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

1 cover the entire sweet spot so skilled artisans
2 can be certain to make all the claims'
3 antibodies, including 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 a 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 -- the testimony was that it will produce
6 every 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 then, there was no evidence that
15 there was some particular antibody that was
16 harder to make that, for some reason, you would
17 expect it 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 if you cut --

15 JUSTICE THOMAS: But I think you're
16 making the point, though -- excuse me for
17 interrupting you. I just want to end the -- 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, if 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 -- 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 have --
3 we only specified the 26 and you -- we came up
4 with 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, process
5 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, 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 -- that it doesn't produce it. The
10 experts explain exactly why you would get all of
11 those. And there is simply no evidence of
12 anybody immunizing mice and saying there's
13 something here missing, this doesn't work, I'm
14 not getting everything I want.

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

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

1 different than the other. So, to the skilled
2 artisan, they're all the same, and --

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

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

11 JUSTICE GORSUCH: You -- you'd accept
12 that?

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

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

21 MR. LAMKEN: Fair.

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

25 MR. LAMKEN: So the Wands factors can

1 be useful, particular cases when properly
2 applied. The problem with the Wands factors is
3 they become something of a checklist that's
4 abstracted and therefore replaces the ultimate
5 statutory standard.

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

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

17 But that's not the question, we're
18 talking about enablement. The question is, can
19 the skilled artisan using the patent and the
20 tools available reliably get to the 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 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 -- a relatively broad
20 patent 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: I -- I -- you know,
7 it's -- it's hard for me to agree with that in
8 the abstract 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 -- it's because
17 it --

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

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

1 So I think, yes, as a general matter,
2 it -- often, if you have a broader claim, it may
3 be harder, but it's hard to say that in every
4 art for every circumstance that makes it more
5 difficult.

6 JUSTICE GORSUCH: Thank you.

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

9 CHIEF JUSTICE ROBERTS: What --

10 JUSTICE KAGAN: What --

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

18 Could you flesh out "reasonably" a
19 little bit for me?

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

1 to skilled artisans.

2 So, for example, if a patent, for
3 example, taught you to make metal airplanes, you
4 wouldn't invalidate it because somebody said,
5 gee, you know what, it would be really hard to
6 make one out of lead. That's the type of thing
7 you would automatically set aside.

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

15 CHIEF JUSTICE ROBERTS: Well, how long
16 --

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

22 CHIEF JUSTICE ROBERTS: Well, I don't
23 -- how -- how long? And that may be the wrong
24 measure, but, if you're judging reasonableness,
25 how much experimentation do you have to put into

1 it? I mean, part of the allegation in -- in --
2 in your case is that this is simply trial and
3 error. And so how long does it take?

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

13 CHIEF JUSTICE ROBERTS: Well --

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

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

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

23 JUSTICE SOTOMAYOR: Producing them is
24 one thing. Identifying them, do the whole
25 process, don't take a piece.

1 MR. LAMKEN: I'm sorry?

2 JUSTICE SOTOMAYOR: Then continue with
3 Justice --

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

12 And so what the -- what it is is not a
13 trial and error like you're going through one
14 after the other. You start with that 3,000 and
15 you use our two anchor antibodies, and it simply
16 costs \$30 -- this is the record, according to
17 Appeals Appendix 3909 -- to go through those
18 3,000 to knock it down to 384.

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

25 So, if someone's going to say it's

1 undue experimentation to take these 3,000
2 antibodies that the mice produce, these
3 humanized mice produce, and put it in a machine
4 and wait for it to -- at the cost of \$30, that's
5 undue experimentation, that is very odd. It's
6 totally divorced from the nature of the art.

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

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

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

25 So are you saying that if we find

1 undue experimentation with respect to a
2 particular species, you know, that should not be
3 enough to invalidate the patent?

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

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

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

19 MR. LAMKEN: So, in -- in term -- in
20 -- in sort of numerical terms, how -- how many
21 one-offs can you have?

22 If you have so many that it means that
23 you're searching for a needle in a haystack and
24 you don't have instructions on how to do it so
25 that it's -- it is that trial and error for

1 years on end, it's Edison and Consolidated
2 Electric going through every type of, then you
3 would not be enabled, and there's a case called
4 Atlas Powder from the Federal Circuit that
5 explains that.

6 JUSTICE JACKSON: But I thought -- I
7 guess I thought you would have to have the undue
8 experimentation standard apply to every species.

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

18 JUSTICE JACKSON: So what are the
19 categories here?

20 MR. LAMKEN: So, in -- in this case,
21 there isn't evidence before the jury that it
22 really matters whether you bind to two, three,
23 or seven. In fact, Sanofi's own expert
24 testified that it has no correlation, there's no
25 correlation between the number of amino acids

1 that are bound and the blocking. And that's at
2 Court of Appeals Appendix 3787.

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

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

22 JUSTICE JACKSON: I guess I just -- I
23 -- I --

24 MR. LAMKEN: -- the creativity of an
25 art -- the creativity of --

1 JUSTICE JACKSON: Yes, I understand
2 your point, I think, but, I mean, you -- you've
3 -- you've claimed 26, you say there's 300 or
4 something antibodies, and then there's evidence
5 that, you know, millions more can be made.

6 So how is it that you've satisfied
7 enablement by focusing in on a -- on the smaller
8 group?

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

14 JUSTICE JACKSON: With -- without
15 undue experimentation?

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

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

25 JUSTICE JACKSON: And that's in the

1 First -- the Federal Circuit's case law, or are
2 you just saying that right now?

3 MR. LAMKEN: Well, actually, if you
4 look at page 11a of the appendix, where the
5 court quotes a decision called McRO, that's
6 actually the standard the Federal Circuit
7 ordinarily would use but departed from in this
8 case because it was --

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

17 MR. LAMKEN: So I think the parties
18 all agree that the cumulative effort, the idea
19 of reach the full scope, that that cannot be
20 sustained. Everybody agrees on that.

21 I think the next question --

22 JUSTICE KAGAN: And everybody agrees
23 also, I take it from your answers to Justice
24 Gorsuch's question, that there is a requirement
25 that the full scope of the invention has to be

1 embodied?

2 MR. LAMKEN: Enabled.

3 JUSTICE KAGAN: Has to be enabled.

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

5 The content of that is a subject of some
6 disagreement, and then the question, once this
7 Court says --

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

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

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

1 would describe the process --

2 JUSTICE GORSUCH: Put that aside --

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

4 JUSTICE GORSUCH: -- put that aside.

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

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

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

18 MR. LAMKEN: Other than -- no, I don't
19 think beyond that. But I think that the key
20 question on which we all agree and what's
21 actually critically important for this Court to
22 do, there should be no mistake that the court of
23 appeals' decision saying that you reach the full
24 scope or, page 15a, where they do this
25 evaluation and they say the evidence showed that

1 the scope of the claims encompasses millions of
2 candidates, and it would be necessary to first
3 generate and then screen each candidate antibody
4 to determine whether it meets the double
5 function limitations, that's a statement saying
6 you got to be able to make them all. That can't
7 be right.

8 And even having that -- even if
9 there's uncertainty as to what the Federal
10 Circuit meant by that, that uncertainty calls
11 for the Court to bring clarity, because you
12 should -- make no mistake: This is a very
13 damaging decision. It -- the impact is
14 tremendous.

15 You cannot -- the PTAB now has twice
16 invoked the decision for the idea that you have
17 to be able to make them all within a reasonable
18 period of time. There has to be able to do a
19 cumulative scope test.

20 And companies can't invest billions of
21 dollars in new therapies when they confront the
22 risk that their patents will be invalidated
23 based on the cumulative effort that -- necessary
24 to make them all. And it's just why you have,
25 for example, 14 amicus briefs on our side and

1 14 amicus briefs on the other side.

2 JUSTICE GORSUCH: I've got a lot of
3 amicus briefs.

4 MR. LAMKEN: Yes.

5 JUSTICE GORSUCH: I've got so many
6 friends I can hardly stand it.

7 (Laughter.)

8 MR. LAMKEN: It's --it's -- with
9 friends like that, you end up staying up late
10 reading.

11 But the key is, on this, if there's
12 uncertainty about what the Federal Circuit did
13 or are doing, the answer is actually to bring
14 clarity. The case is critically important to
15 industry and at least that.

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

1 hypothetical embodiment that won't work. It's
2 from that perspective. And that means --

3 JUSTICE GORSUCH: Let's --

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

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

16 MR. LAMKEN: So --

17 JUSTICE GORSUCH: But -- but would you
18 want a remand to try again?

19 MR. LAMKEN: -- so, at the very least,
20 we should have a remand so that we try again
21 under the proper standard without the -- reach
22 the full scope standard or try to hypothesize
23 how long it takes to make millions of antibodies
24 and then test each of them.

25 JUSTICE BARRETT: But -- but why? If

1 -- if -- I mean, maybe I misunderstood Justice
2 Gorsuch's question.

3 JUSTICE GORSUCH: I don't think you
4 did.

5 JUSTICE BARRETT: But, if the Federal
6 Circuit got it right, I don't understand why
7 you're saying a remand is in order.

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

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

25 And then, if they have that, they

1 should also say why it matters, why this is
2 something that genuinely impedes skilled
3 artisans from making and using the invention --

4 JUSTICE SOTOMAYOR: Can I quote --

5 MR. LAMKEN: -- because --

6 JUSTICE SOTOMAYOR: -- two sections
7 from the Federal Circuit -- two statements it
8 made, and you tell me whether they're right or
9 wrong.

10 The Federal said -- Circuit said: It
11 was "appropriate" to look at the amount of
12 effort needed to obtain embodiments outside the
13 scope of the disclosed examples.

14 Is that a correct statement of law by
15 this -- Federal Circuit?

16 MR. LAMKEN: So in part.

17 JUSTICE SOTOMAYOR: It said -- no,
18 that's what it said, to look at the amount,
19 appropriate to look at the amount.

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

23 If you're talking about making another
24 embod -- another embodiment that's not
25 specifically characterized --

1 JUSTICE SOTOMAYOR: It said --

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

3 JUSTICE SOTOMAYOR: -- to look at the
4 amount of effort needed to obtain embodiments
5 outside the scope of the disclosed example.

6 MR. LAMKEN: So I think, if it said an
7 embodiment, that would be correct. Embodiments
8 means that you're looking at the -- the full
9 scope or the -- the -- the -- what it called
10 reaching the full scope, and I think that is
11 incorrect. When you get --

12 JUSTICE SOTOMAYOR: All it said, it
13 was appropriate to look at.

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

17 JUSTICE SOTOMAYOR: Why is it appropo
18 -- inappropriate to at least look at it --

19 MR. LAMKEN: To look at --

20 JUSTICE SOTOMAYOR: -- as one of the
21 Wands factors?

22 MR. LAMKEN: Yeah. So the effort to
23 make every single embodiment within the
24 invention simply means that if you have an
25 invention of any scope, it's not going to be

1 enabled. There may be millions of ways to make
2 the James Watt steam engine, but you're not
3 invalidated simply because it would take a long
4 time to make all of those different variants of
5 the steam engine.

6 This Court can do the best service for
7 the Federal Circuit if it does one thing beyond
8 simply saying this cumulative effort standard
9 has no place in the law, and that would be to
10 say, look --

11 JUSTICE SOTOMAYOR: That's fine,
12 counsel.

13 MR. LAMKEN: I'm sorry?

14 JUSTICE SOTOMAYOR: That's fine. You
15 answered my question.

16 MR. LAMKEN: Okay. Thank you.

17 JUSTICE SOTOMAYOR: There's nothing
18 wrong with it. You just don't want them to do a
19 fairly simple one.

20 MR. LAMKEN: No, I think it's -- it's
21 not correct if you're looking at embodiments in
22 the plural. If you're looking at an embodiment
23 in the singular, that would be correct. And
24 what they did wrong was they looked at how long
25 it takes to make the supposed millions. If each

1 of those is in -- individually enabled, you can
2 make each one individually and reliably, test it
3 individually and reliably, that's an enabled
4 invention.

5 How long it takes to make -- to make
6 all of them cumulatively simply has no bearing,
7 and this Court can do a service and bring back
8 to -- the -- the incentives to create these
9 life-saving -- these life-saving inventions by
10 making it clear that that just doesn't have a
11 place, and --

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

14 MR. LAMKEN: I think that by bringing
15 it back to the focus of this Court's cases,
16 which is we're looking at skilled artisans,
17 someone concrete trying to make the invention,
18 and we're looking at reasonableness and not the
19 hypothetical efforts to try and figure out ways
20 to break the invention.

21 And so, if you're going to look at
22 that, you're going to have to show two things if
23 you're going to invalidate a PTO patent. One is
24 you're going to have to show some embodiment,
25 there's got to be something out there, some

1 variant, something, some category that requires
2 undue experimentation to make.

3 And if you have that, you also have to
4 say why it matters to the skilled artisan, how
5 does this really genuinely impede the guy in the
6 lab coat from making and using your invention
7 across its scope.

8 JUSTICE ALITO: Is there something
9 unique about the Federal Circuit's decision in
10 this case, or has it been applying essentially
11 the same approach to the enablement of antibody
12 genus claims since around nine -- 2004?

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

1 So, yes, I think it's been a -- a -- a
2 trajectory as opposed to a point, but this is
3 actually the ultimate point.

4 JUSTICE ALITO: Well, if it isn't --
5 if what they did here isn't fundamentally
6 different from what they've been doing for quite
7 a period of time, would you stand by the
8 suggestion that the Federal Circuit has
9 inhibited research for antibody-based
10 pharmaceuticals?

11 MR. LAMKEN: I think the Federal
12 Circuit has been doing that for some time, but
13 it hasn't been quite so stark or quite so
14 apparent until now. And I think that's why the
15 Lemley article really was catching onto it.

16 But this brings in very stark
17 contrast, stark relief, exactly what the Federal
18 Circuit is doing and why it has gone so far that
19 you just can't invest in antibody research if
20 you can't adequately protect the scope of the
21 antibodies you invented.

22 Amgen had the first antibodies here.
23 Amgen -- before Amgen and before our patent,
24 these were not known antibodies. And we're --
25 our patent teaches everybody how to make each

1 and every antibody they might ever want to make,
2 including the defendants' -- the competitor --
3 the supposed competitor antibodies.

4 And if that's true, there's simply no
5 good reason why you would take away the patent.
6 You don't -- the -- the patent depends on what
7 the skilled artisan can do, not to create a
8 hypothetical of the infringer who says, gee, you
9 know, I can imagine an -- a hypothetical
10 antibody that can't be made.

11 In this Court's cases, like Minerals
12 Separation, they don't hypothesize limits. Like
13 Minerals Separation, the Court didn't
14 hypothesize, you know what, there might be an
15 ore out there for which this is going to be too
16 hard, even though there are infinite varieties
17 of compositions of ores and each presented its
18 own particular difficulties.

19 The Court -- Justice Story in Carver
20 didn't say, gee, you know what, I can imagine a
21 type of cotton for this -- which this might not
22 work. The Court in Mowry didn't say, you know
23 what, there might be some train wheels for which
24 this cooling process won't work.

25 That isn't what the Court does. You

1 look at concrete evidence, what are the skilled
2 artisans doing, is there something here that
3 can't be done, and if there is, you ask if it
4 matters.

5 JUSTICE ALITO: Can you explain how
6 your roadmap differs from the basic research
7 plan that you and your competitors have been
8 using since the mid-2000s when you were all
9 attempting to discover or identify antibodies
10 that bind to PCSK9 and block LDL receptors?

11 MR. LAMKEN: Yes. And I think the
12 first and most critical thing about the roadmap
13 is these two new antibodies that didn't exist
14 before our invention, one that sits a little bit
15 on the left of that -- of the PCSK9, one on the
16 -- little bit on -- on the right of PCSK9.

17 And what those do is they allow you to
18 find everything that will bind to the sweet spot
19 in PCSK9 because they cover it completely.
20 Because the way this is done is you do a
21 competition assay. If one antibody is covering
22 it and it blocks the other antibody from doing
23 it, you know that they're binding to the same
24 spot.

25 By providing these two, that is a

1 shortcut to finding these because you run your
2 competition assays against these two. And
3 that's why in the roadmap the very first step
4 are these two antibodies that didn't previously
5 exist but will lead you, they're your divining
6 rod, your magnetometer or whatever you want to
7 call it to all the antibodies within the claims.

8 CHIEF JUSTICE ROBERTS: Thank you,
9 counsel.

10 Justice Thomas, anything further?

11 JUSTICE THOMAS: Mr. Lamken, several
12 times you referred to invention of the
13 antibodies, and I think I'm somewhat confused as
14 to exactly what your invention is. You said
15 it's not just the 26, but it -- it definitely is
16 not millions. So what is it exactly? Because I
17 do -- we talk about enablement and we talk about
18 someone being able to replicate it, but we're
19 not talking about what has been invented with
20 any particular precision.

21 MR. LAMKEN: Right. And I think the
22 claims are that -- which define the invention,
23 the class of antibodies that bind to a
24 particular spot, that, what's called the sweet
25 spot, and therefore have what is a desired

1 effect, which is blocking this PCSK9 from
2 interacting with the --

3 JUSTICE THOMAS: Yeah, I understand
4 all that, but --

5 MR. LAMKEN: And I think I could
6 clarify a little.

7 JUSTICE THOMAS: -- which ones? I
8 mean --

9 MR. LAMKEN: Yeah, I should clarify.

10 JUSTICE THOMAS: Yeah.

11 MR. LAMKEN: When you say an
12 invention, like the James Watt steam engine, you
13 don't say which variant, which embodiment of the
14 steam engine have you claimed. It's the steam
15 engine, that principle, the invention which
16 cover -- encompasses myriad types of inventions.

17 There might be -- and this Court's
18 cases describe it -- there can be lots and lots
19 of different variations on an invention, but
20 what -- to determine what the invention is, you
21 look at the claim, and the claim tells you what
22 the scope of that invention is here.

23 And the fact that it's described in
24 terms of the way -- binds to a particular
25 location which has been decried as functional,

1 but that actually is an important way of doing
2 things, the antibody science, because it leads
3 to a shape -- a shape that fits into that
4 unusual sweet spot.

5 It's also -- it -- also clear that you
6 can do that because -- because 112(b) -- we're
7 talking about 112(a) right now as that's
8 enablement. But, when you talk about how the
9 patents are claimed, that's a different section
10 of the Patent Act. It's Section 112(b). And it
11 says that the claims have to be -- particularly
12 point out and distinctly claim the subject
13 matter which the invention regards as the
14 invention. That's just not at issue here.

15 The PTO regularly issues patents which
16 have that sort of functional piece that says
17 things that fit in this location or have this
18 characteristic. And the very first --

19 JUSTICE THOMAS: I know you refer to
20 the steam engine, but that's not -- it just
21 seems as though -- I -- I grant you that, it --
22 but it seems as though you're actually trying to
23 patent the use of steam pressure and -- which
24 you could use for almost anything, and -- and
25 that's -- and that makes it very difficult

1 because then you're looking at what can it be
2 used for.

3 So, here, I'm -- I'm still not getting
4 -- if you said we're just patenting the 26 that
5 we have found or the 300 that we have found, I
6 don't think we would be having this discussion,
7 and what I'm trying to understand is what it is
8 that you're patenting beyond the antibodies that
9 are there, those 300 or those 26.

10 MR. LAMKEN: Right. And I think, if
11 you're asking what is the category or the group
12 of meaningfully distinct antibodies that fit in
13 that claim, that are -- fit that claim, we're
14 talking something in the range of 400.

15 But, if the question is different, if
16 it's asking what -- what do you mean when you
17 say the antibodies that bind to a particular
18 sweet spot and therefore block, that category is
19 what we invented. That didn't exist before. We
20 teach the world how to --

21 JUSTICE THOMAS: So you invented the
22 category, so you're not claiming just the
23 antibodies but the whole category of those
24 antibodies?

25 MR. LAMKEN: That -- that is the

1 nature of a -- a genus claim or any claim that
2 has considerable scope. We don't claim just the
3 variants of the steam engine. You categorize
4 the steam engine, and that's entirely
5 legitimate.

6 JUSTICE THOMAS: So let me ask you
7 this question. How do you respond to the
8 example in one of the amicus briefs about the --
9 the -- the complicated lock and that you simply
10 figure out the combinations by trial and error?

11 MR. LAMKEN: Yeah. And I think the
12 answer is, for -- for enablement here, which is
13 the question, the roadmap gives you all of the
14 antibodies that are going to fit to that spot.
15 All the ones that are going to fit into those
16 hills and valleys, the evidence is the roadmap
17 gives them all because, if the mouse has the DNA
18 to produce them and the robust immunization
19 protocol is going to give you something across
20 the full spectrum of the claims, that is within
21 the claims.

22 And I should close -- I should point
23 out that this enhances innovation. Look, the
24 patent means that others aren't going to go in
25 separately -- they're going to look for things

1 that are separately patentable. It pushes them
2 away from sort of copycat antibodies that
3 operate on identical principles and identical
4 ways with identical results.

5 If you truly want different therapies,
6 you protect this sort of patent, and it tells
7 people, well, if you're going to do this sort
8 of -- sort of thing, it has to be better and
9 separately patentable as a result, or it pushes
10 them to completely different nonantibody proced
11 -- treatments.

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

24 CHIEF JUSTICE ROBERTS: Thank you.

25 Justice Alito?

1 Justice Sotomayor?

2 Justice Gorsuch?

3 Justice Kavanaugh?

4 JUSTICE KAVANAUGH: Just a couple
5 things to make sure I'm clear. You said to
6 Justice Gorsuch, I think, that you accept the
7 Federal Circuit precedent in Wands. Are our
8 precedents also precedents that you accept, or
9 are there any that you would say have steered us
10 in the wrong direction as we approach this?

11 MR. LAMKEN: Your Honor, I -- I accept
12 all this Court's precedents, and I think I
13 should be clear about Wands. We think those
14 factors can in individual cases be helpful on
15 the facts, but it's been abstracted to replace
16 what is actually the statutory text. And this
17 Court's approach was just to concretely look at
18 actual examples, the concrete -- look at the
19 skilled artisan, concrete -- look at
20 reasonable -- reasonable enablement, not to look
21 at the abstract hypotheticals of, gee, is there
22 some outer limit that I could find that doesn't
23 -- just no impact on what the skilled artisans
24 really need to do, which is make and use to
25 practice the invention.

1 JUSTICE KAVANAUGH: In the interest of
2 providing clarity, the Solicitor General's brief
3 at pages 14 and 15 had three hypotheticals about
4 cake, stew, and bread. I don't know if you're
5 remembering all three of those hypotheticals,
6 but do you agree with how they presented those,
7 if you remember them?

8 MR. LAMKEN: So I -- I'm having a hard
9 time remembering what they were exactly, but,
10 certainly, if the skilled artisan knows what the
11 ingredients -- what the ratios for the
12 ingredients are for cake, you wouldn't
13 invalidate the patent simply because it doesn't
14 give the ratios. That's something the skilled
15 artisan can provide.

16 And when you're using something -- and
17 sometimes things like that, which are chemical
18 interactions, aren't particularly good analogies
19 when you're dealing with a biological invention,
20 which is the way you make and use this, the way
21 you generate these antibodies isn't by following
22 a -- a cake and bread formula. It's by
23 super-immunizing the mice, taking the results
24 and filtering them down using this high through
25 speed -- this high-throughput process that takes

1 those very quickly down to the ones you desire.

2 And if that gets you every embodiment
3 within the claim or every embodiment that
4 anybody cares about, it's enabled. And someone
5 who has the clear and convincing burden before
6 the jury, it's a critical point, and then, when
7 the jury rules against them, they have the
8 burden of proving that no reasonable juror could
9 think they failed to meet their clear and
10 convincing burden, that's a very high burden,
11 and it means you're going to have to come with
12 something concrete that can't be made or
13 requires undue experimentation and explain why
14 it matters.

15 JUSTICE KAVANAUGH: Thank you.

16 CHIEF JUSTICE ROBERTS: Justice
17 Barrett?

18 JUSTICE BARRETT: Just one question.
19 What if before the jury you have an expert who
20 shows why? I mean, proving the negative would
21 be pretty hard for Sanofi to do, right? So what
22 if you have an expert who can tell the jury this
23 is why the -- the function described would not
24 be capable of producing them all?

25 MR. LAMKEN: Yes. So I think that is

1 one way to do it, and they could even also say
2 it would take undue effort. But, in this case,
3 it's interesting because you have no testimony
4 saying why it would be in principle, on some
5 reasoned basis, harder to make Praluent or the
6 competitor antibodies than what Amgen produced.
7 And, in fact, our expert, Dr. Rees, explained
8 that he thought that even Praluent was among our
9 original 384 because the mouse's DNA can make it
10 and you have a super-immunization protocol,
11 which means you get a robust result across the
12 claims.

13 And so, against that evidence, when
14 they have the burden of proof, they're going to
15 have to explain pretty convincingly to the jury,
16 clear and convincing evidence, why there's
17 something out there that isn't easy enough to
18 make that it doesn't constitute undue
19 experimentation.

20 JUSTICE BARRETT: Thank you.

21 CHIEF JUSTICE ROBERTS: Justice
22 Jackson?

23 JUSTICE JACKSON: So I understand your
24 burden points, but is there evidence in this
25 record that the experimentation required to

1 produce undisclosed species using your roadmap
2 is routine as it --

3 MR. LAMKEN: Yes, Your Honor. It is
4 -- the -- the -- the methods disclosed in
5 the thing -- in the -- in the roadmap are
6 routine as routine can be. This is what skilled
7 artisans have been doing since 1988, and the
8 Wands factors, we said this is routine.
9 Filtering out what they call the hybridomas or
10 what the antibodies that aren't wanted to get
11 the antibodies you want is routine.

12 And I give you one example. So our
13 expert explained that the -- that all these
14 machines that are used for would be in any
15 properly organized lab and would do it rapidly
16 and very quickly, thousands of wells, hundreds
17 of plates, in a very short period of time.
18 That's as routine as routine can be. This is
19 what antibody scientists do.

20 JUSTICE JACKSON: And can I just go
21 back to Justice Thomas's point? So, given the
22 routine nature of this, can you just help me to
23 understand the numbers? So you did this and got
24 26, but you say there are 300.

25 MR. LAMKEN: So the patent itself

1 explains -- and this is on page 236 of the court
2 of appeals appendix -- that when we did around
3 two panels of 10 mice, we got 3,000, which were
4 filtered down to 384. The 26 are something
5 different. The 26 are the ones where we went
6 through and figured out the exact amino acid
7 sequence and then listed them in the patent.

8 And there's a reason why you don't go
9 and do 384 amino acid sequences for every one of
10 them in the patent. First is that patent laws
11 never required you to list all of your
12 embodiments in there. That's just never been a
13 rule. And it's not a rule for good reason. The
14 Patent Act requires you to make -- have your
15 patent be concise. Our patent is already 380
16 pages long with just those 26 amino acids
17 sequences.

18 JUSTICE JACKSON: All right. But
19 isn't the -- is the question whether, starting
20 with the 26, someone without undue
21 experimentation could get to the 384 and then
22 possibly to the 3,000? Is that the way to look
23 at this?

24 MR. LAMKEN: No, Your Honor. I think
25 the -- the 3,000 amount it initially produces,

1 only 384 are going to bind to the sweet spot,
2 and so you don't want to go the reverse
3 direction to the ones that don't bind to the
4 sweet spot, so --

5 JUSTICE JACKSON: All right. But at
6 least to the 384?

7 MR. LAMKEN: Right. So you would go
8 from your 3,000 to your 384, and that's where
9 you stop.

10 Now, if you want to make variants of
11 those that may not be meaningfully distinct, you
12 can do something called conservative
13 substitution, and the patent explains that that
14 is also a routine and well-known way of doing
15 it. You take one of the amino acids --

16 JUSTICE JACKSON: Can I just ask you
17 as a very simple --

18 MR. LAMKEN: Yeah.

19 JUSTICE JACKSON: So you say that you
20 are claiming the class of antibodies that bind
21 to a particular spot and therefore block.
22 That's my sort of --

23 MR. LAMKEN: Mm-hmm.

24 JUSTICE JACKSON: -- shorthand for
25 what you've said. So is that class comprised of

1 384 species or more?

2 MR. LAMKEN: I -- you know, it's
3 somewhere in the 400 range. I couldn't tell you
4 if there's -- that it -- that's exactly 384. I
5 would say that that 384 probably covers the full
6 range of meaningfully distinct antibodies. It
7 was probably --

8 JUSTICE JACKSON: So, when we see
9 millions, someone said millions, you -- you say
10 that's not even a -- a reasonable estimation?

11 MR. LAMKEN: So it's important to --
12 for me that the millions comes from a different
13 way of making additional antibodies. You start
14 with one that works, one of those 26, for
15 example, and you swap out an amino acid or two
16 for one that's very similar according to a table
17 that's in our patent.

18 JUSTICE JACKSON: So would you be
19 claiming those or not?

20 MR. LAMKEN: Yes. So those -- those
21 are fully enabled because it's very routine.
22 The patent describes that it's routine to swap
23 out one amino acid for another that's very
24 similar. And the -- the evidence shows that
25 those routinely work.

1 But, even if it were, you know, you
2 could make millions that way and you could count
3 hypothetically by swapping out every single one
4 of these amino acids along this chain, you can
5 count --

6 JUSTICE JACKSON: So just to be clear,
7 you're -- beyond the 400, you claim all of the
8 swaps?

9 MR. LAMKEN: Yeah. So those swaps are
10 all enabled. They're all within the claims.
11 There's two pieces to it, though. First, an
12 antibody scientist isn't going to look at that
13 near-identical twin and say that's a different
14 antibody. That's -- they're 99.9 percent
15 similar. That's going to be basically the same
16 antibody.

17 But, even if you want to consider that
18 a different antibody, it's enabled because
19 everybody is able to do that routine process, a
20 swapping out the amino acid, everybody. If you
21 want to test it to confirm that it works, you --
22 probably not necessary because the evidence
23 showed that they all reliably work, Sanofi
24 didn't identify a single one that doesn't work,
25 that somehow breaks its ability to bind. If you

1 want to do testing, that's routine.

2 So any one you want to make from those
3 26 by doing an amino acid swap, you can make it.
4 And that is the -- that is clearly enablement.
5 That's what you're looking for, the ability to
6 make the next one and always succeed in making
7 it and it's routine across the board.

8 JUSTICE JACKSON: And you think that
9 gives -- gives others enough notice as to what
10 you've claimed? I mean, to the extent that you
11 could swap out any of the antibodies and
12 suddenly we're in the millions, I guess I had
13 understood the patent also was -- to some
14 extent, your specifications were about notice to
15 other people and other inventors.

16 MR. LAMKEN: So, the -- the --
17 certainly, it's very easy to determine whether
18 or not you're inside or outside the claims, and
19 there's two different techniques you could use.
20 One was I talk about was the competition assays.
21 If you compete with something that binds to the
22 sweet spot, and if you can't bind when that's
23 already present on the sweet spot, then you're
24 within the claims because you also bind to the
25 sweet spots.

1 There's also something called alanine
2 scanning, and alanine scanning in 2008 was very
3 common, and it not only tells you if you bind to
4 the sweet spot; it actually tells you the
5 specific residues that you bind to in the sweet
6 spot. So, yes, we --

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

9 MR. LAMKEN: Well, yeah. You -- you
10 would have to do that, but it is routine to do
11 that and was routine in 2008. And it's not at
12 all -- when you're dealing with some very --
13 something very small, you can't always just sort
14 of hold it up and look at it to see if it
15 matches. You're going to have to do a little
16 bit of work to make sure that it's --

17 JUSTICE JACKSON: All right.

18 MR. LAMKEN: But that's routine.

19 JUSTICE JACKSON: Thank you.

20 CHIEF JUSTICE ROBERTS: Thank you,
21 counsel.

22 MR. LAMKEN: Thank you.

23

24

25

1 CHIEF JUSTICE ROBERTS: Mr. Clement.

2 ORAL ARGUMENT OF PAUL D. CLEMENT

3 ON BEHALF OF THE RESPONDENTS

4 MR. CLEMENT: Mr. Chief Justice, and
5 may it please the Court:

6 Section 112 sets forth the heart of
7 the patent bargain: The more you claim, the
8 more you need to enable. If you claim a lot and
9 enable a little, the public is short-changed and
10 the patent is invalid. The Federal Circuit has
11 long enforced that basic principle by requiring
12 the patentee to enable the full scope of the
13 patent without undue experimentation.

14 Amgen does not take issue with that
15 test, with the Wands factors, I think, or the
16 vast bulk of the Federal Circuit's enablement
17 precedent. But the full scope test, which they
18 don't take issue with at least as I understand
19 it, dooms their claims here, as well illustrated
20 by the chart on page 15 of the red brief.

21 Amgen claims antibodies that -- that
22 bind on 16 residues in the epitope, but their --
23 their specification does not enable skilled
24 artisans to reliably produce them when they bind
25 at 10 or more. And those aren't hypothetical

1 examples. Those are the competitive antibodies
2 that independently develop by their competitors
3 in the four right-hand columns. They're
4 disclosed embodiments, that 26 do not bind at
5 more than nine residues. They've overclaimed,
6 they've underenabled, their patent is invalid.

7 This Court has long applied the same
8 principle in *Morse*, in *Lamp*, and in *Holland*
9 *Furniture*. Samuel Morse invented the telegraph.
10 He did not invent the fax machine. That is why
11 this Court correctly rejected the final broad
12 functional claim in his patent.

13 Thomas Edison discovered the key to
14 incandescent light, but we'd all be fumbling
15 around in the dark if this Court had not
16 invalidated the broad unenabled claims in *Sawyer*
17 and *Man's* patent in the *Lamp* case.

18 The stakes here are comparable.
19 Pfizer independently developed its own antibody
20 and patented it by amino acid sequence. It
21 seemed like a promising candidate, but it failed
22 in clinical testing.

23 If Pfizer had followed Amgen's lead
24 and claimed the whole genus for its own, we
25 would have no large molecule therapy for

1 cholesterol. We're better off with two
2 competing independently developed therapies.

3 I welcome the Court's questions.

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

7 You -- you made the point that the
8 more you claim, the more you have to enable.
9 And I think it's important to -- since starting
10 point is what you claim, I'd like to have a good
11 sense of exactly what we are talking about.

12 MR. CLEMENT: So the numbers don't
13 lie, Justice Thomas. I mean, my friend likes to
14 come up with that 384 number. That is not the
15 scope of what they have claimed as their
16 invention.

17 The numbers don't lie. They have
18 claimed millions and millions of antibodies.
19 And their reassurance that, don't worry, all of
20 those millions that you get with conservative
21 substitution, they're all going to work the
22 same, that's inconsistent with their own
23 expert's testimony in the court below.

24 Dr. Rees and Dr. Petsko testified to
25 this. Dr. Petsko, their expert, Court of Appeal

1 -- Appeals Appendix page 3891, says, if you
2 change one thing in the antibody sequence, you
3 have to retest it. You have to go through that
4 whole experimental process again to confirm that
5 it binds in the right place.

6 And, I mean, look, it -- I -- I can
7 imagine this is frustrating because Mr. Lamken
8 and I are going to tell you different things
9 about the way the science works here. Please
10 don't take my word for it. Please don't take
11 Mr. Lamken's word for it.

12 I urge you to read Sir -- Sir Gregory
13 Winter's amicus brief. He has gotten a Nobel
14 Prize for his contributions to this field, and
15 he will tell you that you can't look at function
16 -- and part of the problem here is these are
17 purely functional claims. You can't look at
18 function and say, oh, that tells me about the
19 structure of the antibodies that are going to
20 bind and block in the right way, and you also
21 can't look at the structure of one antibody and
22 say, oh, well, if I just tweak it a little bit,
23 it's going to do exactly the same thing.

24 Sir Gregory Winter doesn't think that.
25 Their own expert doesn't think that.

1 And if I could try to address one
2 thing that's come up. I do not agree with Mr.
3 Lamken that everybody here says that the
4 cumulative effort is irrelevant.

5 It is not a -- an appropriate test
6 standing alone, which is why the Federal Circuit
7 didn't apply it as the test. It never even used
8 the word "cumulative." But, as Justice
9 Sotomayor in her question said, is it an
10 appropriate consideration? Yes, it's an
11 appropriate consideration.

12 And if I could illustrate that with a
13 hypothetical. Here's a situation where the
14 cumulative effort to exhaust the species would
15 not be particularly relevant.

16 If I came up with a brand-spanking-new
17 process for making paint and I claimed that
18 process in all the paints that were produced as
19 a result of that as new compositions of matter
20 and one step in my process patent was add
21 pigment for the desired color, well, then a
22 skilled artisan would be able to use that, an
23 actual roadmap, and they would say, all right, I
24 want robin egg blue, and they could produce it
25 every time. And if they wanted chartreuse

1 instead, they could produce it anytime.

2 Now, obviously, there's a lot of
3 colors in the rainbow, so to actually produce
4 every one of them would take a lot of time and
5 it wouldn't invalidate the patent because it
6 enables the skilled artisan to produce what they
7 want every single time. But this patent does
8 not work this way. What they give you is their
9 roadmap is trial and error.

10 JUSTICE GORSUCH: I -- I -- Mr.
11 Clement, I appreciate that clarification, but,
12 as I understand it, there is a point of
13 agreement with respect to cumulative effort,
14 that that should not be dispositive.

15 MR. CLEMENT: Absolutely --

16 JUSTICE GORSUCH: Is that right?

17 MR. CLEMENT: -- Justice Gorsuch.

18 JUSTICE GORSUCH: Okay. Okay.

19 MR. CLEMENT: And that's not just
20 to --

21 JUSTICE GORSUCH: No, I -- no, I --
22 that's that's great.

23 MR. CLEMENT: Yeah.

24 JUSTICE GORSUCH: That's enough.

25 The other -- the other point Mr.

1 Lamken suggested that we -- we should clarify is
2 that -- that there has to be a reasonable
3 embodiment, not an embodiment -- enablement,
4 sorry -- in every instance, that it just needs
5 to be reasonable.

6 Do you agree with that as well? I
7 don't know much turns on it in your case because
8 millions are millions and -- and reasonableness
9 is going to be somewhere -- you -- you could
10 still prevail under that standard, but do -- do
11 you -- do you agree with him that it's
12 reasonable enable -- enablement, not -- not down
13 to every jot and tittle in every --

14 MR. CLEMENT: Yes. I think reasonable
15 is just maybe the flip side of undue
16 experimentation.

17 JUSTICE GORSUCH: Yeah. Exactly.

18 MR. CLEMENT: Right, so --

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

21 MR. CLEMENT: Well --

22 JUSTICE GORSUCH: -- for -- for this
23 Court?

24 MR. CLEMENT: -- nothing, except maybe
25 a DIG.

1 (Laughter.)

2 MR. CLEMENT: I mean, that -- that
3 seems -- and -- and, honestly --

4 JUSTICE KAGAN: And, Mr. Clement, is
5 there any other point of law that you feel as
6 though you and Mr. Lamken are in disagreement
7 on?

8 MR. CLEMENT: Well, I -- I think there
9 is a disagreement as follows.

10 Mr. Lamken thinks it's very helpful to
11 his case that somebody who runs the -- the
12 experiments necessary in the roadmap is going to
13 produce an antibody within the range every time.

14 And I think that can't be right, it
15 can't be particularly interesting, because that
16 rewards breadth. And what -- what skilled
17 artisans want is not to randomly generate
18 something within the broad range that's claimed,
19 but they want to be able to pick a specific
20 embodiment, not a hypothetical one but a
21 specific one.

22 So just to give you a concrete
23 example, I mean, if -- if they claimed a 15
24 binder, there are 15 binders in the real world.
25 If you want to use their roadmap to produce a 15

1 binder, you are consigned to trial and error.

2 JUSTICE KAGAN: So I understand that
3 as a view of the inadequacy of their roadmap,
4 but are you trying to suggest that it's
5 reflective of a disagreement about what the
6 legal principles or legal standards are?

7 MR. CLEMENT: I -- I think it must be,
8 because Mr. Lamken is a very smart man, and he
9 makes a big deal out of the fact that, don't
10 worry, this produces something in the range
11 every time, and skilled artisans can produce
12 something in the range every time, and if you
13 give them an infinite amount of time, they will
14 produce everything in the range.

15 And he seems to think that that's good
16 enough as a matter of law to enable his patent.
17 And I think, wow, that is not close to good
18 enough. That consigns people skilled in the art
19 to Sisyphean tasks forever, and it's not what
20 they do.

21 And one of the things I find
22 particularly persuasive about Sir Gregory
23 Winter's brief is he explains this roadmap is
24 not a shortcut at all. It just describes the
25 routine processes that people use to make

1 independent inventions, the same process that
2 Pfizer used, that Merck used, that we use to get
3 our own independent antibodies, and then it adds
4 additional steps that somebody skilled in the
5 art wouldn't want to do and are just basically
6 an additional step, additional test they have to
7 run to see whether they infringe, because the
8 people skilled in the art don't really care
9 where it binds. They -- they care that it
10 blocks.

11 But figuring out where it binds,
12 whether it binds to the 15 that they've claimed
13 as part of their roadmap, is actually a useless
14 process that slows down the artisan in the
15 field.

16 And -- and I do think there's an
17 important point that shouldn't get lost in all
18 of this. Part of the reason, I agree, this
19 isn't a close case is because what they are
20 trying to do, there's no meaningful structure in
21 these genus claims, and the structure they've
22 given is an elaborate description of the
23 epitope, the 15 or 16 residues on the PCSK9
24 where you want the antibodies to -- to -- to
25 bind.

1 The problem is and the reason they
2 can't claim that as an invention is because of
3 this Court's Myriad case, because that exist in
4 nature. These antibodies are independently
5 generated by scientists, but the antigen and the
6 epitope, all of that exists, in -- you know, in
7 -- in nature.

8 And so what you have before you is a
9 particularly pernicious kind of claim because
10 not only is it a full -- a -- a genus claim
11 that's purely functional or double functional,
12 as the Federal Circuit described it, but it's
13 really a workaround of Myriad because,
14 basically, they're pointing to something that
15 exists in nature and they're saying, we claim
16 everything that works to bind there and block.

17 JUSTICE JACKSON: Mr. -- Mr. Clement
18 --

19 JUSTICE ALITO: Mr. Clement, could
20 I -- I just take you back to what you said about
21 cumulative time and effort? Is time and effort
22 relevant at all, or is it the nature of the
23 effort that's required?

24 MR. CLEMENT: So --

25 JUSTICE ALITO: You say cumulative

1 time and effort is -- is not the test, but at
2 the other extreme is the relevant factor, the
3 effort necessary to make and use any individual
4 embodiment. So just -- would you just clarify
5 what -- what is the relevance of time and
6 effort?

7 MR. CLEMENT: So I -- I think they are
8 both relevant. I actually agree with Mr. Lamken
9 that they're both sort of relevant evidence that
10 gets to the ultimate inquiry, which is, is there
11 undue experimentation?

12 And in some respects, the more
13 important word isn't "undue;" it's
14 "experimentation." And let me just contrast the
15 particular claims that go by antibody sequence,
16 our claim to Praluent, their claim to Repatha,
17 the Pfizer claims. They give you the amino acid
18 sequence. And so somebody -- a skilled artisan
19 every time doesn't have to really engage in any
20 independent experimentation. They can look at
21 it. They can reproduce the amino acid sequence.
22 Regardless of how time much it takes, there's no
23 experimentation in there at all.

24 But, under their broad genus claims,
25 you can't do that. You can do it as to the 26,

1 and we'll -- we'll give them the 26, but, as the
2 chart on page 15 shows, we're not even close to
3 infringing the 26. We are structurally
4 fundamentally different.

5 So, to get to the genus, what you do
6 is you go in a lab and you start injecting mice
7 and you inject them with the anti -- the -- the
8 antigen, PCSK9, and then you get a bunch of
9 antibodies that are produced. Then you pour
10 them over and see which ones bind on PCSK9. And
11 you might be able to test them for blocking.
12 And then --

13 JUSTICE JACKSON: But, Mr. -- Mr.
14 Clement, isn't the -- isn't the issue whether or
15 not that is not routine or that's undue? I
16 mean, you sort of took undue out of it, but, as
17 I read the test or understood the test, some
18 experimentation by the skilled artist is
19 allowed. So how do we know whether the steps
20 that you're talking about are undue for the
21 purpose of this -- of this standard?

22 MR. CLEMENT: Well, here's -- here's
23 the thing, Just -- Justice Jackson: I think the
24 problem is certain -- in -- in certain
25 scientific areas, a -- a form of experimentation

1 is routine, but it's still experimentation, and
2 it's still not what you're supposed to get in a
3 -- when a patent, you're not supposed to just
4 say, all right, do what we did, start from
5 scratch, start with mice --

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

15 MR. CLEMENT: And -- and -- and -- and
16 then I must have misspoke, because that is not
17 my position at all. And just in --

18 JUSTICE JACKSON: Isn't that what
19 predictability is about? And isn't the work of
20 predictability in your argument that you say,
21 unless you can predictably, by doing what the
22 roadmap says, reach this particular result, the
23 patent is invalid?

24 MR. CLEMENT: No. Predictability goes
25 to experimentation and undue. If you have

1 something that enables the skilled artisan to
2 pick essentially any point in the genus, as in
3 my paint example. I want a particular shade of
4 paint. I can produce that one very readily. I
5 mean, maybe I have to do a little bit of mixing
6 with the pigment, but that doesn't -- that's not
7 the kind of thing -- that's the reasonableness.
8 That's not a problem.

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

21 And I don't think it's an accident --
22 just to go to this Court's cases and the cases
23 my friend relies on, I don't think it's an
24 accident that all his best cases are process
25 patents because, if you think about a process

1 patent, it's often going to be the case that if
2 it's -- you know, if you have a process patent
3 for making bricks or for cooling railroad tires,
4 well, if it's a humid day, it might react a
5 little bit differently. You might have to tweak
6 it a little bit to get the mix right on a humid
7 day that's different from a day when it's zero
8 humidity. And, in the same way, if it's 90
9 degrees out, maybe your cooling process for the
10 -- the wheels differs if it's 30 degrees out.

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

14 But it seems quite strange to me that
15 when you're claiming compositions of matter and
16 millions and millions of them, that the only way
17 that you can get there is to essentially
18 replicate the experimental process that the four
19 innovative companies went through to come up
20 with these in the first place, plus, as Sir
21 Gregory Winter says, an additional step that
22 doesn't help anybody but just ends up taking
23 more time because you're basically testing as to
24 whether or not you infringe their patent.

25 JUSTICE SOTOMAYOR: Mr. Clement, could

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

11 You're saying there's more to this
12 process than that. So break it down to me into
13 steps so that I can understand why you're saying
14 that this is undue. I -- I understand it with
15 the paint.

16 MR. CLEMENT: Right.

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

19 MR. CLEMENT: So, in -- in this
20 process, let me just hypothetically say what
21 would happen if I wanted to say -- if I were a
22 scientist and I wanted to say I want to use
23 their roadmap to produce a 15 binder because I
24 want to test whether the 15 binder is any better
25 than the 7 binder, which is their Repatha, and I

1 want to be able to test that. I'm a scientist.

2 So here's what I would have to do.

3 JUSTICE SOTOMAYOR: All right.

4 MR. CLEMENT: I would have to --

5 JUSTICE SOTOMAYOR: So the difference
6 is, in his way of doing this, he's not telling
7 me how to find his -- he's not going to give me
8 a way to get to his drug without undue
9 experimentation? Is that your point?

10 MR. CLEMENT: That is my point. It's
11 not my only point --

12 JUSTICE SOTOMAYOR: Okay.

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

20 JUSTICE SOTOMAYOR: Well, I don't
21 think we care about what people want. We care
22 about what's being claimed and --

23 MR. CLEMENT: Okay.

24 JUSTICE SOTOMAYOR: Okay. So --

25 MR. CLEMENT: But -- but he's the one

1 actually who cares what a skilled artisan wants.

2 JUSTICE SOTOMAYOR: Okay.

3 MR. CLEMENT: And what's being claimed
4 is this entire genus. And if I want to pick a
5 spot --

6 JUSTICE SOTOMAYOR: So go back and
7 tell me what --

8 MR. CLEMENT: Yep.

9 JUSTICE SOTOMAYOR: -- steps you have
10 to do to get to him.

11 MR. CLEMENT: Okay. So I have to
12 start by injecting mice --

13 JUSTICE SOTOMAYOR: To his --

14 MR. CLEMENT: -- which is not just
15 done with, like, you know, computers. It's done
16 by scientists in the lab. They inject the mice
17 with the antigen. Then they get --

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

20 (Laughter.)

21 MR. CLEMENT: Okay. Well -- probably
22 more skilled than I am. But -- so -- so -- so
23 you get the results of that. You get a whole
24 bunch of antibodies. And then you have to
25 figure out which ones are essentially candidates

1 to bind on PCSK9.

2 JUSTICE SOTOMAYOR: So does a computer
3 do that? And why is it undue?

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

5 JUSTICE SOTOMAYOR: Do they have to
6 look under a microscope? What do they have to
7 do?

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

16 And that is a time-consuming process.
17 It is not just a simple matter of, like, running
18 a computer. Again, people do that in the labs.
19 I don't understand all the details, to be -- to
20 be candid.

21 But -- but -- but here's what I do
22 understand, is, at that process, let's say they
23 get, you know, 26 or 384. Then they -- then --
24 then, if what they wanted was a 15 binder to
25 start with, they've got to figure out whether

1 they got one, and there's an excellent chance
2 that they didn't get one of those at all.

3 JUSTICE GORSUCH: Can I ask this
4 question?

5 MR. CLEMENT: Sure.

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

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

10 JUSTICE GORSUCH: No? Why?

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

17 JUSTICE GORSUCH: Well, let me -- let
18 me just pause there for a second. I understand
19 completely your argument -- well, I think I
20 understand completely, let me put it that way,
21 your argument about conservative substitution
22 and the potential millions of variants and --
23 and the trial and error that's required there.

24 I'm not sure I understand how that
25 applies to the 384.

1 MR. CLEMENT: So, like, honestly, the
2 384, I just have to take Mr. Lamken's word for
3 it. I mean, he says that, oh, Praluent might
4 have been in there. I mean, please. If
5 Praluent were in there, their scientists would
6 have produced that evidence.

7 And if you look at the chart at page
8 15, it is not a surprise. I assume that the 26
9 --

10 JUSTICE GORSUCH: That's a -- that's a
11 nice demonstrative.

12 MR. CLEMENT: Yeah.

13 JUSTICE GORSUCH: I've got it.

14 MR. CLEMENT: Yeah.

15 JUSTICE GORSUCH: Yeah.

16 MR. CLEMENT: It -- it -- I assume the
17 26 were -- must have been representative of the
18 384, right? Otherwise, why not make one of
19 those other 384, one -- the ones you do by amino
20 acid sequence.

21 So, if you look at the 26 that they
22 give you the amino acid sequence, they look
23 structurally nothing like the four antibodies
24 that were independently developed by other
25 companies. That is very striking to me.

1 JUSTICE GORSUCH: Thank you.

2 CHIEF JUSTICE ROBERTS: Justice
3 Thomas?

4 Justice Alito?

5 Justice Sotomayor? No?

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

13 So why -- why is it that Professor
14 Lemley is wrong in your view?

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

22 Now it may be that in this particular
23 area of antibody science, given the current
24 state of the science, that you may not have an
25 ability to functionally claim a genus, and

1 that's kind of -- at -- at some level nobody's
2 fault. It's just the way the science works.

3 And, personally, I think that's great,
4 and -- because what it does is it allows
5 different companies to independently develop
6 different large molecule therapies to deal with
7 the same malady.

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

15 I mean, I -- I -- I want to make clear
16 my friend and I do disagree on a factual matter.
17 He wants you to believe that everything in this
18 genus is fungible. And, of course, it's
19 fungible with respect to the two functions
20 claimed by definition, but it's not -- they're
21 not functional. They are different compositions
22 of matter. They can work very different ways.
23 Somebody can tolerate one and not the other.

24 And the best evidence of that is the
25 Pfizer experience, right? The Pfizer antigen --

1 antibody is in this genus, and when it went into
2 clinical testing, it fell down.

3 So, if -- if Amgen's had fallen down
4 for the same reasons that -- that -- that
5 Pfizer's did, we'd be without the treatment
6 because it claimed the whole genus and --

7 JUSTICE KAGAN: So -- so --

8 MR. CLEMENT: -- they wouldn't enable
9 it.

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

18 I hear you saying that he might be
19 right about the Federal Circuit's test
20 invalidating most of these patents, but that's
21 okay because we shouldn't want these patents
22 around.

23 MR. CLEMENT: You know, the truth has
24 a way of leaking out. I mean, yeah, I mean, I
25 am saying that --

1 (Laughter.)

2 MR. CLEMENT: -- because -- because --
3 because I think functional genus claims are
4 terrible. I think they retard the science. And
5 I don't think you have to look beyond this
6 Court's cases.

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

15 And look at the Lamp case. I mean,
16 they claimed the entire genus of all fibrous
17 text -- textiles. Turns out the one that they
18 discovered didn't work very well and was a lousy
19 lamp. And Edison had to go through all this
20 different work to find out that there actually
21 is like a subgenus. It's called bamboo. That
22 stuff all works and it all has the same
23 structurally common feature of really parallel
24 fibers. And that's the way -- I'm not against
25 all genus claims, but you got to get some

1 structure in there.

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

12 JUSTICE KAGAN: Thank you.

13 CHIEF JUSTICE ROBERTS: Justice
14 Gorsuch?

15 Justice Kavanaugh?

16 Justice Barrett?

17 Justice Jackson?

18 JUSTICE JACKSON: So there are some
19 fields where there is a degree of
20 unpredictability or randomness, and I guess I'm
21 just a little worried that your view on this
22 would mean that we would not be able to have
23 patents where some experimentation was required.

24 Can you just speak to that a little
25 bit more? I mean, again, I hear you in some

1 ways suggesting that the specification has to
2 absolutely get a skilled artisan to the endpoint
3 of every species in the genus a hundred percent
4 of the time exactly as indicated.

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

14 MR. CLEMENT: So I -- I think what I
15 would say is I do think the test should be undue
16 experimentation. It should not be zero
17 tolerance, no experimentation.

18 JUSTICE JACKSON: Okay.

19 MR. CLEMENT: But I also do think, if
20 you're going to start with the text, which I
21 assume you always do, then what you would say is
22 you start with the idea that you have to make
23 and use the invention, and the invention is
24 defined by the full -- by the -- by the claims
25 in the invention, and -- and, in that sense,

1 Amgen's the master of their own claims, the
2 master of their own patent. And then you look
3 at those, and if they claim a lot, I mean, you
4 -- you have to enable the full scope of what you
5 claim.

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

13 He wants to say, oh, well, this --
14 these are just hypothesized things that couldn't
15 be invented here given the current state of the
16 science.

17 With all due respect, balderdash. I
18 mean, there are four disclosed patents here with
19 anti -- amino acid sequence that the competitors
20 have made that are on the chart.

21 Now, if you are a skilled artisan in
22 the field and you want to produce the 15 binder
23 that Pfizer did, you can produce it a hundred
24 percent of the time by duplicating the amino
25 acid sequence.

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

8 JUSTICE JACKSON: All right. One --

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

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

17 And I had understood, in terms of the
18 way the -- the burdens work, a little
19 complicated, but that you had to have evidence
20 disproving that by clear and convincing
21 evidence.

22 So do you? And, if so, what is your
23 evidence?

24 MR. CLEMENT: So I -- I appreciate the
25 question, and this really goes back to the

1 suggestion that there is sort of a lurking legal
2 difference here, because the reason I don't have
3 evidence that says that that claim is not true
4 is because it implicitly says if you take
5 forever. I can't tell you that if you run these
6 experiments, you won't eventually get Praluent,
7 Pfizer, the Merck embodiments, but, unlike the
8 patent, where you can start and say, all right, I
9 want -- I want to test that, so I'm going to --
10 I'm going to reproduce that. You can't do that.

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

16 CHIEF JUSTICE ROBERTS: Thank you,
17 counsel.

18 MR. CLEMENT: Thank you.

19 CHIEF JUSTICE ROBERTS: Ms. Sinzduk?

20 ORAL ARGUMENT OF COLLEEN R. SINZDAK

21 FOR THE UNITED STATES, AS AMICUS CURIAE,
22 SUPPORTING THE RESPONDENTS

23 MS. SINZDAK: Mr. Chief Justice, and
24 may it please the Court:

25 I think I want to pick up where

1 Respondents' counsel left off with a very
2 important fact, and that is that if an antibody
3 has already been created, a scientist who wants
4 to make that antibody is not going to go into a
5 laboratory and inoculate a mouse.

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

16 And I also do not want you to take
17 my -- my word on the science, but I do want you
18 to take the expert testimony on the science.
19 And I think that if you look at Trial Transcript
20 20 -- 225, you will see that -- that
21 Respondents' expert explained that the amino
22 acid sequence is the recipe.

23 If you look at the Winter brief at 14,
24 it explains that the amino acid sequence is the
25 recipe.

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

8 So the reason here, just on the -- on
9 the clear facts that this is not an enabled
10 genus, is that they have not given the
11 information that a person skilled in the art
12 would need to make and use all of the antibodies
13 within the genus. It really is that simple.

14 And I think that we need to be very
15 careful about when we hear claims that this is
16 complicated science, and we need to start going
17 beyond the sort of -- the basic text that says
18 you have to be able to make and use the
19 invention. We have to start relaxing the rules,
20 and we have to say not can you make and use
21 every antibody within the genus, but, oh, do you
22 really need a particular antibody? You know,
23 does it really matter, I think, is what
24 Petitioners' counsel said.

25 It is very dangerous, I think, to

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

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

21 And, here, we know that the
22 Respondents, they built a different mousetrap,
23 right? That their antibody, it binds to
24 different parts of the antigen. So it is
25 different. It is not simply the same.

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

11 And Amgen says we can't use the
12 doctrine of equivalents here, and the reason is
13 because they're not equivalent, and because
14 they're not equivalent, you have to enable all
15 of the different antibodies.

16 So, again, this is just the basic
17 principles. It is the enablement requirement
18 that has been in the law since the beginning.

19 And I think, Justice Kagan, you said,
20 well -- well, actually, Professor Lem -- Lemley
21 is very worried that this enablement requirement
22 is going to harm innovation.

23 But Professor Lemley has a new article
24 from 2023, Yale Law Journal, which is called
25 "The Antibody Patent Paradox." And in that, he

1 says, you know, it doesn't look like these
2 antibody patents -- it doesn't look like these
3 genus patents are enabled, but there is this
4 doctrine of equivalents, and maybe it would take
5 care of all of these innovation problems.

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

14 So I think there are some concerns
15 going on with -- with the enablement
16 requirement. I still actually think that the --
17 the concerns that Lemley is expressing can be
18 dealt with through the doctrine of equivalents,
19 and I can explain a little more, I -- what I
20 think is happening there with respect to
21 chemical genuses. But, whether you think that's
22 true or not, it's simply an entirely different
23 question.

24 I think, Justice Jackson, you were
25 talking a little bit about the predictability

1 and this is an unpredictable area of -- of -- of
2 -- of science and how are we going to deal with
3 those sorts of things.

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

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

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

21 And when we kind of make these
22 predictions, you can stifle innovation. And I
23 think this is another sort of response to the
24 Lemley brief. What happens when you allow a
25 genus patent that will -- that -- that -- that

1 -- that will -- will cover not just something
2 that has been invented but also things that have
3 not yet been made and used is that nobody else
4 has the incentive to go out and make and use
5 them.

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

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

21 MS. SINZDAK: Sure.

22 JUSTICE GORSUCH: You -- you -- you --
23 you've emphasized full enablement, and that's
24 certainly what Wood, for example, says from this
25 Court. But at -- at least your -- your

1 colleagues both seem to suggest that there might
2 be some elbow room, non curat lex room in there
3 somewhere, reasonableness. What do you think?
4 What does the government think?

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

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

24 JUSTICE GORSUCH: Okay.

25 MS. SINZDAK: So I think there you

1 would have a little bit of reasonableness.

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

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

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

23 MS. SINZDAK: No.

24 JUSTICE GORSUCH: Okay.

25 MS. SINZDAK: It -- it certainly would

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

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

24 And it's not even -- they're not only
25 claiming antibodies made by mice; they're

1 claiming these antibodies that bind and block
2 made through any process.

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

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

1 conservative substitution, that might -- I -- I
2 think what he was saying is that, you know,
3 that -- that's -- that's in addition to those
4 400.

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

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

17 MS. SINZDAK: I did not hear anything.

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

1 investment.

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

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

16 CHIEF JUSTICE ROBERTS: Justice
17 Thomas?

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

22 It seems as though, as Mr. Clement
23 said, that the broader -- the more you claim,
24 the more on -- you must focus on the enablement
25 analysis. And you -- I don't think you

1 commented on that.

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

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

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

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

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

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

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

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

25 But, if you say, no, it doesn't

1 matter, you can claim all of those anyway,
2 there's less incentive to find that, sort of
3 that -- that magic key, which I should not say
4 magic, it's science.

5 (Laughter.)

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

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

14 MS. SINZDAK: So --

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

19 MS. SINZDAK: So I -- I think, first
20 of all, you -- you could DIG the case. We do
21 not think that the Federal Circuit said anything
22 wrong here. I think that some of the arguments
23 that we're hearing from Petitioners suggest that
24 it might be useful to clarify that you really do
25 need to enable each of the different embodiments

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

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

15 CHIEF JUSTICE ROBERTS: Justice Kagan?
16 Justice Gorsuch?

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

1 uncertainty about the legal standard, and then
2 everyone would know it's up to Congress.

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

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

25 JUSTICE KAVANAUGH: Thank you.

1 CHIEF JUSTICE ROBERTS: Justice

2 Barrett?

3 Justice Jackson?

4 Thank you, counsel.

5 Rebuttal, Mr. Lamken?

6 REBUTTAL ARGUMENT OF JEFFREY A. LAMKEN

7 ON BEHALF OF THE PETITIONERS

8 MR. LAMKEN: Thank you.

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

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

25 And all this tells me that the bottom

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

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

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

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

1 Each of those is enabled.

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

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

22 With respect to Morse's eighth claim,
23 yes, everybody forgets about Morse's seventh
24 claim, and Morse's seventh claim was, in effect,
25 you use electromagnetism using -- to produce the

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

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

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

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

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

24 The roadmap is fully enabling because
25 you can come up with that 27th, the 28th, or the

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

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

17 CHIEF JUSTICE ROBERTS: A minute.

18 MR. LAMKEN: Thank you so much.

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

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

4 Thank you, Your Honor.

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

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

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