understand what a violation is, of Federal  
12     law, without looking at both the rights section and the  
13     remedy section?

14                  MR. WAXMAN: Well, the --

15                  JUSTICE GORSUCH: Because the -- a violation  
16     is circumscribed in a certain way here by the remedies  
17     provided by Federal law.

18                  MR. WAXMAN: Well -- so I don't -- this may  
19     be a definitional failure of communication, but "shall"  
20     either means "shall." The remedy question is who --  
21     who, if anybody, can do anything about it, if you don't  
22     comply with "shall," right?

23                  JUSTICE SOTOMAYOR: That -- that's -- no.  
24     It's not quite that. "Shall" is if you want to invoke  
25     this Federal process, this is what you have to do.

1 MR. WAXMAN: Okay. So --

2 JUSTICE SOTOMAYOR: All right? So if you  
3 don't invoke the Federal process, what remains? That's  
4 not a remedy. That's a different Federal process, the  
5 declaratory-judgment process. That's what (C) says.

6 Under your reading, (B) and (C) become  
7 superfluous, because if you can get a State law  
8 information-exchange provision under (C) or -- or under  
9 State law, why give the remedy of starting a  
10 declaratory-judgment action at all?

11 MR. WAXMAN: Okay. All right. So let me go  
12 right to Section 9. I'm not trying to avoid it.  
13 Section -- you have to look -- what Section 9 says.  
14 (9) (C) is, if you will, an exception or a clarification  
15 of (9) (A). The background principle is that Congress  
16 has established an artificial act of infringement, which  
17 is the submission of the ABLA, the submission of the  
18 biosimilar application.

19 That is actionable. There is a Federal  
20 cause of action under Section 281, which gives Federal  
21 district courts jurisdiction to adjudicate patent  
22 disputes. Under the Declaratory-Judgment Act and this  
23 Court's decision in *MedImmune v. Genentech*, you can  
24 bring a declaratory judgment any time you want so long  
25 as there is a level of immediacy, which, by definition,

1     there is, if an artificial act of infringement has  
2     already occurred.

3                 Now, what (9)(A) says is notwithstanding  
4     those background rules, if the biosimilar applicant  
5     chooses the (k) route and provides the application and  
6     the manufacturing information, we're making an exception  
7     to the general availability of declaratory judgments.  
8     No one can file a declaratory-judgment action until the  
9     notice of commercial marketing is given.

10                What (9)(C) simply does is it has -- (9)(C)  
11     says if you don't provide that (2)(A) information, you,  
12     the applicant, can't ever file for a  
13     declaratory-judgment action, but (9)(C) doesn't remedy  
14     the sponsor's harm for two reasons. Number one, it has  
15     no real operative effect with respect to the sponsor,  
16     because recall what (9)(A) -- the (9)(A) limitation is  
17     implicated, as the first clause indicates, only in those  
18     circumstances in which the application and the  
19     manufacturing information is provided.

20                JUSTICE BREYER: No. I think it does.

21                MR. WAXMAN: And (9)(C) simply confirms what  
22     is -- what should be obvious, which is if it isn't  
23     provided, the sponsor is left to his background rights  
24     to -- to litigate the declaratory-judgment action.

25                JUSTICE BREYER: So why haven't you driven

1 us to the following conclusion, which will be  
2 unsatisfactory, again, from everybody's point of view?  
3 We said you're right --

4 MR. WAXMAN: Setting the bar pretty low for  
5 me.

6 (Laughter.)

7 JUSTICE BREYER: You're right. "Shall"  
8 means "shall." Okay? But let's stop there because,  
9 first, the Federal part, which you just read, doesn't  
10 say that's the only remedy or that there are others.  
11 But even if it did, we wouldn't know whether California  
12 law picked up just the substantive part, or the  
13 substantive plus the remedy. And even if we knew that,  
14 we wouldn't know whether some other State would be free  
15 to pick up in their own State law "shall," but not  
16 exclusivity as to remedy. And those involve either  
17 preemption questions, or questions of interpretation of  
18 State law, and none of that is briefed. And, therefore,  
19 we stop. "Shall" means "shall." How do you like that?  
20 No, you don't, but tell me why not.

21 MR. WAXMAN: I -- no. I like -- I like  
22 "shall means shall." I -- I still want to get back  
23 to -- to the -- make the (9) (C) point, but let me  
24 address your State law question first.

25 We know, without question, the California



1 Supreme Court in *Rose v. Bank of America* and the  
2 Solicitor General's Amicus brief to this Court in that  
3 case, makes clear what California says. California law  
4 is not incorporating into State law Federal remedies.  
5 It says it is a violation of our State law, fair  
6 commercial practices law, to violate a command of  
7 another sovereign's law.

8 That establishes the --

9 CHIEF JUSTICE ROBERTS: Well, that is fine.  
10 But we also have pretty well-established preemption  
11 laws. I would -- you know, this is a very reticulated  
12 statute with enormous consequences, and you're reading  
13 along and you finally figure it out, and all of a sudden  
14 up pops California law.

15 MR. WAXMAN: Well --

16 CHIEF JUSTICE ROBERTS: And not only that, I  
17 mean, if we apply California law, then, presumably, in  
18 some circumstances, we apply the law of every other  
19 State and maybe they reach different consequences. And  
20 if as your friends on the other side are right, that  
21 there's no Federal cause of action for this type  
22 of relief, then it seems odd to say but there's going to  
23 be -- you get the same thing under State law.

24 MR. WAXMAN: Well, let me -- let me address  
25 that head on.

1 CHIEF JUSTICE ROBERTS: Not to prejudge the  
2 issues, maybe.

3 MR. WAXMAN: First of all, the preemption  
4 question, there's no ambiguity about whether preemption  
5 was waived. At page 26A of the petition --

6 CHIEF JUSTICE ROBERTS: Oh, no. I  
7 understand that, but I'm not going to interpret a  
8 Federal statute based on the decisions of one party to  
9 waive the argument or not.

10 MR. WAXMAN: I completely understand that.  
11 In Bates v. Dow Agrosience, the Court rejected my  
12 argument that the -- the farmer in question had a remedy  
13 under, I believe, it was Texas State law for the  
14 violation of a substantive -- Texas State law made a  
15 violation of State law a violation of a substantive  
16 provision of the Federal FIFRA statute. And I argued in  
17 that case for the defendant that Congress had considered  
18 what remedies, if any, to provide to individual farmers  
19 and had made an advertent decision not to provide any.

20 This Court pretty emphatically rejected my  
21 argument and said that because Texas had made it a  
22 violation of Texas law to fail to comply with a  
23 provision of the Federal FIFRA, the plaintiff could get  
24 a remedy available under Texas law.

25 Now, here, I mean, the -- there's nothing --

1 I mean, I -- I agree that we -- you know, it's somehow  
 2 unsatisfying to say, well, the only -- the injunction  
 3 that was sought, the order that we went in to say, look,  
 4 you have to order them to give us this manufacturing  
 5 information and give us notice at a time when it's  
 6 coherent to talk about notice about what, and we -- the  
 7 only remedy that the California statute provides is  
 8 injunctive relief. It doesn't allow for damages at all.  
 9 And we're entitled to this. We're a California company.  
 10 They're violating our laws.

11 I understand that it's unsatisfactory and  
 12 that, ultimately, some day perhaps, this Court will have  
 13 to decide whether it's -- whether there is a Federal  
 14 enforcement, even if State law didn't exist, although I  
 15 do want to suggest that if this Court says, look,  
 16 "shall" means "shall," and you must if you -- if you  
 17 choose to -- to parachute onto the back of their  
 18 information, you have to at least let them know that  
 19 you're doing it and what you're doing. And in order to  
 20 give them notice in time --

21 JUSTICE SOTOMAYOR: But that --

22 MR. WAXMAN: -- for a court to --

23 JUSTICE SOTOMAYOR: -- that -- really, the  
 24 State law would end up, under your theory, forcing a  
 25 biosimilar to invoke Phase I. Because at every stage,

1     you -- where they choose to opt out, they -- you will  
2     just run to court and say, my State law remedy is force  
3     them to take the next step. Give me the application,  
4     then identify, then do this. You're going to -- there's  
5     no longer a choice.

6                   MR. WAXMAN: So, Justice Sotomayor, two  
7     points. Number one, in terms of shouldn't all this --  
8     shouldn't all this patent litigation be done early and  
9     often, everybody understands that the applicant, the  
10    biosimilar applicant under this Phase I, Phase II  
11    process alone decides which patents at issue in the  
12    exchange of lists are going to be adjudicated. The  
13    patent -- the applicant announces -- the applicant can  
14    say to the sponsor, in Phase I, we're going to litigate  
15    all of the patents that are on the (1)(3) lists. The  
16    only qualification is if the -- if the applicant says,  
17    I'm not going to -- I don't want to litigate any of  
18    these things now. I want to wait and see what's  
19    approved.

20                   The sponsor has the election of choosing one  
21    patent, presumably the patent on the molecule itself, to  
22    adjudicate. So the -- the -- it is in the applicant's  
23    hands to get all of this litigation on artificial acts  
24    of infringement upfront.

25                   JUSTICE SOTOMAYOR: You're -- you're just --

1 all you're saying to me is that there's built-in  
2 incentives --

3 MR. WAXMAN: Now, let --

4 JUSTICE SOTOMAYOR: -- for the applicant to  
5 invoke and participate in phase 1.

6 MR. WAXMAN: Now, let me --

7 JUSTICE SOTOMAYOR: What you're not telling  
8 me is, it's no longer a choice --

9 MR. WAXMAN: So let me explain --

10 JUSTICE SOTOMAYOR: -- because State law can  
11 force them --

12 MR. WAXMAN: So --

13 JUSTICE SOTOMAYOR: -- through you seeking  
14 injunctions to participate unwillingly.

15 MR. WAXMAN: Okay. Let me -- let me go back  
16 to (9), which I think is the source of Sandoz's argument  
17 that the statute already provides remedies for the two  
18 violations that we allege occurred here.

19 And if I may, let me -- let me address the  
20 two substantive provisions differently, because they say  
21 that (9)(B) is the remedy for a violation of the 180-day  
22 notice, and (9)(C) is a remedy for the violation of not  
23 providing the information.

24 The notion that (9)(B) is a remedy for the  
25 failure to provide 180-day notice is -- is crazy.

1 The -- what (8) (A) says is, you can't file a  
2 declaratory-judgment action until you get the notice.  
3 And what they say is, well, but the remedy of not giving  
4 notice is that you can file a declaratory-judgment  
5 action. And not only that, you can file a  
6 declaratory-judgment action and you must file a  
7 declaratory-judgment action at a time when you don't  
8 know when, if ever, the FDA will approve, what it will  
9 approve, or for what purposes and by what means. And if  
10 there is a violation of the 180-day notice period, the  
11 first time that the -- the sponsor is going to know  
12 about it is when the FDA approves.

13 JUSTICE GORSUCH: Well, what's -- what's  
14 wrong with that? Why can't you argue that the notice is  
15 defective and seek a declaratory judgment on that basis,  
16 that the notice is insufficient, doesn't provide you  
17 with adequate notice as required by statute?

18 MR. WAXMAN: Well, that -- that, of course,  
19 is exactly what we claim. They gave -- they purported  
20 to give us notice the day after they --

21 JUSTICE GORSUCH: Right.

22 MR. WAXMAN: -- filed their application. We  
23 said, that's not valid, that's not the right time. The  
24 question -- I'm separating out the substantive question  
25 of when notice has to be given --

1 JUSTICE GORSUCH: I understand that. If  
2 you --

3 MR. WAXMAN: -- and the remedy.

4 JUSTICE GORSUCH: If you say the notice  
5 itself is defective, apart from when it's given, because  
6 it doesn't provide enough information, isn't that a  
7 possible remedy right there?

8 MR. WAXMAN: Well, yes. In an instance in  
9 which -- the notice simply says we are going to begin  
10 commercial marketing in 180 -- no less than 180 days.  
11 Our -- the -- you know, the issue in this case is -- the  
12 substantive issue -- I'll leave aside the enforcement  
13 question -- is that's not notice. In order to notice  
14 something, you can't provide notice of something when  
15 you don't even know it's going to happen. That is,  
16 notice ordinarily and, for that matter, logically  
17 implies that the preconditions that are outside your  
18 control have been satisfied.

19 If I say -- this notice early tells you  
20 what? It tells you I filed an application. And if they  
21 approve my application, I intend to start marketing  
22 immediately. I don't know whether they will approve my  
23 application. I don't know, if they approve it, whether  
24 they will change the substance, whether they will change  
25 the indications.

1 JUSTICE KAGAN: But isn't that true of a lot  
2 of what this Act contemplates? I mean, all the round 1  
3 litigation can occur before the approval is given.

4 MR. WAXMAN: That's right. And that's the  
5 reason why you have to have -- that's why (8) (A) has  
6 to -- the notice has to come at a time when we know what  
7 it is that's approved. That is, the parties may  
8 choose --

9 JUSTICE KAGAN: But I guess what I'm saying  
10 is that it seems as though this statute contemplates  
11 that you can do a lot of this process prior to the  
12 approval, but that's not a necessary piece of  
13 information you need in order to start evaluating  
14 whether there's infringement.

15 MR. WAXMAN: So, Justice Kagan, the -- let's  
16 say Phase I starts. I mean, I think I probably ought to  
17 talk about what happens -- their remedy for not  
18 providing the -- the (1) (2) information at all. But  
19 let's say the parties decide, okay, we've -- we've each  
20 listed all of these patents that are potentially  
21 applicable. That list is coherent if the sponsor knows  
22 what the application and what manufacturing processes  
23 are there for. If we don't know that, we have to list  
24 every patent that we have on every manufacturing process  
25 that we own, which is incoherent.



1                   But let's assume that the parties say, okay,  
2     here are the list of patents. How many does it make  
3     sense for us to adjudicate now? It certainly makes  
4     sense for us to adjudicate the patents on the molecule  
5     and perhaps the purposes of the molecule. It may be we  
6     think it makes sense to get a court to adjudicate all of  
7     them. But even in that instance, number one, under  
8     (1) -- the statute in (1)(7) recognizes that the sponsor  
9     may well obtain other patents after the lists are  
10    exchanged. That has happened in this case.

11                  And in the Apotex case that my friend was  
12    addressing where they said there are no other patents  
13    available, it is about to happen in that case, too,  
14    because the -- the PTO has just allowed claims that read  
15    on that patent. So, number one, there can be and often  
16    will be other patents.

17                  Number two, even if you adjudicate -- get an  
18    adjudication on the artificial act of infringement,  
19    number one, if you follow the process, the sponsor gets  
20    a mandatory injunction under 271(d)(4). And in any  
21    event, if it turns out that what the FDA has said is,  
22    well, you know, there have been a lot of -- we require  
23    lots and lots of amendments to the application. In this  
24    case they require -- there were 30 amendments made from  
25    the time the application was filed until it was granted.

1           If it turns out that when the FDA issues its  
2   license, it's licensed something materially different  
3   than what the application was, the parties and -- and  
4   the district court have to have some opportunity to say,  
5   wait a minute, I mean we adjudicated patent infringement  
6   on the assumption that the manufacturing process would  
7   be X, Y, and Z, but the FDA didn't approve it. They  
8   insisted on A, B, and C, and there has to be some  
9   period -- and that's what the 180 days does -- to allow  
10   the parties to say even with respect to the phase I  
11   patents, we now have a real dispute.

12           The FDA has approved something different  
13   than what the application was, and the -- the -- the  
14   sponsor has to be given some period of time in order to  
15   figure out what the FDA has approved, and a district  
16   judge has to be given some period of time to evaluate,  
17   like what are these patents, what is this compound, what  
18   are the manufacturing processes, is -- are the --

19           JUSTICE SOTOMAYOR: I'm sorry, Mr. Waxman.  
20   Assume that there has been phase I, round one and round  
21   two before the approval. The district court has decided  
22   one of two things. There is a patent infringement.  
23   It's issued an injunction. The FDA has narrowed the  
24   scope of things substantially.

25           If the applicant was seeking the world and

1 the FDA is the one who narrowed it, why isn't it fair to  
2 the licensed product holder to let that injunction  
3 continue until there's now certainty that there isn't?  
4 If the -- if the patent infringement process ended up  
5 saying no infringement, district court agreed and there  
6 is no injunction, so these licensed products is going to  
7 deal with goods in the market, but they've gotten a shot  
8 at this, and the claims are now even more narrow.

9 MR. WAXMAN: So --

10 JUSTICE SOTOMAYOR: They lost on all the  
11 wider ones.

12 I -- I'm not sure what unfairness there is  
13 to the license.

14 MR. WAXMAN: So --

15 JUSTICE SOTOMAYOR: If you -- if you go  
16 through the process the way it's anticipated.

17 MR. WAXMAN: Number one, it is very -- we've  
18 not had a situation, and it is remarkably unlikely that  
19 we will get to a situation in which there are no patent  
20 disputes left to be resolved once the license issues  
21 both because, as has happened with respect to our  
22 product at issue in this case, and in the Apotex case,  
23 the FDA -- the -- the PTO has indeed issued us a patent  
24 that bears on this that we couldn't include in the  
25 lists.

1           Number two, everybody needs some time to be  
2   able to figure out whether your hypothesis is right,  
3   which is that what the FDA has approved is narrower than  
4   what the application was, not broader. And all that the  
5   180-day period does is give us, the referenced product  
6   sponsor, an opportunity to figure that out.

7           I mean, we have to -- the -- the -- (8) (C)  
8   requires the parties to cooperate and expedite discovery  
9   once the preliminary injunction is filed so that we can  
10  figure out, for example, what manufacturing processes  
11  the FDA has approved. That's not made public at the  
12  time that they approve the license.

13           Thank you.

14           CHIEF JUSTICE ROBERTS: Thank you, counsel.

15           Three minutes, Ms. Maynard.

16           REBUTTAL ARGUMENT OF DEANNE E. MAYNARD

17           ON BEHALF OF THE PETITIONER IN 15-1039

18           MS. MAYNARD: Thank you, Your Honor.

19           There can be no doubt that the judgment that  
20  we've petitioned on is a Federal judgment. The -- the  
21  Federal Circuit issued a Federal injunction and  
22  dismissed their State law claims.

23           Two, the -- the statute -- Congress, when it  
24  wanted to provide for an injunctive relief of the (1)  
25  procedures, it did so. It provided for it in only one

1 instance: Violations of the confidentiality provisions  
2 in (1)(1)(H). And significantly, that's also the only  
3 provision that Congress called a failure to do something  
4 in (1)(1) a violation. Yet, Amgen wants you to read the  
5 statute and to read those -- the rest of these  
6 provisions as implicitly entitling them to an injunction  
7 that Congress chose not to provide, and instead they  
8 want to call the remedies Congress did provide as the  
9 backup. I -- that's a very odd way to read the statute.

10 The rights here are patent rights. The  
11 remedies they were given were patent remedies, and they  
12 are forceful. They gave them artificial infringement  
13 actions in the case where you participate in an  
14 exchange, and in the case where you don't. Congress  
15 shows no concern in the notice of commercial marketing  
16 provision with notice being too early. It says at least  
17 180 days. And when you lift the gate, it allows the --  
18 the -- the sponsor to go to court and litigate any  
19 remaining patent rights they have.

20 Justice Breyer, the -- Congress knew how to  
21 require something to come after one event and before  
22 another. It does it in the very next provision,  
23 (1)(8)(B). Does not do it in the notice provision. You  
24 shouldn't read that requirement into the word  
25 "licensed," which is just a description of the

1     biosimilar.

2                   Congress would not have extended the 12-year  
3     exclusivity period in such a bizarre way. That was a  
4     very hotly debated item, and it would extend the  
5     exclusivity period in every case, even when there are no  
6     patent rights to litigate.

7                   Our approach fully allows them to vindicate  
8     their patent rights. We wrote them and we told them to  
9     sue us. Now, they delayed, but they could have sued us  
10    right away. That was the provision Congress allowed.  
11    And in that suit they got our application, they  
12    requested as common in -- in patent cases to request all  
13    of our FDA correspondence. We have a -- a duty to  
14    continue updating them.

15                  They added -- they -- they were issued new  
16    patent during the suit. They have added that patent to  
17    the suit, which is also common in patent litigation.

18                  A lot of what they are telling you blinks  
19    reality about the way the world works, and with respect,  
20    those kinds of policy arguments are for the Congress.

21                  This statute works if you just apply it  
22    according to its terms. The shall conditions are all  
23    conditions precedent, and that's made clear by the  
24    (1)(6) provision which says, they shall sue. It would  
25    be a very odd Federal law to say that is a violation of

1 Federal law, not to bring suit. It isn't.

2 Congress provided consequences. If they  
3 decide not to sue, then they can only get a reasonable  
4 royalty. These are -- these are shalls, and they do  
5 mean must, but the government says they don't mean must  
6 in all circumstances. They mean must if you want to  
7 continue in this process. And if you don't continue in  
8 the process, there are benefits and burdens to both the  
9 applicant and the sponsor at every step. And if you go  
10 through the statute, and I recognize it's a very  
11 articulated scheme, it's all one coherent whole, and it  
12 gives them a very powerful remedy.

13 CHIEF JUSTICE ROBERTS: Thank you, counsel.

14 The case is submitted.

15 (Whereupon, at 11:16 a.m., the case in the  
16 above-entitled matter was submitted.)

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<b>A</b>	52:22 57:3,4,6 57:17	4:4 15:12 17:7 19:3 26:21 38:5 42:10 61:4	53:4 58:25 63:9	36:24 40:3,19 41:18 42:10 52:19 56:7 58:12,15 60:3 60:11
<b>a.m</b> 1:22 4:2 63:15	<b>adjudicated</b> 44:25 52:12 58:5	<b>Amgen's</b> 4:23 27:18 42:20	<b>applicant's</b> 52:22	<b>approves</b> 39:19 54:12
<b>AbbVie's</b> 42:11	<b>adjudication</b> 39:15 57:18	<b>amicus</b> 2:6 3:7 23:24 49:2	<b>applicants</b> 15:24 19:5 34:19	<b>April</b> 1:18
<b>ABLA</b> 46:17	<b>Administration</b> 21:15	<b>announce</b> 6:9 7:18	<b>application</b> 5:8 7:2,17 8:17,17 12:22 13:3 14:21 15:10,12 15:16,17 16:7 18:4 19:11,11 24:6,23,25 31:6 37:6 38:8 41:16 43:11,12 46:18 47:5,18 52:3 54:22 55:20,21,23 56:22 57:23,25 58:3,13 60:4 62:11	<b>argue</b> 11:12 54:14
<b>able</b> 8:4 11:12 42:4 60:2	<b>advance</b> 9:2 41:12	<b>announced</b> 5:23 36:23	<b>applied</b> 37:3	<b>argued</b> 26:22 27:1,3 50:16
<b>above-entitled</b> 1:20 63:16	<b>advances</b> 38:12	<b>announces</b> 52:13	<b>apply</b> 4:18 5:17 49:17,18 62:21	<b>arguing</b> 28:23 29:5
<b>absence</b> 28:3	<b>advantage</b> 34:20	<b>answer</b> 6:24 11:17 12:15 13:5 20:21 21:14 22:9 28:13 31:10,14	<b>applications</b> 7:1 12:20 42:6	<b>argument</b> 1:21 3:2,5,9,12 4:3 4:10 14:2 18:16 23:23 28:3 29:18 34:5,13 37:19 50:9,12,21 53:16 60:16
<b>accepted</b> 24:25 42:6	<b>advertent</b> 50:19	<b>answered</b> 36:8	<b>approval</b> 5:23 5:24 6:1,15 7:4 7:21,25 8:17 8:17 9:1 14:18 35:10 37:10 39:1,21 40:8 42:11 56:3,12 58:21	<b>arguments</b> 11:1 27:20 28:25 62:20
<b>account</b> 21:6	<b>agency</b> 10:15,15 10:16 11:2,10 13:11,19 21:14 25:2	<b>answers</b> 21:24 22:7	<b>approach</b> 62:7	<b>Article</b> 41:16
<b>act</b> 4:14 7:2,3 9:2,4 16:13 18:5,5 25:9 39:5 41:14 42:5 46:16,22 47:1 56:2 57:18	<b>agency's</b> 22:2 <b>ago</b> 25:11	<b>ANTHONY</b> 2:4 3:6 23:23	<b>appropriate</b> 23:10	<b>articulated</b> 63:11
<b>action</b> 15:4 16:5 19:14,24 23:12 28:10 30:2 31:8,25 32:4 43:22 44:19 46:10,20 47:8 47:13,24 49:21 54:2,5,6,7	<b>agree</b> 18:8 23:3 28:2 43:25 51:1	<b>anticipated</b> 59:16	<b>approval</b> 5:23 5:24 6:1,15 7:4 7:21,25 8:17 8:17 9:1 14:18 35:10 37:10 39:1,21 40:8 42:11 56:3,12 58:21	<b>artificial</b> 15:13 32:4 41:14 46:16 47:1 52:23 57:18 61:12
<b>actionable</b> 46:19	<b>agreed</b> 59:5	<b>anybody</b> 19:24 45:21	<b>approve</b> 5:10 6:10,12 7:1 8:24 38:17 39:22,22 54:8 54:9 55:21,22 55:23 58:7 60:12	<b>artificial-infri...</b> 16:13
<b>actions</b> 4:16 14:1 23:10 32:17 61:13	<b>agrees</b> 13:15	<b>apart</b> 55:5	<b>approved</b> 8:4 9:3 13:5 14:20	<b>aside</b> 27:5 39:21 55:12
<b>acts</b> 15:13,19 52:23	<b>Agroscience</b> 45:5 50:11	<b>Apotex</b> 22:19,20 27:12 57:11 59:22		<b>asked</b> 11:6 22:8 29:19 45:2
<b>added</b> 62:15,16	<b>Ah</b> 32:18	<b>appeals</b> 27:4		<b>asking</b> 7:5,6 17:21 18:23 28:16 29:17
<b>additional</b> 39:24	<b>aiming</b> 6:25	<b>APPEARAN...</b> 2:1		<b>asks</b> 40:7
<b>address</b> 14:23 24:11 30:15 36:20 37:6 48:24 49:24 53:19	<b>AL</b> 1:6,11	<b>appendix</b> 8:9 27:8 40:24,24		<b>aspect</b> 9:12
<b>addressing</b> 57:12	<b>allege</b> 53:18	<b>applicable</b> 56:21		<b>aspects</b> 34:24
<b>adequate</b> 54:17	<b>allow</b> 8:23 9:1 13:8,22 15:15 23:5,9 51:8 58:9	<b>applicant</b> 4:16 11:25 13:2,4 16:1 17:13 19:18 22:14,14 24:8,24,25 31:5 33:12,15 43:2,10,12 47:4,12 52:9 52:10,13,13,16		<b>Assistant</b> 2:4
<b>adjudicate</b> 37:14 46:21	<b>allowed</b> 15:12 57:14 62:10			<b>assume</b> 7:16
	<b>allowing</b> 28:20			
	<b>allows</b> 7:3 41:5 61:17 62:7			
	<b>ambiguity</b> 10:25 11:1 50:4			
	<b>ambiguous</b> 11:7			
	<b>amendments</b> 57:23,24			
	<b>America</b> 49:1			
	<b>Amgen</b> 1:6,11			



<p>57:1 58:20  <b>assuming</b> 6:13  20:1 29:18  36:2,11,12,15  <b>assumption</b>  14:18 29:18  58:6  <b>assurances</b>  25:24  <b>atmospheric</b>  38:16  <b>authority</b> 10:16  21:21 22:1  25:4  <b>authorize</b> 40:16  <b>automatic</b> 5:2  <b>availability</b> 47:7  <b>available</b> 29:21  50:24 57:13  <b>avoid</b> 46:12  <b>aware</b> 19:7</p> <hr/> <p style="text-align: center;"><b>B</b></p> <hr/> <p><b>b</b> 32:1,13 41:1  41:12 43:10  44:2 46:6  53:21,24 58:8  61:23  <b>back</b> 6:20 14:16  22:9 24:19  29:13 31:11  44:19 48:22  51:17 53:15  <b>back-and-forth</b>  19:20  <b>background</b>  46:15 47:4,23  <b>backup</b> 61:9  <b>Bank</b> 49:1  <b>bar</b> 19:22,23,24  22:21 48:4  <b>barred</b> 33:16  <b>based</b> 9:20  15:16 29:5  50:8  <b>basically</b> 37:22  <b>basis</b> 16:6,18</p>	<p>17:2,7 18:6  27:23 54:15  <b>Bates</b> 45:5 50:11  <b>bears</b> 59:24  <b>beginning</b> 14:17  31:21  <b>begs</b> 31:2,4  <b>behalf</b> 2:2,8 3:4  3:11,14 4:11  34:14 60:17  <b>belief</b> 33:23  <b>believe</b> 19:1  21:19 25:10  26:10 27:3  50:13  <b>believing</b> 16:6  <b>benefits</b> 34:20  63:8  <b>best</b> 29:25,25  44:21  <b>better</b> 11:14  34:8  <b>big</b> 28:17  <b>bio</b> 19:13  <b>biological</b> 8:22  10:9 12:11  <b>biosimilar</b> 5:4,8  5:16,17 6:13  7:1 8:16,24  12:13 16:16,22  16:23 18:11,12  19:10 20:3  24:6 31:5  34:18 35:15  37:4,10 38:4,6  38:17,21 42:10  42:11,15 46:18  47:4 51:25  52:10 62:1  <b>biosimilars</b> 4:14  5:20 20:10  37:1 38:11,12  <b>bizarre</b> 62:3  <b>blinks</b> 62:18  <b>block</b> 16:1  <b>blue</b> 8:11 11:21  18:3</p>	<p><b>book</b> 25:13  <b>bookmark</b> 44:18  <b>boom</b> 29:15  <b>Breyer</b> 10:4,14  11:5,20 12:2,5  12:7,9 13:7,12  13:16 14:6  21:25 32:6,11  32:17,21 33:2  33:6,14,17,21  34:4 47:20,25  48:7 61:20  <b>Breyer's</b> 13:10  14:17 21:11,19  24:20 40:13  <b>brief</b> 8:11 11:21  14:23 18:3  24:16,22 49:2  <b>briefed</b> 48:18  <b>bring</b> 16:18  17:25 19:2  21:1 23:9  31:24 46:24  63:1  <b>bringing</b> 14:1  18:11 19:24  <b>broader</b> 60:4  <b>built-in</b> 53:1  <b>bump</b> 29:16  <b>burdens</b> 63:8</p> <hr/> <p style="text-align: center;"><b>C</b></p> <hr/> <p><b>C</b> 3:1 4:1 18:2  34:3 43:19,20  43:23 44:17  46:5,6,8,14  47:10,10,13,21  48:23 53:22  58:8 60:7  <b>California</b> 45:2  45:3 48:11,25  49:3,3,14,17  51:7,9  <b>call</b> 8:3 9:2 61:8  <b>called</b> 25:10  61:3  <b>calls</b> 7:25</p>	<p><b>Caraco</b> 25:10  <b>cares</b> 40:10  <b>case</b> 4:4 11:10  14:14 16:18  20:11 22:19  27:6 29:1,2,2  39:10 42:21  45:2 49:3  50:17 55:11  57:10,11,13,24  59:22,22 61:13  61:14 62:5  63:14,15  <b>cases</b> 62:12  <b>cause</b> 28:10 30:2  44:19 46:20  49:21  <b>cell</b> 38:14  <b>certain</b> 19:16  20:25 29:15  44:12 45:16  <b>certainly</b> 18:15  25:4 27:17  31:6 37:14  57:3  <b>certainty</b> 59:3  <b>change</b> 55:24,24  <b>check</b> 10:18,19  <b>chemical</b> 40:6  40:12  <b>Chief</b> 4:3,12  13:10,14 14:6  16:21 17:9  18:7,19 21:18  23:16,18,20,22  24:1 28:9,22  29:3 34:10,11  34:12,15 41:21  41:25 49:9,16  50:1,6 60:14  63:13  <b>choice</b> 43:8 52:5  53:8  <b>choose</b> 34:19  51:17 52:1  56:8  <b>chooses</b> 47:5</p>	<p><b>choosing</b> 52:20  <b>chose</b> 61:7  <b>Circuit</b> 4:25 7:7  27:5,10 30:22  37:8,13 60:21  <b>Circuit's</b> 14:13  <b>circumscribed</b>  45:16  <b>circumstances</b>  47:18 49:18  63:6  <b>citation</b> 8:9  <b>claim</b> 27:1,6  28:6 30:12,13  30:23,24 54:19  <b>claims</b> 30:17  57:14 59:8  60:22  <b>clarification</b>  46:14  <b>clarify</b> 6:8 21:17  <b>clause</b> 47:17  <b>clauses</b> 29:10  <b>cleanest</b> 30:4  <b>clear</b> 25:9 27:11  49:3 62:23  <b>Close</b> 26:17  <b>coherent</b> 51:6  56:21 63:11  <b>coherently</b>  36:23  <b>combination</b>  10:24  <b>come</b> 12:19  24:17 33:22  56:6 61:21  <b>comes</b> 29:1  <b>command</b> 49:6  <b>comment</b> 13:19  <b>commercial</b>  4:22 5:1 9:23  9:25 10:3,9  11:22 12:4,6  22:22,24 32:24  33:10 36:5,12  36:16,22 40:25  41:7 42:13</p>
---	--	--	---	--

47:9 49:6 55:10 61:15 <b>commercially</b> 10:23 <b>commission</b> 5:10 <b>common</b> 62:12 62:17 <b>communication</b> 45:19 <b>company</b> 16:4 51:9 <b>compare</b> 25:9 <b>competitor</b> 39:7 39:9 42:21 <b>complaint</b> 45:1 <b>complete</b> 10:8 <b>completely</b> 6:17 50:10 <b>complicated</b> 21:5 34:23 35:2 <b>complied</b> 36:3 <b>complies</b> 19:12 <b>comply</b> 20:3,5 27:14 45:6,22 50:22 <b>complying</b> 30:12 30:22 31:15 <b>compound</b> 40:15 58:17 <b>comprehensive</b> 4:14,19 28:12 28:20 <b>concern</b> 61:15 <b>concerns</b> 13:6 <b>concluded</b> 36:5 <b>conclusion</b> 48:1 <b>condition</b> 31:15 <b>conditions</b> 62:22 62:23 <b>confidentiality</b> 61:1 <b>confirms</b> 47:21 <b>Congress</b> 13:5 14:11 15:9 16:12 18:1	21:5 24:3 25:15 28:19 29:8 31:18 34:17 40:2 46:15 50:17 60:23 61:3,7,8 61:14,20 62:2 62:10,20 63:2 <b>consequence</b> 15:9 20:21 32:1 41:2 43:8 43:8 <b>consequences</b> 4:20 24:8,11 24:13,16 31:23 49:12,19 63:2 <b>consider</b> 9:5 <b>considered</b> 50:17 <b>considering</b> 28:13 <b>consistent</b> 26:2 38:6 <b>contemplated</b> 31:19 <b>contemplates</b> 22:13 56:2,10 <b>context</b> 25:17 39:18 44:13 <b>continue</b> 20:13 31:16 59:3 62:14 63:7,7 <b>contours</b> 44:11 <b>contrast</b> 7:3 <b>control</b> 22:14 23:4 55:18 <b>controversy</b> 15:18 <b>convincing</b> 13:17 <b>cooperate</b> 60:8 <b>copy</b> 19:11 43:12 <b>correct</b> 6:15 35:10 <b>correspondence</b> 62:13	<b>counsel</b> 34:10 60:14 63:13 <b>course</b> 23:11 54:18 <b>court</b> 1:1,21 4:6 4:13 11:16 24:2 27:4 29:2 29:11,23 30:1 30:16 34:16 41:10,20 49:1 49:2 50:11,20 51:12,15,22 52:2 57:6 58:4 58:21 59:5 61:18 <b>Court's</b> 34:24 34:25 46:23 <b>courts</b> 4:18 24:17 33:22 46:21 <b>covers</b> 16:19,20 17:5 <b>crazy</b> 53:25 <b>create</b> 34:17 38:21 <b>created</b> 4:14 7:8 15:14 16:13 <b>creates</b> 23:2 <b>crucial</b> 10:25 <b>crystallizes</b> 15:18 <b>curiae</b> 2:6 3:7 23:24 <b>curious</b> 28:4 <b>cuts</b> 9:12 <hr/> <b>D</b> <hr/> <b>D</b> 4:1 <b>D.C</b> 1:17 2:2,5,8 <b>damages</b> 51:8 <b>dance</b> 24:18 <b>data</b> 17:13 37:12 39:6,8,13 42:3 43:9 <b>date</b> 8:16,19,19 10:2 12:4,5 <b>day</b> 13:22 32:22	32:23 33:10,22 51:12 54:20 <b>days</b> 9:17 10:2,7 12:3,5 18:4 24:24 25:3 39:15,24 55:10 58:9 61:17 <b>days'</b> 9:13 <b>de-linked</b> 6:18 <b>deal</b> 22:14 59:7 <b>DEANNE</b> 2:2 3:3,13 4:10 60:16 <b>debated</b> 62:4 <b>decide</b> 18:12 29:23 30:1 43:23 51:13 56:19 63:3 <b>decided</b> 4:6 58:21 <b>decides</b> 5:10 40:14,17 43:2 52:11 <b>decision</b> 27:11 45:5 46:23 50:19 <b>decisions</b> 50:8 <b>declaratory</b> 19:24 29:20 32:17,25 33:21 46:24 47:7 54:15 <b>declaratory-ju...</b> 14:1 15:4 16:4 19:14 23:9,12 31:8 43:22 46:5,10,22 47:8,13,24 54:2,4,6,7 <b>declined</b> 25:17 <b>deemed</b> 27:6 <b>defeat</b> 39:3 <b>defective</b> 54:15 55:5 <b>defendant</b> 50:17 <b>defer</b> 22:2 <b>defined</b> 38:13	<b>definition</b> 16:15 16:22 35:15 40:16 46:25 <b>definitional</b> 45:19 <b>delay</b> 5:3 25:7 <b>delayed</b> 62:9 <b>delegation</b> 11:13 <b>Department</b> 2:5 <b>describe</b> 12:13 <b>description</b> 61:25 <b>detailed</b> 24:3,14 27:21 34:17 <b>determination</b> 22:3 <b>develop</b> 5:20 <b>developed</b> 38:4 <b>difference</b> 21:8 21:10 <b>differences</b> 25:18 <b>different</b> 13:20 16:25 25:14 26:12 27:22 39:18 46:4 49:19 58:2,12 <b>differently</b> 53:20 <b>directly</b> 45:4 <b>discovery</b> 15:6 16:8 60:8 <b>dismissed</b> 60:22 <b>dispute</b> 35:19 58:11 <b>disputes</b> 4:16 24:4 34:18 35:20 39:16 46:22 59:20 <b>disregard</b> 34:21 <b>distinct</b> 18:15 <b>district</b> 41:9 46:21 58:4,15 58:21 59:5 <b>divorce</b> 44:10 <b>doing</b> 11:13 14:3 22:5 30:9
--	---	---	---	--

51:19,19 <b>doubt</b> 60:19 <b>Dow</b> 45:5 50:11 <b>driven</b> 47:25 <b>drug</b> 21:15 42:11 <b>duty</b> 62:13	<b>engage</b> 15:23 22:12 <b>enjoin</b> 41:13 <b>enjoined</b> 41:24 <b>enormous</b> 49:12 <b>entitled</b> 15:5 41:1 51:9 <b>entitling</b> 61:6 <b>ESQ</b> 2:2,4,8 3:3 3:6,10,13 <b>established</b> 32:5 46:16 <b>establishes</b> 24:7 49:8 <b>estop</b> 19:12 <b>ET</b> 1:6,11 <b>evaluate</b> 42:4 58:16 <b>evaluating</b> 24:5 41:20 56:13 <b>event</b> 38:2 57:21 61:21 <b>everybody</b> 13:24 32:24 33:22 52:9 60:1 <b>everybody's</b> 48:2 <b>exact</b> 18:2 <b>exactly</b> 14:19 15:1,7,8 17:7 17:18 18:1 19:3 27:25 54:19 <b>example</b> 42:10 60:10 <b>exceeds</b> 11:13 <b>exception</b> 46:14 47:6 <b>exchange</b> 4:24 6:17 15:24 16:2 19:6,19 19:20,25 20:8 20:23 22:12 23:1 27:15 33:25 36:4 52:12 61:14 <b>exchanged</b>	57:10 <b>exchanges</b> 13:24 <b>exclusive</b> 5:7 24:16 26:15,24 26:25 31:9 36:19 43:21 <b>exclusively</b> 12:19 <b>exclusivity</b> 6:3,5 8:15,25 14:10 23:7 37:12,16 39:7,9,13 48:16 62:3,5 <b>exist</b> 51:14 <b>expect</b> 12:21,23 13:4 <b>expedite</b> 60:8 <b>experience</b> 38:7 <b>expert</b> 13:19 <b>expiration</b> 42:15 <b>explain</b> 19:23 21:7,9 44:20 53:9 <b>explaining</b> 13:14 <b>explanation</b> 13:17 <b>explicit</b> 22:1 <b>expressly</b> 7:3 9:1 24:6 <b>extend</b> 62:4 <b>extended</b> 62:2 <b>extra</b> 4:7 23:17 <b>extremely</b> 35:2	27:13,14 <b>fails</b> 20:5 31:23 <b>failure</b> 45:19 53:25 61:3 <b>fair</b> 49:5 59:1 <b>faith</b> 20:2 <b>far</b> 13:17 <b>faring</b> 13:3 <b>farmer</b> 50:12 <b>farmers</b> 50:18 <b>favor</b> 29:19 <b>FDA</b> 5:10,15 6:1 6:4,9,12,15,18 6:22,24 8:23 11:4 14:11,25 17:13 21:20 22:5 24:5,21 25:11,14,16,16 35:9 36:23 37:3,5,5,14,21 38:17,22,24 39:19 40:2,3 40:14 41:17 42:5 54:8,12 57:21 58:1,7 58:12,15,23 59:1,23 60:3 60:11 62:13 <b>FDA's</b> 25:24,25 37:10 39:20 <b>fear</b> 15:25 <b>Federal</b> 4:25 7:7 14:12 27:5,8,9 27:10,13 28:8 28:10,14 29:21 30:12,14,22,23 30:25 37:8,12 41:9 44:25 45:6,11,17,25 46:3,4,19,20 48:9 49:4,21 50:8,16,23 51:13 60:20,21 60:21 62:25 63:1 <b>field</b> 11:7 <b>FIFRA</b> 50:16,23	<b>figure</b> 28:21 49:13 58:15 60:2,6,10 <b>figured</b> 13:21 <b>file</b> 16:4 19:10 20:23 23:12 31:7 47:8,12 54:1,4,5,6 <b>filed</b> 38:8 54:22 55:20 57:25 60:9 <b>files</b> 19:10 <b>filing</b> 33:10 <b>filings</b> 14:25 <b>fill</b> 28:21 <b>finally</b> 49:13 <b>find</b> 11:7 13:17 <b>fine</b> 49:9 <b>finished</b> 6:14 35:25 <b>first</b> 4:4 8:20 10:3,9 12:4,5 12:24 16:11 22:5,11 23:4 31:4 36:21 41:5,6 44:24 47:17 48:9,24 50:3 54:11 <b>five</b> 4:7 8:4 39:11 <b>fix</b> 7:7 <b>follow</b> 20:22 57:19 <b>followed</b> 36:2 <b>following</b> 38:2 38:15 48:1 <b>Food</b> 21:14 <b>force</b> 35:22 52:2 53:11 <b>forceful</b> 61:12 <b>forcing</b> 51:24 <b>forecloses</b> 9:24 <b>forefront</b> 33:13 <b>foremost</b> 41:5 <b>form</b> 26:23 <b>forth</b> 29:13 <b>found</b> 27:8
<hr/> <b>E</b> <hr/> e 2:2 3:1,3,13 4:1,1,10 18:2 21:3 32:1 60:16 <b>E(2)(c)</b> 15:22 <b>earlier</b> 6:10 13:1 30:16 <b>early</b> 4:15 13:6,8 21:13 24:4 37:23 38:1 52:8 55:19 61:16 <b>early-enough</b> 23:12 <b>ecosystem</b> 21:5 <b>effect</b> 47:15 <b>effective</b> 6:1,4 6:22 7:20,21 8:16,18 14:12 14:14,14 37:11 37:13,15 39:1 <b>eight</b> 5:9,20 29:10 <b>either</b> 45:20 48:16 <b>election</b> 52:20 <b>element</b> 10:1 <b>embeds</b> 25:11 <b>emphasize</b> 19:4 <b>emphatically</b> 50:20 <b>enacted</b> 24:3 <b>enacting</b> 28:20 <b>ended</b> 37:5 59:4 <b>enforce</b> 27:9 <b>enforcement</b> 51:14 55:12 <b>enforcing</b> 27:23		<hr/> <b>F</b> <hr/> <b>facilities</b> 38:19 <b>fact</b> 12:22 13:18 13:20 18:24 28:15 36:6 38:6 39:9 40:21 42:19 <b>factory</b> 38:21 <b>fail</b> 24:9 30:21 45:6 50:22 <b>failed</b> 15:9 <b>failing</b> 20:16		

<b>free</b> 13:24 32:24 48:14	44:12 46:20 63:12	<b>guided</b> 34:23	<b>hypothesis</b> 60:2	<b>indicate</b> 26:15
<b>Friday</b> 42:8	<b>giving</b> 54:3	<b>gut</b> 13:23 33:9	<b>I</b>	<b>indicates</b> 47:17
<b>friend</b> 37:25 57:11	<b>go</b> 6:13,20 11:9	<b>H</b>	<b>idea</b> 13:3 22:5	<b>indications</b> 55:25
<b>friends</b> 39:17 49:20	13:25 14:16	<b>H</b> 61:2	24:19 29:14	<b>individual</b> 50:18
<b>frozen</b> 32:18	16:1 19:5,19	<b>habit</b> 28:19	<b>identical</b> 16:23	<b>industry</b> 14:25
<b>fully</b> 62:7	22:9,25 29:14	<b>half</b> 37:3	40:5,10,12,16	<b>informal</b> 22:3
<b>function</b> 29:4	33:25 35:15,18	<b>hand</b> 39:2	<b>identify</b> 30:17	<b>information</b> 4:24 6:16
<b>future</b> 11:9 21:2	36:21 41:3,9	<b>hands</b> 52:23	31:21,23 52:4	15:23 16:2
<b>G</b>	41:12 43:2	<b>happen</b> 12:16,17	<b>identifying</b> 25:12	19:6,19 20:23
<b>G</b> 4:1	44:25 46:11	13:22 55:15	<b>II</b> 6:14 42:18	22:12 23:1
<b>gate</b> 22:25 23:8	53:15 59:15	57:13	52:10	24:23 27:14
61:17	61:18 63:9	<b>happened</b> 22:19	<b>III</b> 41:16	29:12 32:23
<b>gee</b> 32:8	<b>goes</b> 10:15 31:11	40:1 42:20	<b>illustrating</b> 34:6	33:12,13,20
<b>gene</b> 38:12	40:13	57:10 59:21	<b>immediacy</b> 46:25	34:21 36:4
<b>Genentech</b> 46:23	<b>going</b> 5:10 8:4	<b>happens</b> 20:4	<b>immediately</b> 35:14 55:22	43:13 44:12
<b>general</b> 2:5 47:7	11:8 13:4,22	22:16 26:25	<b>imminency</b> 41:11	47:6,11,19
<b>General's</b> 49:2	13:23,23 14:20	56:17	<b>implicated</b> 47:17	51:5,18 53:23
<b>generally</b> 6:21	16:1,5,6 18:11	<b>hard</b> 28:12 44:9	<b>implications</b> 11:9	55:6 56:13,18
<b>generic</b> 40:7	19:2 25:7 38:1	<b>harm</b> 47:14	<b>implicitly</b> 61:6	<b>information-e...</b> 46:8
<b>getting</b> 13:2 36:9	38:7,21 39:2	<b>Hatch-Waxman</b> 7:3 9:2,4 15:17	<b>implies</b> 55:17	<b>infringe</b> 16:7
<b>Ginsburg</b> 21:7	40:15 49:22	25:9 39:5,12	<b>importance</b> 37:1	<b>infringement</b> 15:13,20 18:5
21:19 22:24	50:7 52:4,12	39:14,18 40:3	<b>important</b> 41:2	21:2,9 24:5
<b>Ginsburg's</b> 22:9	52:14,17 54:11	40:4,7	<b>imposed</b> 27:9	31:25 32:4
<b>give</b> 4:7 8:9 20:6	55:9,15 59:6	<b>havoc</b> 27:24	<b>incentives</b> 20:13	41:14 42:2
27:14 28:12	<b>good</b> 8:3 20:2	<b>he'll</b> 33:17,17	20:15 33:8,11	46:16 47:1
29:12 31:6	42:24	<b>head</b> 49:25	53:2	52:24 56:14
32:14,18,22,23	<b>good-faith</b> 16:6	<b>hear</b> 4:3	<b>incentivized</b> 15:24	57:18 58:5,22
32:25 33:12,17	16:18 17:2,7	<b>heard</b> 13:20	<b>incidentally</b> 8:7	59:4,5 61:12
33:18 35:1,9	18:6	43:20	<b>inclined</b> 34:22	<b>infringes</b> 16:24
35:12 40:20	<b>goods</b> 59:7	<b>hey</b> 8:3 32:14	<b>include</b> 59:24	17:10 18:12
46:9 51:4,5,20	<b>GORSUCH</b> 26:14,18 27:17	<b>highly</b> 15:24	<b>including</b> 45:4,7	<b>injunction</b> 23:11
52:3 54:20	27:25 28:2	16:16 17:3,14	<b>incoherent</b> 56:25	23:13 27:6,9,9
60:5	43:14,18 44:3	27:21	<b>inconsistent</b> 26:10	28:16 29:22
<b>given</b> 17:3,24	44:5,9,16,21	<b>holder</b> 19:13	<b>incorporating</b> 49:4	41:1,7,10,18
18:25 23:14	45:8,10,15	59:2	<b>independent</b> 6:15	51:2 57:20
42:12 47:9	54:13,21 55:1	<b>Honor</b> 4:9 6:2		58:23 59:2,6
54:25 55:5	55:4	7:15 8:6,10 9:9		60:9,21 61:6
56:3 58:14,16	<b>gotten</b> 59:7	9:22 11:4,15		<b>injunctions</b> 29:5
61:11	<b>government</b> 9:5	14:10 15:7		53:14
<b>gives</b> 16:2 22:13	44:1 63:5	16:9 17:1		<b>injunctive</b> 51:8
25:3 33:19	<b>grant</b> 37:14	18:18,20 19:15		60:24
	<b>granted</b> 42:7	22:11 60:18		<b>insisted</b> 58:8
	57:25	<b>hotly</b> 62:4		<b>insofar</b> 9:12
	<b>great</b> 22:14 23:4	<b>huge</b> 11:8		
	<b>guess</b> 56:9	<b>Humira</b> 42:12		

<b>inspected</b> 38:18	<b>jurisdiction</b>	54:13,21 55:1	55:22,23 56:6	<b>let's</b> 7:16 43:14
<b>instance</b> 15:23	46:21	55:4 56:1,9,15	56:23 57:22	43:15 48:8
33:12 55:8	<b>Justice</b> 2:5 4:3	58:19 59:10,15	<b>knows</b> 56:21	56:15,19 57:1
57:7 61:1	4:12 5:6,13,19	60:14 61:20	<b>L</b>	<b>letters</b> 26:6
<b>insufficient</b>	5:22 6:6,8,19	63:13	<b>I</b> 19:22,23 20:23	<b>level</b> 46:25
54:16	6:20,24 7:9,11	<b>Justice's</b> 21:18	20:24,24 24:10	<b>license</b> 5:15,18
<b>intend</b> 55:21	7:14,16,22 8:2	<b>K</b>	24:18 26:15,24	6:4 10:17
<b>intending</b> 15:2	8:7,12,14 9:7	<b>k</b> 6:2 7:20 8:8	29:11 30:22	12:15,17 14:11
<b>intent</b> 6:9 19:10	9:10,15,16,20	11:25 12:12	31:22 33:13,25	14:13 35:16
<b>interject</b> 27:22	10:4,14 11:5	24:23 43:10,11	34:3 42:25	36:19 37:6,14
<b>interpret</b> 11:6	11:18,20,23	47:5	43:19,20 52:15	37:15 58:2
21:21 50:7	12:2,5,7,9,14	<b>Kagan</b> 17:15,19	56:18 57:8,8	59:13,20 60:12
<b>interpretation</b>	12:18 13:2,7	17:20,23 18:17	60:24 61:2,4	<b>licensed</b> 5:11,13
11:11,12 21:23	13:10,10,12,14	18:23 56:1,9	61:23 62:24	8:20 9:5,18
48:17	13:16 14:6,16	56:15	<b>language</b> 32:7	10:10,12,20
<b>intimately</b> 24:22	14:17 16:3,10	<b>Kennedy</b> 5:6,13	32:12 37:9	12:12,21,22,24
<b>invoke</b> 45:24	16:21 17:9,15	5:19,22 6:20	<b>lapsed</b> 19:2	12:25 19:13
46:3 51:25	17:18,20,23	8:2,7,12,14 9:7	<b>Laughter</b> 20:19	30:17 58:2
53:5	18:7,17,19,23	9:10,15,16,20	48:6	59:2,6 61:25
<b>involve</b> 48:16	19:9 20:1,10	11:18,23 12:14	<b>launch</b> 36:5,12	<b>licensing</b> 36:22
<b>involved</b> 21:14	20:14,15,18	12:18 13:2	36:16	<b>licensure</b> 25:15
24:22 25:15	21:7,11,18,19	24:20	<b>law</b> 26:21 27:1,6	31:20 37:4
35:20	21:25 22:9,24	<b>kept</b> 14:21	28:6,8,10,15	<b>lift</b> 61:17
<b>irrelevant</b> 41:16	23:1,16,18,20	<b>key</b> 15:14	28:15,18 29:6	<b>lifts</b> 22:25 23:8
<b>issue</b> 4:21,23,23	23:22 24:1,20	<b>kicking</b> 37:22	29:23 30:3,10	<b>limitation</b> 47:16
11:10 14:23	24:20 25:20,23	<b>kind</b> 7:4 10:18	30:11,13,13,14	<b>limited</b> 21:1
35:12 38:24	26:2,6,11,14	10:19 17:4	30:23,23,24,25	<b>line</b> 38:15
39:10 42:1,25	26:18 27:17,25	<b>kinds</b> 62:20	44:19,24,25	<b>list</b> 31:24 32:5
44:24,25 45:4	28:2,9,22 29:3	<b>knew</b> 48:13	45:6,12,17	56:21,23 57:2
52:11 55:11,12	29:17 30:6,9	61:20	46:7,9 48:12	<b>listed</b> 56:20
59:22	30:19 31:2,11	<b>know</b> 10:11 11:8	48:15,18,24	<b>lists</b> 22:15 52:12
<b>issued</b> 26:8	32:6,11,17,21	13:4 14:3,8,8	49:3,4,5,6,7,14	52:15 57:9
58:23 59:23	33:2,6,14,17	14:19 15:4,5	49:17,18,23	59:25
60:21 62:15	33:21 34:4,10	16:5,21 17:11	50:13,14,15,22	<b>litigate</b> 23:6
<b>issues</b> 50:2 58:1	34:11,12,15	17:12,21 18:8	50:24 51:14,24	47:24 52:14,17
59:20	35:3,6,13,18	22:3,4 26:3,9	52:2 53:10	61:18 62:6
<b>item</b> 62:4	36:7,11,15,18	26:13,19 29:9	60:22 62:25	<b>litigation</b> 4:18
<b>J</b>	37:18,21 40:13	30:16,16 37:5	63:1	6:17 13:6
<b>Joint</b> 27:7	41:3,21,25	37:15 38:5,8	<b>laws</b> 49:11 51:10	15:16 17:25
<b>judge</b> 58:16	43:14,18 44:3	38:11 39:25	<b>lawsuit</b> 20:24	18:10,12 21:13
<b>judgment</b> 28:5	44:5,9,16,21	40:8,9 41:11	<b>layperson</b> 13:18	22:16,17 23:2
29:20 46:24	45:8,10,15,23	41:12,15,19	<b>leave</b> 26:24 30:3	23:4 24:5,12
54:15 60:19,20	46:2 47:20,25	42:4,10 48:11	38:22 55:12	26:11 29:16
<b>judgments</b>	48:7 49:9,16	48:14,25 49:11	<b>leaves</b> 39:21	35:14 36:5
32:25 47:7	50:1,6 51:21	51:1,18 54:8	<b>left</b> 5:4 22:20	38:1 39:20
<b>jumps</b> 33:22	51:23 52:6,25	54:11 55:11,15	47:23 59:20	42:18,22,22
	53:4,7,10,13			45:1 52:8,23

56:3 62:17 <b>location</b> 40:19 <b>logically</b> 55:16 <b>long</b> 6:12,14,19 6:21 25:11 37:4 46:24 <b>longer</b> 52:5 53:8 <b>look</b> 4:19 11:17 16:7 18:10 20:16 28:6 29:9 32:13 34:1 40:21 46:13 51:3,15 <b>looking</b> 8:11 31:3 40:23 45:12 <b>lost</b> 59:10 <b>lot</b> 10:19 34:8 56:1,11 57:22 62:18 <b>lots</b> 57:23,23 <b>low</b> 48:4	22:24 32:19 40:25 41:7 42:14 47:9 55:10,21 61:15 <b>materially</b> 58:2 <b>matter</b> 1:20 5:19 18:23 55:16 63:16 <b>Maynard</b> 2:2 3:3,13 4:5,6,8 4:9,10,12 5:12 5:15,25 6:7,16 6:23 7:10,13 7:15,19,24 8:6 8:10,13,15 9:9 9:14,19,22 10:13 11:4,15 11:19,21,24 12:3,8,11,17 13:13 14:5,8 15:7 16:9,11 17:1,12,16,18 17:22 18:1,18 18:20 19:3,15 20:9,12,17,20 21:17 22:7 23:19,21 60:15 60:16,18 <b>mean</b> 6:9 8:2,5 16:22 17:20 22:13 41:17 43:25 49:17 50:25 51:1 56:2,16 58:5 60:7 63:5,5,6 <b>means</b> 10:22,22 10:24 13:21 18:16 25:2 27:22 37:13 43:16,23 45:20 48:8,19,22 51:16 54:9 <b>mechanism</b> 26:25 <b>MedImmune</b> 46:23 <b>merely</b> 34:19	<b>mess</b> 29:8 <b>million</b> 38:20 <b>minute</b> 58:5 <b>minutes</b> 4:7 60:15 <b>misread</b> 4:25 <b>missing</b> 28:17 <b>misunderstood</b> 18:21 <b>modifies</b> 12:5 <b>molecule</b> 36:24 40:5,8,12 52:21 57:4,5 <b>months</b> 7:1,14 12:21 36:21 39:15 <b>moot</b> 27:7 28:7 30:10 <b>mooted</b> 30:20 <b>morning</b> 4:4 <b>muck</b> 24:17	19:10 20:6 22:21,23 23:5 23:7 25:3 27:14 32:8,15 32:18,22,24 33:10 35:9 36:22 40:14,20 40:22,25 41:5 42:13 47:9 51:5,6,20 53:22,25 54:2 54:4,10,14,16 54:17,20,25 55:4,9,13,13 55:14,16,19 56:6 61:15,16 61:23 <b>noticed</b> 10:5 <b>notifies</b> 24:24 <b>notion</b> 37:25 38:7,20 41:13 53:24 <b>notwithstandi...</b> 47:3 <b>number</b> 32:22 38:3 47:14 52:7 57:7,15 57:17,19 59:17 60:1	50:6 <b>okay</b> 6:22 7:10 7:13,18 16:11 32:13 34:4 35:5,7 43:15 43:17 44:4,23 45:9 46:1,11 48:8 53:15 56:19 57:1 <b>once</b> 22:25 32:14 36:23 41:17 43:1,1,5 43:7 59:20 60:9 <b>one's</b> 27:1 <b>ones</b> 23:3 35:21 59:11 <b>open</b> 30:3 38:22 <b>operate</b> 18:25 <b>operating</b> 11:7 <b>operative</b> 47:15 <b>opinion</b> 25:10 26:6 28:14 <b>opinions</b> 26:8 <b>opportunity</b> 58:4 60:6 <b>opposite</b> 14:3 <b>opt</b> 52:1 <b>oral</b> 1:20 3:2,5,9 4:10 23:23 34:5,13 <b>orange</b> 25:12 <b>order</b> 30:17 34:1 45:2 51:3,4,19 55:13 56:13 58:14 <b>orderly</b> 33:9 <b>ordinarily</b> 55:16 <b>original</b> 41:15 <b>ought</b> 56:16 <b>outside</b> 55:17
<hr/> <b>M</b> <hr/> <b>maker</b> 38:5,6 <b>making</b> 6:1,4 13:24 34:9 47:6 <b>mandate</b> 44:2 <b>mandates</b> 34:21 45:7 <b>mandatory</b> 31:15 57:20 <b>manifest</b> 39:3 <b>manufacturing</b> 36:25 38:18 40:11,19 43:13 47:6,19 51:4 56:22,24 58:6 58:18 60:10 <b>market</b> 8:5 10:23 15:2 39:9,11 59:7 <b>marketing</b> 4:23 5:1,3 9:6,24,25 10:3,9 11:22 12:4,6 22:22		<hr/> <b>N</b> <hr/> <b>N</b> 3:1,1 4:1 <b>narrow</b> 59:8 <b>narrowed</b> 35:19 35:21 58:23 59:1 <b>narrower</b> 60:3 <b>necessary</b> 56:12 <b>need</b> 22:1,1,17 23:13 56:13 <b>needs</b> 60:1 <b>negotiate</b> 33:8 <b>never</b> 22:17,18 31:24 39:25 <b>new</b> 22:18 32:3 62:15 <b>news</b> 8:3 <b>nope</b> 38:25 <b>note</b> 15:12 <b>notice</b> 4:22,25 9:13,23 10:2,5 10:7,21,22,23 11:22,25 12:10 12:23 13:18,21 13:22 15:10	<hr/> <b>O</b> <hr/> <b>O</b> 3:1 4:1 <b>obtain</b> 57:9 <b>obvious</b> 47:22 <b>obviously</b> 16:12 <b>occur</b> 56:3 <b>occurred</b> 47:2 53:18 <b>occurs</b> 36:4 39:20 41:11 42:18 <b>odd</b> 49:22 61:9 62:25 <b>Oddly</b> 13:16 <b>off-ramp</b> 31:18 <b>office</b> 21:16,20 <b>oh</b> 11:18 32:2	<hr/> <b>P</b> <hr/> <b>P</b> 2:8 3:10 4:1 34:13 <b>page</b> 3:2 11:19 15:22 24:22

27:7 28:7 40:24 50:5 <b>panels</b> 37:8,12 <b>parachute</b> 51:17 <b>paragraph</b> 34:5 <b>paramount</b> 36:25 <b>part</b> 20:8 28:23 48:9,12 <b>participate</b> 19:18 53:5,14 61:13 <b>particular</b> 38:14 <b>particularly</b> 14:20 <b>parties</b> 15:23 22:12,25 23:3 24:19 56:7,19 57:1 58:3,10 60:8 <b>party</b> 50:8 <b>patent</b> 4:16,18 5:4 6:17 13:9 14:15 16:19,19 17:5,10,16,25 18:10,10,13,17 19:1,2 21:8,13 21:15,20 24:4 24:4,11 36:4 39:16,20 42:1 46:21 52:8,13 52:21,21 56:24 57:15 58:5,22 59:4,19,23 61:10,11,19 62:6,8,12,16 62:16,17 <b>patents</b> 15:25 22:15,18,20 23:6 25:12 31:22,24 35:20 42:16 52:11,15 56:20 57:2,4,9 57:12,16 58:11 58:17 <b>path</b> 24:10 29:14 31:16,19	<b>peek</b> 43:23 <b>pending</b> 22:20 <b>people</b> 13:23 18:24 33:8 <b>period</b> 5:7,14,16 6:5 8:25 12:19 14:10 19:21 20:25 23:7 31:25 35:23,25 37:7,16 39:6,7 39:8,13,14,19 54:10 58:9,14 58:16 60:5 62:3,5 <b>periods</b> 39:6 <b>permitted</b> 43:24 <b>petition</b> 4:22,22 4:24 50:5 <b>petitioned</b> 25:16 60:20 <b>Petitioner</b> 1:4 2:3,7 3:4,8,14 4:11 23:25 26:22 60:17 <b>Petitioners</b> 1:12 2:9 3:11 34:14 <b>phase</b> 6:13,14 19:12 35:13 42:18,18 51:25 52:10,10,14 53:5 56:16 58:10,20 <b>phases</b> 22:10,11 <b>phone</b> 8:3 <b>phrase</b> 35:3 <b>phrasing</b> 12:13 <b>pick</b> 48:15 <b>picked</b> 48:12 <b>picture</b> 11:14 <b>piece</b> 28:17,19 56:12 <b>piggyback</b> 30:14 43:5 <b>place</b> 42:5 <b>plaintiff</b> 50:23 <b>please</b> 4:13 24:2 34:16	<b>plus</b> 6:10,22 12:16,18 36:13 36:16,21 48:13 <b>point</b> 10:24 14:12 15:8,15 15:21 19:16 23:5 25:16 31:4,4 36:21 42:23,24 48:2 48:23 <b>pointed</b> 37:25 <b>points</b> 6:23 29:15 52:7 <b>policing</b> 24:18 29:11 <b>policy</b> 62:20 <b>pops</b> 49:14 <b>position</b> 25:24 25:25 26:1,3 26:12,20 27:18 27:24 28:25 35:8 37:22 38:25 <b>possibility</b> 13:23 37:23 <b>possible</b> 29:22 55:7 <b>possibly</b> 43:22 <b>post-license</b> 35:22 <b>potent</b> 43:4 <b>potentially</b> 56:20 <b>power</b> 10:19 <b>powerful</b> 20:12 23:14 63:12 <b>practical</b> 5:19 <b>practice</b> 17:23 18:24 <b>practices</b> 49:6 <b>precedent</b> 31:16 62:23 <b>precise</b> 18:5 <b>precisely</b> 27:10 40:8,9 <b>preconditions</b> 55:17	<b>predicated</b> 30:24 <b>preempted</b> 27:2 27:4,21 30:19 <b>preemption</b> 26:23 28:3,11 28:23 30:3 31:12 48:17 49:10 50:3,4 <b>prejudge</b> 50:1 <b>preliminary</b> 23:11,13 41:1 41:6,10 60:9 <b>premise</b> 9:15 <b>presented</b> 28:13 <b>pressure</b> 38:16 <b>presumably</b> 49:17 52:21 <b>pretty</b> 37:23 48:4 49:10 50:20 <b>primary</b> 26:20 <b>principle</b> 46:15 <b>prior</b> 56:11 <b>probably</b> 56:16 <b>problem</b> 7:8 18:9 21:23 32:6,7 <b>procedural</b> 24:7 <b>procedures</b> 34:17 60:25 <b>proceed</b> 4:8 <b>proceedings</b> 13:19 <b>process</b> 6:17,18 7:12 9:11,12 19:5,16 20:8 20:14 24:3 25:7,12,14 38:13,18 39:12 40:11,19 43:13 45:25 46:3,4,5 52:11 56:11,24 57:19 58:6 59:4,16 63:7,8 <b>processes</b> 36:25 41:8,19 56:22	58:18 60:10 <b>produce</b> 17:14 <b>product</b> 8:20,21 10:9,12 12:1 12:11 14:18 16:1,4,17,19 16:20 17:5,6,6 17:14,14 19:13 35:17,18 38:5 39:10 41:8 42:20 59:2,22 60:5 <b>products</b> 19:1 43:5 59:6 <b>prohibits</b> 5:25 6:4 <b>prove</b> 43:4 <b>provide</b> 5:1 10:6 10:21 11:25 12:9,10 15:10 15:10,11 19:18 25:1 43:1,12 47:11 50:18,19 53:25 54:16 55:6,14 60:24 61:7,8 <b>provided</b> 10:17 10:18 15:9 18:2 44:14 45:17 47:19,23 60:25 63:2 <b>provides</b> 15:19 20:12 29:24 31:17 47:5 51:7 53:17 <b>providing</b> 18:4 53:23 56:18 <b>provision</b> 5:1 6:3 9:24 10:1 11:22 21:3 22:22,24 34:2 40:22 46:8 50:16,23 61:3 61:16,22,23 62:10,24 <b>provisions</b> 9:6 11:6 21:21
--	--	---	---	---

29:6 53:20 61:1,6 <b>PTO</b> 57:14 59:23 <b>PTO's</b> 26:1 <b>public</b> 60:11 <b>publicly</b> 5:24 <b>pure</b> 43:4 <b>purported</b> 54:19 <b>purpose</b> 13:7,8 22:23 35:23 36:1 39:3 <b>purposes</b> 40:9 40:17 41:16,19 44:5 54:9 57:5 <b>put</b> 7:16 22:15 28:16 33:7 35:6 <b>putting</b> 27:5 <b>puzzle</b> 28:17,19	25:14 38:23 45:24 <b>quote</b> 43:10,10 <hr/> <b>R</b> <b>R</b> 4:1 <b>rare</b> 5:21 <b>reach</b> 49:19 <b>read</b> 11:24 32:8 32:9 34:4 37:9 48:9 57:14 61:4,5,9,24 <b>reading</b> 9:25 13:15,15 14:13 32:7 35:22 46:6 49:12 <b>ready</b> 4:8 <b>real</b> 47:15 58:11 <b>reality</b> 62:19 <b>really</b> 28:16 51:23 <b>reason</b> 10:24 31:1 37:17 38:10 40:1,2 56:5 <b>reasonable</b> 21:2 63:3 <b>reasons</b> 38:2 47:14 <b>rebuttal</b> 3:12 23:17 60:16 <b>recall</b> 47:16 <b>recognize</b> 63:10 <b>recognizes</b> 57:8 <b>record</b> 38:19 <b>reference</b> 8:15 8:21 38:5 <b>reference-pro...</b> 16:16,17 <b>referenced</b> 8:20 12:1 35:17 42:11,20 43:5 60:5 <b>referenced-pr...</b> 43:9 <b>referring</b> 6:3 <b>Regardless</b> 4:16	<b>regular</b> 39:12 42:15 43:2 <b>regulation</b> 25:6 <b>regulations</b> 11:11 13:11 <b>regulatory</b> 22:1 <b>rejected</b> 50:11 50:20 <b>relates</b> 41:14 <b>relevant</b> 39:6 42:16 <b>relief</b> 26:21 49:22 51:8 60:24 <b>remaining</b> 61:19 <b>remains</b> 43:19 46:3 <b>remand</b> 29:22 <b>remarkably</b> 59:18 <b>remedies</b> 43:24 45:16 49:4 50:18 53:17 61:8,11,11 <b>remedy</b> 20:11 23:14 26:15 27:13 29:21 31:7,9 43:20 43:21 44:10,13 44:16 45:13,20 46:4,9 47:13 48:10,13,16 50:12,24 51:7 52:2 53:21,22 53:24 54:3 55:3,7 56:17 63:12 <b>remember</b> 31:20 <b>repeatedly</b> 34:18 <b>reported</b> 38:3 <b>request</b> 62:12 <b>requested</b> 62:12 <b>require</b> 57:22,24 61:21 <b>required</b> 20:7,7 30:1 54:17	<b>requirement</b> 31:5,7 43:1 61:24 <b>requires</b> 10:2 30:5 60:8 <b>reserve</b> 23:19 <b>resolution</b> 4:15 13:8 21:13 24:4 <b>resolve</b> 30:4 <b>resolved</b> 59:20 <b>resolving</b> 34:18 <b>respect</b> 13:13 21:11 41:3 47:15 58:10 59:21 62:19 <b>Respondent</b> 1:15 <b>Respondents</b> 1:7 <b>rest</b> 28:6 61:5 <b>rests</b> 28:7,9 <b>result</b> 4:17 <b>reticulated</b> 49:11 <b>review</b> 25:7 38:22 42:6 <b>right</b> 6:16 8:12 11:5 12:18 13:12 14:13 16:15 18:1,9 19:17 21:9 26:18 32:16,20 33:1,2 43:16 44:10,11,12,13 45:22 46:2,11 46:12 48:3,7 49:20 54:21,23 55:7 56:4 60:2 62:10 <b>rights</b> 5:4 14:15 45:12 47:23 61:10,10,19 62:6,8 <b>ROBERTS</b> 4:3 13:10 16:21 17:9 18:7,19 23:18,20,22	28:9,22 29:3 34:10,12 41:21 41:25 49:9,16 50:1,6 60:14 63:13 <b>Rose</b> 49:1 <b>round</b> 21:9 35:19,20,22,24 35:24 37:23 38:1 56:2 58:20,20 <b>rounds</b> 21:8 <b>route</b> 43:2,3 47:5 <b>royalties</b> 21:2 <b>royalty</b> 63:4 <b>rule</b> 29:19 34:8 <b>rule-making</b> 21:20 25:17 <b>rules</b> 47:4 <b>ruling</b> 5:3 <b>run</b> 5:9 6:5,15 8:25 9:17,18 12:20 37:12 39:23 52:2 <b>runs</b> 23:7 37:16 <hr/> <b>S</b> <b>S</b> 3:1 4:1 <b>safe</b> 43:4 <b>sake</b> 29:18 <b>Sandoz</b> 1:3,14 4:4 12:23,25 15:11 27:3 <b>Sandoz's</b> 4:21 53:16 <b>satisfied</b> 55:18 <b>saying</b> 17:10 20:3 21:12 29:11 30:10 53:1 56:9 59:5 <b>says</b> 8:16 10:6 11:24 20:24 23:10 28:7 30:7,7 37:9 39:1 40:25 43:6,7 44:1,2
--	---	---	---	---



46:5,13 47:3 47:11 49:3,5 51:15 52:16 54:1 55:9 61:16 62:24 63:5 <b>scheme</b> 4:15,19 27:21 29:8,14 63:11 <b>scope</b> 24:11 58:24 <b>SEC</b> 14:25 <b>second</b> 12:24 22:17 <b>secretary</b> 8:19 24:24 <b>section</b> 32:15,22 45:12,13 46:12 46:13,13,20 <b>see</b> 11:11 23:16 52:18 <b>seek</b> 23:11 41:6 54:15 <b>seeking</b> 19:14 41:13 53:13 58:25 <b>self-contained</b> 4:15 <b>send</b> 24:18 32:23 <b>sense</b> 6:21 57:3 57:4,6 <b>sensible</b> 25:5 <b>sentence</b> 10:8 <b>separate</b> 6:18 <b>separated</b> 25:16 <b>separating</b> 54:24 <b>sequencing</b> 38:12 <b>series</b> 24:7 29:13 <b>set</b> 14:11 24:10 33:7 42:4 <b>SETH</b> 2:8 3:10 34:13 <b>Setting</b> 48:4 <b>settled</b> 42:22	<b>settlement</b> 42:19 <b>seven</b> 42:5 <b>shalls</b> 63:4 <b>shape</b> 26:23 <b>shift</b> 42:25 <b>shot</b> 59:7 <b>show</b> 13:6 <b>shows</b> 61:15 <b>side</b> 14:19 15:3 20:4,5,5 26:21 37:25 39:17 43:21 49:20 <b>sides</b> 11:2 <b>significantly</b> 61:2 <b>similar</b> 16:16,23 17:14,24 18:15 <b>similarities</b> 17:4 <b>similarity</b> 17:3 18:25 <b>simply</b> 33:10 40:11 47:10,21 55:9 <b>sit</b> 35:1 <b>situation</b> 14:20 15:19 18:2 19:7 35:2 59:18,19 <b>situations</b> 19:4,6 21:6 22:2 26:3 <b>small</b> 40:5 <b>society</b> 20:16 <b>Solicitor</b> 2:4 49:2 <b>solve</b> 21:22 <b>somebody</b> 14:2 14:2 <b>somewhat</b> 11:7 <b>soon</b> 41:4 <b>sorry</b> 6:6 18:21 19:9 30:6 40:23 45:10 58:19 <b>Sotomayor</b> 6:6,8 6:19,24 7:9,11 7:14,16,22 14:16 16:3,10	19:9 20:1,10 20:14,15,18 23:1 25:20,23 26:2,6,11 29:17 30:6,9 30:19 31:2,11 35:3,6,13,18 36:7,11,15,18 37:18,21 41:3 45:23 46:2 51:21,23 52:6 52:25 53:4,7 53:10,13 58:19 59:10,15 <b>sought</b> 26:21 51:3 <b>source</b> 53:16 <b>sovereign's</b> 49:7 <b>specifics</b> 16:22 <b>specifies</b> 24:8 40:18 <b>sponsor</b> 4:17 5:17 8:22 12:1 16:17 17:5 20:22,24 21:1 22:13 23:3,6,9 23:10 24:9 31:23,24 41:5 47:15,23 52:14 52:20 54:11 56:21 57:8,19 58:14 60:6 61:18 63:9 <b>sponsor's</b> 16:17 34:21 39:8 43:9 47:14 <b>sponsors</b> 5:1 20:13 23:15 <b>spot</b> 43:15 <b>spotting</b> 44:3 <b>stage</b> 20:24 29:11 31:22 51:25 <b>stand</b> 35:1 <b>standard</b> 17:3 <b>start</b> 4:21 14:1 15:4 24:18	27:22 55:21 56:13 <b>started</b> 4:5 21:12 42:13 <b>starting</b> 35:14 46:9 <b>starts</b> 56:16 <b>State</b> 26:21 27:1 27:6 28:6,15 28:18 29:6,23 30:3,10,11,13 30:13,23,24 44:19,23 45:3 45:6 46:7,9 48:14,15,18,24 49:4,5,19,23 50:13,14,15 51:14,24 52:2 53:10 60:22 <b>State-by-State</b> 27:23 <b>States</b> 1:1,21 2:6 3:7 13:14 23:24 27:22 28:21 <b>statute</b> 5:2,25 6:2 7:20,25 8:23,25 9:6 12:12 13:8,15 14:9 15:14 17:15 18:25 20:12 23:14 24:6,15,17 25:21,22 27:10 29:4,7 30:2,4,7 30:7,8,12 31:7 31:15,17,18 34:24 35:24 36:2 37:9 38:25 39:4,5 43:6 45:2,3 49:12 50:8,16 51:7 53:17 54:17 56:10 57:8 60:23 61:5,9 62:21 63:10	<b>statute's</b> 34:20 <b>statutes</b> 28:20 45:3 <b>statutory</b> 11:13 21:23 <b>stay</b> 5:2 23:2 <b>step</b> 24:18 52:3 63:9 <b>steps</b> 19:12 24:7 24:9 31:17 <b>stick</b> 22:4 <b>stop</b> 35:13 48:8 48:19 <b>strengthens</b> 37:18 <b>strong</b> 27:20 28:24 33:11 <b>stuck</b> 22:6 <b>stuff</b> 15:1 <b>subjected</b> 22:21 <b>submission</b> 46:17,17 <b>submits</b> 43:11 <b>submitted</b> 17:13 63:14,16 <b>subsection</b> 8:18 8:21 11:25 12:12 24:23 29:10 40:22 41:1 43:10,11 <b>subsections</b> 29:10 <b>subsequent</b> 27:11 <b>subside</b> 9:11 <b>substance</b> 55:24 <b>substantially</b> 58:24 <b>substantive</b> 48:12,13 50:14 50:15 53:20 54:24 55:12 <b>sudden</b> 32:24 49:13 <b>sue</b> 15:12 17:3,7 17:17 18:6,9 18:11,17,21
---	---	---	---	---

20:4,25 62:9 62:24 63:3 <b>sued</b> 62:9 <b>sufficient</b> 29:12 42:3 <b>sufficiently</b> 18:14 <b>suggest</b> 51:15 <b>suggested</b> 7:7 <b>suggesting</b> 23:2 <b>suing</b> 17:9 <b>suit</b> 16:18 19:2 21:1,2 62:11 62:16,17 63:1 <b>superfluous</b> 46:7 <b>supporting</b> 2:6 3:8 23:25 32:8 <b>suppose</b> 5:6 <b>supposed</b> 33:3,4 33:7 <b>Supreme</b> 1:1,21 49:1 <b>sure</b> 6:11 9:14 21:5 44:7 59:12 <b>synthesis</b> 40:6 40:12 <b>system</b> 33:6,7	37:1 40:4 <b>technical</b> 11:6 <b>tell</b> 5:6 7:22 15:1 16:10 48:20 <b>telling</b> 9:21 53:7 62:18 <b>tells</b> 41:1 55:19 55:20 <b>tempting</b> 34:25 <b>ten</b> 5:20 <b>tentative</b> 7:4 9:1 <b>tentatively</b> 9:3 <b>terms</b> 28:11 52:7 62:22 <b>testing</b> 43:3 <b>Teva</b> 39:11 <b>Teva's</b> 42:21 <b>Texas</b> 50:13,14 50:21,22,24 <b>text</b> 9:23,24,25 11:16 14:9 16:13 21:24 22:7 <b>Thank</b> 4:9 8:14 13:12 23:21 34:10,11 60:13 60:14,18 63:13 <b>thanks</b> 28:14 <b>theory</b> 51:24 <b>therapeutic</b> 36:24 40:9,17 <b>thereof</b> 10:24 <b>thing</b> 14:6 16:14 17:10,11 25:5 32:14 49:23 <b>things</b> 14:9 23:8 23:8 34:6 38:15 52:18 58:22,24 <b>think</b> 7:4,6 9:24 11:15,16 21:4 21:22,23,24 22:7 25:8 27:20 28:18,24 29:3,4,7,25 31:13 32:3,10 34:22,22 41:3	47:20 53:16 56:16 57:6 <b>thought</b> 16:12 35:20,23 <b>Three</b> 60:15 <b>time</b> 5:11 9:17 9:18 19:21 20:25 23:19 24:14 41:6 46:24 51:5,20 54:7,11,23 56:6 57:25 58:14,16 60:1 60:12 <b>times</b> 41:22 <b>timing</b> 6:21 10:1 24:11 <b>tip</b> 39:2 <b>told</b> 25:6 62:8 <b>tough</b> 32:9 <b>Trademark</b> 21:16 <b>tremendous</b> 33:8 <b>true</b> 12:7 56:1 <b>try</b> 6:25 <b>trying</b> 7:11 46:12 <b>turn</b> 4:23 9:23 <b>turns</b> 57:21 58:1 <b>tutorial</b> 35:1 <b>two</b> 6:23 14:9 15:13,19,19 16:15 21:8,10 22:10,11 23:8 23:8 37:8,12 39:6 47:14 52:6 53:17,20 57:17 58:21,22 60:1,23 <b>type</b> 49:21	34:7 35:8 44:11,13 45:11 50:7,10 51:11 55:1 <b>understanding</b> 15:15 <b>understands</b> 52:9 <b>unfairness</b> 59:12 <b>United</b> 1:1,21 2:6 3:7 13:14 23:24 <b>unsatisfactory</b> 48:2 51:11 <b>unsatisfying</b> 51:2 <b>unwillingly</b> 53:14 <b>updating</b> 62:14 <b>upfront</b> 52:24 <b>use</b> 16:20 34:18 34:20 39:8 <b>uses</b> 12:12 17:6 36:24 41:8 <b>usually</b> 44:12	53:22 54:10 61:4 62:25 <b>violations</b> 53:18 61:1 <hr/> <b>W</b> <hr/> <b>wait</b> 7:17 42:15 52:18 58:5 <b>waive</b> 50:9 <b>waived</b> 50:5 <b>walk</b> 19:22 <b>want</b> 6:19,20 16:11 19:4 30:15 44:7,19 44:22 45:24 46:24 48:22 51:15 52:17,18 61:8 63:6 <b>wanted</b> 60:24 <b>wants</b> 61:4 <b>warmed</b> 36:9 <b>Washington</b> 1:17 2:2,5,8 <b>Waxman</b> 2:8 3:10 4:6 34:12 34:13,15 35:5 35:11,17 36:1 36:9,14,17,20 37:20,24 41:23 42:3 43:14,17 43:25 44:4,7 44:15,18,23 45:9,14,18 46:1,11 47:21 48:4,21 49:15 49:24 50:3,10 51:22 52:6 53:3,6,9,12,15 54:18,22 55:3 55:8 56:4,15 58:19 59:9,14 59:17 <b>way</b> 4:17 10:17 10:18,21 11:9 17:15 18:24 19:17 20:16 22:10 26:23
<hr/> <b>T</b> <hr/> <b>T</b> 3:1,1 <b>take</b> 4:17 6:12 6:21 10:14 11:16 14:23 24:9 26:22,22 31:16 32:7 34:20 38:14,19 52:3 <b>taken</b> 26:12 27:24 28:25 <b>takes</b> 5:19 6:25 7:14 38:3 <b>talk</b> 14:25 24:14 34:24 51:6 56:17 <b>talking</b> 8:8 34:2	<hr/> <b>T</b> <hr/> <b>T</b> 3:1,1 <b>take</b> 4:17 6:12 6:21 10:14 11:16 14:23 24:9 26:22,22 31:16 32:7 34:20 38:14,19 52:3 <b>taken</b> 26:12 27:24 28:25 <b>takes</b> 5:19 6:25 7:14 38:3 <b>talk</b> 14:25 24:14 34:24 51:6 56:17 <b>talking</b> 8:8 34:2	<hr/> <b>U</b> <hr/> <b>ultimately</b> 25:18 51:12 <b>understand</b> 6:11 9:14 26:20	<hr/> <b>V</b> <hr/> <b>v</b> 1:5,13 4:4 45:5 46:23 49:1 50:11 <b>vacate</b> 29:22 <b>valid</b> 17:16,25 19:1 54:23 <b>validity</b> 42:1 <b>versus</b> 37:2 <b>vett</b> 28:25 <b>view</b> 48:2 <b>views</b> 13:20 <b>vindicate</b> 62:7 <b>violate</b> 49:6 <b>violating</b> 30:24 31:18 51:10 <b>violation</b> 26:16 45:6,11,15 49:5 50:14,15 50:15,22 53:21	<hr/> <b>W</b> <hr/> <b>wait</b> 7:17 42:15 52:18 58:5 <b>waive</b> 50:9 <b>waived</b> 50:5 <b>walk</b> 19:22 <b>want</b> 6:19,20 16:11 19:4 30:15 44:7,19 44:22 45:24 46:24 48:22 51:15 52:17,18 61:8 63:6 <b>wanted</b> 60:24 <b>wants</b> 61:4 <b>warmed</b> 36:9 <b>Washington</b> 1:17 2:2,5,8 <b>Waxman</b> 2:8 3:10 4:6 34:12 34:13,15 35:5 35:11,17 36:1 36:9,14,17,20 37:20,24 41:23 42:3 43:14,17 43:25 44:4,7 44:15,18,23 45:9,14,18 46:1,11 47:21 48:4,21 49:15 49:24 50:3,10 51:22 52:6 53:3,6,9,12,15 54:18,22 55:3 55:8 56:4,15 58:19 59:9,14 59:17 <b>way</b> 4:17 10:17 10:18,21 11:9 17:15 18:24 19:17 20:16 22:10 26:23

29:4 30:1,4 33:9 38:13 41:20 45:16 59:16 61:9 62:3,19 <b>ways</b> 16:25 <b>we'll</b> 4:3 14:3 <b>we're</b> 8:4 13:22 14:3 25:7 30:10 31:3 39:1 40:21 47:6 51:9,9 52:14 <b>we've</b> 8:3 25:6 27:24 28:25 43:20 56:19,19 59:17 60:20 <b>Wednesday</b> 1:18 <b>well-established</b> 49:10 <b>went</b> 39:11 51:3 <b>wider</b> 59:11 <b>word</b> 9:6 13:21 32:8 34:19 61:24 <b>work</b> 8:5 22:10 29:7 32:9 33:8 34:7 <b>works</b> 17:16 19:17 26:9 62:19,21 <b>world</b> 58:25 62:19 <b>wouldn't</b> 15:5 35:13,21 39:3 48:11,14 <b>wreak</b> 27:23 <b>written</b> 4:19 <b>wrong</b> 26:19 54:14 <b>wrongly</b> 5:3 <b>wrote</b> 62:8	<hr/> <b>Y</b> <hr/> <b>Y</b> 58:7 <b>Yang</b> 2:4 3:6 23:22,23 24:1 25:8,20,21,25 26:5,8,13,14 26:17 27:3,19 28:1,5,18,24 29:7,25 30:8 30:11,21 31:9 31:13 32:10,16 32:20 33:1,5 33:11,15,19,24 34:11 <b>yeah</b> 11:20,23 12:7,7 21:25 26:5 33:2,14 33:14 <b>year</b> 5:7,9,18,18 5:23,23 6:10 6:10 7:17,21 7:25 8:24 12:25 38:8,8,9 38:22 42:12 <b>years</b> 5:9,20 6:5 8:4,19 12:16 12:18,19 14:15 36:12,19,21 37:3,4,11,11 37:15 38:4 39:2,11,23 41:12 42:5	<b>10</b> 7:1,14 12:21 38:4 <b>10:05</b> 1:22 4:2 <b>100</b> 38:20 <b>11:16</b> 63:15 <b>12</b> 6:5,10,10,22 7:21 8:1,19,24 12:16,18 14:15 36:12,16,19,20 37:2,2,4,11,11 37:15 38:23 39:2,23 <b>12-day</b> 5:14 <b>12-year</b> 5:7,16 14:10,12 35:23 35:25 37:7 62:2 <b>14</b> 42:6 <b>15-1039</b> 1:4 2:3 2:7 3:4,8,14 4:4,11 23:25 60:17 <b>15-1195</b> 1:12 2:9 3:11 34:14 <b>18</b> 38:15 <b>180</b> 9:13,16 10:2 10:7 12:3,5 37:2 39:15,24 55:10,10 58:9 61:17 <b>180-day</b> 5:2 22:21 40:22 42:13 53:21,25 54:10 60:5	25:3 <b>200</b> 38:20 <b>2017</b> 1:18 <b>23</b> 3:8 13:25 <b>24</b> 28:7 <b>24a</b> 8:13,14 27:7 <b>25</b> 28:7 <b>25a</b> 27:7 <b>26</b> 1:18 <b>262(k)(7)</b> 37:10 <b>262(l)(8)</b> 40:23 <b>26A</b> 50:5 <b>271</b> 15:22 21:3 <b>271(A)</b> 39:12 <b>271(d)(4)</b> 57:20 <b>271(e)(2)</b> 31:25 <b>281</b> 46:20	<b>8</b> 35:11 38:9 40:25 41:2,5 54:1 56:5 60:7 61:23 <b>8A</b> 21:3
	<hr/> <b>Z</b> <hr/> <b>Z</b> 58:7	<hr/> <b>2</b> <hr/> <b>2</b> 5:7 18:2 26:16 30:22 31:4 32:15,15,22,23 33:10,13,22 35:14,20,22,24 36:3 37:23 38:1 42:25 43:6,15,23 44:1,11 47:11 56:18 <b>20</b> 18:4 24:24	<hr/> <b>3</b> <hr/> <b>3</b> 31:22 33:25 52:15 <b>30</b> 39:15 57:24 <b>30-month</b> 39:19 <b>31A</b> 40:24 <b>32A</b> 24:22 <b>34</b> 3:11 <b>39A</b> 11:19	<hr/> <b>9</b> <hr/> <b>9</b> 13:25 19:22,23 26:15,24 34:3 43:19,19,19,20 43:23 44:17 46:12,13,14,15 47:3,10,10,13 47:16,16,21 48:23 53:16,21 53:22,24 <b>9(a)</b> 13:25
	<hr/> <b>0</b> <hr/> <b>1</b> <hr/> <b>1</b> 6:10,22 12:16 12:18 19:12 21:9 32:22,22 35:19,24 36:16 43:7,10 44:2 53:5 56:2 61:2 61:4 <b>1/2</b> 14:15	<hr/> <b>4</b> <hr/> <b>4</b> 3:4 5:9,18,18 7:17 38:8	<hr/> <b>4</b> <hr/> <b>4</b> 3:4 5:9,18,18 7:17 38:8	
	<hr/> <b>X</b> <hr/> <b>x</b> 1:2,8,10,16 10:23 58:7	<hr/> <b>5</b> <hr/> <b>5</b> 42:7 <b>5A</b> 15:22 18:3	<hr/> <b>5</b> <hr/> <b>5</b> 42:7 <b>5A</b> 15:22 18:3	
		<hr/> <b>6</b> <hr/> <b>6</b> 5:23 20:23,24 21:3 32:1 36:13,21 38:9 62:24 <b>60</b> 3:14	<hr/> <b>6</b> <hr/> <b>6</b> 5:23 20:23,24 21:3 32:1 36:13,21 38:9 62:24 <b>60</b> 3:14	
		<hr/> <b>7</b> <hr/> <b>7</b> 5:23 6:2 7:20 57:8	<hr/> <b>7</b> <hr/> <b>7</b> 5:23 6:2 7:20 57:8	
		<hr/> <b>8</b> <hr/> <b>8</b>	<hr/> <b>8</b> <hr/> <b>8</b>	