

SUPREME COURT OF THE UNITED STATES

IN THE SUPREME COURT OF THE UNITED STATES

AMGEN INC., ET AL.,)
Petitioners,)
v.) No. 21-757
SANOFI, ET AL.,)
Respondents.)

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3 AMGEN INC., ET AL.,)
4 Petitioners,)
5 v.) No. 21-757
6 SANOFI, ET AL.,)
7 Respondents.)
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9
10 Washington, D.C.
11 Monday, March 27, 2023
12

13 The above-entitled matter came on for
14 oral argument before the Supreme Court of the
15 United States at 10:05 a.m.
16

17 APPEARANCES:

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19 behalf of the Petitioners.
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24 for the United States, as amicus curiae,
25 supporting the Respondents.

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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 21-757, Amgen versus Sanofi.

Mr. Lamken.

ORAL ARGUMENT OF JEFFREY A. LAMKEN

ON BEHALF OF THE PETITIONERS

MR. LAMKEN: Thank you, Mr. Chief Justice, and may it please the Court:

Amgen invented a new class of antibodies that lower cholesterol that bind to a small spot on PCSK9, the sweet spot, and thereby block that protein from binding to and destroying LDL receptors that remove cholesterol. Amgen had in hand 384 examples before the Texas article Sanofi cites as hypothesizing such antibodies, before Sanofi began researching PCSK9.

This case concerns the reason -- the requirement that patents enable skilled artisans to make and use the invention. The roadmap in Amgen's patents allows skilled artisans to easily make those antibodies every time using two new anchor antibodies that cover the entire

1 sweet spot so skilled artisans can be certain to
2 make all the claims' antibodies, including
3 defendants' examples.

4 The Federal Circuit here never
5 identified a single actual antibody that's in
6 the claims that can't be made or requires undue
7 experimentation. Instead, it invoked something
8 that no one will defend is even relevant here:
9 the cumulative effort to make all or some large
10 group of an invention's potentially myriad
11 variations.

12 This Court's cases, however, reflect
13 the Act's pragmatic boots-on-the-ground focus on
14 enabling skilled artisans who want to practice
15 the invention on a concrete action, making and
16 using the invention. Patents thus satisfy the
17 law when sufficiently definite to guide
18 artisans' successful application of the
19 invention wherein there's some practical way of
20 putting them into operation, requiring
21 reasonableness with due regard to the patent's
22 subject matter.

23 In concrete terms, that means that
24 those who are seeking to overto the P --
25 overturn the PTO's issuance of the patents and

1 verdicts upholding them, here two verdicts, have
2 to do two things: one, at least have evidence
3 of some variant of the invention, some category,
4 that require what this Court has called
5 painstaking experimentation, and, two, if they
6 identify that, show why that matters to skilled
7 artisans, because the statute is about skilled
8 artisans seeking to make and use the invention
9 and reasonableness, not theoretical far corners
10 never shown to affect the ability to do so.

11 I, of course, welcome the Court's
12 questions.

13 JUSTICE THOMAS: Mr. Lamken, would you
14 take a minute and tell us exactly what the
15 invention is?

16 MR. LAMKEN: Yes. It's the class of
17 antibodies that bind to a particular spot --

18 JUSTICE THOMAS: Well, let's -- let's
19 deal with that. The -- you only have 26 that
20 you have invented, right?

21 MR. LAMKEN: No, that's not correct.
22 The patent states that there -- that Amgen had
23 384. There are only 26 that are specified by
24 amino acid structure where you put out in the
25 patent, as an example, here's the structure of

1 the -- the antibody.

2 JUSTICE THOMAS: So does this process
3 only produce 386?

4 MR. LAMKEN: No, Your Honor. It --
5 the testimony was that it will produce every
6 antibody within the claims. And there's a
7 reason for that. Our expert explained that,
8 first, you get a -- if you do the
9 super-immunization protocol, you get a robust
10 response across the spectrum. And, in addition,
11 if the mouse -- this is a humanized transgenic
12 mouse. If it has the DNA in it to produce that
13 antibody, it will produce that antibody.

14 And there was no evidence that there
15 was some particular antibody that was harder to
16 make that, for some reason, you would expect it
17 more difficult to come out of that.

18 JUSTICE THOMAS: So, in other words,
19 you can't say how many?

20 MR. LAMKEN: No, Your Honor, I think
21 we can say how many, and I think there's two
22 things. First, the evidence shows in this art
23 that about 400 you would get from -- coming out
24 of the mouse. That's the number that we came up
25 with, the -- the number that Sanofi came up

1 with, and anybody else came up with. And that's
2 all that's known to date.

3 And you wouldn't expect there to be a
4 large number because it's a very tight, small
5 sweet spot. It's got unusual hills and valleys.
6 It's 15 amino acids out of 700. So you wouldn't
7 expect there to be a lot to do there.

8 To get to a larger number, you would
9 have to engage in a process which is called
10 conservative substitution, which means you take
11 one of the ones you know already works, and you
12 take one amino acid out or two amino acids out,
13 and you swap in a very similar amino acid, one
14 that behaves very similarly, and you can --

15 JUSTICE THOMAS: But I think you're
16 making the point, though -- excuse me for
17 interrupting you. I just want to end my
18 consumption of the time. But -- but, in saying
19 that, you don't know how many there are because
20 that -- if you're going to -- the others are
21 going to add, that's a part of your process,
22 whether it's conservative or random.

23 MR. LAMKEN: No, Your Honor, I think
24 that when you do the conservative substitution,
25 antibody scientists aren't going to consider

1 those near-identical twins to be distinct
2 antibodies. They're 99.99 percent similar, and
3 nobody is going to consider them distinct.

4 But even if you were to say, well,
5 gee, there's a large number out there, the
6 difficulty of making any next antibody is
7 straightforward. The -- the record is clear and
8 the -- and the patents points out that this is
9 sort of a routine process. It's very easy to go
10 and say, I'm going to swap out this amino acid
11 for another. According to the table, it tells
12 you which ones to do. And it's routine to test
13 it. And so it only gets in the way of making
14 any antibody you want. If you're saying, gee --

15 JUSTICE SOTOMAYOR: I'm sorry --

16 MR. LAMKEN: -- what's the cumulative
17 effort to make them all --

18 JUSTICE SOTOMAYOR: -- if -- if -- if
19 it's so easy, why haven't you made all the 400?

20 MR. LAMKEN: Pardon?

21 JUSTICE SOTOMAYOR: Why haven't you
22 made the 400 if it's that easy?

23 MR. LAMKEN: So it's easy --

24 JUSTICE SOTOMAYOR: And what happened
25 and why did it take you so long to do the

1 post-filing discovery of more?

2 MR. LAMKEN: So the reason we -- we
3 only specified the 26 and you -- we came up with
4 384 is a skilled artisan in this area isn't
5 looking for every possible antibody. They're
6 just looking for ones that bind to the right
7 place and, therefore, block.

8 And so, once you get those, your job
9 is done. You've got exactly --

10 JUSTICE SOTOMAYOR: Could you tell me
11 how your patent is different from finding
12 antibodies, the process? What's unique about
13 your process?

14 MR. LAMKEN: Well, the patent isn't
15 for process. It's for the class of antibodies
16 themselves, right?

17 JUSTICE SOTOMAYOR: Oh, I know what
18 you're -- but -- but it sounds to me like it's
19 all about just process.

20 MR. LAMKEN: Well, Justice --

21 JUSTICE SOTOMAYOR: You're -- you're
22 telling researchers find all these antibodies.
23 And you tell me that process is common.
24 Everybody knows how to find those. And then
25 what's your next step for the process?

1 MR. LAMKEN: Well, Your Honor, when
2 you're talking about the --

3 JUSTICE SOTOMAYOR: Or the method?

4 MR. LAMKEN: -- the -- yeah, the
5 process or method, which is --

6 JUSTICE SOTOMAYOR: Right.

7 MR. LAMKEN: -- the -- the enablement,
8 how you get those, and it starts with something
9 that didn't exist before, and that's these two
10 anchor antibodies that cover the two parts of
11 the sweet spot, and that allows you to find
12 anything that's going to bind the sweet spot
13 because they'll compete with that, and that's
14 the first step.

15 After that, it sets forth a
16 super-immunization protocol --

17 JUSTICE SOTOMAYOR: Except that you
18 found and all of your disclosures only have
19 three or four or five sweet spots, but you're
20 claiming up to 26, and I don't think you've
21 disclosed any -- any binding that's up to 26.

22 MR. LAMKEN: Right. I think, if
23 you're referring to the 16 amino acid residue --

24 JUSTICE SOTOMAYOR: I'm sorry, I
25 misspoke.

1 MR. LAMKEN: Yeah.

2 JUSTICE SOTOMAYOR: Sixteen, yes.

3 MR. LAMKEN: And -- and so that chart
4 that I think that you're referring to has two
5 key characteristics about it. The first is the
6 evidence was that everything on that chart is
7 enabled. The fact that our -- the ones that we
8 identified as the 26 examples in ours doesn't
9 mean that it doesn't produce it. The experts
10 explain exactly why you would get all of those.
11 And there is simply no evidence of anybody
12 immunizing mice and saying there's something
13 here missing, this doesn't work, I'm not getting
14 everything I want.

15 And so, on this record and in this
16 art, it's understood that -- that all of those
17 are enabled, all those can be made. And so the
18 chart doesn't work against us in that way.

19 And the nature of the chart itself
20 actually explains why there's full enablement
21 here. This is a chart of a bunch of -- a bunch
22 of antibodies that work. They bind to the sweet
23 spot and they block, and none of them is -- is
24 identified to work better or different than the
25 other. So, to the skilled artisan, they're all

1 the same, and --

2 JUSTICE GORSUCH: Mr. Lamken, just a
3 few questions I hope that are quick ones. Do --
4 do you agree that a patent fails the enablement
5 test if it would force a person skilled in the
6 art to undertake undue experiment to produce the
7 claimed invention?

8 MR. LAMKEN: I think that's a -- a
9 fair statement of the law --

10 JUSTICE GORSUCH: You -- you accept
11 that?

12 MR. LAMKEN: -- undue experiment --
13 painstaking experimentation to produce the
14 invention. And, by that, I would mean the
15 various categories or classes within that
16 invention that would be important to a skilled
17 artisan, yes.

18 JUSTICE GORSUCH: I'll take that as a
19 yes.

20 MR. LAMKEN: Fair.

21 JUSTICE GORSUCH: Okay. Do you accept
22 the Wands factors? Do you think they're useful?
23 Do you think this Court should endorse them?

24 MR. LAMKEN: So the Wands factors can
25 be useful in particular cases when properly

1 applied. The problem with the Wands factors is
2 they become something of a checklist that's
3 abstracted and therefore replaces the ultimate
4 statutory standard.

5 The statute's about looking at a
6 skilled artisan, a person there, the guy in a
7 lab coat in his lab or a mechanic in his office,
8 and it's about reasonably enabling them to make
9 and use the invention. It's not about this
10 checklist.

11 Now I'll give you one example how it
12 gets abstracted and doesn't work, and that's
13 predictability. The Federal Circuit tends to
14 say, gee, it's predictable or it's not
15 predictable in the art just generally.

16 But that's not the question where
17 you're talking about enablement. The question
18 is, can the skilled artisan using the patent and
19 the tools available reliably get to the
20 invention?

21 JUSTICE GORSUCH: So sometimes is the
22 answer for that one?

23 MR. LAMKEN: Yeah, I think the answer
24 is they once probably were, but they kind of
25 have outgrown their utility because they've

1 become abstracted and tend to replace what
2 really you should ask every time.

3 JUSTICE GORSUCH: That first test that
4 we talked about a moment ago?

5 MR. LAMKEN: The Wands test.

6 JUSTICE GORSUCH: Okay.

7 MR. LAMKEN: Yeah, the Wands factors.

8 JUSTICE GORSUCH: Well, no, the Wands
9 factors are useful to the extent they illuminate
10 what we discussed is the standard but not when
11 they don't.

12 MR. LAMKEN: I think that's right.
13 And then you need to ask each one with respect
14 to the standard itself, not in the abstract.

15 JUSTICE GORSUCH: Okay. And do you
16 agree that the broader the patent, the more
17 difficult it is to prove enablement?

18 MR. LAMKEN: Not necessarily, Your
19 Honor. You could have a relatively broad patent
20 and you just need to have enablement
21 commensurate with its scope. And if the -- if
22 -- for example, if you have lots of categories
23 within that patent, then you would have to
24 enable what is important to the artisan within
25 the category.

1 JUSTICE GORSUCH: But, as a general
2 matter, would you agree that the broader the
3 patent, the more you have to do to show what a
4 skilled artisan would have to undertake to
5 accomplish?

6 MR. LAMKEN: You know, it -- it's hard
7 for me to agree with that in the abstract
8 because it always depends --

9 JUSTICE GORSUCH: Well, I understand
10 --

11 MR. LAMKEN: -- on the nature of the
12 --

13 JUSTICE GORSUCH: -- it would be hard
14 for you to agree with it.

15 (Laughter.)

16 MR. LAMKEN: No, it's --

17 JUSTICE GORSUCH: But is it a fair
18 statement of the law?

19 MR. LAMKEN: It's -- it has to be
20 commensurate at the start, but harder and
21 broader aren't necessarily synonymous. You can
22 have something that's harder because it's
23 narrower because somebody leaves out a key thing
24 to get that narrow part that's within the claim.

25 So I think, yes, as a general matter,

1 often, if you have a broader claim, it may be
2 harder, but it's hard to say that in every art
3 for every circumstance that makes it more
4 difficult.

5 JUSTICE GORSUCH: Thank you.

6 MR. LAMKEN: It's always with
7 reasonableness with due nature of the art.

8 CHIEF JUSTICE ROBERTS: You mentioned
9 I think a couple of times there, and you do on
10 your reply brief at page 7, you said the --
11 where an invention has many embodiments, the
12 patent enables the invention's full scope if
13 skilled artisans can reasonably make and use
14 variations.

15 Can you flesh out "reasonably" a
16 little bit for me?

17 MR. LAMKEN: Yes. I think that it
18 means that when you're looking at it, you're
19 looking at what's important to the skilled
20 artisan. If you can find just some oddity that
21 can't be made, that doesn't invalidate the
22 patent because we're looking at what's important
23 to skilled artisans.

24 So, for example, if a patent, for
25 example, taught you to make metal airplanes, you

1 wouldn't invalidate it because somebody said,
2 gee, you know what, it would be really hard to
3 make one out of lead. That's the type of thing
4 you would automatically set aside.

5 So you always look at it from the
6 perspective of the skilled artisan, and you ask
7 two questions: Is there something here that
8 takes undue experimentation, what this call --
9 calls painstaking experimentation, to make? And
10 if you can find something, that might be
11 concrete enough.

12 CHIEF JUSTICE ROBERTS: Well, how long
13 --

14 MR. LAMKEN: And then the next
15 question is, does it matter? Does it somehow
16 impede the skilled artisan from practice --
17 reasonably practicing that full scope of the
18 invention?

19 CHIEF JUSTICE ROBERTS: Well, I don't
20 -- how -- how long? And that may be the wrong
21 measure, but, if you're judging reasonableness,
22 how much experimentation do you have to put into
23 it? I mean, part of the allegation in -- in --
24 in your case is that this is simply trial and
25 error. And so how long does it take?

1 MR. LAMKEN: Right. And I think the
2 answer is it always depends. You're looking at
3 the skilled artisan and you're saying what is a
4 skilled artisan in this art willing to do. It
5 might take a long time for a skilled mechanic,
6 for example, to build an old Buick from the
7 ground up, a year, but it's not unenabled
8 because the instructions are there, he knows how
9 to do it --

10 CHIEF JUSTICE ROBERTS: Well --

11 MR. LAMKEN: -- there's no wrong turn.

12 CHIEF JUSTICE ROBERTS: -- how long
13 did it take Amgen to come up with one?

14 MR. LAMKEN: With the 384? It's --
15 from start to finish, injecting the mice and
16 coming out, it's a matter of months to produce
17 them. And I think it's important, and if the
18 Court will indulge me to describe how you get
19 from --

20 JUSTICE SOTOMAYOR: Producing them is
21 one thing. Identifying them, do the whole
22 process, don't take a piece.

23 MR. LAMKEN: I'm sorry?

24 JUSTICE SOTOMAYOR: Then continue with
25 Justice --

1 MR. LAMKEN: Okay. Yes. I -- it's --
2 I think it's important to explain what's
3 involved in getting from the 3,000 that Amgen,
4 for example, got by immunizing two panels of 10
5 mice or the 1500 that Sanofi got from injecting
6 a panel of mice down to the 384 that you're
7 looking for, because that's in concrete terms
8 what we're talking about.

9 And so what -- what it is is not a
10 trial and error like you're going through one
11 after the other. You start with that 3,000 and
12 you use our two anchor antibodies, and it simply
13 costs \$30 -- this is the record, according to
14 Appeals Appendix 3909 -- to go through those
15 3,000 to knock it down to 384.

16 And why is that? It's because, in
17 2008, at the time, there's these high throughput
18 machines with wells of 384, and the testimony is
19 that the robotics do it very rapidly and very
20 quickly, thousands of wells, hundreds of plates,
21 in a very short period of time.

22 So, if someone's going to say it's
23 undue experimentation to take these 3,000
24 antibodies that the mice produce, these
25 humanized mice produce, and put it in a machine

1 and wait for it to -- at a cost of \$30, that's
2 undue experimentation, that is very odd. It's
3 totally divorced from the nature of the art.

4 And, in fact, the Wands decision that
5 we all have been citing back in 1988, back then,
6 35 years ago, described and said, look, the
7 process of filtering out the antibodies that you
8 don't want, getting rid of that byproduct, is
9 something that skilled artisans are prepared to
10 do in the ordinary course. This is just what
11 antibody scientists do. It's not due -- undue
12 experimentation.

13 The patent examiner that looked at
14 this understood that it was not undue
15 experimentation, somebody who is himself skilled
16 in the art. Two juries didn't think it was
17 undue experimentation.

18 JUSTICE JACKSON: Can I ask you a
19 clarifying question, though, because I guess I'm
20 just trying to understand your argument relative
21 to species versus genus.

22 So are you saying that if we find
23 undue experimentation with respect to a
24 particular species, you know, that should not be
25 enough to invalidate the patent?

1 In other words, doesn't that undue
2 experimentation have to apply to every species?

3 MR. LAMKEN: No, I'm not -- we're not
4 saying that it would have to apply to every
5 species. If you find undue experimentation to
6 make a particular species, the next question is,
7 okay, does that matter to the skilled artisan,
8 or is this just an outlier because the PTO, as
9 they say, it has to be commensurate with
10 the scope, it has to reasonably correlate. But,
11 if you just have a one-off that doesn't mean
12 anything to skilled artisans, you're not going
13 to invalidate the patent.

14 JUSTICE JACKSON: How many of those
15 one-offs can you have, though?

16 MR. LAMKEN: So, in -- in term -- in
17 sort of numerical terms, how -- how many
18 one-offs can you have?

19 If you have so many that it means that
20 you're searching for a needle in a haystack and
21 you don't have instructions on how to do it so
22 that it's -- it is that trial and error for
23 years on end, it's Edison and Consolidated
24 Electric going through every type of, then you
25 would not be enabled, and there's a case called

1 Atlas Powder from the Federal Circuit that
2 explains that.

3 JUSTICE JACKSON: But I thought -- I
4 guess I thought you would have to have the undue
5 experimentation standard apply to every species.

6 MR. LAMKEN: No, Your Honor, I think
7 it would -- you would do it for every category
8 that matters. So, if there's meaningful
9 categories -- and there's a case from the
10 Federal Circuit called Auto Tech that explains
11 this. If there's meaningful categories, then
12 you would have to enable across those
13 categories, what FibroGen called across the
14 scope of the claim. So --

15 JUSTICE JACKSON: So what are the
16 categories here?

17 MR. LAMKEN: So, in -- in this case,
18 there isn't evidence before the jury that it
19 really matters whether you bind to two, three,
20 or seven. In fact, Sanofi's own expert
21 testified that it has no correlation, there's no
22 correlation between the number of amino acids
23 that are bound and the blocking. And that's at
24 Court of Appeals Appendix 3787.

25 So, in a case like this, where you

1 don't have evidence that they are anything but
2 fungible, then you may only have one category.
3 But, in Auto Tech, for example, that was an --
4 it was an impact sensor patent, and there were
5 two types. There was mechanical and there was
6 electrical. And it only taught skilled artisans
7 how to do the mechanical sensors, not -- not the
8 electrical. And, for that reason, there was a
9 -- a requisite part of the invention that wasn't
10 taught, that skilled artisans couldn't do.

11 And so, when you have that, then you
12 have an enablement problem. But the fact that
13 somebody can go and pick out one tiny
14 enablement -- one tiny embodiment and say, oh,
15 gee, this one would be hard to do, that swaps in
16 for the perspective of the skilled artisan, the
17 person who matters here, someone who wants to
18 practice the claim --

19 JUSTICE JACKSON: I guess I just -- I
20 -- I --

21 MR. LAMKEN: -- the creativity of an
22 art -- the creativity of --

23 JUSTICE JACKSON: Yes, I understand
24 your point, I think, but, I mean, you -- you've
25 -- you've claimed 26, you say there's 300 or

1 something antibodies, and then there's evidence
2 that, you know, millions more can be made.

3 So how is it that you've satisfied
4 enablement by focusing in on -- on the smaller
5 group?

6 MR. LAMKEN: So, no, Your Honor, I
7 think that when you're enabling, the question
8 is, can the skilled artisan, using the
9 instructions you have, make the various
10 embodiments, make the various variants? And --

11 JUSTICE JACKSON: With -- without
12 undue experimentation?

13 MR. LAMKEN: Without undue
14 experimentation, and that's exactly right, for
15 any one who has to take undue experimentation.
16 And if you find one that takes undue
17 experimentation, the next question is, okay,
18 does that matter? Does it really meaningfully
19 impede somebody, the skilled artisan, the guy
20 who cares, from doing it?

21 And it's just never been the law --

22 JUSTICE JACKSON: And that's in the
23 First -- the Federal Circuit's case law, or are
24 you just saying that right now?

25 MR. LAMKEN: Well, actually, if you

1 look at page 11a of the appendix, where the
2 court quotes a decision called McRO, that's
3 actually the standard the Federal Circuit
4 ordinarily would use but departed from in this
5 case because it was --

6 JUSTICE KAGAN: Mr. Lamken, putting
7 aside what the Federal Circuit said in -- in --
8 in the opinion here and the different views of
9 how that should be read, do you understand the
10 parties now all to agree on the appropriate
11 legal test, and are we simply arguing now about
12 how that test applies in this case?

13 MR. LAMKEN: So I think the parties
14 all agree that the cumulative effort, the idea
15 of reach the full scope, that that cannot be
16 sustained. Everybody agrees on that.

17 I think the next question --

18 JUSTICE KAGAN: And everybody agrees
19 also, I take it from your answers to Justice
20 Gorsuch's question, that there is a requirement
21 that the full scope of the invention has to be
22 embodied?

23 MR. LAMKEN: Enabled.

24 JUSTICE KAGAN: Has to be enabled.

25 MR. LAMKEN: I think that's right.

1 The content of that is a subject of some
2 disagreement, and then the question, once this
3 Court says --

4 JUSTICE KAGAN: Yeah, so I guess what
5 I'm asking is, putting aside any application to
6 this test, what do you think the parties don't
7 agree on at this point with respect to
8 principles of law?

9 MR. LAMKEN: Yeah. So I think the
10 differences are as follows: The government
11 would propose a requirement that you have a
12 structure that unifies your genus, and I don't
13 think that can be sustained under the law.

14 It makes sense that if you have -- you
15 enable people to make your invention by
16 structure, they have to build it, that you would
17 teach the skilled artisan the structure that he
18 has to build. But, when you have an invention
19 that's biological in nature, that's made by the
20 mouse, the super-immunized mouse they do here,
21 you wouldn't describe it by structure; you would
22 describe the process --

23 JUSTICE GORSUCH: Put that aside --

24 MR. LAMKEN: -- of how to make that.

25 JUSTICE GORSUCH: -- put that aside.

1 Any other disagreements on law? And, if not,
2 why isn't this just a fact-bound dispute?

3 MR. LAMKEN: Yeah, so it's not a
4 fact-bound dispute in the slightest because
5 there is a disagreement also -- Sanofi's test is
6 what they call the specific undisclosed
7 embodiment test, where, if you hypothesize one,
8 that you -- that's it. That destroys the
9 patent. But that can't be right either. This
10 Court's cases don't go through and
11 hypothesize --

12 JUSTICE GORSUCH: Okay. So put that
13 aside. Any -- any other disagreements on law?

14 MR. LAMKEN: Other than -- no, I don't
15 think beyond that. But I think that the key
16 question on which we all agree and what's
17 actually critically important for this Court to
18 do, there should be no mistake that the court of
19 appeals' decision saying that you reach the full
20 scope or, page 15a, where they do this
21 evaluation and they say the evidence showed that
22 the scope of the claims encompasses millions of
23 candidates, and it would be necessary to first
24 generate and then screen each candidate antibody
25 to determine whether it meets the double

1 function limitations, that's a statement saying
2 you got to be able to make them all. That can't
3 be right.

4 And even having that -- even if
5 there's uncertainty as to what the Federal
6 Circuit meant by that, that uncertainty calls
7 for the Court to bring clarity, because you
8 should -- make no mistake: This is a very
9 damaging decision. The impact is tremendous.

10 You cannot -- the PTAB now has twice
11 invoked the decision for the idea that you have
12 to be able to make them all within a reasonable
13 period of time. There has to be a cumulative
14 scope test.

15 And companies can't invest billions of
16 dollars in new therapies when they confront the
17 risk that their patents will be invalidated
18 based on the cumulative effort necessary to make
19 them all. And this is why you have, for
20 example, 14 amicus briefs on our side and
21 14 amicus briefs on the other side.

22 JUSTICE GORSUCH: I've got a lot of
23 amicus briefs.

24 MR. LAMKEN: Yes.

25 JUSTICE GORSUCH: I've got so many

1 friends I can hardly stand it.

2 (Laughter.)

3 MR. LAMKEN: It's --it's -- with
4 friends like that, you end up staying up late
5 reading.

6 But the key is, on this, if there's
7 uncertainty about what the Federal Circuit did
8 or are doing, the answer is actually to bring
9 clarity. The case is critically important to
10 industry and at least that.

11 And, once you get there, the question
12 is, well, what other guidance can the Court
13 bring? What other guidance should the Court
14 give? And, for us, the critical guidance the
15 Court can give is that you're looking from this
16 Court's cases the perspective of the skilled
17 artisan who's seeking to make it. It's a
18 reasonableness standard, which means that you're
19 not looking -- you're not from the perspective
20 of somebody trying to create, oh, here's my
21 hypothetical embodiment that won't work. It's
22 from that perspective. And that means --

23 JUSTICE GORSUCH: Let's --

24 MR. LAMKEN: -- in concrete terms --

25 JUSTICE GORSUCH: -- let -- let's

1 say -- let's say we think that the Federal
2 Circuit's decision is properly read to embody
3 the test we've -- we've discussed this morning
4 and that the fact -- the dispute really is
5 fact-bound. Do you want a remand for a redo
6 under the -- under -- if we were to clarify what
7 we understand the Federal Circuit's test to be
8 and that you agree on and that Mr. Clement may
9 -- may or may not agree on, we'll find out?

10 MR. LAMKEN: So --

11 JUSTICE GORSUCH: But would you want a
12 remand to try again?

13 MR. LAMKEN: -- so, at the very least,
14 we should have a remand so that we try again
15 under the proper standard without the -- reach
16 the full scope standard or try to hypothesize
17 how long it takes to make millions of antibodies
18 and then test each of them.

19 JUSTICE BARRETT: But why? If -- if
20 -- I mean, maybe I misunderstood Justice
21 Gorsuch's question.

22 JUSTICE GORSUCH: I don't think you
23 did.

24 JUSTICE BARRETT: But, if the Federal
25 Circuit got it right, I don't understand why

1 you're saying a remand is in order.

2 MR. LAMKEN: Well, I don't think -- I
3 mean, the key is the Federal Circuit could not
4 possibly have gotten it right because of what I
5 just read to you from page 15, where it looks at
6 the effort to make each and every antibody of
7 the potential millions. And so, at the very
8 least, it has taken into account a feature that
9 everybody now before this Court says isn't even
10 relevant. And we should go back for that.

11 But I think, if you look at from what
12 we're asking and what we think the Court's
13 further guidance should be, at the very least,
14 somebody who's trying to overturn a PTO-issued
15 patent and two jury verdicts should at least say
16 here's an actual antibody, an actual embodiment,
17 that is difficult to make. It requires undue
18 experimentation to get there.

19 And then, if they have that, they
20 should also say why it matters, why this is
21 something that genuinely impedes skilled
22 artisans from making and using the invention --

23 JUSTICE SOTOMAYOR: Can I quote --

24 MR. LAMKEN: -- because --

25 JUSTICE SOTOMAYOR: -- two sections

1 from the Federal Circuit -- two statements it
2 made, and you tell me whether they're right or
3 wrong.

4 The Federal said -- Circuit said: It
5 was "appropriate" to look at the amount of
6 effort needed to obtain embodiments outside the
7 scope of the disclosed examples.

8 Is that a correct statement of law by
9 the Federal Circuit?

10 MR. LAMKEN: So in part.

11 JUSTICE SOTOMAYOR: It said -- no,
12 that's what it said, to look at the amount,
13 appropriate to look at the amount.

14 MR. LAMKEN: And, if you're talking
15 about the amount to make all or some number, the
16 answer is no, it's not.

17 If you're talking about making another
18 embody -- another embodiment that's not
19 specifically characterized --

20 JUSTICE SOTOMAYOR: It said --

21 MR. LAMKEN: -- by amino acids --

22 JUSTICE SOTOMAYOR: -- to look at the
23 amount of effort needed to obtain embodiments
24 outside the scope of the disclosed example.

25 MR. LAMKEN: So I think, if it said an

1 embodiment, that would be correct. Embodiments
2 means that you're looking at the -- the full
3 scope or the -- the -- what it called reaching
4 the full scope, and I think that is incorrect.
5 When you get --

6 JUSTICE SOTOMAYOR: All it said, it
7 was appropriate to look at.

8 MR. LAMKEN: Right. I don't think
9 anybody but this Court thinks that the effort to
10 make them all is --

11 JUSTICE SOTOMAYOR: Why is it
12 inappropriate to at least look at it --

13 MR. LAMKEN: To look at --

14 JUSTICE SOTOMAYOR: -- as one of the
15 Wands factors?

16 MR. LAMKEN: Yeah. So the effort to
17 make every single embodiment within the
18 invention simply means that if you have an
19 invention of any scope, it's not going to be
20 enabled. There may be millions of ways to make
21 the James Watt steam engine, but you're not
22 invalidated simply because it would take a long
23 time to make all of those different variants of
24 the steam engine.

25 This Court can do the best service for

1 the Federal Circuit if it does one thing beyond
2 simply saying this cumulative effort standard
3 has no place in the law, and that would be to
4 say, look --

5 JUSTICE SOTOMAYOR: That's fine,
6 counsel.

7 MR. LAMKEN: I'm sorry?

8 JUSTICE SOTOMAYOR: That's fine. You
9 answered my question.

10 MR. LAMKEN: Okay. Thank you.

11 JUSTICE SOTOMAYOR: There's nothing
12 wrong with it. You just don't want them to do a
13 fairly simple one.

14 MR. LAMKEN: No, I think it's -- it's
15 not correct if you're looking at embodiments in
16 the plural. If you're looking at an embodiment
17 in the singular, that would be correct. And
18 what they did wrong was they looked at how long
19 it takes to make the supposed millions. If each
20 of those is individually enabled, you can make
21 each one individually and reliably, test it
22 individually and reliably, that's an enabled
23 invention.

24 How long it takes to make all of them
25 cumulatively simply has no bearing, and this

1 Court can do a service and bring back to -- the
2 -- the incentives to create these life-saving --
3 these life-saving inventions by making it clear
4 that that just doesn't have a place, and --

5 JUSTICE JACKSON: And you said we can
6 do one thing beyond that, and what is that?

7 MR. LAMKEN: I think that by bringing
8 it back to the focus of this Court's cases,
9 which is we're looking at skilled artisans,
10 someone concrete trying to make the invention,
11 and we're looking at reasonableness and not the
12 hypothetical efforts to try and figure out ways
13 to break the invention.

14 And so, if you're going to look at
15 that, you're going to have to show two things if
16 you're going to invalidate a PTO patent. One is
17 you're going to have to show some embodiment,
18 there's got to be something out there, some
19 variant, something, some category that requires
20 undue experimentation to make.

21 And if you have that, you also have to
22 say why it matters to the skilled artisan, how
23 does this really genuinely impede the guy in the
24 lab coat from making and using your invention
25 across its scope.

1 JUSTICE ALITO: Is there something
2 unique about the Federal Circuit's decision in
3 this case, or has it been applying essentially
4 the same approach to the enablement of antibody
5 genus claims since around 2004?

6 MR. LAMKEN: So, as the Lemley article
7 points out, there's been sort of a trajectory as
8 it's been getting clearer and clearer what the
9 -- what the Federal Circuit's doing in its basic
10 hostility to the breadth of claims, and I think
11 that this is basically the apogee. We've
12 reached an endpoint where, frankly, the industry
13 can't take it any longer because you can't
14 invest \$2.6 billion if the breadth of your
15 claims is such that it means you can't get
16 adequate protection because, if you cover
17 everything you invented, then it's invalid
18 because it's too hard to make them all.

19 So, yes, I think it's been a -- a
20 trajectory as opposed to a point, but this is
21 actually the ultimate point.

22 JUSTICE ALITO: Well, if it isn't --
23 if what they did here isn't fundamentally
24 different from what they've been doing for quite
25 a period of time, would you stand by the

1 suggestion that the Federal Circuit has
2 inhibited research for antibody-based
3 pharmaceuticals?

4 MR. LAMKEN: I think the Federal
5 Circuit has been doing that for some time, but
6 it hasn't been quite so stark or quite so
7 apparent until now. And I think that's why the
8 Lemley article really was catching onto it.

9 But this brings in very stark
10 contrast, stark relief, exactly what the Federal
11 Circuit is doing and why it has gone so far that
12 you just can't invest in antibody research if
13 you can't adequately protect the scope of the
14 antibodies you invented.

15 Amgen had the first antibodies here.
16 Amgen -- before Amgen and before our patent,
17 these were not known antibodies. And our patent
18 teaches everybody how to make each and every
19 antibody they might ever want to make, including
20 the defendants' -- the competitor -- the
21 supposed competitor antibodies.

22 And if that's true, there's simply no
23 good reason why you would take away the patent.
24 You don't -- the patent depends on what the
25 skilled artisan can do, not to create a

1 hypothetical of the infringer who says, gee, you
2 know, I can imagine a hypothetical antibody that
3 can't be made.

4 In this Court's cases, like Minerals
5 Separation, they don't hypothesize limits. Like
6 in Minerals Separation, the Court didn't
7 hypothesize, you know what, there might be an
8 ore out there for which this is going to be too
9 hard, even though there are infinite varieties
10 of compositions of ores and each presented its
11 own particular difficulties.

12 The Court -- Justice Story in Carver
13 didn't say, gee, you know what, I can imagine a
14 type of cotton for this -- which this might not
15 work. The Court in Mowry didn't say, you know
16 what, there might be some train wheels for which
17 this cooling process won't work.

18 That isn't what the Court does. You
19 look at concrete evidence, what are the skilled
20 artisans doing, is there something here that
21 can't be done, and if there is, you ask if it
22 matters.

23 JUSTICE ALITO: Can you explain how
24 your roadmap differs from the basic research
25 plan that you and your competitors have been

1 using since the mid-2000s when you were all
2 attempting to discover or identify antibodies
3 that bind to PCSK9 and block LDL receptors?

4 MR. LAMKEN: Yes. And I think the
5 first and most critical thing about the roadmap
6 is these two new antibodies that didn't exist
7 before our invention, one that sits a little bit
8 on the left of that -- of the PCSK9, one a
9 little bit on the right of PCSK9.

10 And what those do is they allow you to
11 find everything that will bind to the sweet spot
12 in PCSK9 because they cover it completely. The
13 way this is done is you do a competition assay.
14 If one antibody is covering it and it blocks the
15 other antibody from doing it, you know that
16 they're binding to the same spot.

17 By providing these two, that is a
18 shortcut to finding these because you run your
19 competition assays against these two. And
20 that's why in the roadmap the very first step
21 are these two antibodies that didn't previously
22 exist but will lead you, they're your divining
23 rod, your magnetometer or whatever you want to
24 call it to all the antibodies within the claims.

25 CHIEF JUSTICE ROBERTS: Thank you,

1 counsel.

2 Justice Thomas, anything further?

3 JUSTICE THOMAS: Mr. Lamken, several
4 times you referred to invention of the
5 antibodies, and I think I'm somewhat confused as
6 to exactly what your invention is. You said
7 it's not just the 26, but it -- it definitely is
8 not millions. So what is it exactly? Because I
9 do -- we talk about enablement and we talk about
10 someone being able to replicate it, but we're
11 not talking about what has been invented with
12 any particular precision.

13 MR. LAMKEN: Right. And I think the
14 claims are that -- which define the invention,
15 the class of antibodies that bind to a
16 particular spot, what's called the sweet spot,
17 and therefore have what is a desired effect,
18 which is blocking this PCSK9 from interacting
19 with the --

20 JUSTICE THOMAS: Yeah, I understand
21 all that, but --

22 MR. LAMKEN: And I think I could
23 clarify a little.

24 JUSTICE THOMAS: -- which ones? I
25 mean --

1 MR. LAMKEN: Yeah, I should clarify.

2 JUSTICE THOMAS: Yeah.

3 MR. LAMKEN: When you say an
4 invention, like the James Watt steam engine, you
5 don't say which variant, which embodiment of the
6 steam engine have you claimed. It's the steam
7 engine, that principle, the invention which
8 encompasses myriad types of inventions.

9 There might be -- and this Court's
10 cases describe it -- there can be lots and lots
11 of different variations on an invention, but to
12 determine what the invention is, you look at the
13 claim, and the claim tells you what the scope of
14 that invention is here.

15 And the fact that it's described in
16 terms of the way it binds to a particular
17 location which has been decried as functional,
18 but that actually is an important way of doing
19 things, the antibody science, because it leads
20 to a shape -- a shape that fits into that
21 unusual sweet spot.

22 It's also -- also clear that you can
23 do that because -- because 112(b) -- we're
24 talking about 112(a) right now as that's
25 enablement. But, when you talk about how the

1 patents are claimed, that's a different section
2 of the Patent Act. It's Section 112(b). And it
3 says that the claims have to be -- particularly
4 point out and distinctly claim the subject
5 matter which the invention regards as the
6 invention. That's just not at issue here.

7 The PTO regularly issues patents which
8 have that sort of functional piece that says
9 things that fit in this location or have this
10 characteristic. And the very first --

11 JUSTICE THOMAS: I know you refer to
12 the steam engine, but that's not -- it just
13 seems as though -- I -- I grant you that, but it
14 seems as though you're actually trying to patent
15 the use of steam pressure and -- which you could
16 use for almost anything, and -- and that's --
17 and that makes it very difficult because then
18 you're looking at what can it be used for.

19 So, here, I'm -- I'm still not getting
20 -- if you said we're just patenting the 26 that
21 we have found or the 300 that we have found, I
22 don't think we would be having this discussion,
23 and what I'm trying to understand is what it is
24 that you're patenting beyond the antibodies that
25 are there, those 300 or those 26.

1 MR. LAMKEN: Right. And I think, if
2 you're asking what is the category or the group
3 of meaningfully distinct antibodies that fit in
4 that claim, that fit that claim, we're talking
5 something in the range of 400.

6 But, if the question is different, if
7 it's asking what -- what do you mean when you
8 say the antibodies that bind to a particular
9 sweet spot and therefore block, that category is
10 what we invented. That didn't exist before. We
11 teach the world how to --

12 JUSTICE THOMAS: So you invented the
13 category, so you're not claiming just the
14 antibodies but the whole category of those
15 antibodies?

16 MR. LAMKEN: That -- that is the
17 nature of a -- a genus claim or any claim that
18 has considerable scope. We don't claim just the
19 variants of the steam engine. You categorize
20 the steam engine, and that's entirely
21 legitimate.

22 JUSTICE THOMAS: So let me ask you
23 this question. How do you respond to the
24 example in one of the amicus briefs about the --
25 the complicated lock and that you simply figure

1 out the combinations by trial and error?

2 MR. LAMKEN: Yeah. And I think the
3 answer is, for -- for enablement here, which is
4 the question, the roadmap gives you all of the
5 antibodies that are going to fit to that spot.
6 All the ones that are going to fit into those
7 hills and valleys, the evidence is the roadmap
8 gives them all because, if the mouse has the DNA
9 to produce them and the robust immunization
10 protocol is going to give you something across
11 the full spectrum of the claims, that is within
12 the claims.

13 And I should close -- I should point
14 out that this enhances innovation. Look, the
15 patent means that others aren't going to go in
16 separately -- they're going to look for things
17 that are separately patentable. It pushes them
18 away from sort of copycat antibodies that
19 operate on identical principles and identical
20 ways with identical results.

21 If you truly want different therapies,
22 you protect this sort of patent, and it tells
23 people, well, if you're going to do this sort
24 of -- sort of thing, it has to be better and
25 separately patentable as a result, or it pushes

1 them to completely different nonantibody
2 treatments.

3 Novartis, for example, has an siRNA
4 solution that they -- they're working on. Novo
5 Nordisk is looking at a small molecule, which
6 means you might be able to take it as a pill.
7 Or you have antibodies that work by a different
8 principle. So Novartis has an H1 fab that binds
9 outside the sweet spot but blocks anyway, or
10 Merck has something called 1G089 which binds on
11 another location still, but it mitigates the
12 impact of PCSK9 not by blocking but by affecting
13 how it affects when it's absorbed into the
14 matter.

15 CHIEF JUSTICE ROBERTS: Thank you.

16 Justice Alito?

17 Justice Sotomayor?

18 Justice Gorsuch?

19 Justice Kavanaugh?

20 JUSTICE KAVANAUGH: Just a couple
21 things to make sure I'm clear. You said to
22 Justice Gorsuch, I think, that you accept the
23 Federal Circuit precedent in Wands. Are our
24 precedents also precedents that you accept, or
25 are there any that you would say have steered us

1 in the wrong direction as we approach this?

2 MR. LAMKEN: Your Honor, I accept all
3 this Court's precedents, and I think I should be
4 clear about Wands. We think those factors can
5 in individual cases be helpful on the facts, but
6 it's been abstracted to replace what is actually
7 the statutory text. And this Court's approach
8 was just to concretely look at actual examples,
9 the concrete -- look at the skilled artisan,
10 concrete -- look at reasonable -- reasonable
11 enablement, not to look at the abstract
12 hypotheticals of, gee, is there some outer limit
13 that I could find that has just no impact on
14 what the skilled artisans really need to do,
15 which is make and use to practice the invention.

16 JUSTICE KAVANAUGH: In the interest of
17 providing clarity, the Solicitor General's brief
18 at pages 14 and 15 had three hypotheticals about
19 cake, stew, and bread. I don't know if you're
20 remembering all three of those hypotheticals,
21 but do you agree with how they presented those,
22 if you remember them?

23 MR. LAMKEN: So I -- I'm having a hard
24 time remembering what they were exactly, but,
25 certainly, if the skilled artisan knows what the

1 ingredients -- what the ratios for the
2 ingredients are for cake, you wouldn't
3 invalidate the patent simply because it doesn't
4 give the ratios. That's something the skilled
5 artisan can provide.

6 And when you're using something -- and
7 sometimes things like that, which are chemical
8 interactions, aren't particularly good analogies
9 when you're dealing with a biological invention,
10 which is the way you make and use this, the way
11 you generate these antibodies isn't by following
12 a cake and bread formula. It's by
13 super-immunizing the mice, taking the results
14 and filtering them down using this high through
15 speed -- this high-throughput process that takes
16 those very quickly down to the ones you desire.

17 And if that gets you every embodiment
18 within the claim or every embodiment that
19 anybody cares about, it's enabled. And someone
20 who has the clear and convincing burden before
21 the jury, it's a critical point, and then, when
22 the jury rules against them, they have the
23 burden of proving that no reasonable juror could
24 think they failed to meet their clear and
25 convincing burden, that's a very high burden,

1 and it means you're going to have to come with
2 something concrete that can't be made or
3 requires undue experimentation and explain why
4 it matters.

5 JUSTICE KAVANAUGH: Thank you.

6 CHIEF JUSTICE ROBERTS: Justice
7 Barrett?

8 JUSTICE BARRETT: Just one question.
9 What if before the jury you have an expert who
10 shows why? I mean, proving the negative would
11 be pretty hard for Sanofi to do, right? So what
12 if you have an expert who can tell the jury this
13 is why the -- the function described would not
14 be capable of producing them all?

15 MR. LAMKEN: Yes. So I think that is
16 one way to do it, and they could even also say
17 it would take undue effort. But, in this case,
18 it's interesting because you have no testimony
19 saying why it would be in principle, on some
20 reasoned basis, harder to make Praluent or the
21 competitor antibodies than what Amgen produced.
22 And, in fact, our expert, Dr. Reese, explained
23 that he thought that even Praluent was among our
24 original 384 because the mouse's DNA can make it
25 and you have a super-immunization protocol,

1 which means you get a robust result across the
2 claims.

3 And so, against that evidence, when
4 they have the burden of proof, they're going to
5 have to explain pretty convincingly to the jury,
6 clear and convincing evidence, why there's
7 something out there that isn't easy enough to
8 make that it doesn't constitute undue
9 experimentation.

10 JUSTICE BARRETT: Thank you.

11 CHIEF JUSTICE ROBERTS: Justice
12 Jackson?

13 JUSTICE JACKSON: So I understand your
14 burden points, but is there evidence in this
15 record that the experimentation required to
16 produce undisclosed species using your roadmap
17 is routine as it --

18 MR. LAMKEN: Yes, Your Honor. It --
19 the methods disclosed in the -- in the -- in the
20 roadmap are routine as routine can be. This is
21 what skilled artisans have been doing since
22 1988, and the Wands factors, we said this is
23 routine. Filtering out what they call the
24 hybridomas or the antibodies that aren't wanted
25 to get the antibodies you want is routine.

1 And I give you one example. So our
2 expert explained that -- that all these machines
3 that are used for would be in any properly
4 organized lab and would do it rapidly and very
5 quickly, thousands of wells, hundreds of plates,
6 in a very short period of time. That's as
7 routine as routine can be. This is what
8 antibody scientists do.

9 JUSTICE JACKSON: And can I just go
10 back to Justice Thomas's point? So, given the
11 routine nature of this, can you just help me to
12 understand the numbers? So you did this and got
13 26, but you say there are 300.

14 MR. LAMKEN: So the patent itself
15 explains -- and this is on page 236 of the court
16 of appeals appendix -- that when we did around
17 two panels of 10 mice, we got 3,000, which were
18 filtered down to 384. The 26 are something
19 different. The 26 are the ones where we went
20 through and figured out the exact amino acid
21 sequence and then listed them in the patent.

22 And there's a reason why you don't go
23 and do 384 amino acid sequences for every one of
24 them in the patent. First is the patent law has
25 never required you to list all of your

1 embodiments in there. That's just never been a
2 rule. And it's not a rule for good reason. The
3 Patent Act requires you to make -- have your
4 patent be concise. Our patent is already 380
5 pages long with just those 26 amino acids.

6 JUSTICE JACKSON: All right. But
7 isn't the -- is the question whether, starting
8 with the 26, someone without undue
9 experimentation could get to the 384 and then
10 possibly to the 3,000? Is that the way to look
11 at this?

12 MR. LAMKEN: No, Your Honor. I think
13 the 3,000 amount it initially produces, only 384
14 are going to bind to the sweet spot, and so you
15 don't want to go the reverse direction to the
16 ones that don't bind to the sweet spot, so --

17 JUSTICE JACKSON: All right. But at
18 least to the 384?

19 MR. LAMKEN: Right. So you would go
20 from your 3,000 to your 384, and that's where
21 you stop.

22 Now, if you want to make variants of
23 those that may not be meaningfully distinct, you
24 can do something called conservative
25 substitution, and the patent explains that that

1 is also a routine and well-known way of doing
2 it. You take one of the amino acids --

3 JUSTICE JACKSON: Can I just ask you
4 as a very simple --

5 MR. LAMKEN: Yeah.

6 JUSTICE JACKSON: So you say that you
7 are claiming the class of antibodies that bind
8 to a particular spot and therefore block.
9 That's my sort of --

10 MR. LAMKEN: Mm-hmm.

11 JUSTICE JACKSON: -- shorthand for
12 what you've said. So is that class comprised of
13 384 species or more?

14 MR. LAMKEN: You know, it's somewhere
15 in the 400 range. I couldn't tell you if
16 there's -- that that's exactly 384. I would say
17 that that 384 probably covers the full range of
18 meaningfully distinct antibodies. It was
19 probably --

20 JUSTICE JACKSON: So, when we see
21 millions, someone said millions, you -- you say
22 that's not even a reasonable estimation?

23 MR. LAMKEN: So it's important for me
24 that the millions comes from a different way of
25 making additional antibodies. You start with

1 one that works, one of those 26, for example,
2 and you swap out an amino acid or two for one
3 that's very similar according to a table that's
4 in our patent.

5 JUSTICE JACKSON: So would you be
6 claiming those or not?

7 MR. LAMKEN: Yes. So those -- those
8 are fully enabled because it's very routine.
9 The patent describes that it's routine to swap
10 out one amino acid for another that's very
11 similar. And the evidence shows that those
12 routinely work.

13 But, even if it were, you know, you
14 could make millions that way and you could count
15 hypothetically by swapping out every single one
16 of these amino acids along this chain, you can
17 have --

18 JUSTICE JACKSON: So just to be clear,
19 you're -- beyond the 400, you claim all of the
20 swaps?

21 MR. LAMKEN: Yeah. So those swaps are
22 all enabled. They're all within the claims.
23 There's two pieces to it, though. First, an
24 antibody scientist isn't going to look at that
25 near-identical twin and say that's a different

1 antibody. That's -- they're 99.9 percent
2 similar. That's going to be basically the same
3 antibody.

4 But, even if you want to consider that
5 a different antibody, it's enabled because
6 everybody is able to do that routine process, a
7 swapping out the amino acid, everybody. If you
8 want to test it to confirm that it works, which
9 is probably not necessary because the evidence
10 showed that they all reliably work, Sanofi
11 didn't identify a single one that doesn't work,
12 that somehow breaks its ability to bind. If you
13 want to do testing, that's routine.

14 So any one you want to make from those
15 26 by doing an amino acid swap, you can make it.
16 And that is the -- that is clearly enablement.
17 That's what you're looking for, the ability to
18 make the next one and always succeed in making
19 it and it's routine across the board.

20 JUSTICE JACKSON: And you think that
21 gives -- gives others enough notice as to what
22 you've claimed? I mean, to the extent that you
23 could swap out any of the antibodies and
24 suddenly were in the millions, I guess I had
25 understood the patent also was -- to some

1 extent, your specifications were about notice to
2 other people and other inventors.

3 MR. LAMKEN: So, certainly, it's very
4 easy to determine whether or not you're inside
5 or outside the claims, and there's two different
6 techniques you could use. One I talk about was
7 the competition assays. If you compete with
8 something that binds to the sweet spot, if you
9 can't bind when that's already present on the
10 sweet spot, then you're within the claims
11 because you also bind to the sweet spots.

12 There's also something called alanine
13 scanning, and alanine scanning in 2008 was very
14 common, and it not only tells you if you bind to
15 the sweet spot; it actually tells you the
16 specific residues that you bind to in the sweet
17 spot. So, yes, we --

18 JUSTICE JACKSON: But I've got to do
19 the experiment in order to know this, right?

20 MR. LAMKEN: Yeah. You -- you would
21 have to do that, but it is routine to do that
22 and was routine in 2008. And it's not at all --
23 when you're dealing with some very -- something
24 very small, you can't always just sort of hold
25 it up and look at it to see if it matches.

1 You're going to have to do a little bit of work
2 to make sure that it's --

3 JUSTICE JACKSON: All right.

4 MR. LAMKEN: But that's routine.

5 JUSTICE JACKSON: Thank you.

6 CHIEF JUSTICE ROBERTS: Thank you,
7 counsel.

8 MR. LAMKEN: Thank you.

9 CHIEF JUSTICE ROBERTS: Mr. Clement.

10 ORAL ARGUMENT OF PAUL D. CLEMENT

11 ON BEHALF OF THE RESPONDENTS

12 MR. CLEMENT: Mr. Chief Justice, and
13 may it please the Court:

14 Section 112 sets forth the heart of
15 the patent bargain: The more you claim, the
16 more you need to enable. If you claim a lot and
17 enable a little, the public is short-changed and
18 the patent is invalid. The Federal Circuit has
19 long enforced that basic principle by requiring
20 the patentee to enable the full scope of the
21 patent without undue experimentation.

22 Amgen does not take issue with that
23 test, with the Wands factors, I think, or the
24 vast bulk of the Federal Circuit's enablement
25 precedent. But the full scope test, which they

1 don't take issue with at least as I understand
2 it, dooms their claims here, as well illustrated
3 by the chart on page 15 of the red brief.

4 Amgen claims antibodies that -- that
5 bind on 16 residues in the epitope, but their --
6 their specification does not enable skilled
7 artisans to reliably produce them when they bind
8 at 10 or more. And those aren't hypothetical
9 examples. Those are the competitive antibodies
10 that independently develop by their competitors
11 in the four right-hand columns. They're
12 disclosed embodiments, the 26 do not bind at
13 more than nine residues. They've overclaimed,
14 they've underenabled, their patent is invalid.

15 This Court has long applied the same
16 principle in *Morse*, in *Lamp*, and in *Holland*
17 *Furniture*. Samuel Morse invented the telegraph.
18 He did not invent the fax machine. That is why
19 this Court correctly rejected the final broad
20 functional claim in his patent.

21 Thomas Edison discovered the key to
22 incandescent light, but we'd all be fumbling
23 around in the dark if this Court had not
24 invalidated the broad unenabled claims in *Sawyer*
25 and *Man's* patent in the *Lamp* case.

1 The stakes here are comparable.
2 Pfizer independently developed its own antibody
3 and patented it by amino acid sequence. It
4 seemed like a promising candidate, but it failed
5 in clinical testing.

6 If Pfizer had followed Amgen's lead
7 and claimed the whole genus for its own, we
8 would have no large molecule therapy for
9 cholesterol. We're better off with two
10 competing independently developed therapies.

11 I welcome the Court's questions.

12 JUSTICE THOMAS: Mr. -- Mr. Clement,
13 could you just reiterate or at least expand on
14 what you said about what is being claimed here?

15 You -- you made the point that the
16 more you claim, the more you have to enable.
17 And I think it's important to -- since the
18 starting point is what you claim, I'd like to
19 have a good sense of exactly what we are talking
20 about.

21 MR. CLEMENT: So the numbers don't
22 lie, Justice Thomas. I mean, my friend likes to
23 come up with that 384 number. That is not the
24 scope of what they have claimed as their
25 invention.

1 The numbers don't lie. They have
2 claimed millions and millions of antibodies.
3 And their reassurance that, don't worry, all of
4 those millions that you get with conservative
5 substitution, they're all going to work the
6 same, that's inconsistent with their own
7 expert's testimony in the Court below.

8 Dr. Rees and Dr. Petsco testified to
9 this. Dr. Petsco, their expert, Court of
10 Appeals Appendix page 3891, says, if you change
11 one thing in the antibody sequence, you have to
12 retest it. You have to go through that whole
13 experimental process again to confirm that it
14 binds in the right place.

15 And, I mean, look, I -- I can imagine
16 this is frustrating because Mr. Lamken and I are
17 going to tell you different things about the way
18 the science works here. Please don't take my
19 word for it. Please don't take Mr. Lamken's
20 word for it.

21 I urge you to read Sir -- Sir Gregory
22 Winter's amicus brief. He has gotten a Nobel
23 Prize for his contributions to this field, and
24 he will tell you that you can't look at function
25 -- and part of the problem here is these are

1 purely functional claims. You can't look at
2 function and say, oh, that tells me about the
3 structure of the antibodies that are going to
4 bind and block in the right way, and you also
5 can't look at the structure of one antibody and
6 say, oh, if I just tweak it a little bit, it's
7 going to do exactly the same thing.

8 Sir Gregory Winter doesn't think that.
9 Their own expert doesn't think that.

10 And if I could try to address one
11 thing that's come up. I do not agree with Mr.
12 Lamken that everybody here says that the
13 cumulative effort is irrelevant.

14 It is not an appropriate test standing
15 alone, which is why the Federal Circuit didn't
16 apply it as the test. It never even used the
17 word "cumulative." But, as Justice Sotomayor in
18 her question said, is it an appropriate
19 consideration? Yes, it's an appropriate
20 consideration.

21 And if I could illustrate that with a
22 hypothetical. Here's a situation where the
23 cumulative effort to exhaust the species would
24 not be particularly relevant.

25 If I came up with a brand-spanking-new

1 process for making paint and I claimed that
2 process in all the paints that were produced as
3 a result of that as new compositions of matter
4 and one step in my process patent was add
5 pigment for the desired color, well, then a
6 skilled artisan would be able to use that, an
7 actual roadmap, and they would say, all right, I
8 want robin egg blue, and they could produce it
9 every time. And if they wanted chartreuse
10 instead, they could produce it anytime.

11 Now, obviously, there's a lot of
12 colors in the rainbow, so to actually produce
13 every one of them would take a lot of time and
14 it wouldn't invalidate the patent because it
15 enables the skilled artisan to produce what they
16 want every single time. But this patent does
17 not work this way. What they give you is their
18 roadmap is trial and error.

19 JUSTICE GORSUCH: I -- I -- Mr.
20 Clement, I appreciate that clarification, but,
21 as I understand it, there is a point of
22 agreement with respect to cumulative effort,
23 that that should not be dispositive.

24 MR. CLEMENT: Absolutely --

25 JUSTICE GORSUCH: Is that right?

1 MR. CLEMENT: -- Justice Gorsuch.

2 JUSTICE GORSUCH: Okay. Okay.

3 MR. CLEMENT: And that's not just

4 to --

5 JUSTICE GORSUCH: No, that's great.

6 MR. CLEMENT: Yeah.

7 JUSTICE GORSUCH: That's enough.

8 The other -- the other point Mr.

9 Lamken suggested that we -- we should clarify is

10 that -- that there has to be a reasonable

11 embodiment, not an embodiment -- enablement,

12 sorry -- in every instance, that it just needs

13 to be reasonable.

14 Do you agree with that as well? I

15 don't know much turns on it in your case because

16 millions are millions and -- and reasonableness

17 is going to be somewhere -- you -- you could

18 still prevail under that standard, but do -- do

19 you -- do you agree with him that it's

20 reasonable enablement, not -- not down to every

21 jot and tittle in every --

22 MR. CLEMENT: Yes. I think reasonable

23 is just maybe the flip side of undue

24 experimentation.

25 JUSTICE GORSUCH: Yeah. Exactly.

1 MR. CLEMENT: Right.

2 JUSTICE GORSUCH: Okay. So, if we
3 agree on the law, what's left --

4 MR. CLEMENT: Well --

5 JUSTICE GORSUCH: -- for -- for this
6 Court?

7 MR. CLEMENT: -- nothing, except maybe
8 a DIG.

9 (Laughter.)

10 MR. CLEMENT: I mean, that -- that
11 seems -- and, honestly --

12 JUSTICE KAGAN: And, Mr. Clement, is
13 there any other point of law that you feel as
14 though you and Mr. Lamken are in disagreement
15 on?

16 MR. CLEMENT: Well, I -- I think there
17 is a disagreement as follows.

18 Mr. Lamken thinks it's very helpful to
19 his case that somebody who runs the -- the
20 experiments necessary in the roadmap is going to
21 produce an antibody within the range every time.

22 And I think that can't be right, it
23 can't be particularly interesting, because that
24 rewards breadth. And what -- what skilled
25 artisans want is not to randomly generate

1 something within the broad range that's claimed,
2 but they want to be able to pick a specific
3 embodiment, not a hypothetical one but a
4 specific one.

5 So just to give you a concrete
6 example, I mean, if -- if they claimed a 15
7 binder, there are 15 binders in the real world.
8 If you want to use their roadmap to produce a 15
9 binder, you are consigned to trial and error.

10 JUSTICE KAGAN: So I understand that
11 as a view of the inadequacy of their roadmap,
12 but are you trying to suggest that it's
13 reflective of a disagreement about what the
14 legal principles or legal standards are?

15 MR. CLEMENT: I -- I think it must be,
16 because Mr. Lamken is a very smart man, and he
17 makes a big deal out of the fact that, don't
18 worry, this produces something in the range
19 every time, and skilled artisans can produce
20 something in the range every time, and if you
21 give them an infinite amount of time, they will
22 produce everything in the range.

23 And he seems to think that that's good
24 enough as a matter of law to enable his patent.
25 And I think, wow, that is not close to good

1 enough. That consigns people skilled in the art
2 to Sisyphean tasks forever, and it's not what
3 they do.

4 And one of the things I find
5 particularly persuasive about Sir Gregory
6 Winter's brief is he explains this roadmap is
7 not a shortcut at all. It just describes the
8 routine processes that people use to make
9 independent inventions, the same process that
10 Pfizer used, that Merck used, that we use to get
11 our own independent antibodies, and then it adds
12 additional steps that somebody skilled in the
13 art wouldn't want to do and are just basically
14 an additional step, additional test they have to
15 run to see whether they infringe, because the
16 people skilled in the art don't really care
17 where it binds. They -- they care that it
18 blocks.

19 But figuring out where it binds,
20 whether it binds to the 15 that they've claimed
21 as part of their roadmap, is actually a useless
22 process that slows down the artisan in the
23 field.

24 And -- and I do think there's an
25 important point that shouldn't get lost in all

1 of this. Part of the reason, I agree, this
2 isn't a close case is because what they are
3 trying to do, there's no meaningful structure in
4 these genus claims, and the structure they've
5 given is an elaborate description of the
6 epitope, the 15 or 16 residues on the PCSK9
7 where you want the antibodies to -- to -- to
8 bind.

9 The problem is and the reason they
10 can't claim that as an invention is because of
11 this Court's Myriad case, because that exists in
12 nature. These antibodies are independently
13 generated by scientists, but the antigen and the
14 epitope, all of that exists, you know, in -- in
15 nature.

16 And so what you have before you is a
17 particularly pernicious kind of claim because
18 not only is it a full -- a genus claim that's
19 purely functional or double functional, as the
20 Federal Circuit described it, but it's really a
21 workaround of Myriad because, basically, they're
22 pointing to something that exists in nature and
23 they're saying, we claim everything that works
24 to bind there and block.

25 JUSTICE JACKSON: Mr. Clement --

1 JUSTICE ALITO: Mr. Clement, could
2 I -- I just take you back to what you said about
3 cumulative time and effort? Is time and effort
4 relevant at all, or is it the nature of the
5 effort that's required?

6 MR. CLEMENT: So --

7 JUSTICE ALITO: You say cumulative
8 time and effort is -- is not the test, but at
9 the other extreme is the relevant factor, the
10 effort necessary to make and use any individual
11 embodiment. So just -- would you just clarify
12 what -- what is the relevance of time and
13 effort?

14 MR. CLEMENT: So I think they are both
15 relevant. I actually agree with Mr. Lamken that
16 they're both sort of relevant evidence that gets
17 to the ultimate inquiry, which is, is there
18 undue experimentation?

19 And in some respects, the more
20 important word isn't "undue;" it's
21 "experimentation." And let me just contrast the
22 particular claims that go by antibody sequence,
23 our claim to Praluent, their claim to Repatha,
24 the Pfizer claims. They give you the amino acid
25 sequence. And so somebody -- a skilled artisan

1 every time doesn't have to really engage in any
2 independent experimentation. They can look at
3 it. They can reproduce the amino acid sequence.
4 Regardless of how time much it takes, there's no
5 experimentation in there at all.

6 But, under their broad genus claims,
7 you can't do that. You can do it as to the 26,
8 and we'll -- we'll give them the 26, but, as the
9 chart on page 15 shows, we're not even close to
10 infringing the 26. We are structurally
11 fundamentally different.

12 So, to get to the genus, what you do
13 is you go in a lab and you start injecting mice
14 and you inject them with the -- the -- the
15 antigen, PCSK9, and then you get a bunch of
16 antibodies that are produced. Then you pour
17 them over and see which ones bind on PCSK9. And
18 you might be able to test them for blocking.
19 And --

20 JUSTICE JACKSON: But, Mr. -- Mr.
21 Clement, isn't the -- isn't the issue whether or
22 not that is not routine or that's undue? I
23 mean, you sort of took undue out of it, but, as
24 I read the test or understood the test, some
25 experimentation by the skilled artist is

1 allowed. So how do we know whether the steps
2 that you're talking about are undue for the
3 purpose of this -- of the standard?

4 MR. CLEMENT: Well, here's the thing,
5 Justice Jackson: I think the problem is certain
6 -- in certain scientific areas, a -- a form of
7 experimentation is routine, but it's still
8 experimentation, and it's still not what you're
9 supposed to get in a -- in a patent, you're not
10 supposed to just say, all right, do what we did,
11 start from scratch, start with mice --

12 JUSTICE JACKSON: Yeah, but it
13 sounds like you're -- you're -- it sounds like
14 you are going beyond the undue experimentation
15 test. You're saying that unless the claims in
16 this patent are such that a skilled artisan
17 could pick it up and go right from one to the
18 other without any experimentation, the patent is
19 invalid. And I didn't understand that to be the
20 case.

21 MR. CLEMENT: And -- and -- and -- and
22 then I must have misspoke, because that is not
23 my position at all. Existing --

24 JUSTICE JACKSON: Isn't that what
25 predictability is about? Isn't the work of

1 predictability in your argument that you say,
2 unless you can predictably, by doing what the
3 roadmap says, reach this particular result, the
4 patent is invalid?

5 MR. CLEMENT: No. Predictability goes
6 to experimentation and undue. If you have
7 something that enables the skilled artisan to
8 pick essentially any point in the genus, as in
9 my paint example. I want a particular shade of
10 paint. I can produce that one very readily. I
11 mean, maybe I have to do a little bit of mixing
12 with the pigment, but that doesn't -- that's not
13 the kind of thing -- that's the reasonableness.
14 That's not a problem.

15 But, if you tell me that the way I
16 have to produce robin blue -- robin-egg blue
17 paint is to just throw in a pigment and wait
18 until, like -- I'll get a random color and wait
19 until robin-egg blue comes up, that is both
20 undue and it's experimentation and it's not
21 covered by the patent. I was just trying to
22 explain to Justice Alito that I think both words
23 are important because, you know, there are some
24 things that are -- involve time and effort, but
25 they're really just sort of tweaks at the

1 margins.

2 And I don't think it's an accident --
3 just to go to this Court's cases and the cases
4 my friend relies on, I don't think it's an
5 accident that all his best cases are process
6 patents because, if you think about a process
7 patent, it's often going to be the case that if
8 it's -- you know, if you have a process patent
9 for making bricks or for cooling railroad tires,
10 well, if it's a humid day, it might react a
11 little bit differently. You might have to tweak
12 it a little bit to get the mix right on a humid
13 day that's different from a day when it's zero
14 humidity. And, in the same way, if it's 90
15 degrees out, maybe your cooling process for the
16 -- the wheels differs if it's 30 degrees out.

17 And those are the kind of tweaks that
18 you expect a mechanic to be able to do. And
19 you'd say that's without undue experimentation.

20 But it seems quite strange to me that
21 when you're claiming compositions of matter and
22 millions and millions of them, that the only way
23 that you can get there is to essentially
24 replicate the experimental process that the four
25 innovative companies went through to come up

1 with these in the first place, plus, as Sir
2 Gregory Winter says, an additional step that
3 doesn't help anybody but just ends up taking
4 more time because you're basically testing as to
5 whether or not you infringe their patent.

6 JUSTICE SOTOMAYOR: Mr. Clement, could
7 you put things in simpler form for me? It -- it
8 sounded to me that your adversary was saying
9 that most of this work is done by computers,
10 that you inject the mice, the antigens appear,
11 and the computer then sorts them out to see
12 which have the sweet spot or not. That's what I
13 understood him to say, and if that's true, I
14 don't know why that's undue experimentation or
15 why it's costly or why it's time-consuming.

16 You're saying there's more to this
17 process than that. So break it down to me into
18 steps so that I can understand why you're saying
19 that this is undue. I understand it with the
20 paint.

21 MR. CLEMENT: Right.

22 JUSTICE SOTOMAYOR: But I'm not
23 understanding it with this process, so --

24 MR. CLEMENT: So, in this process, let
25 me just hypothetically say what would happen if

1 I wanted to say -- if I were a scientist and I
2 wanted to say I want to use their roadmap to
3 produce a 15 binder because I want to test
4 whether the 15 binder is any better than the 7
5 binder, which is their Repatha, and I want to be
6 able to test that. I'm a scientist. So here's
7 what I would have to do.

8 JUSTICE SOTOMAYOR: All right.

9 MR. CLEMENT: I would have to --

10 JUSTICE SOTOMAYOR: So the difference
11 is, in his way of doing this, he's not telling
12 me how to find his -- he's not going to give me
13 a way to get to his drug without undue
14 experimentation? Is that your point?

15 MR. CLEMENT: That is my point. It's
16 not my only point --

17 JUSTICE SOTOMAYOR: Okay.

18 MR. CLEMENT: -- because, you know,
19 I'm -- I think this most dramatically
20 illustrates it because I assume that's what
21 somebody in the field would want. They wouldn't
22 want a randomly generated one somewhere in the
23 genus. They'd want to say, well, Mr. Lamken
24 tells you --

25 JUSTICE SOTOMAYOR: Well, I don't

1 think we care about what people want. We care
2 about what's being claimed and --

3 MR. CLEMENT: Okay.

4 JUSTICE SOTOMAYOR: Okay. So --

5 MR. CLEMENT: But -- but he's the one
6 actually who cares what a skilled artisan wants.

7 JUSTICE SOTOMAYOR: Okay.

8 MR. CLEMENT: And what's being claimed
9 is this entire genus. And if I want to pick a
10 spot --

11 JUSTICE SOTOMAYOR: So go back and
12 tell me what --

13 MR. CLEMENT: Yep.

14 JUSTICE SOTOMAYOR: -- steps you have
15 to do to get to him.

16 MR. CLEMENT: Okay. So I have to
17 start by injecting mice --

18 JUSTICE SOTOMAYOR: To his --

19 MR. CLEMENT: -- which is not just
20 done with, like, you know, computers. It's done
21 by scientists in the lab. They inject the mice
22 with the antigen. Then they get --

23 JUSTICE SOTOMAYOR: I did that and I
24 wasn't skilled, but go ahead.

25 (Laughter.)

1 MR. CLEMENT: Okay. Well -- probably
2 more skilled than I am. But -- so -- so -- so
3 you get the results of that. You get a whole
4 bunch of antibodies. And then you have to
5 figure out which ones are essentially candidates
6 to bind on PCSK9.

7 JUSTICE SOTOMAYOR: So does a computer
8 do that? And why is it undue?

9 MR. CLEMENT: I -- I don't --

10 JUSTICE SOTOMAYOR: Do they have to
11 look under a microscope? What do they have to
12 do?

13 MR. CLEMENT: I -- I -- I think it's a
14 process they do in the lab. I don't think they
15 actually do that with the computers. Then they
16 get to the next step, which is they have what
17 you might think of as like their candidate
18 antibodies, and then they have to test them to
19 figure out whether they bind on the -- the 16
20 residues that are claimed.

21 And that is a time-consuming process.
22 It is not just a simple matter of, like, running
23 a computer. Again, people do that in the labs.
24 I don't understand all the details, to be -- to
25 be candid.

1 But -- but -- but here's what I do
2 understand, is, at that process, let's say they
3 get, you know, 26 or 384. Then they -- then --
4 then, if what they wanted was a 15 binder to
5 start with, they've got to figure out whether
6 they got one, and there's an excellent chance
7 that they didn't get one of those at all.

8 JUSTICE GORSUCH: Can I ask this
9 question?

10 MR. CLEMENT: Sure.

11 JUSTICE GORSUCH: So the 26, you
12 agree, fair enough, Mr. Lamken's got that in the
13 bag. What about the 384?

14 MR. CLEMENT: He doesn't get the 384.

15 JUSTICE GORSUCH: No? Why?

16 MR. CLEMENT: He didn't disclose them
17 by -- I mean, he could have got them if he gave
18 me the anti- -- the -- the -- the amino acid
19 sequence for all of them. But the reason that
20 he doesn't get the 384 is because he doesn't
21 tell us anything about the 384. I --

22 JUSTICE GORSUCH: Well, let me just
23 pause there for a second. I understand
24 completely your argument -- well, I think I
25 understand completely, let me put it that way,

1 your argument about conservative substitution
2 and the potential millions of variants and --
3 and the trial and error that's required there.

4 I'm not sure I understand how that
5 applies to the 384.

6 MR. CLEMENT: So, like, honestly, the
7 384, I just have to take Mr. Lamken's word for
8 it. I mean, he says that, oh, Praluent might
9 have been in there. I mean, please. If
10 Praluent were in there, their scientists would
11 have produced that evidence.

12 And if you look at the chart at page
13 15, it is not a surprise. I assume that the 26
14 --

15 JUSTICE GORSUCH: That's -- that's a
16 nice demonstrative.

17 MR. CLEMENT: Yeah.

18 JUSTICE GORSUCH: I've got it.

19 MR. CLEMENT: Yeah.

20 JUSTICE GORSUCH: Yeah.

21 MR. CLEMENT: It -- I assume the 26
22 were -- must have been representative of the
23 384, right? Otherwise, why not make one of
24 those other 384, the ones you do by amino acid
25 sequence.

1 So, if you look at the 26 that they
2 give you the amino acid sequence, they look
3 structurally nothing like the four antibodies
4 that were independently developed by other
5 companies. That is very striking to me.

6 JUSTICE GORSUCH: Thank you.

7 CHIEF JUSTICE ROBERTS: Justice
8 Thomas?

9 Justice Alito?

10 Justice Sotomayor? No?

11 JUSTICE KAGAN: Mr. Clement, can I ask
12 you to address Professor Lemley's brief? He has
13 a -- seems to have a very strong view that these
14 antibody genus claims are valuable -- patents
15 are valuable or potentially so and that the
16 Federal Circuit's test is going to pretty much
17 wipe them out across the board.

18 So why is it that Professor Lemley is
19 wrong in your view?

20 MR. CLEMENT: So I think he's wrong on
21 a number of levels. I think he's wrong that the
22 existing Federal Circuit precedent is going to
23 foreclose all genus claims. I mean, there's the
24 Bayer case that we cite in our brief that's an
25 example of the genus claim that the Federal

1 Circuit recently upheld.

2 Now it may be that in this particular
3 area of antibody science, given the current
4 state of the science, that you may not have an
5 ability to functionally claim a genus, and
6 that's kind of -- at -- at some level nobody's
7 fault. It's just the way the science works.

8 And, personally, I think that's great,
9 and -- because what it does is it allows
10 different companies to independently develop
11 different large molecule therapies to deal with
12 the same malady.

13 And if you look at the Fish &
14 Richardson brief, it goes through and shows that
15 there are a number of situations where there's
16 one antigen or pathogen that people are trying
17 to target and they target with different
18 multiple large molecules, and that can be hugely
19 important.

20 I mean, I -- I -- I want to make clear
21 my friend and I do disagree on a factual matter.
22 He wants you to believe that everything in this
23 genus is fungible. And, of course, it's
24 fungible with respect to the two functions
25 claimed by definition, but it's -- they're not

1 functional. They are different compositions of
2 matter. They can work very different ways.
3 Somebody can tolerate one and not the other.

4 And the best evidence of that is the
5 Pfizer experience, right? The Pfizer antigen --
6 antibody is in this genus, and when it went into
7 clinical testing, it fell down.

8 So, if -- if Amgen's had fallen down
9 for the same reasons that -- that -- that
10 Pfizer's did, we'd be without the treatment
11 because it claimed the whole genus and --

12 JUSTICE KAGAN: So -- so --

13 MR. CLEMENT: -- they wouldn't enable
14 it.

15 JUSTICE KAGAN: -- so -- so tell me if
16 this is wrong. As I understand, Professor
17 Lemley could be wrong for one of two reasons,
18 right? He could be wrong to say that the
19 Federal Circuit test is going to basically
20 invalidate all these patents, or he could be
21 wrong in thinking that these patents are
22 valuable.

23 I hear you saying that he might be
24 right about the Federal Circuit's test
25 invalidating most of these patents, but that's

1 okay because we shouldn't want these patents
2 around.

3 MR. CLEMENT: You know, the truth has
4 a way of leaking out. I mean, yeah, I mean, I
5 am saying that --

6 (Laughter.)

7 MR. CLEMENT: -- because -- because --
8 because I think functional genus claims are
9 terrible. I think they retard the science. And
10 I don't think you have to look beyond this
11 Court's cases.

12 The eighth claim in Samuel Morse's
13 claim, the other ones were nice species,
14 structure, good stuff. The eighth one was a
15 functional genus claim for everything that
16 allows letters to print somewhere else through
17 the use of electricity. This Court deep-sixed
18 it and thank goodness, because Samuel Morse is
19 brilliant, but he didn't invent the fax machine.

20 And look at the Lamp case. I mean,
21 they claimed the entire genus of all fibrous
22 textiles. It turns out the one that they
23 discovered didn't work very well and was a lousy
24 lamp. And Edison had to go through all this
25 different work to find out that there actually

1 is like a subgenus. It's called bamboo. That
2 stuff all works and it all has the same
3 structurally common feature of really parallel
4 fibers. And that's the way -- I'm not against
5 all genus claims, but you got to get some
6 structure in there.

7 And as this Court's cases teach, it's
8 got to be structure that unifies the genus. And
9 what's -- and I love Lemley, but what -- you
10 know, I -- I take Sir Gregory Winter on the
11 science, and what he tells you is, in this area
12 of science, that you just can't get that
13 structural commonality. It just doesn't work.
14 It's -- I mean, somebody will discover it and
15 they will get another Nobel Prize for
16 discovering it.

17 JUSTICE KAGAN: Thank you.

18 CHIEF JUSTICE ROBERTS: Justice
19 Gorsuch?

20 Justice Kavanaugh?

21 Justice Barrett?

22 Justice Jackson?

23 JUSTICE JACKSON: So there are some
24 fields where there is a degree of
25 unpredictability or randomness, and I guess I'm

1 just a little worried that your view on this
2 would mean that we would not be able to have
3 patents where some experimentation was required.

4 Can you just speak to that a little
5 bit more? I mean, again, I hear you in some
6 ways suggesting that the specification has to
7 absolutely get a skilled artisan to the endpoint
8 of every species in the genus a hundred percent
9 of the time exactly as indicated.

10 And I'm just concerned because there
11 are going to be some areas, and perhaps this is
12 one of them, where there's a reasonable degree
13 of unpredictability in terms of the outcome, but
14 you're sort of in the ballpark enough that we
15 would want to make sure that there was
16 innovation in this area with -- with these kinds
17 of companies investing in -- in patenting these
18 kinds of developments.

19 MR. CLEMENT: So I -- I think what I
20 would say is I do think the test should be undue
21 experimentation. It should not be zero
22 tolerance, no experimentation.

23 JUSTICE JACKSON: Okay.

24 MR. CLEMENT: But I also do think, if
25 you're going to start with the text, which I

1 assume you always do, then what you would say is
2 you start with the idea that you have to make
3 and use the invention, and the invention is
4 defined by the full -- by the -- by the claims
5 in the invention, and, in that sense, Amgen's
6 the master of their own claims, the master of
7 their own patent. And then you look at those,
8 and if they claim a lot, then you -- you have to
9 enable the full scope of what you claim.

10 And then, from that starting
11 proposition, which might get you to the idea
12 that there's no experimentation, then I think
13 it's a little bit of, you know, de minimis non
14 curat lex reasonableness, a little bit of play
15 in the joints, but this is where Mr. Lamken and
16 I just see the facts completely different.

17 He wants to say, oh, well, this --
18 these are just hypothesized things that couldn't
19 be invented here given the current state of the
20 science.

21 With all due respect, balderdash. I
22 mean, there are four disclosed patents here with
23 anti -- amino acid sequence that the competitors
24 have made that are on the chart.

25 Now, if you are a skilled artisan in

1 the field and you want to produce the 15 binder
2 that Pfizer did, you can produce it a hundred
3 percent of the time by duplicating the amino
4 acid sequence.

5 But, if you want to use their roadmap
6 to get a 15 binder so you can test to see
7 whether his claim that all of this is fungible
8 is really right and it's no better than the 7
9 binder, I mean, get a big cup of coffee because
10 it is going to take forever to run all of the
11 tests that are going to be necessary --

12 JUSTICE JACKSON: All right. One --

13 MR. CLEMENT: -- and you could you run
14 them all, and you might not get a 15 binder and
15 then you have to start over.

16 JUSTICE JACKSON: One last question on
17 the facts. I understood that Amgen had trial
18 testimony in this case that the roadmap is
19 certain to make all of the claims' antibodies,
20 including Sanofi's, Pfizer's, and Merck's.

21 And I had understood, in terms of the
22 way the burdens work, a little complicated, but
23 that you had to have evidence disproving that by
24 clear and convincing evidence.

25 So do you? And, if so, what is your

1 evidence?

2 MR. CLEMENT: So I appreciate the
3 question, and this really goes back to the
4 suggestion that there is sort of a lurking legal
5 difference here, because the reason I don't have
6 evidence that says that that claim is not true
7 is because it implicitly says if you take
8 forever. I can't tell you that if you run these
9 experiments, you won't eventually get Praluent,
10 Pfizer, the Merck embodiments, but, unlike the
11 paint, where you can start and say, all right,
12 I'm going to -- I'm going to test that, so I'm
13 going to -- I'm going to reproduce that. You
14 can't do that.

15 So the -- the -- the twin claims that
16 my friend keeps making and he seems to think are
17 legally sufficient, and I definitely disagree,
18 are, if you run the test, you're always going to
19 get something in the genus.

20 CHIEF JUSTICE ROBERTS: Thank you,
21 counsel.

22 MR. CLEMENT: Thank you.

23 CHIEF JUSTICE ROBERTS: Ms. Sinzduk?
24
25

1 ORAL ARGUMENT OF COLLEEN R. SINZDAK
2 FOR THE UNITED STATES, AS AMICUS CURIAE,
3 SUPPORTING THE RESPONDENTS

4 MS. SINZDAK: Mr. Chief Justice, and
5 may it please the Court:

6 I think I want to pick up where
7 Respondents' counsel left off with a very
8 important fact, and that is that if an antibody
9 has already been created, a scientist who wants
10 to make that antibody is not going to go into a
11 laboratory and inoculate a mouse.

12 They're going to use the amino acid
13 sequence. That is the recipe for making an
14 antibody. That is why the government says that
15 for the 26 exemplars within the patents, that
16 actually -- where they -- where Amgen has
17 actually listed the amino acid sequence,
18 those -- those antibodies are enabled because,
19 if a scientist wants to go into the lab and it
20 wants to make that antibody, it has the recipe,
21 it has the amino acid sequence.

22 And I also do not want you to take
23 my -- my word on the science, but I do want you
24 to take the expert testimony on the science.
25 And I think that if you look at Trial Transcript

1 20 -- 225, you will see that -- that
2 Respondents' expert explained that the amino
3 acid sequence is the recipe.

4 If you look at the Winter brief at 14,
5 it explains that the amino acid sequence is the
6 recipe.

7 And if you look at Amgen's own brief
8 at 13, it says, how should you start their
9 roadmap. You should go in and you should use
10 the amino acid sequence of the antibodies that
11 they actually invented and make those
12 antibodies, and then you should go through this
13 whole elaborate mouse inoculation process.

14 So the reason here, just on the -- on
15 the clear facts that this is not an enabled
16 genus, is that they have not given the
17 information that a person skilled in the art
18 would need to make and use all of the antibodies
19 within the genus. It really is that simple.

20 And I think that we need to be very
21 careful about when we hear claims that this is
22 complicated science, and we need to start going
23 beyond the sort of -- the basic text that says
24 you have to be able to make and use the
25 invention. We have to start relaxing the rules,

1 and we have to say not can you make and use
2 every antibody within the genus, but, oh, do you
3 really need a particular antibody? You know,
4 does it really matter, I think, is what
5 Petitioners' counsel said.

6 It is very dangerous, I think, to
7 start asking those kinds of questions because
8 the truth is we don't know if it matters. This
9 is an unpredictable field. This is a field
10 where developments are getting made every day.
11 And they haven't made certain antibodies within
12 this genus. We don't know if one of those
13 antibodies is going to be the one that really
14 works to beat the cholesterol problem that
15 causes heart attacks, that works better than
16 everything else, or the one that's going to be
17 tolerated by more patients or the one that's
18 going to be cheaper to manufacture.

19 We don't know that, and so we can't
20 say, oh, does it matter? What we have to ask
21 is, is it different? And this isn't some new
22 rule that I'm coming up with. Under the patent
23 law, it has never been the case that you say,
24 oh, is this better? Do you have -- you don't
25 have to build a better mousetrap; you have to

1 build a different mousetrap.

2 And, here, we know that the
3 Respondents, they built a different mousetrap,
4 right? That their antibody, it binds to
5 different parts of the antigen. So it is
6 different. It is not simply the same.

7 And I actually think you -- you see in
8 the reply brief that even Amgen knows it's not
9 the same, because the government explained that
10 there is a doctrine out there that prevents
11 copyists, that prevents someone from making a
12 great invention and then having someone else
13 just make a tiny change and knock it off, and
14 it's called the doctrine of equivalents, and
15 it's been in this Court's cases for two
16 centuries.

17 And Amgen says we can't use the
18 doctrine of equivalents here, and the reason is
19 because they're not equivalent, and because
20 they're not equivalent, you have to enable all
21 of the different antibodies.

22 So, again, this is just the basic
23 principles. It is the enablement requirement
24 that has been in the law since the beginning.

25 And I think, Justice Kagan, you said,

1 well -- well, actually, Professor Lemley is very
2 worried that this enablement requirement is
3 going to harm innovation.

4 But Professor Lemley has a new article
5 from 2023, Yale Law Journal, which is called
6 "The Antibody Patent Paradox." And in that, he
7 says, you know, it doesn't look like these
8 antibody patents -- it doesn't look like these
9 genus patents are enabled, but there is this
10 doctrine of equivalents, and maybe it would take
11 care of all of these innovation problems.

12 And I think, honestly, even if you
13 look at Footnote 399 of that original Lemley
14 article, "The Death of the Patent Genus," in
15 that footnote, it says, now there is a case
16 happening right now, it's -- it's Amgen versus
17 Sanofi, and it doesn't really seem like that
18 genus is enabled, but, you know, it's not
19 enabled for a different reason.

20 So I think there are some concerns
21 going on with -- with the enablement
22 requirement. I still actually think that the --
23 the concerns that Lemley is expressing can be
24 dealt with through the doctrine of equivalents,
25 and I can explain a little more what I think is

1 happening there with respect to chemical
2 genuses. But, whether you think that's true or
3 not, it's simply an entirely different question.

4 I think, Justice Jackson, you were
5 talking a little bit about the predictability
6 and this is an unpredictable area of -- of -- of
7 -- of science and how are we going to deal with
8 those sorts of things.

9 I think it is correct this is an undue
10 experimentation question, and we're going to
11 say, like, is this something that a person
12 skilled in the art is going to be willing to do?
13 And, quite honestly, at the time of Wands, I
14 think that people were a lot more comfortable
15 doing the mouse inoculation process, and the
16 reason for that -- and I hate to bring in yet
17 another complicated area of science -- but
18 recombinant DNA technology was in its infancy.
19 So I don't know that you really could use an
20 amino acid sequence to go into a lab and just
21 make a particular antibody. So, at that time,
22 actually, if you wanted to claim a particular
23 antibody, what you would do is deposit that
24 antibody -- or it's called a hybridoma of an
25 antibody. You would deposit a hybridoma in a

1 depository, and then, if another scientist or if
2 another company wanted to make that antibody,
3 they could sort of check it out and clone it,
4 and that's how you would make that particular
5 antibody.

6 But, if you wanted to kind of just go
7 into a lab and make an antibody de novo, you
8 really would have to inoculate a mouse and hope.
9 But you don't have to do that anymore, right?
10 At this -- now we have a recipe. And because we
11 have that recipe, I think the idea that you
12 would tell scientists, well, just go and run
13 that mouse process until you get what you're
14 looking for is -- is really absurd.

15 And I would also caution, again, this
16 idea, which I think under- -- under- --
17 undergirds a lot of the arguments here on
18 Petitioners' side, that we need to make new
19 rules for new science. It's a -- it's a
20 dangerous idea. And, you know, you think about
21 Consolidated Edison, where the first people who
22 invented that light bulb with carbon filter
23 paper, they really thought they had the best
24 light bulb. They did, but they were wrong.
25 They were simply wrong.

1 And when we kind of make these
2 predictions, you can stifle innovation. And I
3 think this is another sort of response to the
4 Lemley brief. What happens when you allow a
5 genus patent that will -- that -- that -- that
6 -- that will -- will cover not just something
7 that has been invented but also things that have
8 not yet been made and used is that nobody else
9 has the incentive to go out and make and use
10 them.

11 So let's say you're look -- you have
12 this 15 binder, right? And if you look at
13 Amgen's patent and you look -- the only thing
14 you're going to be told to do is to go and
15 inject a mouse or there's another process, which
16 I do want to mention briefly, but you're going
17 to go inject a mouse -- a mouse and hope for the
18 best, right? But, if a scientist goes into a
19 lab and it takes all of the hard time and effort
20 and it goes through and it finds a 15 binder,
21 that 15 binder belongs to Amgen. And that's
22 just not the basic patent quid pro quo.

23 JUSTICE GORSUCH: Counsel, can I just
24 ask you a question about the legal standard?

25 MS. SINZDAK: Sure.

1 JUSTICE GORSUCH: You -- you -- you --
2 you've emphasized full enablement, and that's
3 certainly what Wood, for example, says from this
4 Court. But at least your -- your colleagues
5 both seem to suggest that there might be some
6 elbow room, non curat lex room in there
7 somewhere, reasonableness. What do you think?
8 What does the government think?

9 MS. SINZDAK: I think there is always
10 room for reasonableness, but I do think that the
11 need to be reasonable needs to be tempered with
12 the need not to accept sort of pronouncements
13 about -- about what is and is not different. So
14 I -- I -- or what does -- what embodiments do
15 and do not matter. So I think, again, the
16 doctrine of equivalents is really, I think,
17 where a lot of this reasonableness concern gets
18 taken care of.

19 I would also say that -- that -- that
20 the Federal Circuit has -- and I think quite
21 correctly -- said that, you know, if you claim a
22 genus of wooden baseball bats and every person
23 skilled in the art knows that you can't make a
24 baseball bat out of -- out of pine, then you
25 don't have to say except pine because the -- the

1 -- the strict -- the plain text of the statute
2 says a person skilled in the art.

3 JUSTICE GORSUCH: Okay.

4 MS. SINZDAK: So I think there you
5 would have a little bit of reasonableness.

6 JUSTICE GORSUCH: And then a similar
7 question with respect to cumulative efforts.
8 There was some discussion about that and maybe
9 some -- some agreement that -- that cumulative
10 effort may not be the right -- it may be a
11 consideration, but it's not -- surely not a
12 dispositive one if the patent did clearly
13 specify every single time you're going to
14 produce a winner.

15 And the problem here, as I understand
16 Respondent, is that that's no guarantee.
17 There's -- even if you do everything right and
18 you follow all of it, conservative substitution,
19 you're going to have some winners and you're
20 going to have some losers.

21 But, if -- if you could, for example,
22 every single time get a winner, then the fact
23 that it would require a long time to get them
24 all wouldn't -- wouldn't necessarily defeat a
25 patent, would it?

1 MS. SINZDAK: No.

2 JUSTICE GORSUCH: Okay.

3 MS. SINZDAK: It certainly would not.
4 I do agree with Respondent it can be relevant,
5 and I think it can particularly be relevant if,
6 for example, you figure out that 10 of a million
7 types of -- there's a million types of ammonia
8 in the world and 10 of them are going -- can be
9 used instead of gasoline to run superefficient
10 cars, right? But you don't know which 10, so
11 you just claim the genus of ammonia that can be
12 used to run cars, and then what you're saying is
13 you have to go out there and try them. And you
14 may actually have to try all a million of them
15 so -- to get to those 10. And so there the
16 cumulative effort is relevant because you're
17 going to be there testing and testing and
18 testing.

19 So just a few minor factual points.
20 First of all, I think that 400 number is
21 misleading because, first of all, it's -- it's a
22 -- or the 385 number. So that is, if you --
23 that's how many they got when they ran this
24 mouse process once, but this is not a process --
25 a product by process claim. They're not only

1 claiming those, you know, 385.

2 And it's not even -- they're not only
3 claiming antibodies made by mice; they're
4 claiming these antibodies that bind and block
5 made through any process.

6 And I also think that, you know, at
7 least looking at their expert testimony, I'm not
8 sure that all of the competitor antibodies can
9 be made with that mouse process, and -- and I
10 say that only because I look at Trial Transcript
11 758, and if you look at that, their expert is
12 talking about the various competitor antibodies,
13 and it says, you know, you can run the mouse and
14 we think you would get Praluent by running the
15 mouse experiments. But, actually, you would
16 need to -- to get this phage library to -- to
17 find -- to -- to make another of the competitor
18 antibodies.

19 To me, that looks like they're saying
20 the mouse has some limitations, so you're going
21 to need to use a different process. And I
22 actually think you -- you heard Petitioners'
23 counsel up here conceding that you're not going
24 to be able to -- you know, there -- you're not
25 necessarily going to make everything with the

1 mouse because you're going to have some of these
2 conservative substitution -- you're going to
3 make some -- some antibodies with conservative
4 substitution, and I -- I think what he was
5 saying is that, you know, that -- that's --
6 that's in addition to those 400.

7 So I -- I -- I -- I do think just as a
8 factual point there -- there are -- we need to
9 be careful and precise. And what I would urge
10 the Court is to look at the Winter brief but
11 then to also just focus on the legal question
12 here, and I think answering that legal question
13 just means reiterating the enablement inquiry
14 that this Court has been applying and applying
15 and applying for 200 years.

16 CHIEF JUSTICE ROBERTS: Counsel, is
17 there anything that Mr. Clement said this
18 morning with which the government disagrees?

19 MS. SINZDAK: I did not hear anything.

20 CHIEF JUSTICE ROBERTS: Okay. And on
21 the doctrine of equivalents, wouldn't that be
22 less protective of the investment someone might
23 make to pursue these inventions in terms of its,
24 I would say, maybe I'm not remembering right
25 from earlier cases, but it seems to me that that

1 would be less protective and therefore less of
2 an encouragement to investment.

3 MS. SINZDAK: I -- I mean, to the
4 extent that Petitioner is asking for protection
5 for things that they have not made -- enabled
6 people to make and use, I think you're right,
7 because I don't think the doctrine of
8 equivalents is going to get them things they
9 haven't invented yet.

10 But I also think that -- that -- that
11 that's just the basic patent quid pro quo. You
12 don't get a patent on anything that you haven't
13 enabled people to make and use. So I guess I
14 would say, yes, not being allowed to have their
15 patent is going to get them less -- less, but
16 that's exactly what the law requires.

17 CHIEF JUSTICE ROBERTS: Justice
18 Thomas?

19 JUSTICE THOMAS: Would you comment
20 briefly on the relationship between the
21 enablement -- enablement inquiry and the claim
22 -- the invention, the claim?

23 It seems as though, as Mr. Clement
24 said, that the broader -- the more you claim,
25 the more you must focus on the enablement

1 analysis. And I don't think you commented on
2 that.

3 MS. SINZDAK: I think that is often
4 the case. You need to provide enough
5 information to enable a person to make any given
6 embodiment of your invention. And, you know,
7 if -- if you've claimed a lot of different
8 things, you may have to put in a lot more
9 information.

10 I would say that sometimes I think
11 it's going to be more -- you're not going to
12 have to give a ton more information. My
13 understanding is that, for example, with respect
14 to a chemical genus, you might be able to say,
15 I'm talking about this family of chemicals that
16 have this helical ring structure, and, you know,
17 this -- this -- this chemical group that hangs
18 off of it can be one of these five things.

19 And -- and that's actually going to
20 enable a chemist, not me, to make tons and tons
21 and tons of different things, or you --

22 JUSTICE THOMAS: So the -- in this
23 area, I -- I think there's -- if I understand
24 your argument and Mr. Clement's, this area
25 doesn't seem to have the same predictive quality

1 that you would find in some of the other areas.
2 For example, his paint mixing would be
3 relatively easy. But, as you move along to the
4 other antibodies in this area, it seems as
5 though there it's trial and error. It's more
6 each one has to be assessed on its own terms.

7 So it would seem to me that the -- it
8 would be -- it would be more difficult to
9 achieve what you just said in this particular
10 area.

11 MS. SINZDAK: I think that is exactly
12 right, but I don't think that that means that
13 you should bend the rules of enablement. And,
14 in fact, I think that could be very dangerous,
15 right, because one of the incentives right now
16 for scientists to figure out the
17 structure/function relationship in antibodies
18 beyond the Nobel Prize, but another incentive is
19 then you could claim broader genuses.

20 If somebody is able to figure out, oh,
21 well, when I identify this antigen, oh, I can
22 figure out what amino acid sequences for every
23 single different antibody that could bind to
24 that antigen, then they would -- they would have
25 a much better case for enablement.

1 But, if you say, no, it doesn't
2 matter, you can claim all of those anyway,
3 there's less incentive to find that, sort of
4 that -- that magic key, which I should not say
5 magic, it's science.

6 (Laughter.)

7 CHIEF JUSTICE ROBERTS: Justice Alito?
8 Justice Sotomayor?

9 JUSTICE SOTOMAYOR: A simple question,
10 maybe not so simple. Mr. Clement at one point
11 in response to Justice Gorsuch said you should
12 DIG this case. If we didn't want to, what could
13 we say to help the Federal Circuit or anyone
14 else who's interested in this area?

15 MS. SINZDAK: So --

16 JUSTICE SOTOMAYOR: What could we say
17 that they didn't say? What could we explain?
18 Your -- Petitioners' counsel has told us what he
19 would wants us to say. What would you want us
20 to say?

21 MS. SINZDAK: So I -- I think, first
22 of all, you could DIG the case. We do not think
23 that the Federal Circuit said anything wrong
24 here. I think that some of the arguments that
25 we're hearing from Petitioners suggest that it

1 might be useful to clarify that you really do
2 need to enable each of the different embodiments
3 that you're claiming, that you can't say these
4 ones don't "matter," because that's simply not
5 the -- not -- first of all, it's hard to know
6 what that means other than if you're invoking
7 the doctrine of equivalents, which Petitioner
8 said he -- he can't invoke, but that requires
9 sort of a predictive judgment that could really
10 freeze innovation by saying, oh, don't worry,
11 don't -- don't find that 15 binder, it doesn't
12 matter.

13 And -- and any -- and -- and, of
14 course, what they're saying is it doesn't
15 matter, but, by the way, if you do find it and
16 it does something truly amazing, we own it.

17 CHIEF JUSTICE ROBERTS: Justice Kagan?
18 Justice Gorsuch?

19 JUSTICE KAVANAUGH: I guess, in
20 response to what you said to Justice Sotomayor,
21 it would be important for this Court to say it
22 essentially agrees with the Federal Circuit
23 because there's been, as Justice Kagan points
24 out, a lot of critiques of the Federal Circuit's
25 approach, and if billions of dollars were on the

1 line, this Court saying as much with -- along
2 the lines that you propose would eliminate that
3 uncertainty about the legal standard, and then
4 everyone would know it's up to Congress.

5 MS. SINZDAK: I -- I -- I -- I agree
6 with that completely. And I think also, with
7 that final point, which is I -- I think an
8 important one that maybe hasn't been discussed
9 here, that to the extent you did think that the
10 Petitioner had a good point that antibodies are
11 just different and basic patent rules don't --
12 don't work, then the person -- then -- then --
13 then the body that needs to -- to make a special
14 antibody exception is going to be Congress, not
15 this Court.

16 I also completely agree that I do
17 think it would be helpful -- to the extent there
18 are scientists still out there making these
19 broad genus claims that are going to stifle
20 innovation, I -- I do think that that's a -- a
21 danger to innovation, especially in the medical
22 field, where, from what people who know better
23 than me tell me, antibody innovation is key,
24 and -- and we don't want people claiming more
25 than they've really invented.

1 JUSTICE KAVANAUGH: Thank you.

2 CHIEF JUSTICE ROBERTS: Justice
3 Barrett?

4 Justice Jackson?

5 Thank you, counsel.

6 Rebuttal, Mr. Lamken?

7 REBUTTAL ARGUMENT OF JEFFREY A. LAMKEN

8 ON BEHALF OF THE PETITIONERS

9 MR. LAMKEN: Thank you.

10 A key fact for this case is that
11 Sanofi has not identified one antibody that
12 would require undue experimentation to make.
13 Sanofi likes its chart. We like that chart as
14 well because the whole purpose of that retrial
15 was so that they could prove that those
16 competitor antibodies aren't made using the
17 roadmap. And the jury disagreed.

18 There is no evidence of anybody ever
19 saying, gee, I tried to make one of those
20 competitor antibodies, it didn't come out the
21 first time. I know the government points out
22 that you might use a phage display for one, but
23 the patent's disclosures explain that you can
24 use the mice and you can use phage displays and
25 this is how you would get them.

1 And all this tells me at the bottom is
2 there's a reason out there why we have trials,
3 why we have juries, and why we have patent
4 examiners, so that we're not retrying all the
5 elements of the case before this Court.

6 Before this Court, the question is did
7 they prove that there's something you can't make
8 or it takes undue experimentation to make, and
9 that evidence -- that proof is simply absent.

10 In terms of Winter, I think it's very
11 interesting to get the functional equivalent of
12 an expert report when you're in the Supreme
13 Court. If the Court's interested in a response
14 to that, it so closely parallels Sanofi's brief
15 in the court of appeals that I would commend the
16 Court to look at our reply brief there and it
17 will have the answers to virtually everything
18 that Mr. Winter has.

19 And turning -- turning to the issue of
20 millions, the question of millions matters only
21 if you're looking at the cumulative effort to
22 get to the millions. If each one is
23 individually enabled, you know how to get there
24 because you can do amino acid substitutions
25 through this conservative substitution, you can

1 get to any one you want, that's enablement.

2 Each of those is enabled.

3 The -- the question of millions
4 becomes not enablement only if you're going to
5 look at the cumulative effort to make each and
6 every one, and I think that is a fundamental
7 point of disagreement. Is it even relevant how
8 hard it is to make all of them as opposed to how
9 hard is it for the skilled artisan to do what
10 skilled artisans do, which is make one that they
11 want.

12 And, in this sense, I would like to
13 respond to Mr. Clement's point that somehow it
14 makes it hard -- our roadmap makes it harder.
15 No, the roadmap makes it much easier because, if
16 you know that it's going to bind to the sweet
17 spot and we give you those two antibodies, those
18 two anchor antibodies that help you figure it
19 out with high throughput testing, quick and easy
20 according to the testimony, if it binds there,
21 it blocks. That's it. You're done. You have
22 an antibody that works.

23 With respect to Morse's eighth claim,
24 yes, everybody forgets about Morse's seventh
25 claim, and Morse's seventh claim was, in effect,

1 you use electromagnetism using -- to produce the
2 motion of the machinery at distance to reproduce
3 letters. We're just like Morse's seventh claim
4 because we have a structure, you're using
5 monoclonal antibodies, and we tell you how to
6 produce them, and these are all monoclonal
7 antibodies that have a characteristic that you
8 can observe, that they bind to a particular
9 place, and by binding in that place, they
10 produce the function you want, blocking.

11 There's a lot of going -- a lot about
12 criticizing functional claiming here. But, in
13 terms of functional claiming, that's not a
14 112(a) question of enablement. That's a 112(b)
15 question, which describes what you have to do to
16 claim. If people don't like functional claims,
17 that's where it goes.

18 And this claim really isn't functional
19 in a relevant sense. The binding is a
20 characteristic you can observe, like what the
21 government called water absorptivity, when it
22 was talking about the -- the Holland Furniture
23 case. It's something you can observe. And if
24 you have that characteristic, you bind and,
25 therefore, you block and you're exactly within

1 the claims.

2 As to the doctrine of equivalents, if
3 you have an antibody that has a different amino
4 acid sequence, that isn't protectable under the
5 doctrine of equivalents because it's not
6 equivalent. Because it has the same effect, it
7 may also block, it doesn't make it equivalent.
8 It's only equivalent if the limitations, the
9 requirements, are equivalent. And so you can
10 swap out maybe one amino acid for one that's
11 very similar, but if an amino acid in your
12 claimed structure is just missing, you just
13 clipped it out, then you would be around, and
14 you would provide no protection whatsoever for
15 people who are creating the antibodies.

16 You invest \$2.6 billion investing and
17 determining that there's a sweet spot that if
18 you bind to you will block and you will be
19 saving lives. And the protection is listed to
20 -- limited to what? The 26 you describe by
21 amino acid sequence? That provides no
22 protection at all because you can always come up
23 with a 27th, and that's the whole point of the
24 roadmap.

25 The roadmap is fully enabling because

1 you can come up with that 27th, the 28th, or the
2 29th, whatever is out there. The testimony was
3 the roadmap will allow you to get to them all.
4 And it's not an infinite test because the
5 evidence in this trial, in this art is there's
6 just nobody who testified and said, gee, I ran
7 the roadmap, I tried, I didn't get what I
8 wanted, something was missing. No evidence that
9 Sanofi on its first panel didn't come up with
10 its -- its antibody, Praluent. No evidence that
11 Amgen on its first trial failed to come up with
12 its antibody. Or any of the other competitors.
13 When you run the roadmap, you get them. The 15
14 binder, if a 15 binder exists, it's going to
15 come out and it's going to be there.

16 If I could turn just very quickly to
17 the -- the issue of DIG, please?

18 CHIEF JUSTICE ROBERTS: A minute.

19 MR. LAMKEN: Thank you so much.

20 This case, you should make no mistake,
21 has incredible impacts. We have two decisions
22 from the PTAB, both characterizing it as a
23 cumulative effort to make all the embodiments
24 test. Nobody can invest billions of dollars
25 with this decision out there. Nobody can invest

1 billions of dollars if it's even relevant.
2 There's a legal dispute about the relevance of
3 that cumulative effort test, and this Court
4 should address it and excise it from the law.

5 Thank you, Your Honor.

6 CHIEF JUSTICE ROBERTS: Thank you,
7 counsel. The case is submitted.

8 (Whereupon, at 11:44 a.m., the case
9 was submitted.)

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