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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. :

- - - - - x

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.

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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

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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