

# SUPREME COURT OF THE UNITED STATES

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IN THE SUPREME COURT OF THE UNITED STATES

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AMGEN INC., ET AL., )  
                                Petitioners, )  
                                v. ) No. 21-757  
SANOFI, ET AL., )  
                                Respondents. )  
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P R O C E E D I N G S

(10:05 a.m.)

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

Mr. Lamken.

ORAL ARGUMENT OF JEFFREY A. LAMKEN

ON BEHALF OF THE PETITIONERS

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

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

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

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

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

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

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

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

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

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

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

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

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

1 the -- the antibody.

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

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

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

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

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

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

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

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

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

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

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

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

15 JUSTICE SOTOMAYOR: I'm sorry --

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

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

20 MR. LAMKEN: Pardon?

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

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

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

1 post-filing discovery of more?

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

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

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

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

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

20 MR. LAMKEN: Well, Justice --

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

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

3 JUSTICE SOTOMAYOR: Or the method?

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

6 JUSTICE SOTOMAYOR: Right.

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

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

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

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

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

1 MR. LAMKEN: Yeah.

2 JUSTICE SOTOMAYOR: Sixteen, yes.

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

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

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

1 the same, and --

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

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

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

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

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

20 MR. LAMKEN: Fair.

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

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

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

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

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

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

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

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

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

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

5 MR. LAMKEN: The Wands test.

6 JUSTICE GORSUCH: Okay.

7 MR. LAMKEN: Yeah, the Wands factors.

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

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

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

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

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

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

9 JUSTICE GORSUCH: Well, I understand  
10 --

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

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

15 (Laughter.)

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

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

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

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

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

5 JUSTICE GORSUCH: Thank you.

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

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

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

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

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

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

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

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

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

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

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

10           CHIEF JUSTICE ROBERTS: Well --

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

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

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

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

23           MR. LAMKEN: I'm sorry?

24           JUSTICE SOTOMAYOR: Then continue with  
25 Justice --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 So, in a case like this, where you

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

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

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

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

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

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

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

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

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

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

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

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

25 MR. LAMKEN: Well, actually, if you

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

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

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

17 I think the next question --

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

23 MR. LAMKEN: Enabled.

24 JUSTICE KAGAN: Has to be enabled.

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

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

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

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

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

23 JUSTICE GORSUCH: Put that aside --

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

25 JUSTICE GORSUCH: -- put that aside.

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

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

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

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

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

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

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

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

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

24 MR. LAMKEN: Yes.

25 JUSTICE GORSUCH: I've got so many

1 friends I can hardly stand it.

2 (Laughter.)

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

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

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

23 JUSTICE GORSUCH: Let's --

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

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

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

10 MR. LAMKEN: So --

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

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

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

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

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

1 you're saying a remand is in order.

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

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

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

23 JUSTICE SOTOMAYOR: Can I quote --

24 MR. LAMKEN: -- because --

25 JUSTICE SOTOMAYOR: -- two sections

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

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

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

10 MR. LAMKEN: So in part.

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

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

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

20 JUSTICE SOTOMAYOR: It said --

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

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

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

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

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

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

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

13 MR. LAMKEN: To look at --

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

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

25 This Court can do the best service for

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

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

7 MR. LAMKEN: I'm sorry?

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

10 MR. LAMKEN: Okay. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 CHIEF JUSTICE ROBERTS: Thank you,

1 counsel.

2 Justice Thomas, anything further?

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

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

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

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

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

1 MR. LAMKEN: Yeah, I should clarify.

2 JUSTICE THOMAS: Yeah.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 out the combinations by trial and error?

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

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

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

1       them to completely different nonantibody  
2       treatments.

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

15                   CHIEF JUSTICE ROBERTS: Thank you.

16                   Justice Alito?

17                   Justice Sotomayor?

18                   Justice Gorsuch?

19                   Justice Kavanaugh?

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

1 in the wrong direction as we approach this?

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

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

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

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

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

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

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

5 JUSTICE KAVANAUGH: Thank you.

6 CHIEF JUSTICE ROBERTS: Justice  
7 Barrett?

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

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

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

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

10 JUSTICE BARRETT: Thank you.

11 CHIEF JUSTICE ROBERTS: Justice  
12 Jackson?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 MR. LAMKEN: Yeah.

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

10 MR. LAMKEN: Mm-hmm.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 JUSTICE JACKSON: All right.

4 MR. LAMKEN: But that's routine.

5 JUSTICE JACKSON: Thank you.

6 CHIEF JUSTICE ROBERTS: Thank you,  
7 counsel.

8 MR. LAMKEN: Thank you.

9 CHIEF JUSTICE ROBERTS: Mr. Clement.

10 ORAL ARGUMENT OF PAUL D. CLEMENT

11 ON BEHALF OF THE RESPONDENTS

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

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

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

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

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

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

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

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

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

11          I welcome the Court's questions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 MR. CLEMENT: Absolutely --

25 JUSTICE GORSUCH: Is that right?

1 MR. CLEMENT: -- Justice Gorsuch.

2 JUSTICE GORSUCH: Okay. Okay.

3 MR. CLEMENT: And that's not just

4 to --

5 JUSTICE GORSUCH: No, that's great.

6 MR. CLEMENT: Yeah.

7 JUSTICE GORSUCH: That's enough.

8 The other -- the other point Mr.

9 Lamken suggested that we -- we should clarify is

10 that -- that there has to be a reasonable

11 embodiment, not an embodiment -- enablement,

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

13 to be reasonable.

14 Do you agree with that as well? I

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

16 millions are millions and -- and reasonableness

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

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

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

20 reasonable enablement, not -- not down to every

21 jot and tittle in every --

22 MR. CLEMENT: Yes. I think reasonable

23 is just maybe the flip side of undue

24 experimentation.

25 JUSTICE GORSUCH: Yeah. Exactly.

1 MR. CLEMENT: Right.

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

4 MR. CLEMENT: Well --

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

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

9 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25           JUSTICE JACKSON: Mr. Clement --

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

6 MR. CLEMENT: So --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 margins.

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

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

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

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

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

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

21 MR. CLEMENT: Right.

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

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

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

8 JUSTICE SOTOMAYOR: All right.

9 MR. CLEMENT: I would have to --

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

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

17 JUSTICE SOTOMAYOR: Okay.

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

25 JUSTICE SOTOMAYOR: Well, I don't

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

3 MR. CLEMENT: Okay.

4 JUSTICE SOTOMAYOR: Okay. So --

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

7 JUSTICE SOTOMAYOR: Okay.

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

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

13 MR. CLEMENT: Yep.

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

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

18 JUSTICE SOTOMAYOR: To his --

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

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

25 (Laughter.)

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

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

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

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

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

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

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

8                   JUSTICE GORSUCH: Can I ask this  
9 question?

10                  MR. CLEMENT: Sure.

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

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

15                  JUSTICE GORSUCH: No? Why?

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

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

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

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

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

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

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

17 MR. CLEMENT: Yeah.

18 JUSTICE GORSUCH: I've got it.

19 MR. CLEMENT: Yeah.

20 JUSTICE GORSUCH: Yeah.

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

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

6                   JUSTICE GORSUCH: Thank you.

7                   CHIEF JUSTICE ROBERTS: Justice  
8                   Thomas?

9                   Justice Alito?

10                  Justice Sotomayor? No?

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

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

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

1 Circuit recently upheld.

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

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

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

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

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

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

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

12 JUSTICE KAGAN: So -- so --

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

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

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

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

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

6                   (Laughter.)

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

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

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

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

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

17 JUSTICE KAGAN: Thank you.

18 CHIEF JUSTICE ROBERTS: Justice  
19 Gorsuch?

20 Justice Kavanaugh?

21 Justice Barrett?

22 Justice Jackson?

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

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

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

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

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

23 JUSTICE JACKSON: Okay.

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

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

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

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

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

25           Now, if you are a skilled artisan in

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

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

12 JUSTICE JACKSON: All right. One --

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

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

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

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

1 evidence?

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

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

20 CHIEF JUSTICE ROBERTS: Thank you,  
21 counsel.

22 MR. CLEMENT: Thank you.

23 CHIEF JUSTICE ROBERTS: Ms. Sinzduk?  
24  
25

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

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

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

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

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

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

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

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

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

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

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

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

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

1 build a different mousetrap.

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

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

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

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

25           And I think, Justice Kagan, you said,

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

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

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

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

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

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

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

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

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

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

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

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

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

25                   MS. SINZDAK: Sure.

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

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

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

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

3 JUSTICE GORSUCH: Okay.

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

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

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

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

1 MS. SINZDAK: No.

2 JUSTICE GORSUCH: Okay.

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

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

1 claiming those, you know, 385.

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

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

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

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

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

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

19 MS. SINZDAK: I did not hear anything.

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

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

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

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

17 CHIEF JUSTICE ROBERTS: Justice  
18 Thomas?

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

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

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

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

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

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

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

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

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

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

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

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

6           (Laughter.)

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

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

15          MS. SINZDAK: So --

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

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

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

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

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

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

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

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

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

1 JUSTICE KAVANAUGH: Thank you.

2 CHIEF JUSTICE ROBERTS: Justice  
3 Barrett?

4 Justice Jackson?

5 Thank you, counsel.

6 Rebuttal, Mr. Lamken?

7 REBUTTAL ARGUMENT OF JEFFREY A. LAMKEN

8 ON BEHALF OF THE PETITIONERS

9 MR. LAMKEN: Thank you.

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

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

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

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

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

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

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

2 Each of those is enabled.

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

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

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

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

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

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

1 the claims.

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

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

25 The roadmap is fully enabling because

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

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

18 CHIEF JUSTICE ROBERTS: A minute.

19 MR. LAMKEN: Thank you so much.

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

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

5 Thank you, Your Honor.

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

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

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