

1 IN THE SUPREME COURT OF THE UNITED STATES

2 - - - - -X

3 LABORATORY CORPORATION :

4 OF AMERICA HOLDINGS, DBA :

5 LABCORP, :

6 Petitioner :

7 V. : No. 04-607

8 METABOLITE LABORATORIES :

9 INC., ET AL. :

10 - - - - -X

11 Washington, D.C.

12 Tuesday, March 21, 2006

13 The above-entitled matter came on for oral

14 argument before the Supreme Court of the United States

15 at 11:12 a.m.

16 APPEARANCES:

17 JONATHAN S. FRANKLIN, ESQ., Washington, D.C., on behalf

18 of the Petitioner.

19 THOMAS G. HUNGAR, ESQ., Deputy Solicitor General,

20 United States Department of Justice, Washington, D.C.,

21 as amicus curiae, supporting the Petitioner.

22 MIGUEL A. ESTRADA, ESQ., Washington, D.C., on behalf

23 of the Respondents.

24

25

1	C O N T E N T S	
2	ORAL ARGUMENT OF	PAGE
3	JONATHAN S. FRANKLIN, ESQ.	
4	On behalf of the Petitioner	3
5	THOMAS G. HUNGAR, ESQ.	
6	On behalf of the United States	
7	Department of Justice, as amicus	
8	curiae, supporting the Petitioner	20
9	MIGUEL A. ESTRADA, ESQ.	
10	On behalf of the Respondents	29
11	REBUTTAL ARGUMENT OF	
12	JONATHAN S. FRANKLIN, ESQ.	
13	On behalf of the Petitioner	48
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

P R O C E E D I N G S

(11:12 a.m.)

JUSTICE STEVENS: We'll hear argument in number 04-607, Laboratory Corporation of America against Metabolite Laboratories.

Mr. Franklin, whenever you're ready, you may proceed.

ORAL ARGUMENT OF JONATHAN S. FRANKLIN
ON BEHALF OF THE PETITIONER

MR. FRANKLIN: Justice Stevens, and may it please the Court:

The patent claim at issue in this case was held to be infringed whenever any doctor looks at a homocysteine test result and reflexively thinks about a basic natural correlation. The result has been multimillion dollar damages and an injunction prohibiting a testing company from conducting important homocysteine tests by any method and for any reason whatsoever.

As broadly construed by the Federal Circuit, this claim is invalid as a matter of law for two closely related reasons. It contravenes both of this Court's settled proscription against effectively patenting laws of nature or natural phenomena as well as the requirement that a patent must fully and clearly describe, disclose and enable an actual invention and must not sweep so far as to

1 encompass more than what was actually invented.

2 JUSTICE KENNEDY: Is that second point -- is
3 that second point definiteness?

4 MR. FRANKLIN: The second point is
5 definiteness, it's enablement.

6 JUSTICE KENNEDY: Does definiteness describe
7 this second aspect that you've just --

8 MR. FRANKLIN: It describes part of it, Your
9 Honor.

10 JUSTICE KENNEDY: Just part of it.

11 MR. FRANKLIN: There is definiteness, there is
12 enablement, there is written description. We think all of
13 those are contravened here.

14 JUSTICE SCALIA: Let's examine them. What if
15 it definitely goes so far as to allow no other use of this
16 natural law that it's discovered? It definitely goes that
17 far, isn't definiteness fully satisfied?

18 MR. FRANKLIN: I think not, Your Honor,
19 because --

20 JUSTICE SCALIA: No?

21 MR. FRANKLIN: -- definiteness would still
22 require that you distinctly claim an invention here and
23 that's one of the things that's absent in this case. But
24 even moving beyond that, Your Honor --

25 JUSTICE KENNEDY: It's indefinite because we

1 don't know where our thoughts will take us? Suppose there a
2 patent which requires looking at the clouds in the sky for
3 10 minutes. I mean, that's maybe absurd, but it's certainly
4 definite.

5 MR. FRANKLIN: Well, Your Honor, if it is
6 definite, then it is certainly not enabling of an actual
7 invention. And here the Morse case, which we have cited in
8 our briefs, comes into play. In that case, the court held
9 that Samuel Morse was entitled to patent his innovative
10 telegraph but he couldn't go further to effectively patent
11 the law of nature or natural phenomenon associated with it
12 and thereby monopolize all manner of devices and processes
13 that he did not invent and did not enable or describe.

14 JUSTICE GINSBURG: But wasn't the issue there
15 what is patentable? I mean this case in the district court
16 was under this definiteness idea, 112. 101 deals with
17 what's patentable. And it seems to me that you -- this case
18 was presented as a definiteness case.

19 MR. FRANKLIN: But it was not just
20 definiteness, Your Honor. It was section 112. But let me
21 get to the Morse case because as we have explained in our
22 reply brief and, in fact, in our opening brief, the Morse
23 case was in fact decided under what is now section 112. The
24 Court cited and quoted the relevant statute which has not
25 changed in any material respect today. The Court made clear

1 that the problem in that case, at page 120 of the opinion,
2 was that Morse claims what he has not described in the
3 manner required by law.

4 And what we have here is the same situation.
5 We have these patentees who are indisputably entitled to
6 patent their innovative method for measuring homocysteine.
7 And LabCorp continues to use that method sometimes and we
8 pay royalties whenever we use that method. But what they
9 couldn't do is what Samuel Morse tried to do and push the
10 envelope, and try to effectively patent the natural
11 phenomenon associated with all homocysteine tests and
12 thereby gain a monopoly over just not the one that they
13 invented, not just those that are in the prior art, which
14 itself would be impermissible, but even yet to be invented
15 assays.

16 And here is the nub of this case. LabCorp has
17 sought to use but has been penalized for using and is
18 prevented from using a more efficient and cost-effective
19 method for assaying homocysteine than the one that these
20 patentees invented. The method that LabCorp seeks to use,
21 which is the Abbott method, reduces the processing time for
22 homocysteine tests down from what was up to 18 hours under
23 the patentee's method down to a manner of minutes.

24 JUSTICE GINSBURG: Is the Abbott test -- that's
25 patented and you're paying royalties for that?

1 MR. FRANKLIN: Actually, I don't know, Your
2 Honor. And, I just don't know whether it's patented but it
3 is certainly not covered by their claims 1 through 12, which
4 have never been -- well, the district court found that those
5 claims didn't apply here, and that's not an issue.

6 The Abbott method is different. It's an
7 immunoassay. It is not the same kind of mass spectrometry
8 gas chromatograph method that they have described. It's
9 much more efficient, it's much more cost-effective and the
10 reason obviously that LabCorp wants to use that method is to
11 more effectively serve patients and their doctors and to
12 meet the burgeoning demand for homocysteine tests. But
13 because these patentees have effectively claimed the patent
14 on the natural correlation that's associated with all
15 homocysteine tests, they have prevented LabCorp from using
16 what the patent laws would seek to encourage, that is, a
17 more cost-effective, innovative, different method, the kind
18 of thing -- exactly the kind of thing that the Court was
19 concerned about in Morse.

20 JUSTICE KENNEDY: The opinion of the Court of
21 Appeals for the Federal Circuit in the appendix begins
22 discussion of claim 13 about page 16a. Are there some, one
23 or two sentences there or a paragraph that you can tell me
24 is completely wrong?

25 MR. FRANKLIN: In the Federal Circuit's --

1 JUSTICE KENNEDY: Yes. You're asking us to
2 reverse this court of appeals decision and I'm looking, and
3 particularly with reference to claim 13, the one we're
4 talking about, I assume, and I'm looking through pages, say,
5 16 and 21 to find something that's absolutely wrong.

6 MR. FRANKLIN: Well, I think what --

7 JUSTICE KENNEDY: You want me to tell the court
8 of appeals, well, you can't do this. But where is it wrong?

9 MR. FRANKLIN: I think where it's wrong, Your
10 Honor, is that it proceeds from an assumption that is wrong
11 in itself and that is --

12 JUSTICE KENNEDY: So you can't point me to any
13 particular sentence that -- that's absolutely wrong?

14 MR. FRANKLIN: I think that the argument in --
15 the Federal Circuit's decision is wrong in its enablement
16 discussion, it's wrong in its written description
17 discussion. I mean, just to take one, the written
18 description posits that this is a valid written description
19 because the inventors, as the Federal Circuit says in its
20 opinion, possessed the correlating step. And I think what's
21 wrong about that, Your Honor, is that nobody can possess the
22 correlation. And that's the nub of this case.

23 JUSTICE KENNEDY: And where does it say this?

24 MR. FRANKLIN: I'm sorry, that is at page -- I
25 believe it's at 17 of the appendix. Let me just make sure

1 I've got the right -- and that was when it talks
2 about --

3 JUSTICE KENNEDY: You see my point? I'm not
4 sure what it is you want me to say went wrong, other than
5 the fact that this patent is, should never have been granted
6 to begin with but that wasn't raised.

7 MR. FRANKLIN: Well, I think it was raised,
8 Your Honor. The validity issue was raised in the district
9 court, it was raised on appeal. The district court had
10 construed the patent as requiring -- and part of the
11 district court's claim construction addressed the issue as
12 to whether or not one could patent a law of nature or
13 effectively patent a scientific idea. The district court
14 said this patent must require something more, and that is at
15 joint appendix page 60. It must require something more than
16 simple existence of the relationship between homocysteine
17 and vitamin deficiencies. And one of the places that the
18 Federal Circuit did get it wrong, Your Honor, was in
19 abandoning that limitation that the district court had
20 imposed on the patent.

21 JUSTICE BREYER: I guess that --

22 JUSTICE SOUTER: But you're arguing now, as I
23 understand it, that the reason you win on definiteness is
24 that it sweeps in even as yet uninvented processes.

25 MR. FRANKLIN: Yes.

1 JUSTICE SOUTER: And it does so by means, in
2 effect, of erecting this umbrella of a natural fact which is
3 intended to cover every process that might be relevant to
4 establishing that natural fact.

5 MR. FRANKLIN: Yes.

6 JUSTICE SOUTER: So that you're saying we
7 cannot -- no court can decide definiteness in this situation
8 without hitting the patentable issue.

9 MR. FRANKLIN: Absolutely, Your Honor. That's
10 exactly what we're arguing. And that's where the Federal
11 Circuit got it wrong. And we did in fact urge the Court --

12 JUSTICE BREYER: But you told the -- you said,
13 judge, if you in fact hold that this claim 13 satisfies
14 section 112 and is sufficiently precise and specific and
15 concise, if you hold that, then the claim would violate
16 Morse?

17 MR. FRANKLIN: Yes, it would violate --

18 JUSTICE BREYER: And you argued that
19 specifically? And so your problem -- I guess that you said
20 that. I mean, you quote it in your supplementary brief on
21 page 6.

22 MR. FRANKLIN: We did say that. Yes.

23 JUSTICE BREYER: And it's the language.

24 MR. FRANKLIN: Yes.

25 JUSTICE BREYER: That's what it said. It

1 didn't say Morse. It said Diehr.

2 MR. FRANKLIN: Diehr, which --

3 JUSTICE BREYER: Dier incorporates Morse.

4 MR. FRANKLIN: Yes.

5 JUSTICE BREYER: As was my understanding.

6 MR. FRANKLIN: Yes.

7 JUSTICE BREYER: So your complaint about the
8 paragraph on 17a is that it did not deal with that
9 argument.

10 MR. FRANKLIN: Yes.

11 JUSTICE BREYER: But I imagine they'll say that
12 simply mentioning it in an oral argument is not enough to
13 get us to think seriously about it.

14 MR. FRANKLIN: Well, it was in the brief, Your
15 Honor, and I think that it was also in, with the premise of
16 everything that we argued, because the district court had
17 already -- and again, I point the Court to joint appendix
18 page 60. The district court had already held that it had to
19 mean -- the patent had to mean something more than the
20 simple relationship, the simple existence of the
21 relationship between elevated homocysteine and vitamin
22 deficiencies. And the premise of the entire Federal Circuit
23 argument and, in fact, to the arguments below was that we
24 don't know what that anything is, because the patent doesn't
25 tell you.

1 The Federal Circuit blew past that, Your Honor,
2 and what the Federal Circuit said, which makes the issue
3 front and center now, is the Federal Circuit said, and this
4 is at 18a. "The correlating step is a simple conclusion
5 that a cobalamin/folate deficiency exists vel non based on
6 the assaying step."

7 And what that means is now, as a result of the
8 Federal Circuit's decision, unlike the district court's
9 decision, we now know that every homocysteine test
10 automatically infringes because every doctor will
11 reflexively look at it and think about the phenomenon
12 associated with it.

13 JUSTICE GINSBURG: You set off the district
14 court and the court of appeals but you don't think the
15 district court got it right, either. You said the district
16 court required something more.

17 MR. FRANKLIN: Yes.

18 JUSTICE GINSBURG: What was the something more
19 and why wasn't that adequate?

20 MR. FRANKLIN: We don't know and that's why it
21 wasn't adequate. That's why we had always argued under
22 indefiniteness and under enablement, under written
23 description. We had no idea. The patent doesn't tell you.
24 We suggested one way. That wasn't -- the Federal Circuit
25 didn't agree with us. The problem with the district

1 court's -- we agreed with the district court's claim
2 construction. That far, we did. But then there was nothing
3 more even adduced at trial, and this was the argument we
4 consistently made. The Federal Circuit then abandoned what
5 the district court did and then we here have it front and
6 center with the patent --

7 JUSTICE GINSBURG: What the district court did
8 is it got, it tried this case and it got a rather large jury
9 verdict.

10 MR. FRANKLIN: Yes.

11 JUSTICE GINSBURG: And I don't understand how
12 you're setting off the district court from the court of
13 appeals when the court of appeals, whatever it said, it
14 affirmed the judgment of the district court.

15 MR. FRANKLIN: It did, but the claim
16 construction is the part of what I'm talking about. At page
17 60, I'll just read what the district court said.
18 "Correlating is a verb and must mean more than the simple
19 existence of a relationship between a high level
20 homocysteine and deficiency in cobalamin or folate."

21 The Federal Circuit's opinion is contrary to
22 that, Your Honor, and that's where this whole issue gets put
23 front and center now. And what we have here under the
24 Federal Circuit's extraordinarily broad construction is we
25 have nothing more than the reflexive mental recognition of a

1 natural correlation preceded by the inherent and generic
2 step of somehow ascertaining the input for that correlation.

3 JUSTICE SCALIA: I could see how that broad
4 interpretation would raise perhaps for the -- clearly raise
5 for the first time the section 101 issue. But, so that
6 should have been clear to you by the time the court of
7 appeals decision came out, right? But did you, in your
8 petition here, rely on 101?

9 MR. FRANKLIN: Well, we relied, Your Honor, on
10 all of -- many, many cases in court interpreting that
11 provision and others under the law of nature doctrine --

12 JUSTICE SCALIA: You never mentioned 101,
13 though, did you?

14 MR. FRANKLIN: We didn't but just as an
15 example, Your Honor. The court's invitation or, to the
16 solicitor general didn't mention 101, but everybody knew
17 what the court was talking about. And let me just -- the
18 petition couldn't have raised -- the petition squarely
19 raised the issue. On page 18, we cited Diamond versus
20 Diehr, Benson, Funk Brothers, Mackay Radio and the Le Roy
21 case from 1852. On page 26, we cited, quoted, relied on
22 Funk Brothers and Mackay Radio again. Page 27 refers back
23 to the authorities at page 18 of the petition. Page 28
24 states that under the Federal Circuit's holding, anyone who
25 claims to be the first to discover scientific correlation

1 could patent it simply by drafting the vague test plus
2 correlate claim.

3 This issue was presented in the petition. It
4 is within the question presented. And, Your Honor, I think
5 that the issue is easy to resolve given the Federal
6 Circuit's broad construction. Under that construction,
7 again, there is nothing more than the recognition of the
8 natural phenomenon preceded by what is the inherent step in
9 any natural correlation of ascertaining the input. And as
10 we have said without contradiction in the opening brief, if
11 this patent is valid, then anyone can gain a patent over a
12 scientific correlation by doing this kind of artful
13 drafting. Einstein could have patented $E=MC^2$ which this
14 Court has stated on more than one occasion could not be
15 patented simply by doing a test plus correlate.

16 To take another hypothetical that was stated in
17 the opening brief without contradiction, if I discover
18 tomorrow a new correlation between having a certain kind of
19 blood type and a medical condition that heretofore people do
20 not know about, I could run down to the Patent Office,
21 patent that correlation and the effect of that would be to
22 monopolize all blood typing, no matter whether it's done
23 through methods in the prior art or methods yet to be
24 developed.

25 JUSTICE ALITO: Is it true as the Respondents

1 argue that a holding in your favor would call into question
2 thousands of patents?

3 MR. FRANKLIN: Well, they don't mention all --
4 the number but I don't think it would call into question a
5 huge swath of patents. It would call into question patents
6 that are like this one, obviously, things that are simply
7 test plus correlate.

8 JUSTICE ALITO: And do you have any idea how
9 many there are of those?

10 MR. FRANKLIN: No. You would have to do an
11 exhaustive search. There are some and I believe that some
12 of the ones that the Respondents cite, some of the claims --
13 and let's distinguish between patents and claims here,
14 because it might invalidate some claims in some patents,
15 which is not unusual because patent drafters often push the
16 envelope. They patent this -- in this case, they have
17 indisputably unchallenged and valid patent claims for a
18 method of measuring homocysteine, but they went further in
19 claim 13. And to the extent there are other patents that
20 might have those kind of claims, yes. But to the extent
21 we're talking about the broader swath of patents dealing
22 with things like genes, no.

23 JUSTICE KENNEDY: Well, if that's -- if there is
24 some likelihood or possibility of this that we should assess,
25 it seems to me that it's imprudent for us to discuss it here

1 when it hasn't been discussed in the court of appeals.

2 MR. FRANKLIN: I think, well, it was, again, it
3 was pressed in the court of appeals. But again, what we're
4 talking about is deciding this case on its facts and
5 obviously to the extent there are other patents that are
6 just like this one, and the court has addressed this in the
7 context of Flook and Diehr and has distinguished between
8 those patents which facially looked rather similar but the
9 court was able to draw the distinctions. The Federal
10 Circuit can draw the distinctions.

11 But if it is a patent that is simply like this
12 one, which claims nothing more than a natural correlation
13 preceded by the inherent step of ascertaining the input, no
14 court, to my knowledge, has ever upheld such a patent before
15 this case.

16 JUSTICE KENNEDY: You're urging on us something
17 like plain error, is about what you're telling us.

18 MR. FRANKLIN: No, I think that we're urging
19 the Court to examine the case that it has before it, look at
20 the patent and we're not asking the Court to go further than
21 this patent. Look at this patent, look at the Federal
22 Circuit's construction and that's something that we will
23 take as a given for purposes of today's proceeding.

24 JUSTICE STEVENS: You're saying this patent, you
25 really mean just claim 13, don't you?

1 MR. FRANKLIN: I'm -- excuse me, Justice. And
2 again, I wanted, as I was saying to Justice Alito, you do
3 need to distinguish between patents and claims. And claim
4 13 is the only claim that's been asserted here. It's the
5 only claim that's being challenged. And let me just --

6 JUSTICE SCALIA: Why shouldn't we do what the
7 Solicitor General proposed, that is, since we don't know for
8 sure, at least I don't know for sure, I'm not enough of a
9 scientist --

10 MR. FRANKLIN: Right.

11 JUSTICE SCALIA: -- whether in fact the section
12 112 determination, as made by the Federal court, excludes all
13 other possible use of this natural phenomenon.

14 Since I don't know that for sure, why shouldn't
15 I tell the Federal Circuit, you know, your definition of
16 correlate raises this issue and you should resolve whether
17 it is true that there is no other possible usefulness for
18 this, no substantial usefulness?

19 MR. FRANKLIN: Quite simply, Your Honor, it's
20 because the Court doesn't need to reach that issue and
21 didn't need to reach it in any of its prior cases save one
22 and that's the Benson case where that issue came up really
23 in one sentence of the opinion. In the Morse case, in the
24 Funk Brothers case, in the Flook case, all of those patents
25 had -- were limited to a particular use.

1 Just take Morse's patent which was limited to
2 just conveying information at a distance through
3 electromagnetism. That was actually one very small sliver
4 of what you can do with electromagnetism. In fact, very,
5 very small. And the Court said, no, it doesn't matter.
6 Where what you have is effectively the patent on the
7 correlation, it doesn't matter whether you've limited it to
8 one use or many uses. So if the Court --

9 JUSTICE SCALIA: Okay.

10 MR. FRANKLIN: -- so I don't think the Court
11 needs to get into that. In Diehr, the Court made that
12 explicit that a field of use -- limiting a patent to a
13 field of use is not going to save that patent from
14 invalidity.

15 Now, if the Court does examine the issue, it
16 ought to do it the way it did it in Benson just by looking
17 at the broad sweep here. And how I would use it, Your
18 Honor, would be to say that in addition to all of the other
19 problems that this patent, as construed by the Federal
20 Circuit, has, it also has an extraordinarily broad
21 pre-emptive sweep. It applies to any homocysteine test, no
22 matter how it's done, no matter what reason it's done, no
23 matter if it's in the prior art, no matter if I invent it
24 tomorrow.

25 It applies to any act of even looking at the

1 test. And here it's not just doctors. If anyone in the
2 audience today learns about this correlation because of this
3 argument, if they're listening carefully, and then they go
4 to their doctor and ask for a test, they will, number one,
5 be inducing infringement; number two, if they look at the
6 test result, now being armed with what we have given them,
7 which is the scientific knowledge that the correlation
8 exists, they will infringe. And there was testimony in
9 trial to that effect.

10 So I don't think the Court needs to get into
11 the inquiry, and I don't think the Patent Office really
12 wants to get into that inquiry either. To have to look at
13 each patent application to determine not just based on
14 what's in it whether it's valid but whether there are other
15 uses not even invented yet that might not be covered.
16 That's not, I submit, what the Patent Office would like to
17 do.

18 If I might reserve the remainder of my time.

19 JUSTICE STEVENS: You may, Mr. Franklin.

20 I think Mr. Hungar is next, Mr. Estrada.

21 MR. ESTRADA: Oh, sorry, Justice Stevens.

22 JUSTICE SCALIA: You're too hungry,

23 Mr. Estrada.

24 JUSTICE STEVENS: Mr. Hungar.

25 ORAL ARGUMENT OF THOMAS G. HUNGAR

1 ON BEHALF OF THE UNITED STATES

2 DEPARTMENT OF JUSTICE AS AMICUS CURIAE

3 MR. HUNGAR: Thank you, Justice Stevens, and
4 may it please the Court:

5 Claim 13 satisfies the written description,
6 enablement and definiteness requirements of section 112 of
7 the patent act. The patent specification sets forth the
8 scope and nature of the claimed invention in terms readily
9 understandable by a person of ordinary skill in the art and
10 it enables such persons to practice the claimed invention.

11 JUSTICE KENNEDY: So you agree or you submit
12 that you can have a definite description of something that's
13 unpatentable because it's too broad?

14 MR. HUNGAR: Well, that obviously assumes the
15 conclusion, Your Honor. But with respect to the
16 definiteness requirement, the challenge seems to be that
17 because the first step of claim 13 is not limited to a
18 particular type of assay but instead claims all assays, that
19 that somehow renders it indefinite, and that argument is
20 simply incorrect as this Court has recognized for over a
21 hundred years.

22 In the Cochrane against Deener case, for
23 example, the Court addressed that question where a process
24 claim was not limited to a particular method of performing a
25 particular step of the process, and the Court said quote, "A

1 process may be patentable irrespective of the particular
2 form of the instrumentalities used", closed quote. And the
3 Court reiterated that principle in the Diehr case.

4 JUSTICE KENNEDY: But, but, but -- well, let's
5 assume that there is a claim that includes something that
6 should not be patentable, because it's too broad or it
7 involves the scientific phenomena, the mechanics of the
8 universe. Can a patent still be definite if it includes
9 that sort of unpatentable claim?

10 MR. HUNGAR: It can be. It might or might not
11 be depending on the circumstances. The Morse case is an
12 example where it was both indefinite and invalid because
13 trying to claim a principle of nature, in effect. But by
14 the same token you can easily have, and in fact you have
15 here, a claim where it's definite in that persons of
16 ordinary skill in the art understand the scope of the
17 claims. They know what is and is not within the scope of
18 the patent, which is, in this case, a question entirely
19 separate from the question whether, as construed by the
20 Court and as understood by the person of ordinary skill in
21 the art, it's valid, under section 101, that is, under the
22 scope of patentable subject matter.

23 JUSTICE STEVENS: What do you think about its
24 validity under 101?

25 MR. HUNGAR: Your Honor, as we suggested in our

1 brief, we don't think that that question is properly before
2 the Court but that --

3 JUSTICE STEVENS: I understand, but I didn't ask
4 you what you said in your brief.

5 MR. HUNGAR: Yes, Your Honor. But that if the
6 Court were to reach that question, we think that while it's
7 unclear because the issue wasn't litigated, there appears to
8 be prima facie evidence of invalidity under Benson, this
9 Court's decision in Benson, because, given what we currently
10 know, it appears that the claim as construed by the court of
11 appeals preempts all substantial practical applications of
12 the correlation. But because that issue wasn't litigated
13 below, if the Court were to reach it, it should remand --

14 JUSTICE STEVENS: To you read the the patent as --
15 talking about step 1, you can use any assay method you want.
16 It doesn't have to be patented. But the correlation, step 2,
17 that any time you ask a doctor to tell us what you think the
18 results of the test mean, that that's an infringement?

19 MR. HUNGAR: That's how the court of appeals
20 construed it, yes, Your Honor. I'm sorry. Is that --

21 JUSTICE STEVENS: And is it possible that that
22 can be patentable, in your view?

23 MR. HUNGAR: Well, again, Your Honor, we --

24 JUSTICE STEVENS: If you just go to the doctor
25 and ask for advice and he says, yes, I've looked at the

1 results; you've got a vitamin B deficiency or whatever it
2 is --

3 MR. HUNGAR: As we indicated --

4 JUSTICE STEVENS: -- he's committed
5 infringement under this patent as I understand it.

6 MR. HUNGAR: As we indicated in our brief, we
7 think that raises a potentially serious pre-emption problem
8 and it also raises the anticipation problem, that is, the
9 section 102 argument which is not before the Court but if it
10 were litigated --

11 JUSTICE STEVENS: It would raise the -- just
12 do you think that that patent is valid? That's what I'm
13 trying to ask you.

14 MR. HUNGAR: Well, we think it has validity
15 problems under section 102 and also under the pre-emption,
16 -- potentially under the pre-emption doctrine. We haven't
17 addressed the other issues that Petitioner seeks to put
18 before the Court involving Diehr and Flook, both because --
19 well, actually for four reasons.

20 First of all, it wasn't pressed or passed upon
21 below, it wasn't -- it's not fairly included within the
22 question presented, which construed at its most broad,
23 broadly, includes only the monopolization issue --

24 JUSTICE STEVENS: I know all that. I'm just
25 really interested in your view of the patent. That's what

1 I'm trying to get to.

2 MR. HUNGAR: Yes, Your Honor. And as I've
3 said, we've identified two areas in which we think there are
4 potentially problems if they were in front of the Court.

5 JUSTICE STEVENS: Do you think there is a 101
6 problem too?

7 MR. HUNGAR: The preemption issue is a 101
8 problem, Your Honor. We haven't addressed -- as I said, we
9 have not taken a position on the broader section 101 issues
10 and we would urge the Court not to do so as well, in a case
11 in which it wasn't presented below, the Court doesn't have
12 the benefit of the lower court's assessment of that
13 question. And given that that question implicates
14 substantial reliance interests and --

15 JUSTICE STEVENS: So we do have a fairly long
16 discussion by the lower court on the infringement issue. In
17 order to find infringement, they had to construe
18 correlation.

19 MR. HUNGAR: Yes, Your Honor.

20 JUSTICE STEVENS: Yes.

21 MR. HUNGAR: But the Court didn't grant
22 certiorari on that question. Yes.

23 JUSTICE BREYER: I didn't understand the
24 definiteness doctrine. I mean, all these things in 1854 I
25 guess weren't so clear. But I think the precise claim in

1 Samuel Morse's case was the use of the motive power of the
2 electric current for making or printing intelligible
3 characters. That sounds absolutely definite. Anyone can
4 understand it.

5 I thought the problem there was that although
6 anyone can understand it, you can't claim something as broad
7 as that. You must intend to claim something narrower. And
8 insofar as it's narrower, it isn't precise. So insofar as
9 it's broad, it's too broad, but definite. And insofar as
10 it's narrow, it's not there, but indefinite. Okay?

11 Precisely the claim that they raised before the
12 Federal Circuit and precisely the claim -- with appropriate
13 citations, and precisely the claim in respect to which the
14 Federal Circuit said nothing.

15 MR. HUNGAR: Your Honor, I may have misspoken
16 before but I think it's probably most accurate to read the
17 Morse case as dealing with a written specification problem,
18 that is, the specification in claim 8, the one Your Honor is
19 referring to, didn't tell anything about the method by which
20 the principle of nature, electromagnetism, would be used.
21 All it did is describe a result, and it purported to claim
22 any, any method involving any number of steps that any
23 inventor might ever invent in the future, even if those
24 steps had nothing to do with -- if there was not a single
25 overlapping step between that new process and Morse's

1 process.

2 JUSTICE BREYER: Yes. And we here apply the
3 correlation to any homocysteine test, any one here, any one
4 in the future, any one that any mind might impend. What's the
5 difference?

6 MR. HUNGAR: Well, the difference is between
7 claiming a -- claiming all methods of achieving a particular
8 result and claiming one process for achieving that
9 particular result and then as one claiming any means of
10 doing one particular step of that process.

11 JUSTICE BREYER: I apply electricity to all
12 methods of putting down letters with electricity. I apply
13 the correlation to all methods of creating a homocysteine
14 test.

15 MR. HUNGAR: Well, again, Your Honor, if it is
16 true that all methods of employing the assay -- excuse me,
17 all methods of employing the correlation are preempted by
18 this patent claim, then it would be invalid under section
19 101. But to the extent the argument is an attempt to go
20 beyond that issue, we submit Morse doesn't support it and
21 indeed this Court's decision's in --

22 JUSTICE BREYER: Oh, no, I'm not talking about
23 going beyond it. I just thought that line between
24 definiteness and 101, 112, 101 is not quite so clear as I
25 would have thought, because it sounds to me relying on the

1 1854 case of Samuel F. B. Morse, they're making the same
2 kind of argument and, indeed, you translated Morse as a
3 definiteness 112 argument, and yet it seemed to me that's
4 the kind of argument they're making.

5 MR. HUNGAR: Yes, Your Honor. And I think it
6 is more properly understood as a specification problem
7 because, as you say, anyone can understand the scope of that
8 claim. It's just that it was not sufficiently described
9 because he was purporting to claim any process even if it
10 had nothing to do with the process he had invented, and
11 that's not what's happening here. They claim a particular
12 step, that is, do an assay, as opposed to some other method,
13 and they claim any method of doing that assay within step 1
14 of the overall claim but they aren't saying -- for instance
15 the analogy would be if they had claimed we've just
16 devised one particular method of determining whether someone
17 has a vitamin deficiency and we therefore claim all other
18 methods of determining whether someone has a vitamin
19 deficiency.

20 JUSTICE SOUTER: Okay, I think you've hit what
21 is the problem for us. When you use the word assay, you
22 assume that that is excluding certain processes. And that's
23 not clear to me. Would you explain that in greater detail?

24 MR. HUNGAR: Well, again, we don't know --

25 JUSTICE SOUTER: I thought an assay was in

1 effect synonymous with any process that gets the relevant
2 data and you're using it in a more -- I think, in answering
3 Justice Breyer's question, you were using it in a narrower
4 sense.

5 MR. HUNGAR: Well, I think that, as understood
6 by a person having ordinary skill in the art, we -- it may
7 be. We don't know because the issue wasn't litigated.

8 JUSTICE SOUTER: But I thought that was the
9 point of your argument, that there are assays and then there
10 are other methods. Did I misunderstand you?

11 MR. HUNGAR: Well, no. Certainly it's
12 conceivable that there are other methods and indeed the
13 patent claim -- the patent specification refers to -- or
14 suggests the possibility of assaying tissue as opposed to
15 fluid. The claim is limited to fluid.

16 I thank the Court.

17 JUSTICE STEVENS: Thank you, Mr. Hungar.

18 Mr. Estrada, it's your turn now.

19 ORAL ARGUMENT OF MIGUEL A. ESTRADA

20 ON BEHALF OF THE ON RESPONDENTS

21 MR. ESTRADA: Thank you, Justice Stevens.

22 Thank you, Justice Stevens, and may it please the Court:

23 This was a hard fought jury trial in which the
24 jury rejected everything LabCorp had to sell. That judgment
25 should be affirmed for three reasons.

1 The first is LabCorp never asked the trial
2 judge or the Federal Circuit to declare this patent invalid
3 under section 101, which is an affirmative defense they had
4 to plead in the answer and prove by clear and convincing
5 evidence.

6 Second, they're simply wrong on the merits of
7 the 101 case under this Court's cases.

8 And third, you can search their brief in vain
9 for a workable test for patentable subject matter that would
10 invalidate this patent and not bring complete havoc to the
11 patent world by calling into question numerous diagnostic
12 tests in medicine and otherwise, pharmaceuticals and other
13 inventions.

14 Let me deal briefly with the waiver question
15 because we don't get a sur-reply brief and there is a lot in
16 the reply brief that I wish I could deal with at length.
17 But I think I will say that it is a collection of cropped
18 quotes and very inventive characterizations of the record.
19 I will give you just two examples.

20 Bottom of page 9, they're trying to get out of
21 their Unitherm problem, never having this raised in the answer
22 or in the rule 50. And the footnote at the bottom of the page
23 discusses the rule 50 and states or at least suggests that this
24 argument in terms was raised before the trial court, concluding
25 with the sentence, "Respondents themselves understood LabCorp to

1 have thereby presented subject matter patentability." They cite
2 to our brief on JMOL.

3 I have that here. This is what we said. "The
4 quick answer to LabCorp's mental steps theme is that LabCorp
5 never pled it in the defense. LabCorp pled invalidity on
6 the basis of 102, 103, 112 on the grounds that the patent
7 was anticipated, obvious, indefinite, non-enabled and
8 procured by inequitable conduct. But the so-called mental
9 steps doctrine goes instead to the question whether patent
10 covers statutory subject matter. That is governed
11 exclusively by section 1, 101. LabCorp has never mentioned
12 that section and has never pled the patent is invalid for
13 covering non-statutory subject matter even, in its present
14 JMOL motion.

15 Footnote: LabCorp failed to assert invalidity
16 on the basis of non-statutory subject matter in any of its
17 five answers or counterclaims or in any of its interrogatory
18 responses. None of its experts, including its patent law
19 expert, made any such assertion in any reports or testimony.
20 That gets translated in the reply brief as we understood
21 this issue was in front of the court.

22 Now, we made that point in our papers. There
23 was no response saying, no, wait, district judge, this isn't
24 the case. Rule on section 101.

25 Not a word.

1 We had the same exchange in the Federal Circuit
2 and, once again, we pointed out this was 101, had been
3 waived six ways from Sunday. Not a response telling the
4 Federal Circuit, this isn't the case, please rule. And this
5 is important because you're being asked to tell trial court
6 and three courts of appeals judges that they committed
7 reversible error for failing to address a question that
8 nobody ever asked them.

9 JUSTICE BREYER: Now what do you say in
10 response to my question to the Solicitor General?

11 MR. ESTRADA: Which question, Justice Breyer?
12 I'm sorry.

13 JUSTICE BREYER: That they thought it was
14 obvious, that they thought that obviously the problem here
15 with this particular claim is that it doesn't say
16 specifically which tests this principle is meant to apply
17 to. So it isn't definite enough. It never occurred to
18 anyone that if you tried to apply it to every test, it was
19 somehow a valid patent, so they made it in the definitive
20 context. Because for 154 years, it's been clear that you
21 can't take a principle of nature like electricity and simply
22 make a claim for all uses of electricity to create letters.
23 That's their analogy.

24 And they thought by referring to the cases and
25 by referring to the failure to point out definitely what the

1 tests were this applied to, it violated 112 because
2 otherwise, it wouldn't be a valid patent, which everyone in
3 the patent field would know. That's at least, I think, what
4 they're saying.

5 MR. ESTRADA: I think it is wrong on the facts
6 and on the law. If it was obvious all along this is an
7 affirmative defense under section 282 of the patent code,
8 that must be pleaded. One certainly can't be excused for
9 failing to plead something that, dare I say, is obvious.

10 But let's deal with the Morse case.

11 Mr. Franklin said it's the same statute at the time.
12 Actually, that is not so. At the time Morse was decided,
13 section 112 and 101 were both together in section 6 of the
14 1836 patent act. In 1870, Congress broke that off. That's
15 important because in Diehr, this Court considered a similar
16 issue with respect to the novelty requirement and concluded
17 that once Congress consciously wrote the novelty requirement
18 out of section 101, it was inappropriate to inject, you
19 know, the novelty considerations into section 101.

20 The second answer to the Morse question,
21 Justice Breyer, is that the test for definiteness is not is
22 this definite in the abstract, but is it really too broad in
23 relation to the inventive contribution as disclosed in the
24 specifications. And the contrast here that is important to
25 keep in mind is between Morse in 1854 and Alexander Graham

1 Bell, claim 5 of that patent.

2 Just to set it up, in the Morse case, claim 8,
3 it had been known for many years that it was possible to
4 transmit using the electromagnetic current but nobody knew
5 how. And in fact, this Court's ruling on page 107 says this
6 was known by men of science everywhere. And the problem was
7 that Morse discovered one particular way to transmit
8 characters at a distance and tried to patent everything that
9 everybody might ever discover using whatever means to print
10 at a distance.

11 Alexander Graham Bell is a good contrast.
12 Claim 5. It was also known that you could use the
13 electronic current to transmit voice. People had tried and
14 tried and tried and, in fact, there was somebody in Germany
15 who successfully transmitted music but not words. This is
16 all in -- in the Court's opinion. Now, Graham Bell
17 discovered that the key was to use continuous undulations in
18 current. Continuous undulations, not discontinuous
19 undulations. And had a patent claim, claim 5, which was
20 very broad. All users of continuous undulations to transmit
21 voice or sound. The Court said that's absolutely right,
22 because he was not trying to claim beyond his inventive
23 contribution to the art.

24 Now, Drs. Stabler and Allen in this case
25 discovered something very important which is all of the

1 medical tests that existed in the art as late as the 1880s
2 -- the 1980s were wrong. People were horribly misdiagnosed.
3 And there was a test that existed but nobody used. This is
4 what the record was.

5 The test for existing homocysteine was almost
6 never used, as Dr. Allen testified to this. There is
7 evidence in the record. This is why we have jury trials.
8 And what happened was this test was solely for attempting to
9 diagnose inherited enzyme defects. This is rare. Nobody
10 used it. There was not a market for it.

11 As a result of the discovery, the medical
12 community came around and concluded that everything they
13 were doing was wrong and the new test combining the
14 knowledge that it was possible to assay for homocysteine --
15 and by the way, the assaying means only measuring -- total
16 homocysteine with the discovery of the correlation could be
17 put together, as Diehr allows, to come up with a better
18 diagnostic test. And at the time, obviously, and this is,
19 again, in the trial testimony, no market for this. Nobody
20 wanted to do it. Everybody was just delighted with the
21 existing tests. And so Dr. Allen and Dr. Stabler had to set
22 up their own lab to do it.

23 It was after the medical community came around
24 that all of the lab companies became interested in doing
25 this commercially. And I go into this level of detail

1 because I think it is in part needed to answer the point
2 made by the Solicitor General. In a world in which there
3 was no commercial use for the existing prior art because it
4 was used rarely, and a market develops solely as a result of
5 people using the test to practice the invention, I think
6 it's analytically incorrect to say that we're trying to
7 monopolize the existing prior art. What has happened is
8 commercial laboratory companies like LabCorp are selling the
9 test to practice our invention. It was open to them to
10 say --

11 JUSTICE STEVENS: No, but let me just interrupt.
12 The -- as I understand it, the alleged infringers don't use
13 the same novel process that you use in your assay, in other
14 words, step 1. They do not use the step 1 in claim 13, is
15 that correct?

16 MR. ESTRADA: Our -- yes and no. I think there
17 is an ambiguity in the question, Justice Stevens, because it
18 is true that the Abbott method --

19 JUSTICE STEVENS: Well, assume it's not Abbott.
20 Just say I come up with a novel method that's not covered by
21 the patent that I can get the assay results. And say a
22 doctor says, would you test the blood under your unpatented,
23 novel method and tell me what the results are?

24 MR. ESTRADA: All right.

25 JUSTICE STEVENS: And now if I do that and then

1 the doctor looks at it and says I think you've got a vitamin B
2 deficiency, has he infringed your patent?

3 MR. ESTRADA: If the test was not ordered for
4 the purpose of diagnosing --

5 JUSTICE STEVENS: It was ordered for the
6 purpose of letting the doctor know exactly what the assay
7 would be. Yes.

8 MR. ESTRADA: Well, unless --

9 JUSTICE STEVENS: He hasn't --

10 MR. ESTRADA: -- there was a purpose for
11 diagnosing the deficiency, I would say no. And while we're
12 on the subject of engaging what our arguments have been all
13 along, we made clear in our brief, and nobody ever
14 responded, at page 38, that claim 13 is only infringed when
15 the assaying and the correlating steps are both performed
16 sequentially for the purpose of diagnosing vitamin B
17 deficiency.

18 JUSTICE STEVENS: Yes, a doctor asked me to
19 perform under my -- my own method, step 1, which I do it and
20 I give him the results and then he tells the patient, I
21 think you've got a vitamin B deficiency, in that case, he
22 has infringed, if I understand your argument.

23 MR. ESTRADA: If he did it for the purposes of
24 trying to determine whether you had a vitamin deficiency.
25 Now, if he did it for the purpose of trying to determine, as

1 in the prior art, whether you had an inherited enzyme
2 condition, that would not be infringing. And this point was
3 addressed, obviously somewhat indirectly because it was
4 never raised in the court of appeals, by the Federal Circuit
5 at page 9a and 10a where the Federal Circuit explained the
6 correlating step was included as a limit for the intended
7 use of the test as a means to distinguish the intended use
8 for this test from the prior art.

9 JUSTICE BREYER: You're onto something, to me,
10 that is absolutely fundamental. You have millions of
11 doctors and scientists and computer people who are working
12 extremely hard to think of useful ideas and if you don't
13 give them an incentive, they may think of less.

14 MR. ESTRADA: Correct.

15 JUSTICE BREYER: And they're all useful. At
16 the same time, if you patent all of their ideas, including
17 very useful mini-micro principle ideas, you will establish
18 monopolies throughout this country beyond belief and it will
19 be difficult for people, without paying vast amounts of
20 money, to use their useful ideas.

21 So what principle do we use to separate the
22 scientific idea which can't be patented from the process
23 which can be? I thought that the claim was settled by
24 Morse, Flook and Diehr. Now would it make sense -- you can
25 answer any part of this question you want.

1 MR. ESTRADA: All right. Let me --

2 JUSTICE BREYER: Would it make sense to send
3 this back and say, look, at least address their argument?
4 You can answer any part of that.

5 MR. ESTRADA: Three answers. Number one, under
6 the patent laws, everybody -- anybody who makes, uses or
7 sells the invention is potentially liable as an infringer.
8 Number two, Congress knows this and it knows that the people
9 who might be liable as infringers are doctors. It passed in
10 1996 section 287(c) of the patent law that gives doctors a
11 defense to infringement for certain things they do in their
12 offices, not this one. So Congress is perfectly aware of
13 all of the policy issues being raised and has chosen to give
14 an answer only so far.

15 The third is it is a fundamental misconception
16 to treat the case as though, even if the section 101 issue
17 is in front of the Court -- and it isn't -- whether the
18 issue is whether section 101 means that something is
19 actually patentable as opposed to what Diehr said, which is,
20 is it possibly patentable. This is subject matter
21 patentability. Is the mouth of the funnel, not the end of
22 the funnel, and all of the outlandish hypotheticals that we
23 have to deal about how this could be patented don't really
24 deal with the reality of the patent code, which is this is
25 the intake funnel. We have doctrines of obviousness,

1 anticipation, 112, many other things, all of which were
2 raised at trial and the jury rejected in this case.

3 But the reason why there may be some
4 superficial appeal to the outlandish hypotheticals, Justice
5 Breyer, is because there is an effort to confuse the issue
6 that they're trying to smuggle belatedly into the case, 101,
7 as though it dealt with whether something is actually
8 patentable as opposed to potentially patentable. And on the
9 latter question, whether something is potentially
10 patentable, we have the extremely broad language of section
11 101 coupled by this Court's cases, in Chakrabarty and Diehr,
12 which said that what Congress intended is for anything under
13 the sun made by man to be potentially patentable. And if
14 there is some more precise policy issue why a particular
15 invention ought not to be patentable, it is found in section
16 102, 103, 112, other parts of the patent code, on which they
17 lost in front of the jury.

18 JUSTICE SCALIA: What was made by man here?

19 What was made by man here? I mean, if you're
20 talking about the type of assay that your client developed,
21 which was involved in other claims, not in 13, then I'd
22 say, yes, that was made by man. But here, what 13 involves
23 is simply discovery of the natural principle that when one,
24 when there is the presence of one substance in a human
25 being, there is a deficiency of two other ones. That's just

1 a natural principle. What's made by man about that?

2 MR. ESTRADA: Well, the -- we don't contend that
3 the second step of the correlation is independently
4 patentable even though the argument is framed as a --
5 argument. What we contend is patentable and what's allowed
6 by Diehr is the inventive spark of putting together the
7 discovery of the correlation with a way found elsewhere to
8 measure these important bodily chemicals to produce a
9 diagnostic test.

10 JUSTICE SCALIA: A way found elsewhere if
11 indeed the Federal Circuit had determined the second step,
12 you know, step 1, do the assay, step 2, correlate. If the
13 Federal Circuit had said, oh, that requires your using a
14 scale to see how much of one there is and how little of the
15 other, but this Federal Circuit says, all correlate means is
16 be aware of the fact that when one substance is high, the
17 other two are going to be low. That's all it means.

18 MR. ESTRADA: Well, that's unfair to the Federal
19 Circuit on two points. Number one, it was very clear to the
20 Federal Circuit, and in fact I think they said that, I can't
21 put my hand on the page, where they said, there is no issue
22 here about step number one. All that people are fighting
23 about is the correlating step and what it means.

24 And the problem that LabCorp had in the Federal
25 Circuit with respect to the correlating step, which is a

1 question they tried to bring up and was cert denied, is that
2 they proposed in the district court the definition that was
3 used by the Federal Circuit, which is a mutual or reciprocal
4 relationship between an elevated level and the vitamin. And
5 so having proposed that, it actually makes sense as a
6 diagnostic test, as the Federal Circuit pointed out with the
7 example of the pregnancy test.

8 Now, Justice Scalia, you asked a question
9 earlier --

10 JUSTICE SCALIA: No, please don't get off it --
11 because this is my biggest problem with the case. I agree
12 that what you've said is simply a statement of the natural
13 phenomenon, that when the one substance is high, the other
14 two are low. And simply to be aware of that natural
15 phenomenon is all that correlation consists of.

16 MR. ESTRADA: Well, it is true but is not
17 necessarily the case that being aware of a natural
18 phenomenon or of a correlation leads you inevitably to an
19 inventive diagnostic test. There is a correlation between
20 being tall and being -- you know, between height and weight.
21 If I tell you that somebody's coming to visit you who is 250
22 pounds, that person is probably not a five year-old. But that
23 gets me nowhere in terms of turning that into useful knowledge
24 that could be patentable.

25 JUSTICE STEVENS: But you do agree, do you

1 not, that step 2 by itself would not be patentable?

2 MR. ESTRADA: I do agree with that, Justice
3 Stevens.

4 JUSTICE STEVENS: Your point is that even
5 though step 2 is performed as the second step of step 1
6 which is also not patentable, you get together for the
7 patent?

8 MR. ESTRADA: That's true. And if you look at
9 the Diehr case, it's a perfect example because Diehr had
10 more steps but it was absolutely true in Diehr that every
11 single step, including the mathematical equation, was part
12 of the prior art. And this Court said that's potentially
13 patentable because you have found a way to put all these
14 disparate things together in a way that makes
15 them potentially useful.

16 JUSTICE BREYER: Does that fall within it?
17 I mean, I can't resist pointing, as one of these briefs
18 did, the phrase anything under the sun that is made by
19 man comes from a committee report that said something
20 different. It said a person may have invented a machine or
21 a manufacture, which may include anything under the sun that
22 is made by man.

23 So referring to that doesn't help solve the
24 problem where we're not talking about a machine or a
25 manufacture. Rather we are talking about what has to be

1 done in order to make an abstract idea fall within the
2 patent act. Now, sometimes you can make that happen by
3 connecting it with some physical things in the world and
4 sometimes you can't.

5 MR. ESTRADA: But Justice Breyer --

6 JUSTICE BREYER: And if you have a clear
7 statement other than Diehr, Flook, Morse, which draws that
8 line properly, let me know.

9 MR. ESTRADA: I think the telephone cases, Bell
10 and Diehr, are cases that absolutely show that under this
11 Court's cases, this is patentable subject matter. Again,
12 we're talking about the mouth of the funnel, not the end of
13 the funnel.

14 But let me point something else, Justice
15 Breyer, which is it came from a committee report but it's
16 already been incorporated in this Court's cases in
17 Chakrabarty and in Diehr as exemplary of Congress'
18 determination to have the mouth of the funnel be very wide.
19 And if there are problems with something being ultimately
20 patentable, they are because there is some other requirement
21 of the patent law that -- that -- that should be looked at.

22 One of the other points on the question that
23 Justice Scalia asked, because I think it is important on
24 whether this question is before the Court, is that the rules
25 of this Court, rule 14(1)(f) mandated the petition shall

1 contain, quote, the statutes involved in the case set out
2 verbatim. And you can pick up the cert petition and indeed
3 there is an appendix which is at the very last page of the
4 petition, and you can look at it and it says, pertinent
5 statutory provisions. There are two statutes, section 112
6 and section 271. You can pick up their blue brief and do
7 the same with the back flap, and we have the fishes and the
8 loaves.

9 Now they have three statutes, 101, 112 and 271.
10 There is no way to construe their question 3 as having been
11 intended all along to encompass a very separate affirmative
12 defense that they never put in front of the trial court or
13 the Federal Circuit.

14 JUSTICE STEVENS: Would the case be different
15 if they quoted section 101 in their appendix?

16 MR. ESTRADA: Yes, I think it would be
17 different, Justice Stevens, because then their argument that
18 this was encompassed within one of the questions in the
19 petition might have some surface plausibility. But it
20 doesn't.

21 Let me just go back and link that point with
22 another aspect of our legal system, which is you see cases
23 of forfeiture and waiver all the time. This term in
24 Unitherm and in Arbaugh, you have already said twice that
25 parties should be held responsible for their procedural

1 defaults. You do that in other areas of the law.

2 And the one that came to mind, to my mind as I
3 was thinking about this case, Justice Stevens, is going all
4 the way back to Wainwright versus Sykes, because you have
5 cases every year involving habeas corpus, where Wainwright
6 versus Sykes says we have to be careful about sandbagging,
7 and we're going to presume that an indigent defendant on
8 trial for his life in a rural county someplace with a lawyer
9 two years out of law school, who can't find the courthouse,
10 consciously chose to save the federal claims so that he
11 could assert later, have it in his back pocket: We're going
12 to have a rule of forfeiture for sandbagging.

13 Empirically, one may well wonder whether that
14 is empirically likely to be true in a great number of cases.
15 But we don't have to wonder in this case because every well
16 advised corporate defendant, if I am their lawyer, I will
17 advise them to hold this in the back pocket and to have a
18 second trip to the trial court and the court of appeals
19 because in the rules in affirmative defense, rule 8 says you
20 have to plead it and the statute says you have to prove it.
21 And it went all the way up the ladder.

22 And if you tell them that they get to start all
23 over again, what you will have is every well advised
24 corporate defendant will be advised by counsel, like me and
25 by Mr. Franklin, that the way to do is to tire the inventor

1 out, have a trial and then we can start all over again. And
2 that's no way to run a legal system, especially when they're
3 coming with the most important questions of patent law to
4 this Court with incredibly far-reaching implications and the
5 best that they can say to the Court about why you shouldn't
6 worry about the consequences is, as they say in the closing
7 pages of the reply brief, rule for us and every other case
8 will have to be considered on its own merits. Which I guess
9 is true as far as it goes but it's about as helpful as
10 telling the Patent Office and the lower courts that life is
11 a fountain. And you know, this Court does not sit to
12 issue --

13 JUSTICE SCALIA: You mean life isn't a
14 fountain?

15 (Laughter.)

16 MR. ESTRADA: I didn't say it wasn't. I just
17 said that the expression of that thought is not helpful.
18 And insofar as this Court sits to advise the lower courts
19 and the government and the patents office and the investing
20 community who could swing billions of dollars on the basis
21 of an issue that was never litigated in the lower courts, I
22 frankly submit, Justice Scalia, that it would be
23 irresponsible for the Court to reach out and deal with a
24 question for which there was never an adequate factual
25 predicate.

1 JUSTICE STEVENS: And Wainwright against Sykes
2 was even decided before AEDPA was passed, too.

3 MR. ESTRADA: Exactly. And Congress actually
4 implemented that in AEDPA. And so my basic point, Justice
5 Stevens, is if that the legal system takes the procedural
6 regularity of our courts seriously enough to enforce them in
7 what would seem to some people to be pretty compelling
8 circumstances of life and death, there is little claim on
9 the legal system for a well heeled corporate defendant who
10 has been adjudged to be a willful infringer by a jury to
11 come to this Court and asked to be put in the starting gate
12 again. There is no way that -- again, that is no way to
13 deal with the legal system.

14 I have nothing further, Justice Stevens.

15 JUSTICE STEVENS: Thank you, Mr. Estrada.

16 Mr. Franklin, I think you have about four and a
17 half minutes left.

18 REBUTTAL ARGUMENT BY JONATHAN S. FRANKLIN

19 ON BEHALF OF THE PETITIONER

20 MR. FRANKLIN: Hopefully I won't, I won't have
21 to use all that.

22 Just a few points, Your Honors. There was a
23 suggestion made that it matters what purpose these tests
24 were undertaken for. That is not true. We had argued
25 extensively that it did matter, that in fact the doctors

1 were using this for not detecting vitamin deficiencies but
2 for detecting heart disease. That was not -- we were not
3 successful on that. What the court of appeals said was any
4 doctor on pain of malpractice will necessarily perform the
5 correlating every time that doctor looks at a test result.
6 So it doesn't matter why the doctor does that.

7 Second, Morse was clearly a case decided under
8 what is now section 112. I think Mr. Hungar admitted that.
9 The language of the case makes that clear. It quotes the
10 relevant statute, and all of this is in our reply brief, and
11 it concludes that the patent in that case was overbroad
12 because it didn't, it contravened what is now section 112
13 and that is how we argued --

14 JUSTICE STEVENS: Weren't 112 and 101 combined
15 at that time?

16 MR. FRANKLIN: They were.

17 JUSTICE STEVENS: Do you disagree with that?

18 MR. FRANKLIN: No, I don't. He is correct on
19 that. But look at the case and how it was decided. It was
20 decided on the basis of what is now section 112. We have
21 cited numerous cases in the lower courts that have
22 interpreted it that way. And I believe Mr. Hungar admitted
23 that too.

24 JUSTICE STEVENS: I don't want to take up your
25 time on rebuttal but I have to ask you, do you have an

1 explanation for not quoting section 101 in your papers?

2 MR. FRANKLIN: I think the explanation is that
3 we cited all of the cases -- for example, Mackay Radio is a
4 case we cited that doesn't itself cite 101. The Court
5 itself never cited 101 in these cases until 1972. It was a
6 judicially created exception for laws of nature and natural
7 phenomena. And of course to the extent it is applicable
8 here, it is applicable either on its own, but also in
9 connection with and as a natural predicate to the 112
10 inquiry. And there I think the analogy to Morse is quite
11 striking. And what -- in Morse, the Court said that he
12 could not monopolize all devices and processes used to
13 transmit the characters at a distance through the natural
14 phenomenon of electromagnetism.

15 Here what these patentees are seeking to do
16 is to monopolize all homocysteine tests that are used to, as
17 they say, detect vitamin deficiencies through the natural
18 correlation that they recite. Morse couldn't do that
19 because it wasn't limited to the one device that he actually
20 invented. Here they cannot do it because it's not limited
21 to the one homocysteine assay that they in fact invented,
22 that we use and that we pay royalties on every time we use.

23 Finally, I think that the primary gatekeepers
24 here on these kinds of things is the Patent & Trademark
25 Office. I think they're trying their best, but what I heard

1 from their representative today is that they're not prepared
2 to do anything about these kinds of patents unless this
3 Court gives them further guidance. We are only asking that
4 the Court give them further guidance on this patent and to
5 say that a patent that claims nothing more than a natural
6 correlation preceded by the inherent and generic step of
7 measuring the input for that correlation is invalid and the
8 judgment that is based upon it should also be reversed.
9 Thank you, Your Honors.

10 JUSTICE STEVENS: Thank you. The case is
11 submitted.

12 (Whereupon, at 12:11 p.m., the case in the
13 above-titled matter was submitted.)
14
15
16
17
18
19
20
21
22
23
24
25