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1 UNITED STATES COURT OF APPEALS

2 FOR THE FEDERAL CIRCUIT

3 Appeal No. 2008-1511

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5 In the Matter of:

6 THERASENSE, INC. (now known as Abbott Diabetes Care, Inc.)

7 and ABBOTT LABORATORIES,

8 Plaintiffs-Appellants,

9 v.

10 BECTON, DICKINSON AND COMPANY and NOVA BIOMEDICAL CORPORATION,

11 Defendants-Appellees

12 and

13 BAYER HEALTHCARE LLC,

14 Defendant-Appellee.

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16 United States Court of Appeals

17 717 Madison Place NW

18 Washington, D.C.

19 November 9, 2010

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21 B E F O R E:

22 HON. RANDALL R. RADER, CHIEF JUDGE

23 HONS. WILLIAM C. BRYSON, TIMOTHY B. DYK, ARTHUR J.

24 GAJARSA, RICHARD LINN, ALLAN D. LOURIE, KIMBERLY A.

25 MOORE, PAULINE NEWMAN, SHARON PROST, CIRCUIT JUDGES

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2 A P P E A R A N C E S :

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12 A t t o r n e y f o r t h e U n i t e d S t a t e s o f A m e r i c a

13 P . O . B o x 1450

14 M a i l S t o p 8

15 A l e x a n d r i a , V A 22313

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17 B Y : R A Y M O N D T . C H E N , E S Q .

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1 PROCEEDINGS

2 THE COURT (J. RADER): morning is Therasense v. Becton. Mr.
3 Whealan.

4 MR. WHEALAN: Thank you, Your Honor. May it please
5 the Court.

6 The time has come for this Court to restore the
7 doctrine of inequitable conduct to its proper origins grounded
8 in Supreme Court precedent. The doctrine, it applies only in
9 egregious cases of fraud where the conduct that occurs caused
10 the issuance of the patent.

11 The Court can accomplish this by taking three steps.
12 First, reaffirming the subjective intense standard laid out in
13 Kingsdown. Second, by applying a materiality standard that
14 requires causation and reliance. And third, by eliminating the
15 balancing sliding scale step that often allows a high finding
16 of materiality to infer intent.

17 As to the first and third of these steps, there is
18 significant agreement between the parties and the significant
19 amicus briefs. As to the second, there is some agreement and
20 some disagreement.

21 Turning first to intent, just to touch on it, the
22 subjective intent standard must be applied correctly. What
23 currently happens often is knowledge of a reference,
24 determination of materiality ten years later in a litigation
25 and no excuse as to why I didn't give it or no recollection.

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1 That is not the way to determine subjective intent. Subjective
2 intent requires that the person accused appreciated the
3 importance of the information, basically looked at it and said
4 this is important to the patent office, and then decided to
5 hide it or misrepresent it in order to deceive the patent
6 office to try to get a patent. That should be the inquiry for
7 subjective intent. And I submit, it should probably come first
8 in the analysis of many of the cases as opposed to second, as
9 it often does.

10 As to materiality, common law fraud, trademark fraud,
11 copyright fraud all require that the person who committed the
12 act got the right because of the conduct.

13 THE COURT (J. LOURIE): But-for -- but-for standard?

14 MR. WHEALAN: Yes, Your Honor. But the real words are
15 really more causation and reliance. Common law fraud, as the
16 Court recognized in Norton, requires a misrepresentation,
17 intent to deceive, and then that the person got the patent that
18 he would not ordinarily have gotten.

19 THE COURT (J. LOURIE): In other words, no harm, no foul.

20 MR. WHEALAN: That's right. If you step back and
21 think, what is this doctrine meant to do?

22 THE COURT (J. DYK): BUT in fact, common law fraud does not
23 require but-for causation.

24 MR. WHEALAN: Excuse me, Your Honor?

25 THE COURT (J. DYK): Common law fraud does not, in fact,

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1 require but-for causation. I mean, the restatement is very
2 clear, is it not, that you can have common law fraud if it's a
3 substantial factor. It doesn't have to be but-for causation.

4 MR. WHEALAN: No, Your Honor, I disagree. The point
5 is that the right was obtained --

6 THE COURT (J. DYK): Yeah, but let me read you from the
7 restatement. This is at 546 com. b. "It is not however,
8 necessary, reliance on the truth of the fraudulent
9 misrepresentation be the sole or even the predominant or
10 decisive factor in influencing his conduct." It is not even
11 necessary that you would not have acted or refrained from
12 acting as he did unless he had relied on the misrepresentation.

13 MR. WHEALAN: Your Honor, in the fraud cases, the
14 Supreme Court cases -- we're not starting from a blank slate --
15 Keystone, Hazel, and Precision --

16 THE COURT (J. DYK): Is what I read wrong?

17 MR. WHEALAN: No, no. I wouldn't challenge a reading
18 of the restatement. But there is -- if the reason what we're
19 trying to do here is act in equity -- to prevent somebody from
20 gaining an advantage based on something he did that gave him a
21 right that he would not ordinarily have gotten, it doesn't make
22 sense to take away that right if what he did did not impact the
23 decision.

24 THE COURT (J. DYK): Well, impact and but-for causation aren't
25 necessarily the same thing. I mean, the Supreme Court cases

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1 are also -- are not consistent with the but-for causation.

2 MR. WHEALAN: So Your Honor, the characterization of
3 the Supreme Court cases by the Supreme Court itself talks about
4 procured by fraud. It lists them as three examples of
5 procurement by fraud. That means the fraud caused the
6 procurement, the fraud caused the getting of the patent where
7 it would not ordinarily have done. The Supreme Court has
8 characterized them that way, this Court has characterized them
9 that way.

10 THE COURT: But in Hazel, the Supreme Court said this
11 would still be fraud on the patent office, even if what was in
12 the affidavit was true, right?

13 MR. WHEALAN: No, Your Honor. I mean, in Hazel, the
14 person basically lied about the significance of the importance
15 of the invention. It was a fraud, I mean, it was a plagiarism,
16 basically, where somebody wrote something about the importance
17 of the invention and then said how great it was and had
18 somebody else sign it who was a leader in the field. And they
19 said it was insurmountable odds, and based on that submission,
20 the patent issued. And so there was a direct connection
21 between the act and the actual conduct.

22 If -- what I think we get lost is the doctrine is not
23 meant to punish and penalize. The doctrine is meant to not
24 reward people that got something they shouldn't have gotten.

25 THE COURT: In both those Supreme Court cases, didn't

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1 the case -- the Court declare patents unenforceable that
2 weren't the subject of the fraud? They didn't just strike down
3 the patents themselves that were at issue in the fraud; they
4 struck down additional patents as well, right?

5 MR. WHEALAN: Well, I don't recall that, Your Honor.
6 It was -- they talked about the actual patent at issue and the,
7 basically, the cases were all about the individual patent, the
8 lying, or the perjury or whatever it was, and then later it was
9 discovered and later those patents were struck down. And they
10 weren't even close cases. They weren't cases of maintenance
11 fees; they weren't cases of CVs; they weren't cases of related
12 information in another application.

13 THE COURT: Speaking of close cases, what's the
14 daylight between the standard you're asking for, whether it's
15 but-for causation, whatever you want to call it, and the one
16 the patent office is advocating, prima facie case,
17 unpatentability?

18 MR. WHEALAN: Well, the difference between -- we
19 didn't pick a standard. What we did was we said, look, we read
20 the case law, we read procured by fraud, we see fraud and IP,
21 and we see this is what's required. I mean, it makes sense,
22 and that's how equity applies. The patent office has suggested
23 now, even though it didn't when it procured the rule in '92
24 that we should look at Rule 56. And we disagree with that for
25 several reasons. But as to your particular question, they

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1 don't just propose (b)(1); (b)(1) is prima facie.

2 THE COURT: Well, I ask you, though, what's the
3 problem with (b)(1).

4 MR. WHEALAN: Well, that's not what they proposed. So
5 what we suggested was a causation, reliance, the examiner would
6 have rejected it. It's pretty close to (b)(1). They proposed,
7 at least in their brief -- we'll hear from them today -- all of
8 56, and (b)(2) would swallow the whole -- (b)(2) would swallow
9 (b)(1). What wouldn't be -- what prima facie thing wouldn't be
10 inconsistent with an argument of patentability? And as some of
11 the amicus points out, (b)(2) would basically be the reasonable
12 examiner standard all over again. Any prior argued wasn't
13 consistent with the argument of patentability, any argument
14 that wasn't consistent with the argument of patentability, and
15 it would just sweep in everything.

16 THE COURT: So you'd be satisfied with just (b)(1)?

17 MR. WHEALAN: Well, I don't think the Court should
18 adopt (b)(1) as a matter of law. There's no reason to do that.
19 They don't have substantive rule-making authority, the Supreme
20 Court wasn't looking at Rule 56. You could say, well, which --
21 they could change it tomorrow and they could be bound by it.
22 They could also, by rule, deal with intent which 56 has the
23 word "known" in twice.

24 THE COURT: Well, let's assume we don't adopt it as a
25 rule that we're subject to complying with. Let's assume we

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1 just take the substance of (b)(1) and adopt it as the judicial
2 ruling.

3 MR. WHEALAN: So I think, again, I wouldn't suggest
4 the Court adopt it because it's the rule. If the Court agrees
5 the causation is required and that the patent wouldn't have
6 issued or an examiner would have rejected it, those are pretty
7 close. And --

8 THE COURT: So prima facie evidence of unpatentability
9 is sufficient in your view to satisfy --

10 MR. WHEALAN: Well, I don't think you -- I mean, if
11 the PTO came in and said we wanted a different, slightly,
12 standard, I don't think that's what we're doing here. What we
13 focused on is the case law and the other areas of IP and the
14 Supreme Court cases that there was no question that these
15 patents were -- the conduct, A, on the intent was really bad
16 and, B, the patents wouldn't have issued, would likely wouldn't
17 have issued. The fact that prima facie is close --

18 THE COURT: Where do we get that from? Where, in the
19 Supreme Court cases, does it say that?

20 MR. WHEALAN: Well --

21 THE COURT: It seems to me they say that Precision and
22 Hazel say the opposite. They're not saying that the patent
23 would not have issued. They're saying that this is information
24 which should have been submitted to the patent office because
25 it would have been relevant.

1 MR. WHEALAN: So in Precision, Your Honor, the patent
2 issued to the wrong person. The person found out, there's an
3 interference, the person found information and made the wrong
4 person swear over the patent to them. Just like in the recent
5 AMC case by this Court where the inventor lied about who's the
6 inventor, a patent would not have issued to that inventor -- a
7 claim would not have issued to that inventor. In Hazel, there
8 was a rejection, basically an affidavit or an article came in
9 that said, no, this is the greatest thing since sliced bread
10 and the guy didn't write it and he didn't believe it, and they
11 allowed the patent. That's causation. And then he --

12 THE COURT: But the court said it wouldn't have made
13 any difference if what was in the affidavit was true.

14 MR. WHEALAN: It didn't -- I don't believe it did say
15 that, Your Honor. The -- well --

16 THE COURT: I can read it to you.

17 MR. WHEALAN: I think -- to be fair, I don't think the
18 Supreme Court, in each of those three cases -- they were
19 focused more on the intent aspect. They were focused on --
20 they used words like "sorted", "corrupt", "bribery". And there
21 wasn't a lot of back and forth of wait a second, you know, this
22 doesn't have this limitation or this didn't have that
23 limitation. It wasn't that type of an analysis. But there was
24 so much evidence of inappropriateness, of fraud, that the
25 patent went down. And then the courts characterized those

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1 cases as a procurement by fraud type case.

2 THE COURT: Mr. Whealan, is the --

3 THE COURT (J GAJARSA): Mr. Whealan, would you apply your theory

4 then to a situation where the individual files in the

5 affidavit, saying in effect that the invention was developed

6 during the first year prior to the filing but in fact

7 afterwards it was proven that the affidavit was in error, it

8 was wrong. Would you say that was inequitable conduct --

9 MR. WHEALAN: Had the --

10 THE COURT: -- or fraud?

11 MR. WHEALAN: If I could answer the question, Your

12 Honor. Had that proper information, the wrong information --

13 THE COURT: The invention --

14 MR. WHEALAN: Would the patent not have issued had the

15 proper information been in front of it?

16 THE COURT: If the invention was sold or used one year

17 prior to the filing of the patent application, would that

18 create a situation which inequitable conduct would apply?

19 MR. WHEALAN: And the affidavit didn't say it was

20 sold?

21 THE COURT (J. GAJARSA): That's right.

22 MR. WHEALAN: And if it was known to the examiner the

23 examiner would have rejected it.

24 THE COURT (J. GAJARSA): Well it's statutory rejection --

25 MR. WHEALAN: Yes, that would be --

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1 THE COURT: -- would it be?

2 MR. WHEALAN: Yes, yes, sir.

3 THE COURT: So we limit all inequitable conduct to
4 those types of actions?

5 MR. WHEALAN: Well, you gave me one example. I didn't
6 say limit. You said is this an affidavit that the falsity of
7 it caused the patent to issue and had the truth of it been
8 known the patent would not have issued, that is a single
9 example of causation required of but-for that the person now
10 has a patent that he can enforce on people that he would not
11 have gotten had he told the truth.

12 The point is when people make minor mistakes or
13 mistakes and the patent would have issued anyway the public is
14 not affected. I mean the patent would have issued either way.
15 If you want to punish them, if you want to disbar them, if you
16 want to take steps against them that's what you should do, but
17 you should not use inequitable doctrine which is not meant to
18 do those things, to step in ten years later and cause this type
19 of --

20 THE COURT (J. GAJARSA): Let's take it one step further. I attest
21 by affidavit that I'm a small business and I apply for a small
22 business exemption by a lower filing fee. That exemption also
23 provides me with a lower maintenance fee. But it turns out
24 that I don't have a small exemption, a small business; I'm a
25 large business. Is that sufficient to establish a problem with

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1 the inequitable conduct?

2 MR. WHEALAN: No.

3 THE COURT: Is that inequitable conduct --

4 MR. WHEALAN: No, it is not.

5 THE COURT: -- for that misrepresentation?

6 MR. WHEALAN: No, it is not. I mean, it may be
7 perjury, but it's not inequitable conduct. The patent would
8 have issued anyway, you would have paid a different amount of
9 money, but the patent would have issued.

10 THE COURT: Well, who knows if the patent would have
11 issued? If I couldn't afford the filing fee or the maintenance
12 fee the patent would not have been maintained or issued.

13 MR. WHEALAN: No, I mean, it would be collateral. It
14 wouldn't be -- it wouldn't be the reason that -- you know, if I
15 tell an examiner that I'm a small entity or a large entity it's
16 not going to affect whether he grants the patent.

17 THE COURT (J. GAJARSA): So I lie to the patent office and it's
18 acceptable?

19 MR. WHEALAN: No, it is not acceptable; this is just
20 not the doctrine to enforce it. And --

21 THE COURT (J. LINN): Mr. Whealan, if applying your test, is a
22 holding of invalidity a predicate to the finding of inequitable
23 conduct?

24 MR. WHEALAN: I don't think it's always a
25 prerequisite; I think it often will be. I think the easiest

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1 way to apply it would be to determine whether or not the
2 information at issue really does invalidate the patent and then
3 if it does or doesn't --

4 THE COURT (J. MOORE): Well, but counsel, don't you have to look
5 at the preponderance of the evidence standard in the broadest
6 reasonable possible construction since this is what the
7 examiner would have rejected the patent as opposed to in an
8 infringement suit when you have clear and convincing evidence
9 and a single construction of the patent.

10 MR. WHEALAN: Right. One would be subjective but-for,
11 one would be objective but-for --

12 THE COURT: So --

13 MR. WHEALAN: -- subjective being the first and
14 objective being the second. And I don't think -- unless we're
15 going to get into the heads of the examiners and unless we're
16 going to get into the heads of what they did or didn't do, I
17 think that the most practical way to apply it is through the
18 type of validity inquiry that we do today.

19 THE COURT: But --

20 MR. WHEALAN: To the extent presumption of validity
21 makes a difference.

22 THE COURT: So are you saying it has to be by a clear
23 and convincing evidence standard and it should be according to
24 the single construction proposed by the District Court as
25 opposed to the broadest reasonable construction? Because

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1 that's what the examiner's looking at when he or she is
2 deciding whether to allow the patent.

3 MR. WHEALAN: Right, you could lower it to the
4 preponderance and the presumption standard. If you do that you
5 would then be running to different invalidity analyses and I
6 think in a case where -- again, where you have the intent --
7 and one of the points I made earlier is when you find that
8 people are really, like, lying about stuff and it's big deal
9 stuff, the applicant is going to have a lot less wiggle room of
10 saying "Well, wait a second, that was under preponderance as
11 opposed to a presumption of validity standard." You know? You
12 didn't see that being argued in the Supreme Court cases. They
13 don't really care.

14 THE COURT: Well wouldn't --

15 MR. WHEALAN: So there's a certain threshold level of
16 this was egregious, this was inappropriate and we're not going
17 to let this occur. And again, I think by focusing on the
18 intent aspect it helps, but in answer to Judge Linn's question,
19 AMC wasn't an invalidity question, it was an inventorship
20 question. So it wouldn't always have to be that type of
21 conduct, but it would be this inventor would not have gotten
22 this claim or a claim because of his conduct. And it seems
23 like the most efficient way to do it would be, you know, after
24 validity is proven one way or the other. I guess there could
25 be a slim case where it doesn't work that way --

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1 THE COURT: So you have to prove either that the
2 patent was invalid or that the invention was made by somebody
3 else?

4 MR. WHEALAN: No, I have to prove that because of the
5 conduct this inventor would not have gotten a claim that he got
6 because of the conduct. That's --

7 THE COURT: So that's a but-for test.

8 MR. WHEALAN: He would -- the information he lied
9 about was material to the grant, it caused the grant, it
10 affected the grant, and had it been properly known the grant
11 wouldn't have occurred.

12 THE COURT: But the Supreme Court really has not
13 adopted the but-for clause though --

14 MR. WHEALAN: Well --

15 THE COURT: -- in any of their cases.

16 MR. WHEALAN: Well, I think they did. I think that in
17 the three cases they didn't analyze the validity issue quite as
18 closely as they did the intent issue. I mean, they didn't go
19 through a claim construction analysis and was there a
20 motivation type analysis. But, you know, in Precision, the
21 wrong inventor got it. In Keystone the brother had used the
22 prior use -- it was kind of your example -- didn't come forward
23 with it and you know there wasn't an argument that it wasn't
24 the embodiment of the invention and then lied about it during
25 the litigation. And then in the third case, Hazel, rejection,

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1 rejection, here's the statement that this is okay, this is the
2 greatest thing by a noble laureate type person and it was
3 allowed.

4 THE COURT: Well, accepting --

5 MR. WHEALAN: So whether the word "but-for" is used,
6 it was directly related to and caused the grant.

7 THE COURT (J. BRYSON): Well, accepting that is true and the
8 Supreme Court cases had those features, thus that was
9 sufficient to render the patents unenforceable, is there
10 anything in those cases that suggests it was necessary, which
11 is of course the question that's before us?

12 MR. WHEALAN: Well, I think that when you have every
13 Supreme Court case that has found a patent unenforceable there
14 was this type of conduct and there's none on the other side,
15 that tells you something. I think also --

16 THE COURT (J. BRYSON): You're talking about a universe of three
17 cases.

18 MR. WHEALAN: Well, five. I mean, Walker Process
19 describes them as fraudulent procurement cases.

20 THE COURT: Well --

21 MR. WHEALAN: And if you take Corona Cord Tire. If
22 you take --

23 THE COURT: You get to five by counting the number of
24 times they've been referred to by --

25 MR. WHEALAN: No, no, no by counting Walker which

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1 described them and then talk about Corona Cord Tire which was
2 an earlier case.

3 THE COURT: Oh, okay.

4 MR. WHEALAN: But it's kind of the other side of the
5 playing field. You have two end zones there where the three
6 that are -- where the patents are held unenforceable it was
7 really bad -- this type of conduct. And there you had an
8 affidavit along the lines of what Judge Gajarsa was saying,
9 that was wrong, possibly reckless, you know, and it could have
10 been, you know, sanctionable, but they said it was not -- it
11 really didn't make a difference because the grant would have
12 happened anyway. And they said we're not even -- not only were
13 they not going to take away the patent they weren't even going
14 to lower the presumption of validity.

15 So again, if you got it because of it, you shouldn't
16 have gotten it and we're not going to let you enforce it. If
17 you did something less you may be sanctionable, you may be
18 disbarred, but the doctrine of equity which is not meant to
19 punish, it is not meant to do that, is not the doctrine to do
20 that in.

21 This -- if you think of it the other way, I mean, I
22 don't know why we all think patent lawyers don't tell the
23 truth. The brief by the Eli Lilly lawyers that said we're
24 honest people, we don't want to lie, we don't want to have the
25 patent blow up, we don't want to get disbarred is telling. I

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1 mean, people are presumed innocent until proven guilty. For
2 some reason we think patent attorneys are guilty until proven
3 innocent.

4 And the complexities. I was talking to a colleague
5 recently. He has hundreds of cases on his docket at a given
6 time. There's no way he could be commonly knowledgeable,
7 photographic memory about what this is. In the three Supreme
8 Court cases where they found it, it was really bad stuff and
9 they said we're not going to let you keep doing this. If you
10 do something less than that, you know, you may be sanctioned,
11 you may be disbarred, but this isn't the doctrine to adopt.

12 THE COURT (J. LINN): And Mr. Whealan, is there a role for the
13 doctrine of inequitable conduct in enforcing the duty to
14 disclose?

15 MR. WHEALAN: By "duty to disclose" do you mean Rule
16 56 or -- I don't quite understand the question, I guess.

17 THE COURT (J. LINN): Rule 56, yes.

18 MR. WHEALAN: Well, I think they're slightly -- I
19 think they're different. Well, certainly different purposes.

20 THE COURT (J. LINN): Put another way, the patent office
21 obviously has an interest in having before it --

22 MR. WHEALAN: Right.

23 THE COURT: -- the best references so that the
24 examination can be the most complete and accurate. So is there
25 a role for the doctrine of inequitable conduct in

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1 encouraging -- incentivizing, if you will, compliance with the
2 patent office requirement to disclose prior art.

3 MR. WHEALAN: I don't think they're synonymous; I
4 don't think they're equal. I think that obviously the doctrine
5 of inequitable conduct would be the most egregious case when
6 you did not give them something. But what has happened is the
7 current doctrine, despite its efforts, has ruined the
8 disclosure of the art. I mean, you read brief after brief that
9 said because of this we don't -- because of this we don't tell
10 you what's the most important stuff. And that's just the
11 opposite of what we want to encourage. We want to encourage
12 people to come forward, give decent stuff, talk about it. If
13 this Court asked me a question about what's the most relevant
14 case on point or what does a case mean, I am not fearful --
15 well, I'm slightly fearful but I'm not fearful of being
16 sanctioned.

17 THE COURT: So we don't --

18 MR. WHEALAN: I will advocate and I will say, and
19 right now patent attorneys are so scared that they cause all
20 this injury to the patent prosecution system and the litigation
21 system and it just isn't worth it.

22 THE COURT (J. RADER): Mr. Whealan, let's save the rest for your
23 rebuttal time.

24 Ms. Krevans?

25 MS. KREVANS: I think --

1 THE COURT (J. RADER): Oh, no, excuse me, I think Mr. Chen's
2 going to go first.

3 Mr. Chen?

4 MR. CHEN: Thank you, Chief Judge Rader. May it
5 please the Court. The PTO greatly appreciates this opportunity
6 to present its views on this very important case.

7 Picking up where Mr. Whealan just left off, I'd say
8 first of all, we agree on the majority of things that Mr.
9 Whealan is arguing about, which is the intent standard and a
10 balancing need to be clarified and repaired, and we
11 substantially agree with him on those positions. And
12 materiality also needs to be clarified. And in terms of the
13 materiality standard, our view is that to say those three
14 Supreme Court cases called for a but-for standard is incorrect
15 because forty years of this court's jurisprudence understood
16 that the kinds of inequitable conduct that could render a
17 patent unenforceable is broader than merely just but-for. And
18 we don't --

19 THE COURT (J. LINN): Isn't Mr. Whealan correct, though, in the
20 sense that under at least the current regime of things
21 applicants, in an abundance of caution and of concern for a
22 subsequent holding of inequitable conduct are, if anything,
23 overloading the patent office with references, many of which
24 may be totally irrelevant and may obscure and not assist the
25 patent office in examining the best priority?

1 MR. CHEN: We agree, Judge Linn, that that is the
2 current situation, that we're seeing essentially reference
3 flooding because right now people don't understand what is the
4 art they need to submit. They are in fear of the inequitable
5 conduct standard. But if this court makes clear what the
6 standard is for materiality and makes clear that the intent
7 standard needs to be a high one, that we're really talking
8 about bad-faith conduct, we believe that -- and specifically on
9 terms of materiality adopting or following the criteria set out
10 in our current Rule 56, that's going to give the definiteness
11 and more peace of mind for applicants to understand what is the
12 art that they should be submitting.

13 In our view the current Rule 56 sets forth a much more
14 focused, definite, and tailored set of criteria that really
15 give applicants understanding of what is the kind of
16 information --

17 THE COURT: Well, what about the but-for --

18 MR. CHEN: -- we must need --

19 THE COURT: Go ahead, please.

20 THE COURT (J. PROST): What about the but-for test that Mr.
21 Whealan was advocating? Would that, in your view, bolster the
22 ability of the patent office to proceed as it should or would
23 that undermine its ability?

24 MR. CHEN: In the end, in our view, but-for or the
25 reasonable examiner standard, they're both sub-optimal for

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1 different reasons. Reasonable examiner because it's deluging
2 us in pathological overcompliance. But-for, the problem with
3 that is, that is permitting a certain scope of gamesmanship and
4 mischief where people are allowed to hide the ball from the
5 examiner on important pieces of information. When you take a
6 particular position on a patentability issue in front of the
7 examiner, that's a pivot point. And when you then learn of
8 information that undermines that patentability position you
9 have taken, then that's the kind of information an examiner
10 needs in order to make a fully informed decision.

11 The basic choice here is if you go with a but-for the
12 choice is do we want these informed decisions based on this
13 information to be done ex-ante or ex-post? Do you want --

14 THE COURT (J. DYK): But the but-for standard will allow
15 someone to lie -- to affirmatively lie to the patent office
16 about a piece of prior art and it wouldn't result in
17 inequitable conduct unless you proved that the piece of prior
18 art would have resulted in a rejection.

19 MR. CHEN: And that's why we categorically disagree
20 with the but-for test because the point of those three Supreme
21 Court cases was when you come to the patent office and you're
22 asking the government to grant you this very important property
23 right that's going to permit you to exclude others from making
24 and using that invention for up to twenty years, you have to
25 act in equity. You cannot engage in some kind of gamesmanship

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1 or mischief. And you have to, in this ex parte process, bring
2 forward all of those facts that the examiner needs to make an
3 informed decision up front.

4 THE COURT: But it doesn't matter to the validity of
5 the patent. The patent office still has the option of a
6 disciplinary proceeding. In other words, bad behavior that
7 doesn't matter to the grant of the patent can still be dealt
8 with.

9 MR. CHEN: Well, first of all, to break apart these
10 two different kinds of patentability categories of information
11 would be inconsistent with what this court's jurisprudence has
12 been. It's always been an understanding that it's broader than
13 just --

14 THE COURT: But we can write on it and it's pretty
15 much --

16 MR. CHEN: We understand that. But at the same time
17 we think it would be inconsistent with the Supreme Court cases.
18 If you look at Keystone, we don't see Keystone as saying there
19 was -- that that particular patent was invalid and then after
20 it was in -- not only was it invalid but it should be barred
21 from enforcement because of some form of inequitable conduct.
22 It talked about possible prior use, a possible prior use that
23 cast doubt on the validity of the patent. And that prior use
24 needed to get to the examiner in the first instance. That's
25 exactly the kinds of information that 56(b)(2) is looking for.

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1 If you have information that's inconsistent with the
2 patentability positions you're taking, that undermines the
3 position, we need to get it first, we need to look at it first
4 rather than hiding that, withholding that, and then letting a
5 patent issue and then letting the market get disrupted and then
6 forcing litigators to go through ten years of litigation, only
7 at the end where ex-post we finally decide whether that patent
8 would have stood up or not in front of the PTO in the first
9 instance. As a matter of policy it's not in the public
10 interest to go through all of that ordeal when there's an
11 opportunity to sign that up in the very first instance. That's
12 the whole point of acting in equity in front of the patent
13 office. There's a public interest at stake here. It's not
14 just a private party versus a private party that one defraud
15 another.

16 THE COURT: Counsel, I think there's some concern that
17 56(b)(2) will swallow the rule, and if I understand Mr.
18 Whealan's position, it is that if you adopt 56(b)(2) there will
19 be no decrease in the flooding. And you said that well, if you
20 tweak the intent standard maybe that might have some effect.
21 But I mean, isn't 56(b)(2) exactly what the law pretty much is
22 right now and this is -- you're in this situation where you're
23 admitting that people are dumping on the office?

24 MR. CHEN: Well, right now the world we're living in
25 is the reasonable examiner standard. And I submit that people

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1 don't know really the full scope of the reasonable examiner
2 standard and they don't know -- it's unpredictable in its
3 application. They don't know what a given District Court judge
4 is going to understand, what their personal conception of
5 that's going to be.

6 MR. CHEN: 56(b)(2), however, is much more specific.
7 As I mentioned before, now we're talking about a pivot point
8 where you've taken a stand in front of the examiner on a
9 particular position with respect to patentability. And now,
10 not only that you know of information that undermines that
11 position, that's either contrary or inconsistent with it.

12 THE COURT: Well, suppose that -- to understand the
13 scope of Rule 56(b)(2), which I'm having some difficulty with,
14 tell me how you apply it in the following scenario. You have a
15 representation made by an applicant through an expert,
16 declaration or otherwise --

17 MR. CHEN: Sure.

18 THE COURT: -- with respect to a question of
19 underlying science. And there is a tiny sliver of scientific
20 opinion that is contrary to the position you are giving to the
21 examiner but it's not the position that's widely held. Are you
22 obliged to call to the examiner that sliver of opposing view on
23 the theory that it is inconsistent with the argument that
24 you're making with respect, ultimately, to patentability?

25 MR. CHEN: Assuming all of that factual statement is

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1 relating to the patentability question, yes, that would fit
2 within (b)(2) because at this point, in terms of understanding
3 this ex parte process, we're trying to give the PTO the chance
4 to make that fully informed decision.

5 Now it may be just a minority view, as you pointed
6 out --

7 THE COURT: No. It seems like --

8 MR. CHEN: -- and that can be expressed in the remarks
9 by the applicant when they're trying to can pair off the
10 majority and minority view.

11 THE COURT: Mr. Chen, there's another -- I'm trying to
12 wrap this up. There's another aspect of the public interest,
13 which is the aspect that I think has brought us here today.
14 And that is that we know inequitable conduct now is being
15 played in a very large number of cases, about a third of those
16 that are filed in the district court. We know that it's
17 sustained in a very small number of those cases. We know that
18 the burden -- the litigation burden is profound, that there are
19 many entities -- many small entities that just cannot afford to
20 go through those doors that are being opened in order to defend
21 themselves. We know all of the additional consequences the
22 briefs are full of. And we know that that is what has happened
23 based on the present state of the law. There seems to be no
24 reason why that would be discontinued, whether it's (b)(1) or
25 (b)(2) or a number of the other things.

1 And my question is isn't this aspect of the public
2 interest, the weight on the patent system, the perhaps
3 discouragement of worthwhile inventions, shouldn't the office
4 also be considering this policy aspect as well as the things
5 that the examiner needs and that should not be withheld?

6 MR. CHEN: Of course, Your Honor. We're -- we
7 recognize that there is that plague out in the litigation.
8 And -- but in our view --

9 THE COURT: So how do you --

10 MR. CHEN: So --

11 THE COURT: How are you resolving it?

12 MR. CHEN: So, the way we tried to resolve it was
13 going back twenty year ago. In fact, if you look at our
14 federal register notice back in '91 and '92, we -- one of the
15 goals of making a clearer standard on materiality was to
16 hopefully minimize the burden of defending yourself against
17 inequitable conduct. Because at that time, we were hearing the
18 same kind of complaints that we're hearing today which is
19 people just feel like the reasonable examiner standard is too
20 unpredictable.

21 THE COURT: Are you saying a return to Kingsdown with
22 its negation of gross negligence --

23 MR. CHEN: Absolutely.

24 THE COURT: -- would work?

25 MR. CHEN: Yes. Driving up the intent standard --

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1 because we're really talking about is bad faith misconduct and
2 that has to be proven by the single-most reasonable inference.
3 And so when you make that clear to the courts and hopefully,
4 Exergen can also help in terms of ratcheting up the pleading
5 requirements for alleging this kind of defense along with a
6 very clear standard of what is the kinds of information we need
7 in order for you to fulfill your duty of candor, to fulfill
8 your duty to act in equity in front of the government. Those
9 pieces together, we feel like there's going to improve the
10 system. So it's a balance --

11 THE COURT (CHIEF J. RADER): Thank you, Mr. Chen.

12 MR. CHEN: Okay. Thank you, Your Honor.

13 THE COURT (CHIEF J. RADER): We got your argument.

14 Now, Ms. Krevans.

15 MS. KREVANS: Good morning. While Mr. Badke are
16 splitting time and we have also tried to split the substance
17 somewhat, with the Court's permission, I'm going to focus on
18 the materiality issue and then Mr. Badke will focus on intent
19 and also address how various proposals might apply to the facts
20 of this specific case.

21 With respect to materiality, let me first say I --
22 with respect to Judge Newman's question about the plague on the
23 system, I think that all the parties and the things that they
24 agree on are proposing things will tighten up the system and
25 will help. Because the current Rule 56 is clearly narrower

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1 than the reasonable examiner standard. And because all parties
2 are proposing that the should have known portion of the intent
3 rule be abolished, that we go back to what Kingsdown said and
4 enforce that. I think it is notable that Abbott ignores this
5 Court's recent decision in Exergen. The plague here is not the
6 number of times that judges actually strike down patents for
7 inequitable conduct and this court affirms that's a very tiny
8 number. It's four in the last two years in all the pieces of
9 patent litigation from this whole country which is a lot of
10 patent litigation. The plague is how many times it's pled.
11 That's what this court addressed in Exergen. It's quite recent
12 and we haven't had time to see yet whether it works. But it
13 should work because the point of Exergen is unless there's a
14 real something there that impresses a district court judge in
15 your pleading, you can't maintain this aspect of litigation.
16 There has to be --

17 THE COURT (J. BRYSON): Doesn't the district court tools to handle
18 that, like Rule 11?

19 MS. KREVANS: Absolutely.

20 THE COURT (J. BRYSON): How often is Rule 11 applied?

21 MS. KREVANS: Well I think in the past, it has not
22 been applied very much, in part because there wasn't a
23 requirement that was enforced by the courts of specific
24 pleading. Now there is because this court has given district
25 courts that tool --

1 THE COURT (J. BRYSON): Specific pleading has always been in the
2 federal rules of civil procedure. It just --

3 MS. KREVANS: It has been --

4 THE COURT: -- hasn't been enforced and Rule 11 hasn't
5 been enforced. So you're saying we don't need to change the
6 requirements? Just leave it the way it is and let the district
7 courts enforce it by Rule 11?

8 MS. KREVANS: No. I'm saying you have changed the
9 pleading requirements with Exergen, in the view of many
10 district courts. And so now they are much tougher and that
11 without -- I'm saying you should make intent a tighter
12 standard. Everyone has proposed that. You should make the
13 materiality rule a narrower standard by adopting current Rule
14 56 which is narrower.

15 THE COURT (J. MOORE): I guess I'm just having trouble seeing
16 daylight between current Rule 56 and the reasonable examiner
17 standard. So tell me exactly what subset of cases, that right
18 now are responsible for this plague, that are not going to be
19 captured by current Rule 56.

20 MS. KREVANS: The reasonable examiner standard says to
21 the applicant, take any piece of information and ask yourself
22 would a reasonable examiner want to see this? That is a much
23 broader standard than looking at Rule -- current Rule 56 in
24 (b)(1) saying, does this piece of information establish a prima
25 facie case of unpatentability?

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1 THE COURT (J. MOORE): I don't think there's any question over
2 (b)(1).

3 MS. KREVANS: That's --

4 THE COURT (J. MOORE): I don't hear a dispute between you all.
5 It's (b)(2) that seems to be the real problem.

6 MS. KREVANS: So (b)(2) says if you are advocating X
7 but you know of a piece of information that says not X, you
8 must submit that when you advocate X so that the examiner has
9 full information. Now, the key here I think -- and the answer
10 to a lot of the complaints that were made in the various amicus
11 briefs from patent bar associations and also some comments that
12 were made back in '92 when the current rule was adopted is --
13 the complaint is this will make people have to scour records
14 and go find things because they might be inconsistent. That's
15 absolutely not what the rule says. The rule says if you know
16 of something that is inconsistent with the position that you
17 are taking, you should submit it. You don't have to go find it
18 but if you know of it, you have to submit it. And that is
19 absolutely correct.

20 THE COURT (J. MOORE): It doesn't have to just be inconsistent
21 with the position you're taking though. The rule says also --
22 or if it's consistent with any opposition that you're giving to
23 the patentability arguments the PTO is proffering and my
24 concern is that is such a broad and amorphous rule, that it's
25 going to swallow up everything.

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1 MS. KREVANS: But it's not because it's either a
2 position that you're advocating or a position that you're
3 taking to refute something the Patent Office advocated. In
4 either case, it's a position that you are actively putting in a
5 paper that you're submitting to the PTO. And when you submit
6 that paper, you have to say to yourself, "Do I know of
7 anything, as I sit here right now, that is contrary to what I
8 am saying?" And if I do, I should submit it. That's Rule
9 56(b)(2).

10 THE COURT (J. MOORE): Suppose the Patent Office rejects your
11 claim as obvious. And the Patent Office has cited a few
12 references and you're going to argue to them that your claims
13 are not obvious. Well then, don't you have a duty, under this
14 rule, to give the Patent Office anything at all that you can
15 think of that arguably favors an obvious determination and
16 wouldn't you cast your net, as a prosecutor, quite broadly to
17 ensure that you're not later going to be found guilty of
18 inequitable conduct for not proffering it.

19 MS. KREVANS: I don't know of anyone who's ever
20 suggested that broad -- apart from, you know, an article
21 saying, "Oh my gosh, let's go chase the law." I don't know of
22 any court who's ever suggested that broad reading of Rule
23 56(b)(2) and I think one way that you can -- it's the specific
24 position you actually put in your paper. You have to make sure
25 it's not incomplete because you omitted -- you've omitted

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1 something, that you know about, that refutes it.

2 And one of the things I think that this court can ask
3 itself is do we really have a plague of Rule 56(b)(2) cases.
4 Let's think about our own opinions. We don't have that many
5 56(b)(2) opinions. There is no Rule 56(b)(2) plague. That's
6 not what your opinions are generally about. So I think you
7 just need to say to yourselves, have people in fact been
8 inundating courts with Rule 56(b)(2) allegations?

9 THE COURT (J. MOORE): Well, couldn't that well be because
10 everybody's dumping on the PTO as Mr. Chen acknowledged?

11 MS. KREVANS: I think the issue is not -- the problem
12 before this court is is the allegation -- the accusation made
13 too often and is that driving bad behavior? The Rule 56(b)(2)
14 allegation is not made very often and you haven't seen it very
15 often.

16 Now I would like to take a crack at --

17 THE COURT (J. BRYSON): Since -- I have the same concern as Judge
18 Moore about the scope of 56(b)(2) and since you say that well,
19 courts haven't and are not likely, presumably, to apply it with
20 the breadth that her example, for example, brought out, can you
21 give us an articulation, a formula of what your view of a Rule
22 56(b)(2), or something equivalent that we should adopt, would
23 be that would exclude the category of cases that Judge Moore
24 set forth. In other words, what do you conceive of as the
25 appropriate scope of that portion of the rule if we were to

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1 adopt it?

2 MS. KREVANS: I think you would take the rule very
3 literally. And it says when you are taking a position or your
4 refuting a position, if you know of information inconsistent
5 with what you are saying, you must submit it. And in Judge
6 Moore's example, the big picture legal label for the issue was
7 obviousness but the specific issue in any particular
8 prosecution is going to be an office action has been sent to
9 the applicant and the office action says we reject your claims
10 under Section 103 and it's because of reference A in
11 combination with reference B.

12 So now you have to come back -- and you're not going
13 to address the law of all obviousness. You're going to
14 reference A in light of reference B. And when you make that
15 argument why reference A and reference B together do not render
16 your currently pending claims obvious, if you say something in
17 that argument, either about what reference A and reference B
18 mean or some other piece of information that you think helps
19 you, your submission needs to also acknowledge if you know of
20 something inconsistent with what you are actually saying. It's
21 not the whole world of obviousness you're dealing with there,
22 it's the specific things you're saying in response to that
23 office action. So I think that the rule is specific and I
24 think it's specific to the things you are saying.

25 And I would like to take a crack, if I might, at these

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1 Supreme Court cases because I do --

2 THE COURT: Well, before you do that, just one
3 specific question.

4 MS. KREVANS: Yes.

5 THE COURT (J. LINN): Are you advocating that we adopt a
6 standard of materiality akin to, if not identical to, that set
7 forth in current Rule 56 or that we adopt a rule that defers to
8 whatever the patent office definition of materiality might be?

9 MS. KREVANS: Bayer is advocating that if the
10 inequitable conduct allegation is that someone has failed to
11 comply with their duty of disclosure to the PTO, that the
12 guidepost against which you measure their alleged failure be
13 the PTO's Rule 56 in effect at the time that the supposed
14 failure took place.

15 THE COURT (J. LINN): And the interpretation of that rule is the
16 interpretation given to it by the patent office?

17 MS. KREVANS: I think the rule is the rule as set
18 forth by the patent office. There is some interpretation of
19 the rule in various MPEP sections which you could look to as
20 helpful guidance perhaps but which is not binding on this
21 court.

22 THE COURT (J. LINN): So what happened if next week the patent
23 office adopts the reasonable examiner standard?

24 MS. KREVANS: If, next week, the patent office adopts
25 the reasonable examiner standard and a week after that someone

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1 is doing something in prosecution and an allegation is later
2 made in litigation that the failed to comply with the duty of
3 candor -- the duty of candor in effect at the time was Rule 56
4 in effect at the time. Now there are inequitable conduct
5 allegations that are not, by their nature, you failed to comply
6 with the patent office's duty of candor and then you wouldn't
7 necessarily be looking to the rule.

8 But here, the nature of the allegations that you get,
9 almost a hundred percent of the time, are this person failed to
10 comply with the duty of candor. And I would submit that it is
11 very, very difficult for patent practitioners if this court is
12 judging their conduct after the fact by a different set of
13 rules than the one that the PTO can require them to comply with
14 in the moment. Because then the patent practitioner is trying
15 to say I have to comply with the PTO's rule but I also am going
16 to try to comply with a different rule that the court might
17 impose on me at a later time if this patent is in litigation.

18 THE COURT: Well, is this a --

19 MS. KREVANS: Patent practitioner is a very hard
20 place.

21 THE COURT: Isn't all of this complexity a result of
22 the fact that the doctrine of inequitable conduct has drifted
23 into the realm of the patent office's duty to disclose and has
24 drifted away from its roots in the three Supreme Court cases
25 we've been talking about?

1 MS. KREVANS: Well, I think yes but for a very
2 different reason than Mr. Whealan puts out there. Those cases
3 do not stand for the proposition that the Supreme Court has
4 laid down a law that patents are held unenforceable only if an
5 act of fraud, as it's put out in Hornbooks with causation and
6 reliance has taken place. In fact -- and that the patent would
7 have issued otherwise. In fact, in one of the cases that was
8 clearly not the case and that's *Keystone*, the first case.

9 And Judge Prost, you are quite right. There were five
10 patents at issue in that case the possible prior use. Not
11 even an adjudicated prior use. A possible prior use was known
12 to the applicant, was not disclosed to the PTO, was brought to
13 the lawyer's attention before the litigation, was also not
14 disclosed by them in litigation. In fact, they found the
15 witness and said we'll pay you some money not to talk to
16 anybody about it.

17 That affected one of the patents. Even in that
18 patent, it was not in any sense found to be the cause of the
19 issuance of that one patent. It didn't have anything to do
20 with the other four. The Supreme Court says unclean hands is
21 going to bar all five because there is a link, although it's
22 not patent issuance, there is a link between the bad behavior
23 and all five patents since you brought the lawsuit on all five
24 together and they all relate to an attack on infringement by a
25 single machine, this ditch digging machine.

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1 But there was no but-for causation even for the one
2 patent that the actual prosecution was involved in. And, in
3 fact, it is absolutely the case, in Hazel-Atlas, Judge Dyk,
4 that the Supreme Court said this declaration -- this article
5 that was offered by someone different than the person who
6 signed it, even if those facts were true, that doesn't excuse
7 the conduct because you pretended that the wrong person wrote
8 it.

9 And I want to give you a hypothetical which I think
10 illustrates the basic problem with the but-for rule. If you
11 sort of combine the facts of Hazel-Atlas and your Ferring
12 case -- Ferring is the inequitable conduct case where the
13 declarants who looked independent didn't disclose them. In
14 fact, they were either employees or paid by the company which
15 was the applicant.

16 You said you have a declaration, all the facts in it
17 are true but the applicant wants to make it look as though it's
18 independent so they pay someone, who does not work for them --
19 they pay a scientist to pretend that they wrote it and they
20 sign it. And they submit a declaration they know to be false,
21 in the sense that the author is not the true author and has
22 been paid to pretend they were, in the course of prosecution.
23 That's the facts of those cases.

24 That is what all of us would call -- that's a false or
25 fraudulent declaration. At the time it's submitted they're

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1 doing it because it's material to an issue that's a problem
2 right then in the prosecution. Later, the claims are amended
3 for a different reason and when the claims issue, the
4 declaration no longer has anything to do with something in the
5 claims.

6 The conduct of that applicant was just as bad as the
7 conduct of those applicants in Hazel-Atlas. But, under Mr.
8 Whealan's proposed rule, under Abbott's proposed rule, nothing
9 happens because this was the deliberate payment of somebody to
10 pretend they wrote something that they didn't, was submitted to
11 the patent office for the purpose of gaining an advantage of
12 prosecution. In the end it didn't matter because something
13 else happened in prosecution but Abbott says that's okay. Even
14 though it was grossly culpable conduct and --

15 THE COURT: No, they don't say it's okay.

16 MS. KREVANS: Well, they -- they say this court should
17 ignore it.

18 THE COURT: They say that the standard of fraud, when
19 you have a clear case of fraud, there are remedies for fraud.

20 MS. KREVANS: How would the patent office ever find
21 out about this? Abbott says the patent office should police
22 this but the patent office doesn't have any kind of ability to
23 police this sort of thing. And what I would -- the reason I
24 think --

25 THE COURT: How many people in the last ten years have

1 been disciplined by the patent office for making
2 misrepresentations or lack of candor?

3 MS. KREVANS: That I cannot tell you. I'm not a
4 patent practitioner myself and I don't track such things. But
5 I would say that most of the time, when facts like this turn
6 up, it's because they turn up in litigation not because the
7 patent office has some way of finding out about them.

8 The reason that I would suggest this court wants to
9 make a return to the law of unclean hands, as it is truly set
10 out in the Supreme Court cases, it's not that they say there's
11 but-for causation reported. They don't say anything like that.
12 They don't even analyze it. Although in some of the cases it
13 was true.

14 The important part is that what those cases tell us is
15 the doctrine here in unclean hands and the important thing is
16 how bad was the behavior of the applicant.

17 THE COURT (J. RADER): Thank you, Ms. Krevans. Mr. Badke?

18 MR. BADKE: Thank you, Your Honor. Bradford J. Badke
19 of Ropes & Gray for Becton, Dickinson and Nova Biomedical, may
20 it please the Court.

21 I think the problem, just to pick up on the but-for
22 issue, I think the problem with the over-disclosure, aside from
23 clarifying the issue of intent, is the inconsistency between
24 the patent office standard and the standard that may be applied
25 by this Court in any given case. And, so, for example, if a

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1 town sets a speed limit at fifty miles an hour, and the Court's
2 enforcing thirty, you're going to get over-disclosure. If it
3 sets eighty as the enforcement level you're going to have
4 under-disclosure, and that's the problem with the but-for test.
5 I mean, a linchpin of our patent system is disclosure, and we
6 don't have an opposition system like they have in Europe, and
7 we depend on the duty of disclosure, and the but-for test will,
8 as the patent office or as some of the amicus briefs have
9 indicated, will cause or will permit people to lie to the
10 patent office. There'll be under-disclosure and all sorts of
11 other issues. So the but-for test doesn't really solve the
12 problem, and solving the problem is if we are more consistent
13 in the standard that's applied between the patent office and
14 the courts that will set out the rule for the practitioners.

15 And I am worried about the practitioners. I'm worried
16 about these accusations of inequitable conduct, but I'm also
17 worried about the public interest. And we rely on this
18 disclosure for a very strong patent system, and that's why it's
19 necessary.

20 One thing that Abbott points out is that they agree
21 that by restoring Kingsdown intent standard that the Court can
22 mitigate the outbreak of inequitable conduct. So it's twofold.
23 If the Court clarifies the intent standard, specific intent,
24 single most reasonable inference and also makes the -- and
25 adopts Rule 56 or whatever the patent office is enforcing, and

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1 if the Court is consistent with the patent office that will
2 also control the outbreak of these charges.

3 THE COURT: Do you agree with that?

4 MR. BADKE: Do I agree with that? Yes.

5 THE COURT (J. NEWMAN): Do you agree that a return to Kingsdown
6 would mitigate the problem?

7 MR. BADKE: Well, by applying specific intent I do
8 believe, Your Honor, that that will help mitigate the problem.
9 Specific intent and single most reasonable inference.

10 Now, I wanted to talk a little bit about intent here.
11 This case, Mr. Whealan spoke about egregious cases. This is
12 one of those egregious cases. The facts here are egregious,
13 and to not find an equitable conduct in this circumstance, I
14 think, would mean that you can't find it in virtually any case.
15 The facts here were egregious. We had a very strong motivation
16 to deceive. As Judge Alsup found, there was a very strong
17 commercial motivation to deceive. Dr. Sanghera had actually
18 helped draft the EPO papers. There was strong knowledge of
19 materiality, and, in fact, these facts would actually fit the
20 but-for standard. There was reliance by the examiner. The
21 examiner allowed the case based on submission of the
22 declaration, and it resulted in a patent. So we, actually,
23 would win, I submit, under the but-four standard.

24 THE COURT: Is there not ambiguity, however, in terms
25 of what the district court found with respect to intent in the

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1 facts of your case?

2 MR. BADKE: I don't think so, Your Honor. Judge Alsup
3 found that there was deliberate withholding. He found that
4 they knew there was material. And he found specific intent.
5 So I don't think that there's any ambiguity in what Judge Alsup
6 decided with regard to intent.

7 THE COURT (J. GAJARSA): But shouldn't we try to eliminate the tie-
8 up of materiality with intent before we find intent. There
9 seems to be in our case law a proposition that we find
10 materiality and then weigh that before we find intent. So if
11 there's a very heavy materiality aspect then intent can be
12 inferred. Why not try to find intent specifically with a
13 standard which could be clear and convincing evidence and then
14 weigh the two together with issues to determine whether or not
15 the materiality is there by clear and convincing evidence and
16 the intent is there by clear and convincing evidence?

17 MR. BADKE: Well, because, I don't think that would
18 work, because there's -- evidence of materiality also applies
19 to intent in the Optium case Judge Prost's concurrence in that
20 indicates that you can, if information is highly material that
21 is evidence of intent. There's lot of materiality, or there's
22 materiality evidence that actually do imply to intent.

23 THE COURT (J. GAJARSA): But aren't you inferring an intent at that
24 point before you can establish it?

25 MR. BADKE: No. It's evidence that you can use to

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1 establish intent along with other information such as knowledge
2 of the reference, knowledge of the materiality and so forth,
3 and if you add those -- motivation to deceive, I mean, all of
4 that information goes into the whole mix of how you establish
5 intent, and, so, and materiality is one thing. And, so, to
6 separate materiality from intent, I think, is a mistake,
7 because, as Judge Prost pointed out, that, you know,
8 materiality does go to the intent consideration.

9 THE COURT (J. GAJARSA): But can you infer intent directly from
10 materiality?

11 MR. BADKE: Not by itself. Not by itself, no.

12 THE COURT: You suggested that you could, it seems to
13 me, no, a moment ago.

14 MR. BADKE: Well, but I didn't mean to say that.

15 THE COURT: If you have enough materiality you can
16 infer intent. That's --

17 MR. BADKE: That isn't what I meant to say, Your
18 Honor. I said it is evidence of intent, but by itself you
19 cannot establish intent. There would have to be other evidence
20 such as knowledge, motivation, whatever, but that's one thing
21 along the lines of the Optium case.

22 THE COURT (J. GAJARSA): So you would agree, then, that intent
23 would have to be established somewhat separately from --

24 MR. BADKE: Yes.

25 THE COURT: -- materiality. Even though materiality

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1 could be strong we shouldn't infer intent directly from
2 materiality.

3 MR. BADKE: That's exactly right, Your Honor. I mean,
4 I'm also concerned about non-meritorious charges against
5 prosecuting attorneys. Something could be highly material, but
6 if the prosecuting attorney doesn't know of it, doesn't
7 appreciate it, that is not a grounds for inequitable conduct.
8 So it's the high materiality or materiality along with some of
9 this other evidence of intent.

10 But in this particular case there was plenty of intent
11 evidence there. Judge Alsup found, and this was supported by
12 experts in the case, that the plain language was, as Judge
13 Alsup found, that this was inconsistent with what they were
14 telling the U.S. Patent Office. Judge Alsup also based his
15 ruling on credibility findings. Found Dr. Sanghera to be
16 disingenuous. I cross-examined Dr. Sanghera, and impeached him
17 several times. Judge Alsup found -- included that. So there
18 was lots of information here. They were well aware of what was
19 going on at the patent office. They were well aware why the
20 patent office allowed the case. This was all affirmed by the
21 majority. In fact, the district court took into account all
22 possible inferences of good faith. There was a very detailed
23 well-reasoned opinion. And the evidence, they're both aware of
24 the duty of candor. Dr. Sanghera was; he was involved in
25 competitive analysis. He was the link to the patent lawyer,

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1 the technical link to the patent lawyer within the company, and
2 he was aware that once he submitted that declaration that he
3 then invoked the duty of candor. So in this particular case
4 the facts are very strong in favor of a finding of deceptive
5 intent.

6 The other thing is that Judge Alsup found that the
7 excuses were simply implausible, and in that regard there
8 were -- there was a moving target on excuses from both Mr. Pope
9 and Dr. Sanghera. One of them was that the argument centered
10 on the type of membrane not on whether it was optional. Both
11 the district court and the majority found that not to be
12 credible.

13 They argued that the information was cumulative. Mr.
14 Pope, it was a constantly changing series of excuses. The
15 district court determined that it wasn't cumulative, and, in
16 fact, there was nothing else on the record that showed that
17 these individuals had taken a different position in Europe than
18 they had in the U.S.

19 This "optionally but preferably" language, that was
20 mere patent phraseology. The majority panel found that there's
21 no secret code, as Judge Alsup put it, in terms of what the
22 word preferably means. That preferably means required. And,
23 in fact, the testimony from both Dr. Sanghera and Mr. Pope was
24 that if you look at this language that was in the European
25 disclosures, the plain English of it, that is inconsistent with

1 the positions that they were taking.

2 There was also testimony from Mr. Pope that he
3 confused the word "whole blood" and "live blood", but, in fact,
4 that was implausible as well, because right within the EPO
5 papers they defined live blood as being in vivo use. That
6 whole patent concerned the use of these blood glucose strips in
7 blood. That's what it was all about. And, so, within those
8 papers they actually define live blood as in vivo use. So it
9 was just implausible that Mr. Pope was confused about that.
10 And, in any event, Dr. Sanghera was the scientist. He knew the
11 difference.

12 Dr. Sanghera met with Mr. Pope both before and after
13 the interview with the examiner. They discussed disclosure.
14 So this is not a case where some patent lawyer was just
15 unaware, forgot about the reference or anything of that nature.
16 There was a plan to withhold. They discussed whether they
17 should disclose it, and they decided not to.

18 So this is a very strong case for deceptive intent,
19 and in terms of materiality it fits within the (b)(2) standard,
20 and I think that even if the Court were to adopt a different
21 standard, whether it's but-for on materiality or modify (b)(2),
22 than this type of information, if this information was not
23 required to be disclosed by the applicant then I think our
24 whole patent system is going to suffer for that and we're going
25 to end up with weaker patents.

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1 So that's all I have on that.

2 THE COURT (CHIEF J. RADER): Thank you, Mr. Badke.

3 MR. BADKE: Okay.

4 THE COURT (CHIEF J. RADER): Mr. Whealan, you have almost eight
5 minutes.

6 MR. WHEALAN: Thank you, Your Honor. Two major
7 points. First, as to Rule 56. There's been a lot of
8 discussion about that. Rule 56 has been in place for twenty
9 years. When they passed it in 1992 the PTO stated these rules
10 do not, quote, "do not define fraud or inequitable conduct",
11 and so it's somewhat surprising that they come forward twenty
12 years later and say it does now.

13 Kingsdown in a hallmark decision and has been in place
14 and so has Rule 56.

15 THE COURT (J. DYK): Well, what do they mean by that? I would
16 have thought they meant by that they're not getting into the
17 intent element. They're just talking about the duty to
18 disclose.

19 MR. WHEALAN: It doesn't say that, Your Honor. It
20 said "do not define fraud or inequitable conduct". They have
21 never come forward before today, before these briefs, and said
22 56 should control, nor should they have. The, as Judge Linn
23 had suggested, the -- what the PTO wants is different than
24 whether or not somebody who's infringing a patent gets away
25 with it or whether somebody who's infringing a patent doesn't

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1 have to pay because of some action. The PTO has a sliding
2 scale of penalties. It can sanction somebody by reprimanding.
3 It can --

4 THE COURT: How many sanctions have there been in the
5 last ten years?

6 MR. WHEALAN: Well, OED brings cases against patent
7 attorneys yearly. So, the point is when they go after patent
8 attorneys, whether they make a minor mistake or major mistakes,
9 that's what the agency is supposed to be doing. Instead, what
10 we have here --

11 THE COURT: But how many lack of candor sanctions have
12 there been?

13 MR. WHEALAN: I don't know. But they haven't been
14 using it, necessarily, because this is how we've been doing it.
15 That doesn't make it right.

16 THE COURT: Mr. Whealan --

17 MR. WHEALAN: The accused infringer here has the
18 incentive to just accuse people of this. There's no harm in
19 doing it to them. They get great discovery. They disqualify
20 the attorney. And even if they lose they still get to call the
21 patent people liars.

22 THE COURT: Mr. Whealan. Judge, you wanted to ask a
23 question.

24 THE COURT (J. NEWMAN): Do you propose to say anything about the
25 merits? I know that your --

1 MR. WHEALAN: Yes, Your Honor.

2 THE COURT: -- opponent raised it, although you had --

3 MR. WHEALAN: So the merits. Three points. One, if
4 the Court changes the standard and clarifies that Kingsdown is
5 the law and that the "should have known" standard should not be
6 applied, it cannot affirm, as Mr. Badke wants, the standard
7 changes. It can act as a court in equity in the first instance
8 on appeal.

9 THE COURT (J. MOORE): But, counsel, this Court found Dr.
10 Sanghera and Mr. Pope to be un-credible and found that they
11 knew and found, I mean, it seems to me while the Court may have
12 parroted the should have known standard in the -- our initial
13 articulation of what the standard should be, what they actually
14 made were fact findings that are completely consistent with
15 Kingsdown.

16 MR. WHEALAN: So it did two things, Your Honor. The
17 Court has said it applied the should have -- it discussed the
18 should have known standard despite Kingsdown. So there it
19 didn't have to know he knew. It just had to know he should
20 have known. And, secondly, it applied the materiality, high
21 materiality --

22 THE COURT (J. MOORE): But the fact findings on intent, you can't
23 disagree. He found them to be un-credible. He found --

24 MR. WHEALAN: I can --

25 THE COURT: -- they knew. They had actual knowledge.

1 MR. WHEALAN: They had knowledge of --

2 THE COURT: I mean, so what do we do with that?

3 MR. WHEALAN: So, Your Honor, they had knowledge of
4 what? They had knowledge of the EPO proceeding, true. There's
5 no evidence, not a single piece of evidence that they had
6 appreciated that this was material important information and
7 that we're not going to give this publicly recorded document to
8 the PTO because we won't get a patent because of it. There's
9 not a shred of evidence on that. And, so, as a --

10 THE COURT: Well, you've moved to materiality in your
11 answer there, that focusing, again, on intent. Isn't it the
12 case that Judge Alsup did find a specific intent to deceive?

13 MR. WHEALAN: He -- I don't think my answer went to
14 materiality, Your Honor.

15 THE COURT: Well --

16 MR. WHEALAN: He didn't -- there was no evidence that
17 he --

18 THE COURT: -- to materiality. Perhaps I didn't
19 understand the --

20 MR. WHEALAN: There was no evidence that Pope read
21 those documents and said this is material. We're not going to
22 give it to the patent office.

23 THE COURT: Well --

24 MR. WHEALAN: There's none of that. There's --

25 THE COURT: With respect, focusing specifically on

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1 what Judge Alsup found, the problem that, when you began your
2 answer I thought where you were going is to say that Judge
3 Alsup didn't apply the right standard --

4 MR. WHEALAN: Right.

5 THE COURT: -- with respect to intent. He made
6 reference to known or should have known, and he made reference
7 to the balancing standard, and he needed to apply the correct
8 standard of intent. And, yet, he does seem to have found,
9 specifically, that there was a specific intent to deceive,
10 which would seem to make the other findings that he made
11 harmless or superfluous, right?

12 MR. WHEALAN: Well, I would respectfully disagree.

13 THE COURT (J. BRYSON): Okay.

14 MR. WHEALAN: The other findings led him to the
15 conclusion of a specific intent to deceive using a different
16 standard and a different sliding scale standard, and what, as
17 articulated, I can't do it better than Judge Linn did in the
18 dissent, explain that where the disagreement really lay as to
19 whether or not they had a good faith believe that this wasn't
20 material. And it wasn't material if you -- I encourage you to
21 read the paragraph below. They were talking about whether or
22 not this was optionally but preferred in live blood. And they
23 then said this is optionally but preferred in live blood.

24 THE COURT (J. DYK): But he specifically disbelieved their
25 explanation, right?

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1 MR. WHEALAN: He disbelieved that they had no reason
2 to believe that that was not material. They thought it was
3 cumulative. And it was two years ago when they had read the
4 information, and they were talking about what types of
5 membranes were being used, and all that sentence does is
6 paraphrase what was above them. This whole case was about what
7 that phrase meant, right? This whole case. The invalid and
8 the aspect of this case, which is not up en banc, was about
9 whether optionally but preferably live blood meant it was
10 required or not for whole blood.

11 It doesn't say whole blood, Your Honor. The words
12 aren't there. They don't say whole blood. It's all inferred.
13 And these people didn't believe that. What they --

14 THE COURT: Does this case satisfy the but-for
15 causation test?

16 MR. WHEALAN: No. Not at all.

17 THE COURT: Why not?

18 MR. WHEALAN: Because the prior art was in front of
19 the examiner and he allowed the patent. This was a
20 characterization of the prior art that neither this court nor
21 the district court relied on to invalidate the patent. But the
22 issue down below was whole blood doesn't require a membrane.
23 What the doctor said was that single sentence does not
24 determine my understanding, does not change my understanding
25 that membranes are needed for whole blood.

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1 And, if it did, this sentence says "preferred in live
2 blood". Therefore, that should be a teaching that it's
3 optional for live blood.

4 THE COURT: They admitted that the plain English
5 meaning of that meant that it wasn't required, right?

6 MR. WHEALAN: Your Honor, this was a medical
7 diagnostic system, and they -- everybody agrees that if you
8 use -- don't use a membrane for blood it's valid. It may be
9 less, but it's valid. And that statement, preferred in live
10 blood, that would mean it's optional for live blood, right,
11 that we don't necessarily have to have it? Today, there's not
12 a single membrane used for a live blood scenario, because
13 there's not a single system without a membrane for live blood.
14 It would be like I said I have a hybrid car that goes thirty
15 miles an hour. I'd prefer it goes 200 miles or 200 miles per
16 gallon. And all of a sudden that's a teaching. They didn't
17 believe that was the teaching. That's all they said one way or
18 the other. And if you go with the (b)(2) standard, which, as
19 some people discuss, basically swallows (b)(1), you will have
20 people looking for an unlimited amount of information that's
21 not disclosed. And they will dig and dig and dig, and they
22 will find something that's inconsistent with an argument, just
23 like here, that wasn't even in the file. It wasn't even -- it
24 was a European case two years ago about a piece of prior art.
25 And it seems like that should not occur. We'd ask the Court to

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1 reverse the finding of inequitable conduct and the resulting
2 finding of an exceptional case, and, in turn, these fees that
3 went along with it. Okay. Thank you, Your Honor.

4 THE COURT (CHIEF J. RADER): Thank you, Mr. Whealan.

5 (End of proceedings)

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CERTIFICATION

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I, Dena Page, certify that the foregoing transcript is a true and accurate record of the proceedings.

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Date: November 10, 2010