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P R O C E E D I N G S

(10:05 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in Case 21-757, Amgen versus Sanofi.

Mr. Lamken.

ORAL ARGUMENT OF JEFFREY A. LAMKEN
ON BEHALF OF THE PETITIONERS

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

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

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

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

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

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

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

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

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

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

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

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

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

1 the -- the antibody.

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

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

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

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

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

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

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

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

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

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

1 post-filing discovery of more?

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

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

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

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

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

20 MR. LAMKEN: Well, Justice --

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

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

3 JUSTICE SOTOMAYOR: Or the method?

4 MR. LAMKEN: The -- yeah, the 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 super
16 immunization protocol --

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

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

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

1 MR. LAMKEN: Yeah.

2 JUSTICE SOTOMAYOR: Sixteen, yes.

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

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

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

1 the same, and --

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

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

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

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

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

20 MR. LAMKEN: Fair.

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

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

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

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

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

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

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

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

1 abstracted and tend to replace what really you
2 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 as the standard but not when
11 they don't.

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

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

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

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

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

9 JUSTICE GORSUCH: Well, I understand
10 --

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

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

15 (Laughter.)

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

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

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

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

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

5 JUSTICE GORSUCH: Thank you.

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

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

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

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

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

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

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

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

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

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

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

10 CHIEF JUSTICE ROBERTS: Well --

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

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

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

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

23 MR. LAMKEN: I'm sorry?

24 JUSTICE SOTOMAYOR: Then continue with
25 Justice --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So, in a case like this, where you

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

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

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

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

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

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

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

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

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

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

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

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

25 MR. LAMKEN: Well, actually, if you

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

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

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

17 I think the next question --

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

23 MR. LAMKEN: Enabled.

24 JUSTICE KAGAN: Has to be enabled.

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

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

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

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

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

23 JUSTICE GORSUCH: Put that aside --

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

25 JUSTICE GORSUCH: -- put that aside.

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

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

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

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

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

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

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

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

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

24 MR. LAMKEN: Yes.

25 JUSTICE GORSUCH: I've got so many

1 friends I can hardly stand it.

2 (Laughter.)

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

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

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

23 JUSTICE GORSUCH: Let's --

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

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

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

10 MR. LAMKEN: So --

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

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

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

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

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

1 you're saying a remand is in order.

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

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

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

23 JUSTICE SOTOMAYOR: Can I quote --

24 MR. LAMKEN: -- because --

25 JUSTICE SOTOMAYOR: -- two sections

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

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

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

10 MR. LAMKEN: So in part.

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

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

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

20 JUSTICE SOTOMAYOR: It said to look at
21 the amount of effort needed to obtain
22 embodiments outside the scope of the disclosed
23 example.

24 MR. LAMKEN: So I think, if it said an
25 embodiment, that would be correct. Embodiments

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

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

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

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

12 MR. LAMKEN: To look at --

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

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

24 This Court can do the best service for
25 the Federal Circuit if it does one thing beyond

1 simply saying this cumulative effort standard
2 has no place in the law, and that would be to
3 say, look --

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

6 MR. LAMKEN: I'm sorry?

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

9 MR. LAMKEN: Okay. Thank you.

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

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

23 How long it takes to make all of them
24 cumulatively simply has no bearing, and this
25 Court can do a service and bring back to -- the

1 -- the incentives to create these life-saving --
2 these life-saving inventions by making it clear
3 that that just doesn't have a place, and --

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

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

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

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

25 JUSTICE ALITO: Is there something

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

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

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

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

1 inhibited research for antibody-based
2 pharmaceuticals?

3 MR. LAMKEN: I think the Federal
4 Circuit has been doing that for some time, but
5 it hasn't been quite so stark or quite so
6 apparent until now. And I think that's why the
7 Lemley article really was catching onto it. But
8 this brings in very stark contrast, stark
9 relief, exactly what the Federal Circuit is
10 doing and why it has gone so far that you just
11 can't invest in antibody research if you can't
12 adequately protect the scope of the antibodies
13 you invented.

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

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

1 know, I can imagine a hypothetical antibody that
2 can't be made.

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

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

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

22 JUSTICE ALITO: Can you explain how
23 your roadmap differs from the basic research
24 plan that you and your competitors have been
25 using since the mid-2000s when you were all

1 attempting to discover or identify antibodies
2 that bind to PCSK9 and block LDL receptors?

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

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

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

24 CHIEF JUSTICE ROBERTS: Thank you,
25 counsel.

1 Justice Thomas, anything further?

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

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

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

21 MR. LAMKEN: And I think --

22 JUSTICE THOMAS: -- which ones?

23 MR. LAMKEN: -- I could clarify a
24 little.

25 JUSTICE THOMAS: I mean --

1 MR. LAMKEN: Yeah, I should clarify.

2 JUSTICE THOMAS: Yeah.

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

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

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

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

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

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

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

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

1 26.

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

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

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

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

23 JUSTICE THOMAS: So let me ask you
24 this question. How do you respond to the
25 example in one of the amicus briefs about the --

1 the complicated lock and that you simply figure
2 out the combinations by trial and error?

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

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

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

1 separately patentable as a result, or it pushes
2 them to completely different nonantibody
3 treatments.

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

15 CHIEF JUSTICE ROBERTS: Thank you.

16 Justice Alito?

17 Justice Sotomayor?

18 Justice Gorsuch?

19 Justice Kavanaugh?

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

1 in the wrong direction as we approach this?

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

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

24 MR. LAMKEN: So I'm having a hard time
25 remembering what they were exactly, but,

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

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

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

1 convincing burden, that's a very high burden,
2 and it means you're going to have to come with
3 something concrete that can't be made or
4 requires undue experimentation and explain why
5 it matters.

6 JUSTICE KAVANAUGH: Thank you.

7 CHIEF JUSTICE ROBERTS: Justice
8 Barrett?

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

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

1 and you have a super-immunization protocol,
2 which means you get a robust result across the
3 claims.

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

11 JUSTICE BARRETT: Thank you.

12 CHIEF JUSTICE ROBERTS: Justice
13 Jackson?

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

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

1 to get the antibodies you want is routine.

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

10 JUSTICE JACKSON: And can I just go
11 back to Justice Thomas's point? So, given the
12 routine nature of this, can you just help me to
13 understand the numbers? So you did this and got
14 26, but you say there are 300.

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

23 And there's a reason why you don't go
24 and do 384 amino acid sequences for every one of
25 them in the patent. First is the patent law has

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

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

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

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

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

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

1 substitution, and the patent explains that that
2 is also a routine and well-known way of doing
3 it. You take one of the amino acids --

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

6 MR. LAMKEN: Yeah.

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

11 MR. LAMKEN: Mm-hmm.

12 JUSTICE JACKSON: -- shorthand for
13 what you've said. So is that class comprised of
14 384 species or more?

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

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

24 MR. LAMKEN: So it's important for me
25 that the millions comes from a different way of

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

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

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

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

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

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

1 near-identical twin and say that's a different
2 antibody. That's -- they're 99.99 percent
3 similar. That's going to be basically the same
4 antibody.

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

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

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

1 understood the patent also was -- to some
2 extent, your specifications were about notice to
3 other people and other inventors.

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

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

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

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

1 it up and look at it to see if it matches.
2 You're going to have to do a little bit of work
3 to make sure that it's --

4 JUSTICE JACKSON: All right.

5 MR. LAMKEN: But that's routine.

6 JUSTICE JACKSON: Thank you.

7 CHIEF JUSTICE ROBERTS: Thank you,
8 counsel.

9 MR. LAMKEN: Thank you.

10 CHIEF JUSTICE ROBERTS: Mr. Clement.

11 ORAL ARGUMENT OF PAUL D. CLEMENT

12 ON BEHALF OF THE RESPONDENTS

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

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

23 Amgen does not take issue with that
24 test, with the Juan factors, I think, or the
25 vast bulk of the federal circuit's enablement

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

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

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

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

1 and Man's patent in the Lamp case. The stakes
2 here are comparable.

3 Pfizer independently developed its own
4 antibody and patented it by amino acid sequence.
5 It seemed like a promising candidate but it
6 failed in clinical testing.

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

12 I welcome the Court's questions.

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

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

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

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

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

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

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

1 are purely functional claims.

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

9 Sir Gregory Winter doesn't think that,
10 their own expert doesn't think that.

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

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

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

1 If I came up with a brand-spanking new
2 process for making paint and I claimed that
3 process in all the paints that were produced as
4 a result of that as new compositions of matter,
5 and one step in my process patent was add
6 pigment for the desired color.

7 Well, then a skilled artisan would be
8 able to use that, an actual roadmap, and they
9 would say, all right, I want robin egg blue and
10 they could produce it every time. And if they
11 wanted chartreuse instead, they could produce it
12 any time.

13 Now, obviously there's a lot of colors
14 in the rainbow, so to actually produce every one
15 of them would take a lot of time and it wouldn't
16 invalidate the patent because it enables the
17 skilled artisan to produce what they won't want
18 every single time.

19 But this patent does not work this
20 way. What they give you is their roadmap is
21 trial and error.

22 JUSTICE GORSUCH: Mr. Clement I
23 appreciate that clarification, but, as I
24 understand it, there is a point of agreement
25 with respect to cumulative effort, that that

1 should not be dispositive.

2 MR. CLEMENT: Absolutely --

3 JUSTICE GORSUCH: Is that right?

4 MR. CLEMENT: -- Justice Gorsuch.

5 That's not to --

6 JUSTICE GORSUCH: That's great.

7 That's enough.

8 The other -- the other point

9 Mr. Lamken suggested that we -- we should

10 clarify is that -- that there has to be a

11 reasonable embodiment, not an embodiment --

12 enablement, sorry -- in every instance, that it

13 just needs to be reasonable.

14 Do you agree with that as well? I

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

16 because millions are millions and -- and

17 reasonableness is going to be somewhere --

18 you -- you could still prevail under that

19 standard, but do -- do you -- do you agree with

20 him that it's reasonable enablement, not -- not

21 down to every jot and tittle in every --

22 MR. CLEMENT: Yes. I think reasonable

23 is just maybe the flip side of undue

24 experimentation.

25 JUSTICE GORSUCH: Yeah. Exactly. So

1 if we agree on the law, what's left for this
2 Court?

3 MR. CLEMENT: Nothing, except maybe a
4 dig.

5 (Laughter.)

6 MR. CLEMENT: That seems -- and,
7 honestly --

8 JUSTICE KAGAN: Is there any other
9 point of law that you feel as though you and
10 Mr. Lamken are in disagreement on?

11 MR. CLEMENT: Well, I -- I think there
12 is a disagreement as follows:

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

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

25 So just to give you a concrete

1 example. I mean, if -- if they claimed a 15
2 binder, there are 15 binders in the real world.
3 If you want to use their roadmap to produce a 15
4 binder, you are consigned to trial and error.

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

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

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

24 I mean, one of the things that I find
25 particularly persuasive about Sir Gregory's

1 brief is he explains this roadmap is not a
2 shortcut at all. It just describes the routine
3 processes that people use to make independent
4 inventions, the same process that Pfizer used,
5 that Merck used, that we use to get our own
6 independent antibodies, and then it adds
7 additional steps that somebody skilled in the
8 art wouldn't want to do and are just basically
9 an additional step, additional test they have to
10 run to see whether they infringe, because the
11 people skilled in the art don't really care
12 where it binds. They -- they care that it
13 blocks.

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

19 And -- and I do think there's an
20 important point that shouldn't get lost in all
21 of this. Part of the reason, I agree, this
22 isn't a close case, is because what they are
23 trying to do, there's no meaningful structure in
24 these genus claims, and the structure they've
25 given is an elaborate description of the

1 epitope, the 15 or 16 residues on the PCSK9
2 where you want the antibodies to -- to bind.

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

10 And so what you have before you is a
11 particularly pernicious kind of claim. Because
12 not only is it a -- a genus claim that's purely
13 functional or double functional, as the federal
14 circuit described it, but it's really a
15 work-around of myriad. Because basically
16 they're pointing to something that exists in
17 nature and they're saying, we claim everything
18 that works to bind there en bloc.

19 JUSTICE JACKSON: Mr. Clement --

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

25 MR. CLEMENT: So --

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

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

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

25 But under their broad genus claims,

1 you can't do that. You can do it as to the 26,
2 and we'll give them the 26, but as the chart on
3 page 15 shows, we're not even close to
4 infringing the 26. We are structurally
5 fundamentally different.

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

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

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

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

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

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

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

23 MR. CLEMENT: No. Predictability goes
24 to experimentation and undue. If you have
25 something that enables the skilled artisan to

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

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

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

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

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

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

23 JUSTICE SOTOMAYOR: Mr. Clement, could
24 you put things in simpler form for me? It -- it
25 sounded to me that your adversary was saying

1 that most of this work is done by computers,
2 that you inject the mice, the antigens appear,
3 and the computer then sorts them out to see
4 which have the sweet spot or not. That's what I
5 understood him to say.

6 And if that's true, I don't know why
7 that's undue experimentation or why it's costly
8 or why it's time-consuming. You're saying
9 there's more to this process than that.

10 So break it down to me into steps so
11 that I can understand why you're saying that
12 this is undue. I understand it with the
13 paint --

14 MR. CLEMENT: Right.

15 JUSTICE SOTOMAYOR: -- but I'm not
16 understanding it with this process, so --

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

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

1 JUSTICE SOTOMAYOR: All right.

2 MR. CLEMENT: I would have to --

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

8 MR. CLEMENT: That is my point. It's
9 not my only point --

10 JUSTICE SOTOMAYOR: Okay.

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

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

21 MR. CLEMENT: Okay. So -- but he's
22 the one actually who cares what a skilled
23 artisan wants.

24 JUSTICE SOTOMAYOR: Okay.

25 MR. CLEMENT: And what's being claimed

1 is this entire genus. And if I want to pick a
2 spot --

3 JUSTICE SOTOMAYOR: So go back and
4 tell me --

5 MR. CLEMENT: Yep.

6 JUSTICE SOTOMAYOR: -- what steps you
7 have to do to get to him.

8 MR. CLEMENT: Okay. So I have to
9 start by injecting mice --

10 JUSTICE SOTOMAYOR: To his --

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

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

17 (Laughter.)

18 MR. CLEMENT: Okay. Well -- probably
19 more skilled than I am. But -- so -- so you get
20 the results of that. You get a whole bunch of
21 antibodies. And then you have to figure out
22 which ones are essentially candidates to bind on
23 PCSK9.

24 JUSTICE SOTOMAYOR: So does a computer
25 do that? And why is it undue?

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

2 JUSTICE SOTOMAYOR: Do they have to
3 look under a microscope? What do they have to
4 do?

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

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

18 But -- but here's what I do
19 understand, is, at that process, let's say they
20 get, you know, 26 or 384. Then they -- then if
21 what they wanted was a 15 binder to start with,
22 they got to figure out whether they got one.
23 And there's an excellent chance that they didn't
24 get one of those at all.

25 JUSTICE GORSUCH: Can I ask this

1 question?

2 MR. CLEMENT: Sure.

3 JUSTICE GORSUCH: So the 26, you
4 agree, fair enough, Mr. Lamken has got that in
5 the bag. What about the 384?

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

7 JUSTICE GORSUCH: No? Why?

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

14 JUSTICE GORSUCH: Let me just pause
15 there for a second. I understand completely
16 your argument, or I think I understand
17 completely, let me put it that way, your
18 argument about conservative substitution and the
19 potential millions of variants and the trial and
20 error that's required there.

21 I'm not sure I understand how that
22 applies to the 384.

23 MR. CLEMENT: So like -- honestly, the
24 384, I just have to take Mr. Lamken's word for
25 it. I mean, he says that, oh, Praluent might

1 have been in there. I mean, please. If
2 Praluent were in there, their scientists would
3 have produced that evidence.

4 And if you look at the chart at page
5 15, it is not a surprise. I assume that the
6 26 --

7 JUSTICE GORSUCH: That's a nice
8 demonstrative.

9 MR. CLEMENT: Yeah.

10 JUSTICE GORSUCH: I've got it.

11 MR. CLEMENT: Yeah. It -- I assume
12 the 26 were -- must have been representative of
13 the 384, right? Otherwise, why not make one of
14 those other 384, the ones you do by amino acid
15 sequence?

16 So you look at the 26 that they give
17 you the amino acid sequence, they look
18 structurally nothing like the 4 antibodies that
19 were independently developed by other companies.
20 That is very striking to me.

21 JUSTICE GORSUCH: Thank you.

22 CHIEF JUSTICE ROBERTS: Justice
23 Thomas?

24 Justice Alito?

25 Justice Sotomayor? No?

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

8 So why is it that Professor Lemley is
9 wrong in your view?

10 MR. CLEMENT: So I think he's wrong on
11 a number of levels. I think he's wrong that the
12 existing federal circuit precedent is going to
13 foreclose all genus claims. I mean, there's the
14 Bayer case that we cite in our brief that's an
15 example of the genus claim that the federal
16 circuit recently upheld.

17 Now it may be that in this particular
18 area of antibody science given the current state
19 of the science that you may not have an ability
20 to functionally claim a genus, and that's kind
21 of -- at -- at some level nobody's fault, it's
22 just the way the science works.

23 And, personally, I think that's great,
24 and -- because what it does is it allows
25 different companies to independently develop

1 different large molecule therapies to deal with
2 the same malady.

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

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

19 And the best evidence of that is the
20 Pfizer experiments, right? The Pfizer antigen
21 -- antibody is in this genus, and when it went
22 into clinical testing, it fell down.

23 So if -- if Amgen's had fallen down
24 for the same reasons that -- that -- that
25 Pfizer's did, we'd be without the treatment

1 because it claimed the whole genus and --

2 JUSTICE KAGAN: So -- so --

3 MR. CLEMENT: -- they wouldn't able
4 it.

5 JUSTICE KAGAN: So -- so tell me if
6 this is wrong. As I understand it, Professor
7 Lemley could be wrong for one of two reasons,
8 right? He could be wrong to say that the
9 federal circuit test is going to basically
10 invalidate all these patents or he could be
11 wrong in thinking that these patents are
12 valuable.

13 I hear you saying that he might be
14 right about the federal circuit's test
15 invalidating most of these patents, but that's
16 okay, because we shouldn't want these patents
17 around.

18 MR. CLEMENT: You know, the truth has
19 a way of leaking out. I mean, yeah, I mean, I
20 understand --

21 (Laughter.)

22 MR. CLEMENT: -- that, because --
23 because -- because I think functional genus
24 claims are terrible. I think they retard the
25 science. And I don't think you have to look

1 beyond this Court's cases.

2 The eighth claim in Samuel Morse's
3 claim, the other ones were nice species,
4 structure, good stuff. The eighth one was a
5 functional genus claim for everything that
6 allows letters to print somewhere else through
7 the use of electricity.

8 This Court deep-sixed it and, thank
9 goodness, because Samuel Morse is brilliant but
10 he didn't invent the fax machine.

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

23 And as this Court's cases teach, it's
24 got to be structure that unifies the genus. And
25 what's -- I love Lemley but what -- you know,

1 I -- I take Sir Gregory Winter on the science.
2 And what he tells you is, in this area of
3 science, you just can't get that structural
4 commonality. It just doesn't work. It's -- I
5 mean, somebody will discover it and they will
6 get another Nobel Prize for discovering it.

7 JUSTICE KAGAN: Thank you.

8 CHIEF JUSTICE ROBERTS: Justice
9 Gorsuch?

10 Justice Kavanaugh?

11 Justice Jackson?

12 JUSTICE JACKSON: So there are some
13 fields where there is a degree of
14 unpredictability or randomness and I guess I'm
15 just a little worried that your view on this
16 would mean that we would not be able to have
17 patents where some experimentation was required.

18 Can you just speak to that a little
19 bit more? I mean, again, I hear you in some way
20 suggesting that the specification has to
21 absolutely get a skilled artisan to the endpoint
22 of every species in the genus 100 percent of the
23 time exactly as indicated.

24 And I'm just concerned because there
25 are going to be some areas, and perhaps this is

1 one of them, where there's a reasonable degree
2 of unpredictability in terms of the outcome, but
3 you're sort of in the ballpark enough that we
4 would want to make sure that there was
5 innovation in this area with -- with these kinds
6 of companies investing in -- in patenting these
7 kinds of developments.

8 MR. CLEMENT: So I -- I think what I
9 would say is, I do think the test should be
10 undue experimentation. It should not be zero
11 tolerance, no experimentation.

12 JUSTICE JACKSON: Okay.

13 MR. CLEMENT: But I also do think, if
14 you're going to start with the text, which I
15 assume you always do, then what you would say
16 is, you start with the idea that you have to
17 make and use the invention, and the invention is
18 defined by the full -- by the -- by the claims
19 in the invention, and, in that sense, Amgen is
20 the master of their own claims, master of their
21 own patent. And then you look at those, and if
22 they claim a lot, then you -- you have to enable
23 the full scope of what you claim.

24 And then, from that starting
25 proposition, which might get you to the idea

1 that there's no experimentation, then I think
2 it's a little bit of, you know, de minimis non
3 curat lex reasonableness, a little bit of play
4 in the joints, but this is where Mr. Lamken and
5 I just see the facts completely different.

6 He wants to say, oh, this -- these are
7 just hypothesized things that couldn't be
8 invented here given the current state of the
9 science.

10 With all due respect, balderdash.
11 There are four disclosed patents here with
12 anti -- amino acid sequence that the competitors
13 have made that are on the chart.

14 Now if you are a skilled artisan in
15 the field and you want to produce the 15 binder
16 that Pfizer did, you can produce it 100 percent
17 of the time by duplicating the amino acid
18 sequence.

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

1 JUSTICE JACKSON: All right, one --

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

5 JUSTICE JACKSON: One last question on
6 the facts. I understood that Amgen had trial
7 testimony in this case that the roadmap is
8 certain to make all of the claims antibodies,
9 including Sanofi's, Pfizer's, and Merck's.

10 And I had understood, in terms of the
11 way that the burdens work, a little complicated,
12 but that you had to have evidence disproving
13 that, by clear and convincing evidence.

14 So do you and, if so, what is your
15 evidence?

16 MR. CLEMENT: So I -- I appreciate the
17 question, and this really goes back to the
18 suggestion that there is sort of a lurking legal
19 difference here.

20 Because the reason I don't have
21 evidence that says that that claim is not true
22 is because it implicitly says, if you take
23 forever. I can't tell you that, if you run
24 these experiments, you won't eventually get
25 Praluent, Pfizer, the Merck embodiments, but,

1 unlike the paint where you can start and say,
2 all right, I'm going to -- I'm going to test
3 that, so I'm going to -- I'm going to reproduce
4 that. You can't do that.

5 So the -- the -- the twin claims that
6 my friend keeps making and he seems to think are
7 legally sufficient, and I definitely disagree,
8 are if you run the test, you're always going to
9 get something in the genus.

10 CHIEF JUSTICE ROBERTS: Thank you,
11 counsel.

12 MR. CLEMENT: Thank you.

13 CHIEF JUSTICE ROBERTS: Ms. Sinzduk?

14 ORAL ARGUMENT OF COLLEEN R. SINZDAK
15 FOR THE UNITED STATES, AS AMICUS CURIAE,
16 SUPPORTING THE RESPONDENTS

17 MS. SINZDAK: Mr. Chief Justice, and
18 may it please the Court.

19 I think I want to pick up where
20 Respondents' counsel left off with a very
21 important fact, and that is that, if an antibody
22 has already been created, a scientist who wants
23 to make that antibody is not going to go into a
24 laboratory and inoculate a mouse.

25 They're going to use the amino acid

1 sequence. That is the recipe for making an
2 antibody. That is why the government says that,
3 for the 26 exemplars within the patents, that
4 actually -- where they -- where Amgen had
5 actually listed the amino acid sequence,
6 those -- those antibodies are enabled, because
7 if a scientist wants to go into the lab and it
8 wants to make that antibody, it has the recipe,
9 it has the amino acid sequence.

10 And I also do not want you to take
11 my -- my word on the science, but I do want you
12 to take the expert testimony on the science.
13 And I think that if you look at trial
14 transcripts 20 -- 225 you will see that -- that
15 Respondents' expert explains that the amino acid
16 sequence is the recipe.

17 If you look at the Winter brief at 14,
18 it explains that the amino acid sequence is the
19 recipe.

20 And if you look at Amgen's own brief,
21 at 13, it says, how should you start their
22 roadmap. You should go in and you should use
23 the amino acid sequence of the antibodies that
24 they actually invented and make those
25 antibodies.

1 And then you should go through this
2 whole elaborate mouse inoculation process.

3 So the reason here, just on the -- on
4 the clear facts that this is not an enabled
5 genus, is that they have not given the
6 information that a person skilled in the art
7 would need to make and use all of the antibodies
8 within the genus.

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

20 It is very dangerous, I think, to
21 start asking those kinds of questions because
22 the truth is we don't know if it matters. This
23 is an unpredictable field. This is a field
24 where developments are getting made every day.
25 And they haven't made certain antibodies within

1 this genus. We don't know if one of those
2 antibodies is going to be the one that really
3 works to beat the cholesterol problem that
4 causes heart attacks, that works better than
5 everything else, or the one that's going to be
6 tolerated by more patients or the one that's
7 going to be cheaper to manufacture.

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

16 And, here, we know that the
17 Respondents, they built a different mousetrap,
18 right? Their antibody, it binds to different
19 parts of the antigen. So it is different. It
20 is not simply the same.

21 And I actually think you -- you see in
22 the reply brief that even Amgen knows it's not
23 the same, because the government explained that
24 there is a doctrine out there that prevents
25 copyists, that prevents someone from making a

1 great invention and then having someone else
2 just make a tiny change and knock it off, and
3 it's called the doctrine of equivalents, and
4 it's been in this Court's cases for two
5 centuries.

6 And Amgen says we can't use the
7 doctrine of equivalents here, and the reason is
8 because they're not equivalent, and because
9 they're not equivalent, you have to enable all
10 of the different antibodies.

11 So, again, this is just the basic
12 principles. It is the enablement requirement
13 that has been in the law since the beginning.

14 And I think, Justice Kagan, you said,
15 well -- well, actually, Professor Lemley is very
16 worried that this enablement requirement is
17 going to harm innovation.

18 But Professor Lemley has a new article
19 from 2023, Yale Law Journal, which is called
20 "The Antibody Patent Paradox." And in that, he
21 says, you know, it doesn't look like these
22 antibody patents -- it doesn't look like these
23 genus patents are enabled. But there is this
24 doctrine of equivalents, and maybe it would take
25 care of all of these innovation problems.

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

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

18 I think, Justice Jackson, you were
19 talking a little bit about the predictability
20 and this is an unpredictable area of -- of -- of
21 -- of science and how are we going to deal with
22 those sorts of things.

23 I think it is correct this is an undue
24 experimentation question, and we're going to
25 say, like, is this something that a person

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

20 But, if you wanted to kind of just go
21 into a lab and make an antibody de novo, you
22 really would have to inoculate a mouse and hope.
23 But you don't have to do that anymore, right?
24 At this -- now we have a recipe. And because we
25 have that recipe, I think the idea that you

1 would tell scientists, well, just go and run
2 that mouse process until you get what you're
3 looking for is -- is really absurd.

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

15 And when we kind of make these
16 predictions, you can stifle innovation. And I
17 think this is another sort of response to the
18 Lemley brief. What happens when you allow a
19 genus patent that will -- that -- that -- that
20 -- that will -- will cover not just something
21 that has been invented but also things that have
22 not yet been made and used is that nobody else
23 has the incentive to go out and make and use
24 them.

25 So let's say you're look -- you have

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

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

14 MS. SINZDAK: Sure.

15 JUSTICE GORSUCH: You -- you -- you --
16 you've emphasized full enablement, and that's
17 certainly what Wood, for example, says from this
18 Court. But at least your -- your colleagues
19 both seem to suggest that there might be some
20 elbow room, non curat lex room in there
21 somewhere, reasonableness. What do you think?
22 What does the government think?

23 MS. SINZDAK: I think there is always
24 room for reasonableness, but I do think that the
25 need to be reasonable needs to be tempered with

1 the need not to accept sort of pronouncements
2 about -- about what is and is not different.
3 So -- I -- I -- or what does -- what embodiments
4 do and do not matter. So I think, again, the
5 doctrine of equivalents is really, I think,
6 where a lot of this reasonableness concern gets
7 taken care of.

8 I would also say that -- that -- that
9 the Federal Circuit has -- and I think quite
10 correctly -- said that, you know, if you claim a
11 genus of wooden baseball bats and every person
12 skilled in the art knows that you can't make a
13 baseball bat out of -- out of pine, then you
14 don't have to say except pine because the -- the
15 -- the strict -- the plain text of the statute
16 says a person skilled in the art.

17 JUSTICE GORSUCH: Okay.

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

20 JUSTICE GORSUCH: And then a similar
21 question with respect to cumulative efforts.
22 There was some discussion about that and maybe
23 some -- some agreement that -- that cumulative
24 effort may not be the right -- it may be a
25 consideration, but it's not -- surely not a

1 dispositive one if the patent did clearly
2 specify every single time you're going to
3 produce a winner.

4 And the problem here, as I understand
5 Respondent, is that that's no guarantee.
6 There's -- even if you do everything right and
7 you follow all of it, conservative substitution,
8 you're going to have some winners and you're
9 going to have some losers.

10 But, if -- if you could, for example,
11 every single time get a winner, then the fact
12 that it would require a long time to get them
13 all wouldn't -- wouldn't necessarily defeat a
14 patent, would it?

15 MS. SINZDAK: No.

16 JUSTICE GORSUCH: Okay.

17 MS. SINZDAK: It certainly would not.
18 I do agree with Respondent it can be relevant,
19 and I think it can particularly be relevant if,
20 for example, you figure out that 10 of a million
21 types of -- there's a million types of ammonia
22 in the world and 10 of them are going -- can be
23 used instead of gasoline to run superefficient
24 cars, right? But you don't know which 10, so
25 you just claim the genus of ammonia that can be

1 used to run cars, and then what you're saying is
2 you have to go out there and try them. And you
3 may actually have to try all a million of them
4 so -- to get to those 10. And so there the
5 cumulative effort is relevant because you're
6 going to be there testing and testing and
7 testing.

8 So just a few minor factual points.
9 First of all, I think that 400 number is
10 misleading because, first of all, it's -- it's a
11 -- or the 385 number. So that is, if you --
12 that's how many they got when they ran this
13 mouse process once, but this is not a process --
14 a product by process claim. They're not only
15 claiming those, you know, 385.

16 And it's not even -- they're not only
17 claiming antibodies made by mice; they're
18 claiming these antibodies that bind and block
19 made through any process.

20 And I also think that, you know, at
21 least looking at their expert testimony, I'm not
22 sure that all of the competitor antibodies can
23 be made with that mouse process, and -- and I
24 say that only because I look at Trial Transcript
25 758, and if you look at that, their expert is

1 talking about the various competitor antibodies,
2 and it says, you know, you can run the mouse and
3 we think you would get Praluent by running the
4 mouse experiments. But, actually, you would
5 need to -- to get this phage library to -- to
6 find -- to -- to make another of the competitor
7 antibodies.

8 To me, that looks like they're saying
9 the mouse has some limitations, so you're going
10 to need to use a different process. And I
11 actually think you -- you heard Petitioners'
12 counsel up here conceding that you're not going
13 to be able to -- you know, there -- you're not
14 necessarily going to make everything with the
15 mouse because you're going to have some of these
16 conservative substitution -- you're going to
17 make some -- some antibodies with conservative
18 substitution, and I -- I think what he was
19 saying is that, you know, that -- that's --
20 that's in addition to those 400.

21 So I -- I -- I -- I do think just as a
22 factual point there -- there are -- we need to
23 be careful and precise. And what I would urge
24 the Court is to look at the Winter brief but
25 then to also just focus on the legal question

1 here, and I think answering that legal question
2 just means reiterating the enablement inquiry
3 that this Court has been applying and applying
4 and applying for 200 years.

5 CHIEF JUSTICE ROBERTS: Counsel, is
6 there anything that Mr. Clement said this
7 morning with which the government disagrees?

8 MS. SINZDAK: I did not hear anything.

9 CHIEF JUSTICE ROBERTS: Okay. And on
10 the doctrine of equivalents, wouldn't that be
11 less protective of the investment someone might
12 make to pursue these inventions in terms of its,
13 I would say, maybe I'm not remembering right
14 from earlier cases, but it seems to me that that
15 would be less protective and, therefore, less of
16 an encouragement to investment.

17 MS. SINZDAK: I -- I mean, to the
18 extent that Petitioner is asking for protection
19 for things that they have not made -- enabled
20 people to make and use, I think you're right,
21 because I don't think the doctrine of
22 equivalents is going to get them things they
23 haven't invented yet.

24 But I also think that -- that -- that
25 that's just the basic patent quid pro quo. You

1 don't get a patent on anything that you haven't
2 enabled people to make and use. So I guess I
3 would say, yes, not being allowed to have their
4 patent is going to get them less -- less, but
5 that's exactly what the law requires.

6 CHIEF JUSTICE ROBERTS: Justice
7 Thomas?

8 JUSTICE THOMAS: Would you comment
9 briefly on the relationship between the
10 enablement -- enablement inquiry and the claim
11 -- the invention, the claim?

12 It seems as though, as Mr. Clement
13 said, that the broader -- the more you claim,
14 the more you must focus on the enablement
15 analysis. And I don't think you commented on
16 that.

17 MS. SINZDAK: I think that is often
18 the case. You need to provide enough
19 information to enable a person to make any given
20 embodiment of your invention. And, you know,
21 if -- if you've claimed a lot of different
22 things, you may have to put in a lot more
23 information.

24 I would say that sometimes I think
25 it's going to be more -- you're not going to

1 have to give a ton more information. My
2 understanding is that, for example, with respect
3 to a chemical genus, you might be able to say,
4 I'm talking about this family of chemicals that
5 have this helical ring structure, and, you know,
6 this -- this -- this chemical group that hangs
7 off of it can be one of these five things.

8 And -- and that's actually going to
9 enable a chemist, not me, to make tons and tons
10 and tons of different things, or you --

11 JUSTICE THOMAS: So the -- in this
12 area, I -- I think there's -- if I understand
13 your argument and Mr. Clement's, this area
14 doesn't seem to have the same predictive quality
15 that you would find in some of the other areas.
16 For example, his paint mixing would be
17 relatively easy. But, as you move along to the
18 other antibodies in this area, it seems as
19 though it's trial and error. It's more each one
20 has to be assessed on its own terms.

21 So it would seem to me that the -- it
22 would be -- it would be more difficult to
23 achieve what you just said in this particular
24 area.

25 MS. SINZDAK: I think that is exactly

1 right, but I don't think that that means that
2 you should bend the rules of enablement. And,
3 in fact, I think that could be very dangerous,
4 right, because one of the incentives right now
5 for scientists to figure out the
6 structure/function relationship in antibodies
7 beyond the Nobel Prize, but another incentive is
8 then you could claim broader genres.

9 If somebody is able to figure out, oh,
10 well, when I identify this antigen, oh, I can
11 figure out what amino acid sequences for every
12 single different antibody that could bind to
13 that antigen, then they would -- they would have
14 a much better case for enablement.

15 But, if you say, no, it doesn't
16 matter, you can claim all of those anyway,
17 there's less incentive to find that, sort of
18 that -- that magic key, which I should not say
19 magic, it's science.

20 (Laughter.)

21 CHIEF JUSTICE ROBERTS: Justice Alito?
22 Justice Sotomayor?

23 JUSTICE SOTOMAYOR: A simple question,
24 maybe not so simple. Mr. Clement at one point
25 in response to Justice Gorsuch said you should

1 DIG this case. If we didn't want to, what could
2 we say to have the Federal Circuit or anyone
3 else who -- who's interested in this area --

4 MS. SINZDAK: So --

5 JUSTICE SOTOMAYOR: -- what could we
6 say that they didn't say? What could we
7 explain? Your Petitioners' counsel has told us
8 what he would wants us to say. What would you
9 want us to say?

10 MS. SINZDAK: So I -- I think, first
11 of all, you could DIG the case. We do not think
12 that the Federal Circuit said anything wrong
13 here. I think that some of the arguments that
14 we're hearing from Petitioners suggest that it
15 might be useful to clarify that you really do
16 need to enable each of the different embodiments
17 that you're claiming that you can't say these
18 ones don't "matter," because that's simply not
19 the -- not -- first of all, it's hard to know
20 what that means other than if you're invoking
21 the doctrine of equivalents, which Petitioner
22 said he -- he can't invoke, but that requires
23 sort of a predictive judgment that could really
24 freeze innovation by saying, oh, don't worry,
25 don't -- don't find that 15 binder, it doesn't

1 matter.

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

6 CHIEF JUSTICE ROBERTS: Justice Kagan?
7 Justice Gorsuch?

8 JUSTICE KAVANAUGH: I guess, in
9 response to what you said to Justice Sotomayor,
10 it would be important for this Court to say it
11 essentially agrees with the Federal Circuit
12 because there's been, as Justice Kagan points
13 out, a lot of critiques of the Federal Circuit's
14 approach, and if billions of dollars were on the
15 line, this Court saying as much with -- along
16 the lines that you propose would eliminate that
17 uncertainty about the legal standard, and then
18 everyone would know it's up to Congress.

19 MS. SINZDAK: I -- I -- I -- I agree
20 with that completely. And I think also, with
21 that final point, which is I -- I think an
22 important one that maybe hasn't been discussed
23 here, that to the extent you did think that the
24 Petitioner had a good point that antibodies are
25 just different and basic patent rules don't --

1 don't work, then the person -- then -- then --
2 then the body that needs to -- to make a special
3 antibody exception is going to be Congress, not
4 this Court.

5 I also completely agree that I do
6 think it would be helpful -- to the extent there
7 are scientists still out there making these
8 broad genus claims that are going to stifle
9 innovation, I -- I do think that that's a -- a
10 danger to innovation and especially in the
11 medical field, where, from what people who know
12 better than me tell me, antibody innovation is
13 key, and -- and we don't want people claiming
14 more than they've really invented.

15 JUSTICE KAVANAUGH: Thank you.

16 CHIEF JUSTICE ROBERTS: Justice
17 Barrett?

18 Justice Jackson?

19 Thank you, counsel.

20 Rebuttal, Mr. Lamken?

21 REBUTTAL ARGUMENT OF JEFFREY A. LAMKEN

22 ON BEHALF OF THE PETITIONERS

23 MR. LAMKEN: Thank you.

24 The key fact in this case is that
25 Sanofi has not identified one antibody that

1 would require undue experimentation to make.
2 Sanofi likes its chart. We like that chart as
3 well because the whole purpose of that retrial
4 was so that they could prove that those
5 competitor antibodies aren't made using the
6 roadmap. And the jury disagreed.

7 There is no evidence of anybody ever
8 saying, gee, I tried to make one of those
9 competitor antibodies, it didn't come out the
10 first time. I know the government points out
11 that you might use a phage display for one, but
12 the patent's disclosures explain that you can
13 use the mice and you can use phage displays and
14 this is how you would get them.

15 And all this tells me at the bottom is
16 there's a reason out there why we have trials,
17 why we have juries, and why we have patent
18 examiners, so that we're not retrying all the
19 elements of the case before this Court.

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

24 In terms of Winter, I think it's very
25 interesting to get the functional equivalent of

1 an expert report when you're in the Supreme
2 Court. If the Court's interested in a response
3 to that, it so closely parallels Sanofi's brief
4 in the court of appeals that I would commend the
5 Court to look at our reply brief there and it
6 will have the answers to virtually everything
7 that Mr. Winter has.

8 And turning -- turning to the issue of
9 millions, the question of millions matters only
10 if you're looking at the cumulative effort to
11 get to the millions. If each one is
12 individually enabled, you know how to get there
13 because you can do amino acid substitutions
14 through this conservative substitution, you can
15 get to any one you want, that's enablement.
16 Each of those is enabled.

17 The -- the question of millions
18 becomes not enablement only if you're going to
19 look at the cumulative effort to make each and
20 every one, and I think that is a fundamental
21 point of disagreement. Is it even relevant how
22 hard it is to make all of them as opposed to how
23 hard is it for the skilled artisan to do what
24 skilled artisans do, which is make one that they
25 want.

1 And, in this sense, I would like to
2 respond to Mr. Clement's point that somehow it
3 makes it hard -- our roadmap makes it harder.
4 No, the roadmap makes it much easier because, if
5 you know that it's going to bind to the sweet
6 spot and we give you those two antibodies, those
7 two anchor antibodies that help you figure it
8 out with high throughput testing, quick and easy
9 according to the testimony, if it binds there,
10 it blocks. That's it. You're done. You have
11 an antibody that works.

12 With respect to Morse's eighth claim,
13 yes, everybody forgets about Morse's seventh
14 claim, and Morse's seventh claim was, in effect,
15 you use electromagnetism using -- to produce the
16 motion of the machinery at distance to reproduce
17 letters. We're just like Morse's seventh claim
18 because we have a structure, you're using
19 monoclonal antibodies, and we tell you how to
20 produce them, and these are all monoclonal
21 antibodies that have a characteristic that you
22 can observe, that they bind to a particular
23 place, and by binding in that place, they
24 produce the function you want, blocking.

25 There's a lot of going -- a lot about

1 criticizing functional claiming here. But, in
2 terms of functional claiming, that's not a
3 112(a) question of enablement. That's a 112(b)
4 question, which describes what you have to do to
5 claim. If people don't like functional claims,
6 that's where it goes.

7 And this claim really isn't functional
8 in a relevant sense. The binding is a
9 characteristic you can observe, like what the
10 government called water absorptivity, when it
11 was talking about the -- the Holland Furniture
12 case. It's something you can observe. And if
13 you have that characteristic, you bind and,
14 therefore, you block and you're exactly within
15 the claims.

16 As to the doctrine of equivalents, if
17 you have an antibody that has a different amino
18 acid sequence, that isn't protectable under the
19 doctrine of equivalents because it's not
20 equivalent. Because it has the same effect, it
21 may also block, it doesn't make it equivalent.
22 It's only equivalent if the limitations, the
23 requirements, are equivalent. And so you can
24 swap out maybe one amino acid for one that's
25 very similar, but if an amino acid in your

1 claimed structure is just missing, you just
2 clipped it out, then you would be around, and
3 you would provide no protection whatsoever for
4 people who are creating the antibodies.

5 You invest \$2.6 billion investing and
6 determining that there's a sweet spot that if
7 you bind to you will block and you will be
8 saving lives. And the protection is listed to
9 -- limited to what? The 26 you describe by
10 amino acid sequence? That provides no
11 protection at all because you can always come up
12 with a 27th, and that's the whole point of the
13 roadmap.

14 The roadmap is fully enabling because
15 you can come up with that 27th, the 28th, or the
16 29th, whatever is out there. The testimony was
17 the roadmap will allow you to get to them all.
18 And it's not an infinite test because the
19 evidence in this trial, in this -- is there's
20 just nobody who testified and said, gee, I ran
21 the roadmap, I tried, I didn't get what I
22 wanted, something was missing. No evidence that
23 Sanofi on its first panel didn't come up with
24 its -- its antibody, Praluent. No evidence that
25 Amgen on its first trial failed to come up with

1 its antibody. Or any of the other competitors.
2 When you run the roadmap, you get them. The 15
3 binder. If a 15 binder exists, it's going to
4 come out and it's going to be there.

5 If I could turn just very quickly to
6 the -- the issue of DIG.

7 CHIEF JUSTICE ROBERTS: A minute.

8 MR. LAMKEN: Thank you so much.

9 This case, you should make no mistake,
10 has incredible impacts. We have two decisions
11 from the PTAB, both characterizing it as a
12 cumulative effort to make all the embodiments
13 test. Nobody can invest billions of dollars
14 with this decision out there. Nobody can invest
15 billions of dollars if it's even relevant.
16 There's a legal dispute about the relevance of
17 that cumulative effort test, and this Court
18 should address it and excise it from the law.

19 Thank you, Your Honor.

20 CHIEF JUSTICE ROBERTS: Thank you,
21 counsel. The case is submitted.

22 (Whereupon, at 11:44 a.m., the case
23 was submitted.)

24

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