IN THE SUPREME COURT OF THE UNITED STATES

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SANDOZ INC., :

Petitioner : No. 15-1039

v. :

AMGEN INC., ET AL., :

Respondents. :

- - - - - - - - - - - - - - - - - - - x

AND

- - - - - - - - - - - - - - - - - - - x

AMGEN INC., ET AL., :

Petitioners : No. 15-1195

v. :

SANDOZ INC., :

Respondent. :

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Washington, D.C.

Wednesday, April 26, 2017

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:05 a.m.

APPEARANCES:

DEANNE E. MAYNARD, ESQ., Washington, D.C.; on behalf of the Petitioner in No. 15-1039.

ANTHONY A. YANG, ESQ., Assistant to the Solicitor General, Department of Justice, Washington, D.C.; for United States, as amicus curiae, supporting the Petitioner in No. 15-1039.

SETH P. WAXMAN, ESQ., Washington, D.C.; on behalf of the Petitioners in No. 15-1195.

C O N T E N T S

P R O C E E D I N G S

(10:05 a.m.)

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

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

MS. MAYNARD: Thank you, Your Honor.

ORAL ARGUMENT OF DEANNE E. MAYNARD

ON BEHALF OF THE PETITIONER IN 15-1039

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

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

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

The Federal Circuit misread the notice of

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

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

MS. MAYNARD: Well --

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

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

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

MS. MAYNARD: The statute prohibits the --

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

JUSTICE SOTOMAYOR: I'm sorry.

MS. MAYNARD: They --

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

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

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

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

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

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

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

JUSTICE SOTOMAYOR: No, no.

MS. MAYNARD: No. Okay.

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

MS. MAYNARD: Okay.

JUSTICE SOTOMAYOR: It takes them 10 months.

MS. MAYNARD: Yes, Your Honor.

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

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

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

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

12.

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

MS. MAYNARD: No, Your Honor.

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

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

JUSTICE KENNEDY: Right.

MS. MAYNARD: -- at 24A.

JUSTICE KENNEDY: 24A. Thank you.

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

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

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

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

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

MS. MAYNARD: Yes, Your Honor.

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

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

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

MS. MAYNARD: Well --

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

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

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

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

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

MS. MAYNARD: Well --

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

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

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

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

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

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

JUSTICE KENNEDY: Oh?

MS. MAYNARD: -- on page 39A.

JUSTICE BREYER: Yeah, I've got it.

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

JUSTICE KENNEDY: Yeah.

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

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

JUSTICE BREYER: So --

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

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

MS. MAYNARD: Because of that --

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

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

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

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

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

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

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

JUSTICE BREYER: That's right. Thank you.

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

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

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

So -- so that's the --

MS. MAYNARD: Well, we --

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE SOTOMAYOR: Tell me how.

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

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

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

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

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

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

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

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

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

MS. MAYNARD: Yes. So if --

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

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

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

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

MS. MAYNARD: No, Your Honor.

CHIEF JUSTICE ROBERTS: So this -- no?

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

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

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

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

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

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

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

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

MS. MAYNARD: This --

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

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

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

MS. MAYNARD: If --

JUSTICE SOTOMAYOR: So --

(Laughter.)

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

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

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

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

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

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

JUSTICE BREYER: Yeah. But you don't

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Yes.

MS. MAYNARD: May I reserve the time?

CHIEF JUSTICE ROBERTS: Yes.

MS. MAYNARD: Thank you.

CHIEF JUSTICE ROBERTS: Mr. Yang.

ORAL ARGUMENT OF ANTHONY A. YANG

FOR UNITED STATES, AS AMICUS CURIAE,

SUPPORTING THE PETITIONER IN 15-1039

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

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

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

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

provide.

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

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

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

JUSTICE SOTOMAYOR: Mr. Yang, do --

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

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

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

the PTO's position. We have --

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

MR. YANG: Yeah.

JUSTICE SOTOMAYOR: -- opinion letters or -- or --

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

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

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

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

MR. YANG: Close.

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

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

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

I will say that it --

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

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

JUSTICE GORSUCH: Exactly.

MR. YANG: Here we --

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. YANG: If the statute --

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

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

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

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

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

So the reason --

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

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

JUSTICE SOTOMAYOR: That goes back to preemption.

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

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

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

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

MR. YANG: Well, I think the --

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

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

MR. YANG: Right.

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

MR. YANG: Right.

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

MR. YANG: That's right.

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

MR. YANG: That -- that is --

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

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

JUSTICE BREYER: Yeah, yeah.

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

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

CHIEF JUSTICE ROBERTS: Mr. Waxman.

ORAL ARGUMENT OF SETH P. WAXMAN

ON BEHALF OF THE PETITIONERS IN 15-1195

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

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

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

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

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

MR. WAXMAN: Okay.

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

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

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

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

MR. WAXMAN: Referenced product.

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

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

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

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

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

MR. WAXMAN: Well --

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

MR. WAXMAN: So let me --

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

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

importance when you're talking about biosimilars.

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

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

The reason --

JUSTICE SOTOMAYOR: That strengthens my argument.

MR. WAXMAN: Well --

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

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

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

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

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

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

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

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

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

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

We don't know that because this has never

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

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: How often is the

issue the validity of the patent rather than its infringement?

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

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

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

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

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

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

MR. WAXMAN: Okay.

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

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

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

JUSTICE GORSUCH: I'm spotting you that --

MR. WAXMAN: Okay.

JUSTICE GORSUCH: -- for purposes of this question.

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

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

MR. WAXMAN: So --

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

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

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

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

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

JUSTICE GORSUCH: I -- I got that.

MR. WAXMAN: Okay.

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

MR. WAXMAN: Well, the --

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

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

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

MR. WAXMAN: Okay. So --

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

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

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

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

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

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

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

JUSTICE BREYER: No. I think it does.

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

JUSTICE BREYER: So why haven't you driven

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

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

(Laughter.)

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

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

We know, without question, the California

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

That establishes the --

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

MR. WAXMAN: Well --

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

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

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

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

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

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

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

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

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

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

JUSTICE SOTOMAYOR: But that --

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

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

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

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

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

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

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

MR. WAXMAN: Now, let --

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

MR. WAXMAN: Now, let me --

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

MR. WAXMAN: So let me explain --

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

MR. WAXMAN: So --

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

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

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

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

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

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

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

JUSTICE GORSUCH: Right.

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

JUSTICE GORSUCH: I understand that. If you --

MR. WAXMAN: -- and the remedy.

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

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

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

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

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

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

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

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

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

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

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

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

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

If the applicant was seeking the world and

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

MR. WAXMAN: So --

JUSTICE SOTOMAYOR: They lost on all the wider ones.

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

MR. WAXMAN: So --

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

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

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

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

Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Three minutes, Ms. Maynard.

REBUTTAL ARGUMENT OF DEANNE E. MAYNARD

ON BEHALF OF THE PETITIONER IN 15-1039

MS. MAYNARD: Thank you, Your Honor.

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

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

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

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

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

biosimilar.

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

The case is submitted.

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