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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MONTANA

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\_\_\_\_\_ BUTTE DIVISION LESLIE VAN DYKE,  
Plaintiff,

-vs- HOWMEDICA CORPORATION, OSTEONICS Civil No. Court  
No. 09-78-BU-SEH 10-35429 Docket of Appeals

---

\_\_\_\_\_ Defendant. TRANSCRIPT OF MOTION HEARING  
PROCEEDINGS

Mike Heard Mansfield 400 in Butte, April Second North  
10:07 Federal 23, Main Montana Floor a.m. 2010 Street  
Courtroom Courthouse BEFORE THE HONORABLE SAM E.  
HADDON  
UNITED STATES DISTRICT JUDGE

Missouri River Courthouse United Great TINA Official  
Falls, C. States - BRILZ, Court 125 Montana District  
Central RPR, Reporter FCRR 59404 Court Avenue West,  
Room 301 Proceedings produced by recorded computer.  
by mechanical stenography, transcript

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

PRESENT VAN DYKE:

ON BEHALF OF THE PLAINTIFF, LESLIE MR. Attorney ANGEL  
803 Bozeman, GEOFFREY West LAW at Babcock Montana FIRM  
Law C. ANGEL 59715

PRESENT OSTEONICS ON CORPORATION:

BEHALF OF THE DEFENDANT, HOWMEDICA MS. Attorney  
CROWLEY P.O. Helena, MARCIA Box FLECK Montana at 797  
DAVENPORT Law PLLP 59624-0797  
and

MS. Attorney GIBBONS One Newark, KIM Gateway M. PC New  
at CATULLO Law Center Jersey 07102

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ll call this matter,  
The court has set this  
78-BU-SEH, Van Dyke versus  
r a motion  
el, we're getting  
ke a call during the  
are now ready to  
in this matter by Mr.  
ted by Ms. Davenport.

edings

Be seated, please,

idant's motion. The  
n. I'm prepared to hear

ou have the

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ORT: Thank you, Your

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roduce Kim Catullo, who flew

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w firm of Gibbons, PC. And

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around the country. And she's

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to you, as well. So I'll turn

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D: Good morning, Your

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Well, glad that you're

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 3 of 37

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number of courts where

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ve been also a majority

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ded. And in fact, that is

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rd, then, to the

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ith a 12(b)(6) motion.

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corners of the

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d,

at this complaint

D: Thank you, Your

it's very clear that it

s is a 12(b)(6) motion

f this PMA Class III

ch is a PMA Class III

l and MDA preemptions

he outset that there is no

bit, if I may, about PMA

Trident System is in fact a PMA

devices are PMA devices. I've  
many years, and I can tell you  
ve had. And I think the Supreme  
ending many pages talking about  
t something that you see all  
ey said, and it's accurate,

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 4 of 37

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Class III devices that come out  
through an extremely  
process, which just does not  
Class III  
- and I don't want to spend too  
obviously, we've put  
Well, it is not a disputed  
so-called Class III  
D: It's not, Your

the PMA approval is  
you're absolutely correct  
device is not in dispute.  
device? And I think that  
that long and  
n they must make for  
fe and effective product.  
t there are no risks  
ctually going through  
evice, like most of these  
And it's up to the FDA  
or not it's -- when you  
fficacy analysis comes

t should move

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c about PMA is that the FDA

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ce after it is put on the

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 5 of 37

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ge the device without going

lation of

continuous reporting

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FDA is vigilant about and my

l another significant point is

oted in Riegel, the FDA must

rice becomes unsafe or

e -- since 2003, they have

s still a PMA-approved

riefly about the significance of

could be clearer that there

as that challenge the safety

. The court went out of

oning

r to this product,

. it's 10 cases now.

thority to Your Honor

untry, where 12(b)(6)

press preemption

inute about implied

e court, that the court in

agreement. I'll say a

s a very early decision in

has been roundly

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top of my head, I can  
  
cally say that Hofts is

again, I have to say that

is just non-existent. And I

criticized about. So, while I

the Hofts court opinion is

to follow the majority of

If the court would like me to

off's claims. I can do that if

to give you an

You have the floor, counsel.

practice of this court to direct

to have

Q: I understand, Your

the allegations

you read through it,

claims, to the extent

is focused on the safety

issue, which is

to be

is preempted. And

the one, is the product

is a general

current good manufacturing

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ere's nothing  
  
do parrot the words  
  
evice. But getting  
  
aw out there that a CGMP  
  
ay to try to get

at one of the federal

around express preemption,

ly general, non-specific

ll be differences between

s are for this PMA

nit that that count fails

count, very simply, there's

But negligence itself was

court, the Supreme Court in

f claim was rejected as

rantees count, and

es both express and

t is -- I'm sorry,

dly based upon the

t you cannot have a

label that went through

label. So at that point,

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rly a preempted --  
  
s, marketability and  
  
, precisely claims  
  
Riegel head on.  
  
and efficacy of the  
  
would submit also

allegations when you look at  
the Consumer Protection Act,  
acknowledges that that is  
in fact, challenges it as  
precisely what the Riegel court

CA. There are things  
1, failure to report all  
under the FDCA. And if  
I, of course, would  
h that, but if there

be expressly preempted,

misrepresentation.

made that that is also a

say about just the overall

through the initial allegations,

r about, actually, is a

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e FDA has to take up.  
  
mption under Buckman kicks  
  
gant to pursue. It's  
  
ould say that on top of  
  
arguments, we also  
  
implied preemption that  
  
recall issue, I mean,  
  
of the complaint; but I  
  
ctually, that the



ed. But I would submit that

sue of the adequacy of the

edronic decision that head-on

e complaint, I -- it was

classic examples of, you

Case 2:09-cv-00078-SEH Document 39 Filed C

s with a PMA product. In

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was recalled, and the court

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does not affect the PMA

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look at is whether or not, at

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PMA product. This product has

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the time of implant

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actually, in closing, would just

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mbly. And in addition to

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ion would prevail, in our

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opposed to getting to

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reasons, Your Honor, we

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C -- Howmedica

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you,

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you, Your

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is filed by Howmedica in

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ases, it is still the

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int meets the requirements

s Supreme Court in Riegel to

a 12(b)(6) motion.

Case 2:09-cv-00078-SEH Document 39 Filed 0

when a product violates federal

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the court today identifies

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which we don't believe

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to Your Honor's determination, we

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to address, through a motion to

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ers that the court does note.

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be brought forward when we

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large statement to make, given

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led, by my count, with 11

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nized that these  
claims under Riegel for  
can show it caused  
ery complicated, but I  
at I see as  
the holding in  
his court, and I don't  
of eight courts  
rt-based claims  
ct in this case, have  
he Supreme Court's  
es, Funk, Covert,

of those cases, certainly,

And, of course, they

t you can state parallel

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ng. I then wanted to go to

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involving the Trident product

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ere the court actually

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ic allegations in the

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ere was no preemption. The

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lled claims could be

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found was my list was almost

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s for the holding that state

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 12 of 37

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Howmedica, and we're

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y, actually found

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rought for breach

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wasn't brought to the

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ered it

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: the defendant in

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inion shopping in

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is-tort designation

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e Trident before -- by

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Hayes actually recognized that

e there are some

e not

ing that the Trident's

resting thing is from that

ssitated the designation

that's present here today was

those cases have been going  
believe, more than a year old  
Howmedica's never brought a  
e court cases. And again, as I  
an 26. And I believe defense  
in all of those  
ny research, it appears  
ty of the cases that she's

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or a decision issued saying  
e case, Delaney, that they  
tion of state law claims,  
ufacturing defect and express  
erly pled. And the court allowed

he court held that  
e plaintiff leave to  
nty and Consumer  
tryker, the court  
al requirements  
cases Howmedica cited  
allel claims may be  
- the majority  
ce, because they were



... we hit the mark when there's a

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... seven of the eleven cases that

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... did not hit

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... believe we hit the mark is Mr.

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... ries are the same. The Hofts

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... e ago, not quite a year. And we

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 14 of 37

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2 ecedent, Hofts is the  
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2 sing this same  
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2 808.1(d)(2) provides  
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ame allegations as Hofts. o requirements in,  
  
ted this preemption argument  
  
country in federal courts, and 808.1(d)(1) provides  
  
ue applicability where the  
  
complaint where the courts o other products in  
  
y pled to state parallel state e practices, in  
  
pted by ted to devices, are not  
  
the court wants to look ssues that may arise with  
  
n the Code of Federal

Specifically addressed

Trade practice is an

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 15 of 37

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preemption issue, and I've read

more than once, it appears to me

that the U.S. Supreme Court, was that

the parallel state law claims. The

court has not yet been able to date explain what

is at issue in Riegel

and why state law claims must be claims that

are preempted by the violation of federal law, which

is why the MDA were not

preempted by the FDA in this case found

If the FDA's

action is based on the

fact that a product

did not exist - could be the basis

of a claim specifically said,

that it would violate federal law,

but it does not violate

state law as argued to the court,

and that is why the Trident as it was

is not preempted by the FDA in this case found seeking state damages

ece of evidence -- the FDA

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omplying with federal law

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 16 of 37

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ucts. As designed, as  
uct. Unfortunately, the  
untry, and they didn't  
t following what we told them  
ng to enforce on behalf of the  
r penalize their past  
ging a state law claim for  
e  
as that were created by their  
irements. Those failures, even  
d have been a violation of  
end by saying that if the court

ts' complaint because  
' injuries, that we have  
respectfully request  
rns through an amendment.  
at's not possible  
y deficiencies it  
-- I understand  
; this complaint was to do  
aint and, I think, in  
got a bad

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hat the FDA told the  
  
that issue of

l Howmedica. What Leslie wants

had to undergo a surgery to

hip, and compensation for the

e law. We are not trying to

ny of the requirements on

We're simply noting that they

a violation of state law. And

c

Thank you, Mr.

our papers, that

claim. What we are

a parallel claim and

he nature

itely correct, and I

ontrary, that these cases

have a parallel claim.

s the case here, that the

ave a parallel claim.

D: Your Honor, I just want to

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parallel claims. I am by no means



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a little bit about  
  
he said that he  
  
in our papers. And  
  
distinction

Huber was not a tort action. It

motion on the express

they specifically said: "We

terwards, and we

injuries in this case." And what

ake it to the Third

motion practice, they were

at, because it did not

warranty. And Judge Linares

ts way to say that a

New Jersey said that "I am

process cannot be a

." And frankly, he said: "If I

e had the Shiley

ers, and I was able to do

go to the Third Circuit

ng Third Circuit precedent, I'm

[Case 2:09-cv-00078-SEH Document 39 Filed 0](#)

gree with you, so I find

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s not expressly preempted." But

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by a 14-year-old precedent."

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f Shiley from the Third

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the case ultimately  
  
r thing about Huber  
  
s case, is actually the  
  
ge felt compelled,  
  
t apply Riegel logic and

of an expressed  
mit that Huber doesn't apply to  
s, you know, a long history  
- or a few other points,  
t Delaney, there was a --  
t of the manufacturing claim.

t. The court said -- again,  
New Jersey before Hayes, that  
tied by Shiley, which is a  
let them have a chance to  
actually chose not to do it

makes much of the fact  
laint on Hofts. I can say  
complaint, I believe we  
omplaints, this  
e interrupt you, counsel,

Case 2:09-cv-00078-SEH Document 39 Filed 0

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activity that has  
  
round the country may be  
  
of scant interest to  
  
ndeavor to conduct an  
  
on what the law says  
  
nd while reading  
  
is sometimes  
  
m and each of them, I

a fellow district court

ubstantive opinion on

ificance, except as the court

at you can't have one

to be appropriate to this

ut having the appropriate

D: Absolutely, Judge.

Case 2:09-cv-00078-SEH Document 39 Filed 0

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a fact, I think the judge in

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helpful to look at the

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ly, make her own

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suggesting by any means that it's

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at that, I believe it was the

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he Ninth Circuit, that

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like to say with

I'm somewhat

ing since February. And

uggest that an

hat it would be a futile

ing to be some

, preempted. They're

f not, they fall within

think it was the

ying: No one wants to be

ractice of the court,

my client, I can tell you very

rs of this sort

tients to be satisfied with

Case 2:09-cv-00078-SEH Document 39 Filed 0

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n, and in this limited case,

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devices going through an

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nt to have companies putting

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nd in most instances improve

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re are going to be times when

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Your Honor, for allowing me

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el, I'm sure, know, and it



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from the extensive  
  
And I have reviewed the  
  
ave read the briefs of  
  
als that have been  
  
d, reviewed these  
  
lemental authority, that  
  
of the court. Some of  
  
: to say that the  
  
of what the issues in  
  
address  
  
rting point to what the

claims is. And as it is

several separate claims;

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a repeated theme is stated.

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plaintiff's lawsuit is premised on

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state law." On page 5, there

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reads the first: "Van Dyke

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of its violations of

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declaration appears on

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mean what it says. Using that

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then specifically to the claims

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One and Two are claims of

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are. And there is an allegation

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carried out consistent with the

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there is also an implied  
ent to Count Three, all of  
Uniform  
ing the Montana Consumer  
tive  
which is tied to the  
ized as one of  
ound, and I take it  
atters are not in  
so-called Class III  
roduct was one that had  
ad been approved by the

reads both express warranty

Act of the Federal Drug and

in this instance marketed and

was

lightly differently: That all

had, in fact, been

l obtained before the product

vious to all, any

e given to this set of laws

United States Supreme Court has

Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 24 of 37

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of a medical device  
  
the pre-market approval  
  
really mean? I read that  
  
claims are, in fact,  
  
relate to the  
  
ce, or to a requirement  
  
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Well, I conclude

us directly to the Riegel case

, I take it to be  
  
t are asserted that are  
  
ess of the device, and  
  
breach of implied

to say that the preemptive

barred common law claims

n, or in test or

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that apply to the

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the conclusion that any state

y as may be said to be

manufacturing, testing,

Count Two, breach of implied

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 25 of 37

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ella of a type of claim that is  
ness component of the statute  
quirements related to the device  
on, Riegel, through the

narrow the preemptive  
grounds that it  
t Congress would,  
ial recourse,' end of  
approved  
the dissent in that  
to say, and this is,  
ealt with other than to  
have explained, this  
for medical devices  
doubt, I conclude that  
ecourse affecting the

is, in fact, barred. And I

r the State of Montana, could

s either different from or in

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hat apply here? Well, I conclude

Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 26 of 37

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e an express warranty claim

ion to the federal warranty

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plaintiff's Consumer

nt Four, that part of the

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ted to the sale of the

phs 88 through 93 of Count

laims of that type are expressly

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ount Five disclose that.

n, that that is a

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: us? Well, it leaves us,

d, with a conclusion that

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the plaintiff claims that

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statements made on the label. And

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 27 of 37

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conclude that the state

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Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 28 of 37

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Case 2:09-cv-00078-SEH Document 39 Filed 0

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Case 2:09-cv-00078-SEH Document 39 Filed C

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r bad law, whether we like

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[Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 31 of 37](#)

31

C E R T I F I C A T E

STATE County OF of MONTANA Cascade ) )

: SS I, TINA C. BRILZ, RPR, FCRR, Official Court  
Reporter and

Notary Public of the State of Montana residing at

Great

Falls, Montana, do hereby certify as follows:

That the foregoing motion hearing was reported by me  
on

April 23, 2010, at 10:07 a.m. in the Second Floor  
Courtroom

in the Mike Mansfield Federal Courthouse in Butte,  
Montana.

That the foregoing thirty (30) pages of typewritten  
material constitute a true and accurate transcription  
of my

stenographic notes which were reduced to writing by  
means of

computer-aided transcription.

I further certify that I am not an attorney nor  
counsel

of any of the parties nor a relative or employee of  
any

attorney or counsel connected with this action or  
otherwise

interested in the event thereof.

IN WITNESS WHEREOF, I have hereunto set my hand and  
affixed my Official Seal on this 14th day of May,  
2010.

REGISTERED NOTARY Montana Montana. October /s/ Tina

PUBLIC residing 11, My TINA C. PROFESSIONAL 2011.

commission Brilz \_\_\_\_\_ for C. at the BRILZ Great

State REPORTER expires Falls, of



26:8

## 1

1 [2] - 5:1, 22:15 **10** [2] - 6:16, 23:20 **10:57** [1] - 30:20 **11** [2] - 11:24, 12:2 **12(b)(6)** [5] - 4:3, 4:13, 6:18, 11:5, 11:25 **14-year-old** [1] - 19:16

## 2

2 [1] - 23:15 **2003** [2] - 6:8, 10:19 **2006** [1] - 10:19 **21** [2] - 15:11, 29:6 **26** [1] - 13:22 **26-plus** [1] - 13:14

## 3

30 [2] - 11:19, 17:15 **337(a)** [1] - 29:7

## 4

4 [1] - 28:23 **5**

5 [1] - 23:17 **8**

**808.1(d)(1)** [1] - 15:15 **808.1(d)(2)** [1] - 15:11 **88** [1] - 27:8 **9**

**93** [1] - 27:8 **96** [1] - 27:13 **98** [1] - 27:13 **A**

**a.m** [1] - 30:20 **able** [1] - 19:12

20, 19:10, 21:13 **accurate** [1] - 4:25 **acknowledge** [2] -

7:6, 18:22 **acknowledged** [2] -

21:21, 21:23 **acknowledges** [1] -

9:10 **acknowledgment** [1] -

9:16 **act** [2] - 5:21, 29:16 **Act** [7] - 9:9, 14:9,

27:4 **action** [2] - 19:5,

29:13 **activity** [1] - 21:1 **addition** [4] - 10:21,

**address** [4] - 11:19, 15:4, 17:16, 23:11 **addressed** [2] - 9:5,

15:22 **addresses** [1] - 10:13 **addressing** [2] -

15:10 **adequacy** [2] - 8:23,

10:23 **adjourned** [1] - 30:19 **admittedly** [1] -

4 **adulterated** [3] -

16:11, 16:12, 18:2 **adulteration** [1] - 18:2

24:8, 27:7, 27:12 **advisory** [1] - 29:22 **affect** [2] -  
- 26:20 **afoul** [1] - 28:13 **afterwards** [1] - 19:19 **Agency** [1] - 24:17 **ago**

21:21 **agree** [1] - 12:8 **allegation** [2] - 8:4,  
23:24 **allegations** [5] - 7:16,

**allow** [1] - 8:7 **allowed** [2] - 14:5,

20:13 **allowing** [1] - 22:20 **almost** [1] - 12:23

20:17, 20:20, 29:17 **amendment** [6] -

17:16, 17:17, 20:13, 22:2, 22:4, 22:6 **analysis** [11] - 4:13,

17:16, 17:17, 20:13, 22:2, 22:4, 22:6 **analysis** [11] - 4:13,

17:16, 17:17, 20:13, 22:2, 22:4, 22:6 **analysis** [11] - 4:13,

5:22, 7:4, 9:1, 10:17, 10:21, 12:5, 19:12, 21:5, 22:15, 24:23 **Angel** [4] - 3:12, 11:8,

5:22, 7:4, 9:1, 10:17, 10:21, 12:5, 19:12, 21:5, 22:15, 24:23 **Angel** [4] - 3:12, 11:8,

5:22, 7:4, 9:1, 10:17, 10:21, 12:5, 19:12, 21:5, 22:15, 24:23 **Angel** [4] - 3:12, 11:8,

5:22, 7:4, 9:1, 10:17, 10:21, 12:5, 19:12, 21:5, 22:15, 24:23 **Angel** [4] - 3:12, 11:8,

5:22, 7:4, 9:1, 10:17, 10:21, 12:5, 19:12, 21:5, 22:15, 24:23 **Angel** [4] - 3:12, 11:8,

29:17, 30:8 **angel** [1] - 18:12 **ANGEL** [2] - 11:9,

29:17, 30:8 **angel** [1] - 18:12 **ANGEL** [2] - 11:9,

29:17, 30:8 **angel** [1] - 18:12 **ANGEL** [2] - 11:9,

29:17, 30:8 **angel** [1] - 18:12 **ANGEL** [2] - 11:9,

17:22 **answer** [1] - 30:2 **anticipate** [1] - 3:10 **anticipated** [2] - 15:2,

17:22 **answer** [1] - 30:2 **anticipate** [1] - 3:10 **anticipated** [2] - 15:2,

17:22 **answer** [1] - 30:2 **anticipate** [1] - 3:10 **anticipated** [2] - 15:2,

15:20 **anyway** [1] - 10:12 **appear** [1] - 25:11 **applicability** [1] -

15:20 **anyway** [1] - 10:12 **appear** [1] - 25:11 **applicability** [1] -

15:20 **anyway** [1] - 10:12 **appear** [1] - 25:11 **applicability** [1] -

15:20 **anyway** [1] - 10:12 **appear** [1] - 25:11 **applicability** [1] -

15:20 **anyway** [1] - 10:12 **appear** [1] - 25:11 **applicability** [1] -

15:20 **anyway** [1] - 10:12 **appear** [1] - 25:11 **applicability** [1] -

15:16 **applied** [1] - 21:11 **apply** [9] - 5:3, 20:6,

15:16 **applied** [1] - 21:11 **apply** [9] - 5:3, 20:6,

15:16 **applied** [1] - 21:11 **apply** [9] - 5:3, 20:6,

20:8, 25:13, 25:21, 26:15, 26:25, 29:8, 30:14 **appreciate** [2] - 22:21,

20:8, 25:13, 25:21, 26:15, 26:25, 29:8, 30:14 **appreciate** [2] - 22:21,

20:8, 25:13, 25:21, 26:15, 26:25, 29:8, 30:14 **appreciate** [2] - 22:21,

30:7 **appropriate** [4] -

30:7 **appropriate** [4] -

21:11, 21:24, 22:5, 24:21 **appropriately** [1] -

21:11, 21:24, 22:5, 24:21 **appropriately** [1] -

21:11, 21:24, 22:5, 24:21 **appropriately** [1] -

30:1 **approval** [10] - 5:3,

30:1 **approval** [10] - 5:3,

5:10, 5:14, 6:7, 8:24, 24:1, 24:18, 24:20, 24:21, 25:6 **approved** [6] - 6:9,

5:10, 5:14, 6:7, 8:24, 24:1, 24:18, 24:20, 24:21, 25:6 **approved** [6] - 6:9,

5:10, 5:14, 6:7, 8:24, 24:1, 24:18, 24:20, 24:21, 25:6 **approved** [6] - 6:9,

5:10, 5:14, 6:7, 8:24, 24:1, 24:18, 24:20, 24:21, 25:6 **approved** [6] - 6:9,

16:21, 17:1, 19:23, 24:15, 26:11 **argue** [2] - 18:16,

16:21, 17:1, 19:23, 24:15, 26:11 **argue** [2] - 18:16,

16:21, 17:1, 19:23, 24:15, 26:11 **argue** [2] - 18:16,

22:20 **argued** [2] - 16:20,

22:20 **argued** [2] - 16:20,

18:21 **arguing** [2] - 3:21,

18:21 **arguing** [2] - 3:21,  
18:17 **argument** [5] - 3:16, 7:13, 15:2, 20:2, 29:18 **arguments** [2] - 10:5,  
18:17 **argument** [5] - 3:16, 7:13, 15:2, 20:2, 29:18 **arguments** [2] - 10:5,  
18:17 **argument** [5] - 3:16, 7:13, 15:2, 20:2, 29:18 **arguments** [2] - 10:5,  
18:17 **argument** [5] - 3:16, 7:13, 15:2, 20:2, 29:18 **arguments** [2] - 10:5,  
10:6 **arise** [1] - 15:20 **assert** [5] - 18:18,  
10:6 **arise** [1] - 15:20 **assert** [5] - 18:18,  
10:6 **arise** [1] - 15:20 **assert** [5] - 18:18,  
28:7, 29:9, 29:15 **asserted** [3] - 23:13,  
28:7, 29:9, 29:15 **asserted** [3] - 23:13,  
25:15, 25:23 **associated** [1] - 5:17 **attached** [1] - 20:22 **attention** [2] - 13:8,  
25:15, 25:23 **associated** [1] - 5:17 **attached** [1] - 20:22 **attention** [2] - 13:8,  
25:15, 25:23 **associated** [1] - 5:17 **attached** [1] - 20:22 **attention** [2] - 13:8,  
23:7 **attorney** [1] - 13:4 **authority** [2] - 6:17,  
23:7 **attorney** [1] - 13:4 **authority** [2] - 6:17,  
23:7 **attorney** [1] - 13:4 **authority** [2] - 6:17,  
23:6 **authorized** [1] - 29:2 **available** [1] - 29:13  
23:6 **authorized** [1] - 29:2 **available** [1] - 29:13  
23:6 **authorized** [1] - 29:2 **available** [1] - 29:13  
23:6 **authorized** [1] - 29:2 **available** [1] - 29:13

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**background** [2] -  
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**background** [2] -  
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24:11, 24:12 **bad** [2] - 17:25, 30:13 **balancing** [1] - 5:21 **ball** [1] - 28:3 **barred** [2] - 25:4,  
24:11, 24:12 **bad** [2] - 17:25, 30:13 **balancing** [1] - 5:21 **ball** [1] - 28:3 **barred** [2] - 25:4,  
24:11, 24:12 **bad** [2] - 17:25, 30:13 **balancing** [1] - 5:21 **ball** [1] - 28:3 **barred** [2] - 25:4,  
24:11, 24:12 **bad** [2] - 17:25, 30:13 **balancing** [1] - 5:21 **ball** [1] - 28:3 **barred** [2] - 25:4,  
24:11, 24:12 **bad** [2] - 17:25, 30:13 **balancing** [1] - 5:21 **ball** [1] - 28:3 **barred** [2] - 25:4,  
24:11, 24:12 **bad** [2] - 17:25, 30:13 **balancing** [1] - 5:21 **ball** [1] - 28:3 **barred** [2] - 25:4,  
24:11, 24:12 **bad** [2] - 17:25, 30:13 **balancing** [1] - 5:21 **ball** [1] - 28:3 **barred** [2] - 25:4,

26:21 **based** [11] - 8:21,  
26:21 **based** [11] - 8:21,  
26:21 **based** [11] - 8:21,  
26:21 **based** [11] - 8:21,  
26:21 **based** [11] - 8:21,

8:25, 9:10, 9:16, 12:10, 12:12, 12:20, 21:5, 26:20, 26:24, 27:18 **basis** [7] - 8:5, 16:14,  
8:25, 9:10, 9:16, 12:10, 12:12, 12:20, 21:5, 26:20, 26:24, 27:18 **basis** [7] - 8:5, 16:14,  
8:25, 9:10, 9:16, 12:10, 12:12, 12:20, 21:5, 26:20, 26:24, 27:18 **basis** [7] - 8:5, 16:14,  
8:25, 9:10, 9:16, 12:10, 12:12, 12:20, 21:5, 26:20, 26:24, 27:18 **basis** [7] - 8:5, 16:14,  
8:25, 9:10, 9:16, 12:10, 12:12, 12:20, 21:5, 26:20, 26:24, 27:18 **basis** [7] - 8:5, 16:14,  
8:25, 9:10, 9:16, 12:10, 12:12, 12:20, 21:5, 26:20, 26:24, 27:18 **basis** [7] - 8:5, 16:14,

19:23, 21:24, 23:12, 28:16, 28:17 **Bausch** [2] - 12:14,  
19:23, 21:24, 23:12, 28:16, 28:17 **Bausch** [2] - 12:14,  
19:23, 21:24, 23:12, 28:16, 28:17 **Bausch** [2] - 12:14,  
19:23, 21:24, 23:12, 28:16, 28:17 **Bausch** [2] - 12:14,

14:11 **becomes** [1] - 6:7 **behalf** [1] - 17:6 **believes** [1] - 17:12 **benefited** [1] - 23:1 **between** [3] - 8:9,  
14:11 **becomes** [1] - 6:7 **behalf** [1] - 17:6 **believes** [1] - 17:12 **benefited** [1] - 23:1 **between** [3] - 8:9,  
14:11 **becomes** [1] - 6:7 **behalf** [1] - 17:6 **believes** [1] - 17:12 **benefited** [1] - 23:1 **between** [3] - 8:9,  
14:11 **becomes** [1] - 6:7 **behalf** [1] - 17:6 **believes** [1] - 17:12 **benefited** [1] - 23:1 **between** [3] - 8:9,  
14:11 **becomes** [1] - 6:7 **behalf** [1] - 17:6 **believes** [1] - 17:12 **benefited** [1] - 23:1 **between** [3] - 8:9,  
14:11 **becomes** [1] - 6:7 **behalf** [1] - 17:6 **believes** [1] - 17:12 **benefited** [1] - 23:1 **between** [3] - 8:9,  
14:11 **becomes** [1] - 6:7 **behalf** [1] - 17:6 **believes** [1] - 17:12 **benefited** [1] - 23:1 **between** [3] - 8:9,  
14:11 **becomes** [1] - 6:7 **behalf** [1] - 17:6 **believes** [1] - 17:12 **benefited** [1] - 23:1 **between** [3] - 8:9,  
14:11 **becomes** [1] - 6:7 **behalf** [1] - 17:6 **believes** [1] - 17:12 **benefited** [1] - 23:1 **between** [3] - 8:9,

18:3, 28:3 **beyond** [2] - 15:8,  
18:3, 28:3 **beyond** [2] - 15:8,  
18:3, 28:3 **beyond** [2] - 15:8,  
18:3, 28:3 **beyond** [2] - 15:8,  
18:3, 28:3 **beyond** [2] - 15:8,

29:24 **bit** [3] - 3:8, 4:19, 19:1 **borders** [1] - 15:9 **breach** [6] - 13:7,  
29:24 **bit** [3] - 3:8, 4:19, 19:1 **borders** [1] - 15:9 **breach** [6] - 13:7,  
29:24 **bit** [3] - 3:8, 4:19, 19:1 **borders** [1] - 15:9 **breach** [6] - 13:7,  
29:24 **bit** [3] - 3:8, 4:19, 19:1 **borders** [1] - 15:9 **breach** [6] - 13:7,  
29:24 **bit** [3] - 3:8, 4:19, 19:1 **borders** [1] - 15:9 **breach** [6] - 13:7,  
29:24 **bit** [3] - 3:8, 4:19, 19:1 **borders** [1] - 15:9 **breach** [6] - 13:7,

14:9, 19:9, 25:17, 25:25, 28:20 **brief** [2] - 23:15, 28:1 **briefing** [1] - 23:1 **briefly** [3] - 6:10, 9:9,  
14:9, 19:9, 25:17, 25:25, 28:20 **brief** [2] - 23:15, 28:1 **briefing** [1] - 23:1 **briefly** [3] - 6:10, 9:9,  
14:9, 19:9, 25:17, 25:25, 28:20 **brief** [2] - 23:15, 28:1 **briefing** [1] - 23:1 **briefly** [3] - 6:10, 9:9,  
14:9, 19:9, 25:17, 25:25, 28:20 **brief** [2] - 23:15, 28:1 **briefing** [1] - 23:1 **briefly** [3] - 6:10, 9:9,  
14:9, 19:9, 25:17, 25:25, 28:20 **brief** [2] - 23:15, 28:1 **briefing** [1] - 23:1 **briefly** [3] - 6:10, 9:9,  
14:9, 19:9, 25:17, 25:25, 28:20 **brief** [2] - 23:15, 28:1 **briefing** [1] - 23:1 **briefly** [3] - 6:10, 9:9,

10:8 **briefs** [4] - 11:10,  
10:8 **briefs** [4] - 11:10,  
10:8 **briefs** [4] - 11:10,  
10:8 **briefs** [4] - 11:10,

17:25, 23:3, 23:5 **bring** [4] - 10:20,  
17:25, 23:3, 23:5 **bring** [4] - 10:20,  
17:25, 23:3, 23:5 **bring** [4] - 10:20,  
17:25, 23:3, 23:5 **bring** [4] - 10:20,

11:13, 12:3, 29:20 **bringing** [1] - 17:8 **brought** [7] - 11:21, 12:22, 13:7, 13:8, 13:20, 14:15, 23:7  
**Buckman** [6] - 10:2, 22:9, 25:2, 28:18, 29:11 **building** [1] - 17:1  
11:13, 12:3, 29:20 **bringing** [1] - 17:8 **brought** [7] - 11:21, 12:22, 13:7, 13:8, 13:20, 14:15, 23:7  
**Buckman** [6] - 10:2, 22:9, 25:2, 28:18, 29:11 **building** [1] - 17:1  
11:13, 12:3, 29:20 **bringing** [1] - 17:8 **brought** [7] - 11:21, 12:22, 13:7, 13:8, 13:20, 14:15, 23:7  
**Buckman** [6] - 10:2, 22:9, 25:2, 28:18, 29:11 **building** [1] - 17:1  
11:13, 12:3, 29:20 **bringing** [1] - 17:8 **brought** [7] - 11:21, 12:22, 13:7, 13:8, 13:20, 14:15, 23:7  
**Buckman** [6] - 10:2, 22:9, 25:2, 28:18, 29:11 **building** [1] - 17:1  
11:13, 12:3, 29:20 **bringing** [1] - 17:8 **brought** [7] - 11:21, 12:22, 13:7, 13:8, 13:20, 14:15, 23:7  
**Buckman** [6] - 10:2, 22:9, 25:2, 28:18, 29:11 **building** [1] - 17:1  
11:13, 12:3, 29:20 **bringing** [1] - 17:8 **brought** [7] - 11:21, 12:22, 13:7, 13:8, 13:20, 14:15, 23:7  
**Buckman** [6] - 10:2, 22:9, 25:2, 28:18, 29:11 **building** [1] - 17:1  
11:13, 12:3, 29:20 **bringing** [1] - 17:8 **brought** [7] - 11:21, 12:22, 13:7, 13:8, 13:20, 14:15, 23:7  
**Buckman** [6] - 10:2, 22:9, 25:2, 28:18, 29:11 **building** [1] - 17:1  
11:13, 12:3, 29:20 **bringing** [1] - 17:8 **brought** [7] - 11:21, 12:22, 13:7, 13:8, 13:20, 14:15, 23:7  
**Buckman** [6] - 10:2, 22:9, 25:2, 28:18, 29:11 **building** [1] - 17:1

C  
C

C  
C

C.F [1] - 15:11 C.F.R [2] - 15:11,  
C.F [1] - 15:11 C.F.R [2] - 15:11,  
C.F [1] - 15:11 C.F.R [2] - 15:11,  
C.F [1] - 15:11 C.F.R [2] - 15:11,

15:15  
15:15  
15:15

cannot [14] - 6:1, 7:21,  
cannot [14] - 6:1, 7:21,  
cannot [14] - 6:1, 7:21,  
cannot [14] - 6:1, 7:21,

8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,  
8:5, 8:22, 9:13, 18:18, 19:18, 19:23, 26:3, 26:15, 27:1, 28:12, 29:22, 30:2 **carried** [1] - 23:25  
**Carson** [1] - 21:19 **case** [38] - 4:6, 4:10,

6:22, 6:23, 8:4, 10:15, 10:23, 11:10, 12:11, 12:19, 13:10, 14:2, 15:9, 16:10, 18:18, 18:23,  
19:7, 19:17, 20:1, 20:4, 20:5, 20:8, 21:11, 21:19, 22:14, 23:4, 25:1, 25:2, 25:7, 25:12, 25:22,  
26:13, 28:18, 28:19, 29:8, 30:11, 30:12 **cases** [19] - 4:9, 6:16,  
6:22, 6:23, 8:4, 10:15, 10:23, 11:10, 12:11, 12:19, 13:10, 14:2, 15:9, 16:10, 18:18, 18:23,  
19:7, 19:17, 20:1, 20:4, 20:5, 20:8, 21:11, 21:19, 22:14, 23:4, 25:1, 25:2, 25:7, 25:12, 25:22,  
26:13, 28:18, 28:19, 29:8, 30:11, 30:12 **cases** [19] - 4:9, 6:16,  
6:22, 6:23, 8:4, 10:15, 10:23, 11:10, 12:11, 12:19, 13:10, 14:2, 15:9, 16:10, 18:18, 18:23,  
19:7, 19:17, 20:1, 20:4, 20:5, 20:8, 21:11, 21:19, 22:14, 23:4, 25:1, 25:2, 25:7, 25:12, 25:22,  
26:13, 28:18, 28:19, 29:8, 30:11, 30:12 **cases** [19] - 4:9, 6:16,  
6:22, 6:23, 8:4, 10:15, 10:23, 11:10, 12:11, 12:19, 13:10, 14:2, 15:9, 16:10, 18:18, 18:23,  
19:7, 19:17, 20:1, 20:4, 20:5, 20:8, 21:11, 21:19, 22:14, 23:4, 25:1, 25:2, 25:7, 25:12, 25:22,  
26:13, 28:18, 28:19, 29:8, 30:11, 30:12 **cases** [19] - 4:9, 6:16,  
6:22, 6:23, 8:4, 10:15, 10:23, 11:10, 12:11, 12:19, 13:10, 14:2, 15:9, 16:10, 18:18, 18:23,





24:9 chose [1] - 20:19 Circuit [6] - 19:13,  
24:9 chose [1] - 20:19 Circuit [6] - 19:13,  
24:9 chose [1] - 20:19 Circuit [6] - 19:13,

19:17, 19:20, 19:25, 20:16, 21:21 cite [2] - 12:25, 14:2 cited [1] - 14:14 citing [1] - 29:6 claim  
[35] - 7:24, 8:16,  
19:17, 19:20, 19:25, 20:16, 21:21 cite [2] - 12:25, 14:2 cited [1] - 14:14 citing [1] - 29:6 claim  
[35] - 7:24, 8:16,  
19:17, 19:20, 19:25, 20:16, 21:21 cite [2] - 12:25, 14:2 cited [1] - 14:14 citing [1] - 29:6 claim  
[35] - 7:24, 8:16,  
19:17, 19:20, 19:25, 20:16, 21:21 cite [2] - 12:25, 14:2 cited [1] - 14:14 citing [1] - 29:6 claim  
[35] - 7:24, 8:16,  
19:17, 19:20, 19:25, 20:16, 21:21 cite [2] - 12:25, 14:2 cited [1] - 14:14 citing [1] - 29:6 claim  
[35] - 7:24, 8:16,  
19:17, 19:20, 19:25, 20:16, 21:21 cite [2] - 12:25, 14:2 cited [1] - 14:14 citing [1] - 29:6 claim  
[35] - 7:24, 8:16,  
19:17, 19:20, 19:25, 20:16, 21:21 cite [2] - 12:25, 14:2 cited [1] - 14:14 citing [1] - 29:6 claim  
[35] - 7:24, 8:16,

9:2, 9:17, 11:13, 13:21, 16:14, 17:8, 18:17, 18:18, 18:19,  
9:2, 9:17, 11:13, 13:21, 16:14, 17:8, 18:17, 18:18, 18:19,  
9:2, 9:17, 11:13, 13:21, 16:14, 17:8, 18:17, 18:18, 18:19,  
9:2, 9:17, 11:13, 13:21, 16:14, 17:8, 18:17, 18:18, 18:19,  
9:2, 9:17, 11:13, 13:21, 16:14, 17:8, 18:17, 18:18, 18:19,  
9:2, 9:17, 11:13, 13:21, 16:14, 17:8, 18:17, 18:18, 18:19,

## Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 32 of 37

1

18:22, 18:24, 19:6, 19:24, 20:13, 21:25, 24:7, 25:20, 25:22, 26:2, 26:20, 27:1, 27:2, 27:5,  
27:11, 27:14, 27:20, 27:22, 28:8, 28:15, 28:19, 29:8, 29:15 claims [44] - 4:16, 6:12, 7:10,  
7:18, 7:22, 9:4, 11:15, 12:3, 12:10, 12:12, 12:15, 12:21, 12:22, 12:25, 13:2, 13:7, 13:16, 14:3,  
14:5, 14:9, 14:10, 14:12, 14:15, 15:6, 16:4, 16:7, 18:15, 21:24, 22:8, 23:13, 23:14, 23:22,  
23:23, 25:4, 25:8, 25:9, 25:15, 27:9, 27:18, 27:23, 27:24, 28:17, 28:18 Class [13] - 4:4, 4:6,  
4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 classic [1] - 10:25 clause [2] -  
25:3,

26:17 clear [7] - 4:16, 4:23,

7:18, 8:4, 8:22, 18:14, 18:25 clearer [1] - 6:11 clearly [4] - 7:19, 9:1,

10:16, 22:12 Clerk [1] - 3:4 CLERK [1] - 3:5 client [2] - 6:4, 22:12 closing [1] - 10:20 Code [3] -  
15:21, 24:5,

29:6 codified [1] - 15:21 comment [2] - 26:9,

29:24 Commercial [1] - 24:5 common [3] - 16:15,

25:4, 25:15 companies [1] - 22:16 company [4] - 6:1, 6:18, 18:1, 18:7 compelled [2] - 19:11,

20:5 compensation [1] -

18:5 complains [1] - 28:6 complaint [22] - 4:15,

7:17, 8:2, 9:18, 9:20, 10:9, 10:24, 11:12, 11:17, 11:20, 11:22,

6, 17:13, 17:19, 17:23, 17:24, 20:21, 20:22, 23:2 complaints [1] -

17:7,

29:2, 29:16 complicated [1] - 12:5 complying [1]

24:4,

conceded [1] - 4:10 concerned [1] - 27:17 concerns [1] - 17:16

9, 27:14, 28:12, 29:12 conclusion [5] -

14, 30:6 conclusory [1] - 10:25 conduct [1] - 21:4 conforming [1] -

15 Congress [1] - 26:9 consistent [1] - 23:25 Consumer [4] - 9:9, 14:9,



[1] - 26:11 **continuous** [1] - 6:3 **contrary** [1] - 18:21 **control** [1] - 5:25

10:9 **Corp.'s** [1] - 11:4 **Corporation** [1] - 3:7

18:20 **correctly** [1] - 18:21 **Cosmetic** [1] - 24:16

[22] - 3:3, 3:8, 4:1, 7:12, 9:10, 11:7, 13:4, 13:22, 13:23, 13:25, 17:21, 20, 20:25, 22:3, 22:23, 23:3, 30:7, 30:15 **Count** [16] - 7:24,

4:6, 24:8, 25:23, 25:25, 26:1, 27:5, 27:8, 27:11, 27:13, 27:20, 27:22

8:21, 9:8, 11:24, 14:21

**country** [5] - 3:21, 6:18, 15:3, 17:3, 21:2 **Counts** [1] - 27:18 **counts** [1] - 23:23 **course** [6] - 3:16,

**country** [5] - 3:21, 6:18, 15:3, 17:3, 21:2 **Counts** [1] - 27:18 **counts** [1] - 23:23 **course** [6] - 3:16,

9:24, 11:16, 11:18, 12:14, 23:3 **Court** [11] - 4:22, 6:6, 7:21, 8:15, 11:13, 13:14, 16:3, 21:6, 24:25, 28:21, 30:10 **COURT** [11] - 3:3, 3:5, 3:8, 3:25, 5:7, 7:12, 11:7, 17:20, 18:12, 20:25, 22:22 **court** [56] - 3:5, 6:13, 6:22, 7:6, 7:7, 7:9, 7:13, 7:14, 8:15, 9:5, 9:12, 10:15, 11:4, 11:16, 11:20, 11:25, 12:2, 12:8, 12:16, 12:19, 13:4, 13:9, 13:11, 13:15, 13:21, 14:5, 14:7, 14:11, 14:22, 15:8, 16:6, 16:20, 17:12, 19:7, 19:10, 20:4, 20:12, 20:14, 20:15, 21:3, 21:4, 21:9, 21:10, 22:10, 22:24, 23:7, 23:9, 27:17, 29:14, 29:19, 29:22, 29:23, 30:1, 30:6, 30:8 **Court's** [1] - 12:12 **court's** [5] - 7:3,

9:24, 11:16, 11:18, 12:14, 23:3 **Court** [11] - 4:22, 6:6, 7:21, 8:15, 11:13, 13:14, 16:3, 21:6, 24:25, 28:21, 30:10 **COURT** [11] - 3:3, 3:5, 3:8, 3:25, 5:7, 7:12, 11:7, 17:20, 18:12, 20:25, 22:22 **court** [56] - 3:5, 6:13, 6:22, 7:6, 7:7, 7:9, 7:13, 7:14, 8:15, 9:5, 9:12, 10:15, 11:4, 11:16, 11:20, 11:25, 12:2, 12:8, 12:16, 12:19, 13:4, 13:9, 13:11, 13:15, 13:21, 14:5, 14:7, 14:11, 14:22, 15:8, 16:6, 16:20, 17:12, 19:7, 19:10, 20:4, 20:12, 20:14, 20:15, 21:3, 21:4, 21:9, 21:10, 22:10, 22:24, 23:7, 23:9, 27:17, 29:14, 29:19, 29:22, 29:23, 30:1, 30:6, 30:8 **Court's** [1] - 12:12 **court's** [5] - 7:3,

9:24, 11:16, 11:18, 12:14, 23:3 **Court** [11] - 4:22, 6:6, 7:21, 8:15, 11:13, 13:14, 16:3, 21:6, 24:25, 28:21, 30:10 **COURT** [11] - 3:3, 3:5, 3:8, 3:25, 5:7, 7:12, 11:7, 17:20, 18:12, 20:25, 22:22 **court** [56] - 3:5, 6:13, 6:22, 7:6, 7:7, 7:9, 7:13, 7:14, 8:15, 9:5, 9:12, 10:15, 11:4, 11:16, 11:20, 11:25, 12:2, 12:8, 12:16, 12:19, 13:4, 13:9, 13:11, 13:15, 13:21, 14:5, 14:7, 14:11, 14:22, 15:8, 16:6, 16:20, 17:12, 19:7, 19:10, 20:4, 20:12, 20:14, 20:15, 21:3, 21:4, 21:9, 21:10, 22:10, 22:24, 23:7, 23:9, 27:17, 29:14, 29:19, 29:22, 29:23, 30:1, 30:6, 30:8 **Court's** [1] - 12:12 **court's** [5] - 7:3,

9:24, 11:16, 11:18, 12:14, 23:3 **Court** [11] - 4:22, 6:6, 7:21, 8:15, 11:13, 13:14, 16:3, 21:6, 24:25, 28:21, 30:10 **COURT** [11] - 3:3, 3:5, 3:8, 3:25, 5:7, 7:12, 11:7, 17:20, 18:12, 20:25, 22:22 **court** [56] - 3:5, 6:13, 6:22, 7:6, 7:7, 7:9, 7:13, 7:14, 8:15, 9:5, 9:12, 10:15, 11:4, 11:16, 11:20, 11:25, 12:2, 12:8, 12:16, 12:19, 13:4, 13:9, 13:11, 13:15, 13:21, 14:5, 14:7, 14:11, 14:22, 15:8, 16:6, 16:20, 17:12, 19:7, 19:10, 20:4, 20:12, 20:14, 20:15, 21:3, 21:4, 21:9, 21:10, 22:10, 22:24, 23:7, 23:9, 27:17, 29:14, 29:19, 29:22, 29:23, 30:1, 30:6, 30:8 **Court's** [1] - 12:12 **court's** [5] - 7:3,

9:24, 11:16, 11:18, 12:14, 23:3 **Court** [11] - 4:22, 6:6, 7:21, 8:15, 11:13, 13:14, 16:3, 21:6, 24:25, 28:21, 30:10 **COURT** [11] - 3:3, 3:5, 3:8, 3:25, 5:7, 7:12, 11:7, 17:20, 18:12, 20:25, 22:22 **court** [56] - 3:5, 6:13, 6:22, 7:6, 7:7, 7:9, 7:13, 7:14, 8:15, 9:5, 9:12, 10:15, 11:4, 11:16, 11:20, 11:25, 12:2, 12:8, 12:16, 12:19, 13:4, 13:9, 13:11, 13:15, 13:21, 14:5, 14:7, 14:11, 14:22, 15:8, 16:6, 16:20, 17:12, 19:7, 19:10, 20:4, 20:12, 20:14, 20:15, 21:3, 21:4, 21:9, 21:10, 22:10, 22:24, 23:7, 23:9, 27:17, 29:14, 29:19, 29:22, 29:23, 30:1, 30:6, 30:8 **Court's** [1] - 12:12 **court's** [5] - 7:3,

9:24, 11:16, 11:18, 12:14, 23:3 **Court** [11] - 4:22, 6:6, 7:21, 8:15, 11:13, 13:14, 16:3, 21:6, 24:25, 28:21, 30:10 **COURT** [11] - 3:3, 3:5, 3:8, 3:25, 5:7, 7:12, 11:7, 17:20, 18:12, 20:25, 22:22 **court** [56] - 3:5, 6:13, 6:22, 7:6, 7:7, 7:9, 7:13, 7:14, 8:15, 9:5, 9:12, 10:15, 11:4, 11:16, 11:20, 11:25, 12:2, 12:8, 12:16, 12:19, 13:4, 13:9, 13:11, 13:15, 13:21, 14:5, 14:7, 14:11, 14:22, 15:8, 16:6, 16:20, 17:12, 19:7, 19:10, 20:4, 20:12, 20:14, 20:15, 21:3, 21:4, 21:9, 21:10, 22:10, 22:24, 23:7, 23:9, 27:17, 29:14, 29:19, 29:22, 29:23, 30:1, 30:6, 30:8 **Court's** [1] - 12:12 **court's** [5] - 7:3,



3:18, 30:17  
3:18, 30:17

**days** [3] - 11:19,  
**days** [3] - 11:19,  
**days** [3] - 11:19,

17:15, 23:8 **dealing** [1] - 4:13 **dealt** [1] - 26:15 **deceptive** [1] - 24:7 **decision** [5] - 6:24, 10:13, 13:8,  
14:1, 14:24 **decisions** [3] - 11:25,  
17:15, 23:8 **dealing** [1] - 4:13 **dealt** [1] - 26:15 **deceptive** [1] - 24:7 **decision** [5] - 6:24, 10:13, 13:8,  
14:1, 14:24 **decisions** [3] - 11:25,  
17:15, 23:8 **dealing** [1] - 4:13 **dealt** [1] - 26:15 **deceptive** [1] - 24:7 **decision** [5] - 6:24, 10:13, 13:8,  
14:1, 14:24 **decisions** [3] - 11:25,  
17:15, 23:8 **dealing** [1] - 4:13 **dealt** [1] - 26:15 **deceptive** [1] - 24:7 **decision** [5] - 6:24, 10:13, 13:8,  
14:1, 14:24 **decisions** [3] - 11:25,

16:4, 23:6 **declaration** [2] - 23:20, 27:25 **deem** [2] - 21:10,  
16:4, 23:6 **declaration** [2] - 23:20, 27:25 **deem** [2] - 21:10,  
16:4, 23:6 **declaration** [2] - 23:20, 27:25 **deem** [2] - 21:10,  
16:4, 23:6 **declaration** [2] - 23:20, 27:25 **deem** [2] - 21:10,

30:10 **defect** [1] - 14:4 **defective** [1] - 23:23 **defects** [1] - 13:15 **defendant** [2] - 3:13,  
30:10 **defect** [1] - 14:4 **defective** [1] - 23:23 **defects** [1] - 13:15 **defendant** [2] - 3:13,  
30:10 **defect** [1] - 14:4 **defective** [1] - 23:23 **defects** [1] - 13:15 **defendant** [2] - 3:13,  
30:10 **defect** [1] - 14:4 **defective** [1] - 23:23 **defects** [1] - 13:15 **defendant** [2] - 3:13,

13:10 **defendant's** [1] - 3:15 **defendants** [1] - 12:8 **defense** [3] - 13:22,  
13:10 **defendant's** [1] - 3:15 **defendants** [1] - 12:8 **defense** [3] - 13:22,  
13:10 **defendant's** [1] - 3:15 **defendants** [1] - 12:8 **defense** [3] - 13:22,  
13:10 **defendant's** [1] - 3:15 **defendants** [1] - 12:8 **defense** [3] - 13:22,

13:23, 13:24 **deficiencies** [1] -  
13:23, 13:24 **deficiencies** [1] -  
13:23, 13:24 **deficiencies** [1] -  
13:23, 13:24 **deficiencies** [1] -

17:18 **Delaney** [4] - 12:13, 14:2, 20:11, 20:12 **design** [1] - 25:18 **designation** [4] -  
17:18 **Delaney** [4] - 12:13, 14:2, 20:11, 20:12 **design** [1] - 25:18 **designation** [4] -  
17:18 **Delaney** [4] - 12:13, 14:2, 20:11, 20:12 **design** [1] - 25:18 **designation** [4] -  
17:18 **Delaney** [4] - 12:13, 14:2, 20:11, 20:12 **design** [1] - 25:18 **designation** [4] -

13:12, 13:13, 13:16, 13:19 **designed** [1] - 17:1 **despite** [1] - 20:5 **detail** [1] - 23:3 **detailed** [1] -  
6:14 **determination** [5] - 5:15, 9:7, 11:18, 16:11, 21:16 **device** [26] - 4:4, 4:7,  
13:12, 13:13, 13:16, 13:19 **designed** [1] - 17:1 **despite** [1] - 20:5 **detail** [1] - 23:3 **detailed** [1] -  
6:14 **determination** [5] - 5:15, 9:7, 11:18, 16:11, 21:16 **device** [26] - 4:4, 4:7,  
13:12, 13:13, 13:16, 13:19 **designed** [1] - 17:1 **despite** [1] - 20:5 **detail** [1] - 23:3 **detailed** [1] -  
6:14 **determination** [5] - 5:15, 9:7, 11:18, 16:11, 21:16 **device** [26] - 4:4, 4:7,  
13:12, 13:13, 13:16, 13:19 **designed** [1] - 17:1 **despite** [1] - 20:5 **detail** [1] - 23:3 **detailed** [1] -  
6:14 **determination** [5] - 5:15, 9:7, 11:18, 16:11, 21:16 **device** [26] - 4:4, 4:7,  
13:12, 13:13, 13:16, 13:19 **designed** [1] - 17:1 **despite** [1] - 20:5 **detail** [1] - 23:3 **detailed** [1] -  
6:14 **determination** [5] - 5:15, 9:7, 11:18, 16:11, 21:16 **device** [26] - 4:4, 4:7,  
13:12, 13:13, 13:16, 13:19 **designed** [1] - 17:1 **despite** [1] - 20:5 **detail** [1] - 23:3 **detailed** [1] -  
6:14 **determination** [5] - 5:15, 9:7, 11:18, 16:11, 21:16 **device** [26] - 4:4, 4:7,  
4:17, 4:24, 5:8, 5:12, 5:13, 5:19, 5:25, 6:1, 6:7, 6:8, 6:9, 7:20, 8:3, 24:13, 24:14, 25:5, 25:10,  
25:11, 25:16, 26:5, 28:11, 29:3 **Device** [3] - 15:14,  
4:17, 4:24, 5:8, 5:12, 5:13, 5:19, 5:25, 6:1, 6:7, 6:8, 6:9, 7:20, 8:3, 24:13, 24:14, 25:5, 25:10,  
25:11, 25:16, 26:5, 28:11, 29:3 **Device** [3] - 15:14,

4:17, 4:24, 5:8, 5:12, 5:13, 5:19, 5:25, 6:1, 6:7, 6:8, 6:9, 7:20, 8:3, 24:13, 24:14, 25:5, 25:10, 25:11, 25:16, 26:5, 28:11, 29:3 **Device** [3] - 15:14,  
4:17, 4:24, 5:8, 5:12, 5:13, 5:19, 5:25, 6:1, 6:7, 6:8, 6:9, 7:20, 8:3, 24:13, 24:14, 25:5, 25:10, 25:11, 25:16, 26:5, 28:11, 29:3 **Device** [3] - 15:14,  
4:17, 4:24, 5:8, 5:12, 5:13, 5:19, 5:25, 6:1, 6:7, 6:8, 6:9, 7:20, 8:3, 24:13, 24:14, 25:5, 25:10, 25:11, 25:16, 26:5, 28:11, 29:3 **Device** [3] - 15:14,  
4:17, 4:24, 5:8, 5:12, 5:13, 5:19, 5:25, 6:1, 6:7, 6:8, 6:9, 7:20, 8:3, 24:13, 24:14, 25:5, 25:10, 25:11, 25:16, 26:5, 28:11, 29:3 **Device** [3] - 15:14,  
4:17, 4:24, 5:8, 5:12, 5:13, 5:19, 5:25, 6:1, 6:7, 6:8, 6:9, 7:20, 8:3, 24:13, 24:14, 25:5, 25:10, 25:11, 25:16, 26:5, 28:11, 29:3 **Device** [3] - 15:14,  
4:17, 4:24, 5:8, 5:12, 5:13, 5:19, 5:25, 6:1, 6:7, 6:8, 6:9, 7:20, 8:3, 24:13, 24:14, 25:5, 25:10, 25:11, 25:16, 26:5, 28:11, 29:3 **Device** [3] - 15:14,

24:16, 25:4 **devices** [13] - 4:19,

24:16, 25:4 **devices** [13] - 4:19,

24:16, 25:4 **devices** [13] - 4:19,

24:16, 25:4 **devices** [13] - 4:19,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

4:20, 5:1, 5:4, 5:20, 6:13, 15:18, 15:19, 22:15, 22:16, 26:11, 26:17 **diamond** [1] - 28:2  
**differences** [1] - 8:9 **different** [1] - 26:23 **differently** [1] - 24:19 **direct** [1] - 7:13 **directly** [2] - 8:14,

25:1

25:1

25:1

**disagree** [1] - 19:14 **disagreement** [1] -

**disagree** [1] - 19:14 **disagreement** [1] -

**disagree** [1] - 19:14 **disagreement** [1] -

**disagree** [1] - 19:14 **disagreement** [1] -

**disagree** [1] - 19:14 **disagreement** [1] -

6:23 **disclose** [1] - 27:13 **discovered** [1] - 13:9 **discussion** [1] - 25:12 **dismayed** [1] - 22:2 **dismissal** [2] - 29:15,  
6:23 **disclose** [1] - 27:13 **discovered** [1] - 13:9 **discussion** [1] - 25:12 **dismayed** [1] - 22:2 **dismissal** [2] - 29:15,

6:23 **disclose** [1] - 27:13 **discovered** [1] - 13:9 **discussion** [1] - 25:12 **dismayed** [1] - 22:2 **dismissal** [2] - 29:15,  
6:23 **disclose** [1] - 27:13 **discovered** [1] - 13:9 **discussion** [1] - 25:12 **dismayed** [1] - 22:2 **dismissal** [2] - 29:15,  
6:23 **disclose** [1] - 27:13 **discovered** [1] - 13:9 **discussion** [1] - 25:12 **dismayed** [1] - 22:2 **dismissal** [2] - 29:15,  
6:23 **disclose** [1] - 27:13 **discovered** [1] - 13:9 **discussion** [1] - 25:12 **dismayed** [1] - 22:2 **dismissal** [2] - 29:15,

30:5 **dismissed** [3] - 12:11,  
30:5 **dismissed** [3] - 12:11,  
30:5 **dismissed** [3] - 12:11,  
30:5 **dismissed** [3] - 12:11,  
30:5 **dismissed** [3] - 12:11,

12:19, 14:18 **dispute** [3] - 4:5, 5:12,  
12:19, 14:18 **dispute** [3] - 4:5, 5:12,  
12:19, 14:18 **dispute** [3] - 4:5, 5:12,  
12:19, 14:18 **dispute** [3] - 4:5, 5:12,

24:12 **disputed** [1] - 5:7 **dissent** [2] - 26:7,  
24:12 **disputed** [1] - 5:7 **dissent** [2] - 26:7,  
24:12 **disputed** [1] - 5:7 **dissent** [2] - 26:7,  
24:12 **disputed** [1] - 5:7 **dissent** [2] - 26:7,  
24:12 **disputed** [1] - 5:7 **dissent** [2] - 26:7,

26:12 **distinction** [1] - 19:4 **distribution** [2] - 25:19, 25:25 **district** [7] - 11:24,  
26:12 **distinction** [1] - 19:4 **distribution** [2] - 25:19, 25:25 **district** [7] - 11:24,  
26:12 **distinction** [1] - 19:4 **distribution** [2] - 25:19, 25:25 **district** [7] - 11:24,  
26:12 **distinction** [1] - 19:4 **distribution** [2] - 25:19, 25:25 **district** [7] - 11:24,  
26:12 **distinction** [1] - 19:4 **distribution** [2] - 25:19, 25:25 **district** [7] - 11:24,  
26:12 **distinction** [1] - 19:4 **distribution** [2] - 25:19, 25:25 **district** [7] - 11:24,

13:6, 19:10, 20:15, 21:2, 21:7, 21:9 **doctrine** [4] - 27:15,  
13:6, 19:10, 20:15, 21:2, 21:7, 21:9 **doctrine** [4] - 27:15,  
13:6, 19:10, 20:15, 21:2, 21:7, 21:9 **doctrine** [4] - 27:15,  
13:6, 19:10, 20:15, 21:2, 21:7, 21:9 **doctrine** [4] - 27:15,  
13:6, 19:10, 20:15, 21:2, 21:7, 21:9 **doctrine** [4] - 27:15,

28:24, 29:8 **documents** [1] - 23:14 **done** [5] - 6:8, 7:21, 21:7, 23:2, 30:7 **doubt** [2] - 26:19,  
28:24, 29:8 **documents** [1] - 23:14 **done** [5] - 6:8, 7:21, 21:7, 23:2, 30:7 **doubt** [2] - 26:19,  
28:24, 29:8 **documents** [1] - 23:14 **done** [5] - 6:8, 7:21, 21:7, 23:2, 30:7 **doubt** [2] - 26:19,  
28:24, 29:8 **documents** [1] - 23:14 **done** [5] - 6:8, 7:21, 21:7, 23:2, 30:7 **doubt** [2] - 26:19,  
28:24, 29:8 **documents** [1] - 23:14 **done** [5] - 6:8, 7:21, 21:7, 23:2, 30:7 **doubt** [2] - 26:19,  
28:24, 29:8 **documents** [1] - 23:14 **done** [5] - 6:8, 7:21, 21:7, 23:2, 30:7 **doubt** [2] - 26:19,

28:25 **down** [1] - 19:8 **dramatically** [1] -  
28:25 **down** [1] - 19:8 **dramatically** [1] -  
28:25 **down** [1] - 19:8 **dramatically** [1] -  
28:25 **down** [1] - 19:8 **dramatically** [1] -  
28:25 **down** [1] - 19:8 **dramatically** [1] -  
28:25 **down** [1] - 19:8 **dramatically** [1] -  
28:25 **down** [1] - 19:8 **dramatically** [1] -

22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9  
**Dyke** [3] - 3:6, 23:18,

22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9  
**Dyke** [3] - 3:6, 23:18,

22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9  
**Dyke** [3] - 3:6, 23:18,

22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9  
**Dyke** [3] - 3:6, 23:18,

22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9  
**Dyke** [3] - 3:6, 23:18,

22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9  
**Dyke** [3] - 3:6, 23:18,

22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9

**Dyke** [3] - 3:6, 23:18,  
22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9  
**Dyke** [3] - 3:6, 23:18,

22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9  
**Dyke** [3] - 3:6, 23:18,

22:17 **draw** [1] - 25:22 **drawn** [1] - 30:6 **dropped** [1] - 28:15 **Drug** [1] - 24:16 **druthers** [1] - 19:12 **due** [1] - 21:8 **during** [1] - 3:9  
**Dyke** [3] - 3:6, 23:18,

28:5 **Dyke's** [3] - 14:24,  
28:5 **Dyke's** [3] - 14:24,  
28:5 **Dyke's** [3] - 14:24,  
28:5 **Dyke's** [3] - 14:24,  
28:5 **Dyke's** [3] - 14:24,

17:13, 23:16 **E**

17:13, 23:16 **E**

17:13, 23:16 **E**

17:13, 23:16 **E**

17:13, 23:16 **E**

17:13, 23:16 **E**

**early** [1] - 6:24 **effective** [1] - 5:16 **effectiveness** [4] -  
**early** [1] - 6:24 **effective** [1] - 5:16 **effectiveness** [4] -  
**early** [1] - 6:24 **effective** [1] - 5:16 **effectiveness** [4] -  
**early** [1] - 6:24 **effective** [1] - 5:16 **effectiveness** [4] -  
**early** [1] - 6:24 **effective** [1] - 5:16 **effectiveness** [4] -  
**early** [1] - 6:24 **effective** [1] - 5:16 **effectiveness** [4] -

25:5, 25:10, 25:16, 26:3 **efficacy** [6] - 4:17,  
25:5, 25:10, 25:16, 26:3 **efficacy** [6] - 4:17,  
25:5, 25:10, 25:16, 26:3 **efficacy** [6] - 4:17,  
25:5, 25:10, 25:16, 26:3 **efficacy** [6] - 4:17,  
25:5, 25:10, 25:16, 26:3 **efficacy** [6] - 4:17,  
25:5, 25:10, 25:16, 26:3 **efficacy** [6] - 4:17,

5:22, 6:12, 7:19, 9:6, 16:21 **eight** [1] - 12:9 **either** [1] - 26:23 **eleven** [1] - 14:21 **emanating** [1] -  
28:5 **emphasized** [1] - 28:4

5:22, 6:12, 7:19, 9:6, 16:21 **eight** [1] - 12:9 **either** [1] - 26:23 **eleven** [1] - 14:21 **emanating** [1] -  
28:5 **emphasized** [1] - 28:4

5:22, 6:12, 7:19, 9:6, 16:21 **eight** [1] - 12:9 **either** [1] - 26:23 **eleven** [1] - 14:21 **emanating** [1] -  
28:5 **emphasized** [1] - 28:4

5:22, 6:12, 7:19, 9:6, 16:21 **eight** [1] - 12:9 **either** [1] - 26:23 **eleven** [1] - 14:21 **emanating** [1] -  
28:5 **emphasized** [1] - 28:4

5:22, 6:12, 7:19, 9:6, 16:21 **eight** [1] - 12:9 **either** [1] - 26:23 **eleven** [1] - 14:21 **emanating** [1] -  
28:5 **emphasized** [1] - 28:4

5:22, 6:12, 7:19, 9:6, 16:21 **eight** [1] - 12:9 **either** [1] - 26:23 **eleven** [1] - 14:21 **emanating** [1] -  
28:5 **emphasized** [1] - 28:4

5:22, 6:12, 7:19, 9:6, 16:21 **eight** [1] - 12:9 **either** [1] - 26:23 **eleven** [1] - 14:21 **emanating** [1] -  
28:5 **emphasized** [1] - 28:4

5:22, 6:12, 7:19, 9:6, 16:21 **eight** [1] - 12:9 **either** [1] - 26:23 **eleven** [1] - 14:21 **emanating** [1] -  
28:5 **emphasized** [1] - 28:4

**enacted** [1] - 16:9 **end** [3] - 17:12, 26:10,  
29:6 **endeavor** [2] - 21:4,  
22:25 **enforce** [2] - 9:21,  
17:6 **enforcement** [1] - 29:4 **entirely** [1] - 29:23 **entitled** [1] - 18:10 **equal** [1] - 15:12 **errors** [1] -  
11:20 **essentially** [1] - 15:13 **established** [1] - 4:9 **event** [1] - 3:11 **evidence** [1] - 16:24 **exactly**  
[1] - 26:16 **examples** [1] - 10:25 **excellent** [1] - 28:2 **except** [2] - 7:14,  
21:10 **exception** [1] - 29:20 **exist** [4] - 11:17, 16:13, 17:11 **existent** [1] - 7:4 **explain** [2] - 16:5,  
19:4 **explained** [1] - 26:16 **express** [20] - 6:11,  
6:19, 8:5, 8:7, 8:11, 8:19, 8:20, 10:5, 13:7, 14:4, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 27:1,  
27:21, 28:4, 28:15 **expressed** [2] - 8:20,  
20:7 **expressly** [7] - 7:22,  
8:16, 9:1, 9:14, 19:15, 27:9, 27:15 **extensive** [2] - 5:14,  
23:1 **extent** [1] - 7:18 **extremely** [4] - 5:2, 8:8, 10:24, 28:1

## F

**face** [2] - 27:6, 27:12 **fact** [22] - 4:6, 4:10, 4:25, 5:12, 5:13, 5:18, 8:22, 9:11, 10:14, 13:24,  
14:14, 20:9, 20:12, 20:20, 20:24, 21:14, 22:8, 24:20, 25:8, 26:21, 27:24, 28:1 **fact-finder** [1] -  
8:22 **factors** [1] - 5:22 **facts** [2] - 7:19, 24:12  
- 9:22, 17:9 **failures** [1] - 17:10 **fair** [1] - 23:9 **fall** [3] - 22:9, 26:2 **false**  
**fashion** [1] - 30:10 **faulty** [1] - 18:5 **FDA** [27] - 5:1, 5:10,  
4, 6:6, 8:10, 10:1, 10:4, 15:20, 16:10, 16:22, 16:24, 17:2, 17:6, 17:10,  
5, 24:15, 25:6, 26:11, 26:21 **FDA's** [1] - 16:11 **FDA-approved** [1] -  
26:11 **FDCA** [4] - 6:2, 9:21,  
9:23, 28:25 **February** [1] - 22:3 **federal** [23] -  
12, 15:3, 15:25, 16:8, 16:17, 16:25, 18:8, 23:17, 23:19, 26:24, 27:2,  
6, 29:1, 29:10, 29:16 **Federal** [2] - 15:21,  
24:16 **federal-law-based** [1]  
- 26:24 **fellow** [1] - 21:9 **felt** [2] - 19:20, 20:5  
21, 23:8 **fictional** [1] - 22:7 **file** [1] - 29:2 **filed** [3] - 11:10, 19:19,  
30:1 **filing** [1] - 17:23 **finally** [1] - 22:1 **finder**  
**firm** [1] - 3:20 **first** [4] - 4:22, 19:5,  
23:12, 23:18 **fitness** [3] - 9:3, 24:3,  
26:1 **Five** [4] - 24:8, 27:12,  
27:13, 27:19 **five** [2] - 4:16, 7:1 **flew** [1] - 3:19  
**fn** [1] - 3:21  
**focused** [2] - 4:14,  
**focused** [2] - 4:14,  
7:19 **follow** [3] - 7:7, 17:10,  
7:19 **follow** [3] - 7:7, 17:10,  
7:19 **follow** [3] - 7:7, 17:10,  
30:12 **followed** [1] - 24:20 **following** [2] - 3:1,  
30:12 **followed** [1] - 24:20 **following** [2] - 3:1,  
30:12 **followed** [1] - 24:20 **following** [2] - 3:1,  
17:4 **Footnote** [1] - 28:22 **footnote** [1] - 28:24 **forth** [1] - 11:12 **forward** [3]

- 4:12,  
17:4 **Footnote** [1] - 28:22 **footnote** [1] - 28:24 **forth** [1] - 11:12 **forward** [3]

- 4:12,  
17:4 **Footnote** [1] - 28:22 **footnote** [1] - 28:24 **forth** [1] - 11:12 **forward** [3]

- 4:12,  
5:23, 11:21 **Four** [5] - 9:10, 24:6, 27:5, 27:8, 27:18 **four** [2] - 4:14, 10:9  
**frame** [1] - 23:21 **frankly** [1] - 19:11 **Funk** [1] - 12:13 **futile** [1] - 22:6 **future** [1] - 17:7

5:23, 11:21 **Four** [5] - 9:10, 24:6, 27:5, 27:8, 27:18 **four** [2] - 4:14, 10:9  
**frame** [1] - 23:21 **frankly** [1] - 19:11 **Funk** [1] - 12:13 **futile** [1] - 22:6 **future** [1] - 17:7

**G**

**G**

**G**

**general** [3] - 7:24, 8:8,  
**general** [3] - 7:24, 8:8,

15:16 **Geoff** [1] - 3:12 **Gibbons** [1] - 3:20 **given** [4] - 11:23,  
15:16 **Geoff** [1] - 3:12 **Gibbons** [1] - 3:20 **given** [4] - 11:23,  
15:16 **Geoff** [1] - 3:12 **Gibbons** [1] - 3:20 **given** [4] - 11:23,  
15:16 **Geoff** [1] - 3:12 **Gibbons** [1] - 3:20 **given** [4] - 11:23,

18:19, 19:20, 24:24 **glad** [1] - 3:25 **government** [1] - 29:1 **grant** [3] - 11:4,

19:18,  
18:19, 19:20, 24:24 **glad** [1] - 3:25 **government** [1] - 29:1 **grant** [3] - 11:4,

19:18,  
20:6 **granted** [2] - 6:19,  
20:6 **granted** [2] - 6:19,

14:8 **granting** [1] - 11:25 **grounds** [3] - 6:19,  
14:8 **granting** [1] - 11:25 **grounds** [3] - 6:19,  
14:8 **granting** [1] - 11:25 **grounds** [3] - 6:19,  
14:8 **granting** [1] - 11:25 **grounds** [3] - 6:19,

8:12, 26:8 **guidance** [3] - 15:22,  
8:12, 26:8 **guidance** [3] - 15:22,  
8:12, 26:8 **guidance** [3] - 15:22,

17:18, 29:19 **H**

17:18, 29:19 **H**

17:18, 29:19 **H**

**hands** [3] - 19:16,  
**hands** [3] - 19:16,

20:16, 22:19 **hard** [1] - 28:1 **hardness** [1] - 28:2 **Hayes** [6] - 12:13,  
20:16, 22:19 **hard** [1] - 28:1 **hardness** [1] - 28:2 **Hayes** [6] - 12:13,  
20:16, 22:19 **hard** [1] - 28:1 **hardness** [1] - 28:2 **Hayes** [6] - 12:13,

12:25, 13:1, 20:4, 20:15, 21:14 **head** [4] - 7:1, 9:5,  
12:25, 13:1, 20:4, 20:15, 21:14 **head** [4] - 7:1, 9:5,  
12:25, 13:1, 20:4, 20:15, 21:14 **head** [4] - 7:1, 9:5,

10:13, 15:4 **head-on** [2] - 10:13,  
10:13, 15:4 **head-on** [2] - 10:13,  
10:13, 15:4 **head-on** [2] - 10:13,



15:4 **hear** [2] - 3:6, 3:16 **hearing** [2] - 3:7,  
15:4 **hear** [2] - 3:6, 3:16 **hearing** [2] - 3:7,  
15:4 **hear** [2] - 3:6, 3:16 **hearing** [2] - 3:7,

17:24 **held** [1] - 14:7

17:24 **held** [1] - 14:7

**helpful** [1] - 21:15 **hip** [1] - 18:5 **history** [1] - 20:9 **hit** [3] - 14:20, 14:22,  
**helpful** [1] - 21:15 **hip** [1] - 18:5 **history** [1] - 20:9 **hit** [3] - 14:20, 14:22,  
**helpful** [1] - 21:15 **hip** [1] - 18:5 **history** [1] - 20:9 **hit** [3] - 14:20, 14:22,  
**helpful** [1] - 21:15 **hip** [1] - 18:5 **history** [1] - 20:9 **hit** [3] - 14:20, 14:22,  
**helpful** [1] - 21:15 **hip** [1] - 18:5 **history** [1] - 20:9 **hit** [3] - 14:20, 14:22,  
**helpful** [1] - 21:15 **hip** [1] - 18:5 **history** [1] - 20:9 **hit** [3] - 14:20, 14:22,

14:23 **hits** [2] - 11:22 **HOC** [1] - 11:4 **Hofts** [10] - 6:22, 7:2,

14:23 **hits** [2] - 11:22 **HOC** [1] - 11:4 **Hofts** [10] - 6:22, 7:2,

14:23 **hits** [2] - 11:22 **HOC** [1] - 11:4 **Hofts** [10] - 6:22, 7:2,

14:23 **hits** [2] - 11:22 **HOC** [1] - 11:4 **Hofts** [10] - 6:22, 7:2,

14:23 **hits** [2] - 11:22 **HOC** [1] - 11:4 **Hofts** [10] - 6:22, 7:2,

7:6, 7:8, 12:15, 14:23, 14:24, 15:1, 15:9, 20:21 **Hofts'** [2] - 17:13,

7:6, 7:8, 12:15, 14:23, 14:24, 15:1, 15:9, 20:21 **Hofts'** [2] - 17:13,

7:6, 7:8, 12:15, 14:23, 14:24, 15:1, 15:9, 20:21 **Hofts'** [2] - 17:13,

7:6, 7:8, 12:15, 14:23, 14:24, 15:1, 15:9, 20:21 **Hofts'** [2] - 17:13,

7:6, 7:8, 12:15, 14:23, 14:24, 15:1, 15:9, 20:21 **Hofts'** [2] - 17:13,

17:14 **holding** [3] - 12:7,

17:14 **holding** [3] - 12:7,

17:14 **holding** [3] - 12:7,

12:12, 12:25 **Honor** [15] - 3:18,

12:12, 12:25 **Honor** [15] - 3:18,

12:12, 12:25 **Honor** [15] - 3:18,

3:24, 4:2, 4:3, 5:9, 6:17, 7:15, 11:3, 11:9, 18:11, 18:14, 20:23, 21:18, 22:20, 30:17 **Honor's** [1]  
- 11:18 **Horowitz** [2] - 12:14,

3:24, 4:2, 4:3, 5:9, 6:17, 7:15, 11:3, 11:9, 18:11, 18:14, 20:23, 21:18, 22:20, 30:17 **Honor's** [1]  
- 11:18 **Horowitz** [2] - 12:14,

3:24, 4:2, 4:3, 5:9, 6:17, 7:15, 11:3, 11:9, 18:11, 18:14, 20:23, 21:18, 22:20, 30:17 **Honor's** [1]  
- 11:18 **Horowitz** [2] - 12:14,

3:24, 4:2, 4:3, 5:9, 6:17, 7:15, 11:3, 11:9, 18:11, 18:14, 20:23, 21:18, 22:20, 30:17 **Honor's** [1]  
- 11:18 **Horowitz** [2] - 12:14,

3:24, 4:2, 4:3, 5:9, 6:17, 7:15, 11:3, 11:9, 18:11, 18:14, 20:23, 21:18, 22:20, 30:17 **Honor's** [1]  
- 11:18 **Horowitz** [2] - 12:14,

3:24, 4:2, 4:3, 5:9, 6:17, 7:15, 11:3, 11:9, 18:11, 18:14, 20:23, 21:18, 22:20, 30:17 **Honor's** [1]  
- 11:18 **Horowitz** [2] - 12:14,

3:24, 4:2, 4:3, 5:9, 6:17, 7:15, 11:3, 11:9, 18:11, 18:14, 20:23, 21:18, 22:20, 30:17 **Honor's** [1]  
- 11:18 **Horowitz** [2] - 12:14,

14:7 **Howmedica** [10] - 3:6,

14:7 **Howmedica** [10] - 3:6,

14:7 **Howmedica** [10] - 3:6,

11:4, 11:10, 13:5, 13:11, 14:14, 16:25, 18:3, 19:14, 23:19 **Howmedica's** [3] -

11:4, 11:10, 13:5, 13:11, 14:14, 16:25, 18:3, 19:14, 23:19 **Howmedica's** [3] -

11:4, 11:10, 13:5, 13:11, 14:14, 16:25, 18:3, 19:14, 23:19 **Howmedica's** [3] -

11:4, 11:10, 13:5, 13:11, 14:14, 16:25, 18:3, 19:14, 23:19 **Howmedica's** [3] -

12:24, 13:20, 23:16 **Huber** [7] - 13:5, 19:1,

12:24, 13:20, 23:16 **Huber** [7] - 13:5, 19:1,

12:24, 13:20, 23:16 **Huber** [7] - 13:5, 19:1,

19:2, 19:3, 19:5, 20:3, 20:8

19:2, 19:3, 19:5, 20:3, 20:8

19:2, 19:3, 19:5, 20:3, 20:8

19:2, 19:3, 19:5, 20:3, 20:8

19:2, 19:3, 19:5, 20:3, 20:8

19:2, 19:3, 19:5, 20:3, 20:8

**identical** [3] - 12:23,

**identical** [3] - 12:23,

**identical** [3] - 12:23,

**identical** [3] - 12:23,

15:13, 23:20 **identifies** [1] - 11:16 **III** [13] - 4:4, 4:6, 4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 **immediate** [1] - 19:20 **implant** [2] - 10:18,

15:13, 23:20 **identifies** [1] - 11:16 **III** [13] - 4:4, 4:6, 4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 **immediate** [1] - 19:20 **implant** [2] - 10:18,

15:13, 23:20 **identifies** [1] - 11:16 **III** [13] - 4:4, 4:6, 4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 **immediate** [1] - 19:20 **implant** [2] - 10:18,

15:13, 23:20 **identifies** [1] - 11:16 **III** [13] - 4:4, 4:6, 4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 **immediate** [1] - 19:20 **implant** [2] - 10:18,

15:13, 23:20 **identifies** [1] - 11:16 **III** [13] - 4:4, 4:6, 4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 **immediate** [1] - 19:20 **implant** [2] - 10:18,

15:13, 23:20 **identifies** [1] - 11:16 **III** [13] - 4:4, 4:6, 4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 **immediate** [1] - 19:20 **implant** [2] - 10:18,

15:13, 23:20 **identifies** [1] - 11:16 **III** [13] - 4:4, 4:6, 4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 **immediate** [1] - 19:20 **implant** [2] - 10:18,

15:13, 23:20 **identifies** [1] - 11:16 **III** [13] - 4:4, 4:6, 4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 **immediate** [1] - 19:20 **implant** [2] - 10:18,

15:13, 23:20 **identifies** [1] - 11:16 **III** [13] - 4:4, 4:6, 4:17, 4:20, 5:1, 5:4, 5:8, 5:19, 6:13, 7:20, 8:23, 24:13, 28:19 **immediate** [1] - 19:20 **implant** [2] - 10:18,

10:19 **implied** [11] - 6:20,

10:19 **implied** [11] - 6:20,

10:19 **implied** [11] - 6:20,

8:19, 9:3, 10:2, 10:6, 22:10, 24:2, 24:3, 25:17, 25:25, 27:19 **importance** [1] - 28:21 **important** [2] - 19:4,

8:19, 9:3, 10:2, 10:6, 22:10, 24:2, 24:3, 25:17, 25:25, 27:19 **importance** [1] - 28:21 **important** [2] - 19:4,

8:19, 9:3, 10:2, 10:6, 22:10, 24:2, 24:3, 25:17, 25:25, 27:19 **importance** [1] - 28:21 **important** [2] - 19:4,

8:19, 9:3, 10:2, 10:6, 22:10, 24:2, 24:3, 25:17, 25:25, 27:19 **importance** [1] - 28:21 **important** [2] - 19:4,

8:19, 9:3, 10:2, 10:6, 22:10, 24:2, 24:3, 25:17, 25:25, 27:19 **importance** [1] - 28:21 **important** [2] - 19:4,

28:24 **impose** [2] - 26:22,

28:24 **impose** [2] - 26:22,

28:24 **impose** [2] - 26:22,

28:24 **impose** [2] - 26:22,

27:1 **improper** [1] - 9:22 **improve** [2] - 22:17 **inappropriate** [1] -

27:1 **improper** [1] - 9:22 **improve** [2] - 22:17 **inappropriate** [1] -

27:1 **improper** [1] - 9:22 **improve** [2] - 22:17 **inappropriate** [1] -



21:3 interesting [7] - 12:17,

12:23, 13:3, 20:3, 21:7, 28:23, 29:21 interestingly [1] -  
12:23, 13:3, 20:3, 21:7, 28:23, 29:21 interestingly [1] -  
12:23, 13:3, 20:3, 21:7, 28:23, 29:21 interestingly [1] -  
12:23, 13:3, 20:3, 21:7, 28:23, 29:21 interestingly [1] -  
12:23, 13:3, 20:3, 21:7, 28:23, 29:21 interestingly [1] -  
12:23, 13:3, 20:3, 21:7, 28:23, 29:21 interestingly [1] -

13:18 interpretation [1] -  
13:18 interpretation [1] -  
13:18 interpretation [1] -  
13:18 interpretation [1] -

24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,  
24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,  
24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,  
24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,  
24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,  
24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,  
24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,  
24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,  
24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,  
24:24 interrupt [1] - 20:25 introduce [1] - 3:19 involved [1] - 28:19 involving [2] - 12:10,

12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,  
12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,  
12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,  
12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,  
12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,  
12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,  
12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,  
12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,  
12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,  
12:18 issue [10] - 5:7, 10:1, 10:8, 10:14, 10:23, 12:10, 15:4, 16:1, 18:2, 18:15 issued [5] - 13:12,

13:13, 14:1, 14:25, 16:5 issues [3] - 15:20,  
13:13, 14:1, 14:25, 16:5 issues [3] - 15:20,  
13:13, 14:1, 14:25, 16:5 issues [3] - 15:20,  
13:13, 14:1, 14:25, 16:5 issues [3] - 15:20,  
13:13, 14:1, 14:25, 16:5 issues [3] - 15:20,  
13:13, 14:1, 14:25, 16:5 issues [3] - 15:20,

23:10, 29:25 itself [4] - 8:14, 24:14,  
23:10, 29:25 itself [4] - 8:14, 24:14,  
23:10, 29:25 itself [4] - 8:14, 24:14,  
23:10, 29:25 itself [4] - 8:14, 24:14,  
23:10, 29:25 itself [4] - 8:14, 24:14,  
23:10, 29:25 itself [4] - 8:14, 24:14,

24:21, 28:25 J

24:21, 28:25 J

24:21, 28:25 J

24:21, 28:25 J

24:21, 28:25 J

24:21, 28:25 **J**

**Jersey** [5] - 3:20, 13:6, 13:14, 19:10, 20:15 **Judge** [3] - 19:9,  
**Jersey** [5] - 3:20, 13:6, 13:14, 19:10, 20:15 **Judge** [3] - 19:9,  
**Jersey** [5] - 3:20, 13:6, 13:14, 19:10, 20:15 **Judge** [3] - 19:9,  
**Jersey** [5] - 3:20, 13:6, 13:14, 19:10, 20:15 **Judge** [3] - 19:9,  
**Jersey** [5] - 3:20, 13:6, 13:14, 19:10, 20:15 **Judge** [3] - 19:9,  
**Jersey** [5] - 3:20, 13:6, 13:14, 19:10, 20:15 **Judge** [3] - 19:9,  
**Jersey** [5] - 3:20, 13:6, 13:14, 19:10, 20:15 **Judge** [3] - 19:9,

21:13, 22:1 **judge** [4] - 20:5,  
21:13, 22:1 **judge** [4] - 20:5,  
21:13, 22:1 **judge** [4] - 20:5,  
21:13, 22:1 **judge** [4] - 20:5,  
21:13, 22:1 **judge** [4] - 20:5,

20:15, 21:9, 21:14 **judges** [1] - 21:7 **judging** [1] - 8:23  
20:15, 21:9, 21:14 **judges** [1] - 21:7 **judging** [1] - 8:23  
20:15, 21:9, 21:14 **judges** [1] - 21:7 **judging** [1] - 8:23  
20:15, 21:9, 21:14 **judges** [1] - 21:7 **judging** [1] - 8:23  
20:15, 21:9, 21:14 **judges** [1] - 21:7 **judging** [1] - 8:23  
20:15, 21:9, 21:14 **judges** [1] - 21:7 **judging** [1] - 8:23

Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 34 of 37

3

**judicial** [2] - 26:10,  
26:20 **justices** [1] - 26:6

## K

**kick** [1] - 4:18 **kicks** [1] - 10:2 **Kim** [2] - 3:19, 3:23

## L

**label** [7] - 8:21, 8:23,  
8:25, 9:10, 9:16, 19:22, 27:24 **label-based** [2] - 9:10,  
9:16 **labeling** [3] - 25:19,  
28:9 **lack** [1] - 29:15 **language** [2] - 11:1,  
26:15 **large** [1] - 11:23 **last** [1] - 23:8 **late** [1] - 3:9 **law** [41] - 3:20, 8:4,  
11:14, 11:15, 12:3, 12:22, 12:25, 13:1, 13:7, 14:3, 14:11, 15:6, 16:4, 16:8, 16:9, 16:15, 16:17,  
16:18, 16:25, 17:8, 17:11, 18:6, 18:8, 18:9, 21:5, 23:17, 23:19, 25:4, 25:15, 25:22, 26:19,  
26:24, 27:18, 28:14, 28:16, 28:20, 29:10, 30:12, 30:13 **law-based** [1] - 27:18 **laws** [2] - 15:25,  
24:24 **lawsuit** [1] - 23:16 **leads** [1] - 29:14 **learned** [1] - 19:2 **least** [2] - 7:1, 29:18 **leave** [3] -  
14:5, 14:8,  
27:16 **leaves** [2] - 27:16,  
28:25 **Leslie** [4] - 17:4, 17:8,  
17:25, 18:3 **liability** [3] - 7:23,  
25:17, 25:23 **lies** [1] - 28:22 **limited** [2] - 15:19,  
22:14 **Linares** [1] - 19:9 **link** [1] - 8:3

12:23, 12:24 **litigant** [3] - 9:20,

10:3, 10:7 **litigants** [1] - 29:1 **lives** [1] - 22:18  
1] - 20:6 **look** [7] - 4:15, 9:8,  
2, 21:15 **looked** [1] - 19:21 **lubrication** [1] - 28:3 **luminous** [1] - 28:1

**ity** [5] - 4:9, 5:4,  
7:7, 13:25, 14:17 **manner** [1] - 29:25

23:24 **manufacturing** [5] -  
), 25:24 **mark** [5] - 11:22,  
:15 **market** [6] - 5:16,  
2, 25:6 **marketability** [1] - 9:3 **marketed** [1] - 24:17 **marketing** [1] -

13:16 **mass-tort** [1] - 13:12 **materials** [1] - 23:4

9 **matters** [2] - 22:25,  
24:12 **MDA** [5] - 4:18, 16:9,  
16:13, 16:19, 17:10 **mean** [7] - 4:18, 5:13, 5:17,  
**means** [5] - 8:9, 16:5, 18:15, 21:17, 26:10 **Medical** [3] - 15:14,  
24:16, 25:4 **medical** [3] - 25:5,  
26:17, 29:2 **Medtronic** [2] - 10:13,  
22:10 **meets** [1] - 11:12 **merchantability** [2] -  
24:4, 26:1 **might** [3] - 26:24,  
24:4, 26:1 **might** [3] - 26:24,  
24:4, 26:1 **might** [3] - 26:24,  
24:4, 26:1 **might** [3] - 26:24,  
29:9, 29:21 **minute** [1] - 6:20 **mirror** [2] - 17:14,  
29:9, 29:21 **minute** [1] - 6:20 **mirror** [2] - 17:14,  
29:9, 29:21 **minute** [1] - 6:20 **mirror** [2] - 17:14,  
29:9, 29:21 **minute** [1] - 6:20 **mirror** [2] - 17:14,  
20:21 **mirroring** [1] - 17:13 **mirrors** [2] - 20:23,  
20:21 **mirroring** [1] - 17:13 **mirrors** [2] - 20:23,  
23:18 **misinterpretation** [1] -  
23:18 **misinterpretation** [1] -  
23:18 **misinterpretation** [1] -  
12:7 **misleading** [1] - 9:12 **misrepresentation** [3] - 9:15, 24:10, 27:11  
**missed** [1] - 17:15 **mixes** [1] - 8:19 **Montana** [6] - 15:9,  
12:7 **misleading** [1] - 9:12 **misrepresentation** [3] - 9:15, 24:10, 27:11  
**missed** [1] - 17:15 **mixes** [1] - 8:19 **Montana** [6] - 15:9,  
12:7 **misleading** [1] - 9:12 **misrepresentation** [3] - 9:15, 24:10, 27:11  
**missed** [1] - 17:15 **mixes** [1] - 8:19 **Montana** [6] - 15:9,  
12:7 **misleading** [1] - 9:12 **misrepresentation** [3] - 9:15, 24:10, 27:11  
**missed** [1] - 17:15 **mixes** [1] - 8:19 **Montana** [6] - 15:9,  
12:7 **misleading** [1] - 9:12 **misrepresentation** [3] - 9:15, 24:10, 27:11  
**missed** [1] - 17:15 **mixes** [1] - 8:19 **Montana** [6] - 15:9,  
16:15, 17:11, 24:5, 24:6, 26:22 **Montana's** [1] - 15:24 **months** [1] - 21:21 **morning** [1] - 3:24  
**most** [4] - 5:19, 14:14,  
16:15, 17:11, 24:5, 24:6, 26:22 **Montana's** [1] - 15:24 **months** [1] - 21:21 **morning** [1] - 3:24  
**most** [4] - 5:19, 14:14,  
16:15, 17:11, 24:5, 24:6, 26:22 **Montana's** [1] - 15:24 **months** [1] - 21:21 **morning** [1] - 3:24  
**most** [4] - 5:19, 14:14,

16:15, 17:11, 24:5, 24:6, 26:22 **Montana's** [1] - 15:24 **months** [1] - 21:21 **morning** [1] - 3:24 **most** [4] - 5:19, 14:14,

16:15, 17:11, 24:5, 24:6, 26:22 **Montana's** [1] - 15:24 **months** [1] - 21:21 **morning** [1] - 3:24 **most** [4] - 5:19, 14:14,

16:15, 17:11, 24:5, 24:6, 26:22 **Montana's** [1] - 15:24 **months** [1] - 21:21 **morning** [1] - 3:24 **most** [4] - 5:19, 14:14,

14:17, 22:17 **motion** [13] - 3:7,

14:17, 22:17 **motion** [13] - 3:7,

14:17, 22:17 **motion** [13] - 3:7,

3:15, 3:16, 3:21, 4:3, 4:13, 11:5, 11:19, 11:21, 11:25, 19:8, 19:18, 22:3 **motions** [1] - 6:18 **move** [1] - 5:23 **MR** [2] - 11:9, 17:22 **MS** [9] - 3:18, 3:24,

3:15, 3:16, 3:21, 4:3, 4:13, 11:5, 11:19, 11:21, 11:25, 19:8, 19:18, 22:3 **motions** [1] - 6:18 **move** [1] - 5:23 **MR** [2] - 11:9, 17:22 **MS** [9] - 3:18, 3:24,

3:15, 3:16, 3:21, 4:3, 4:13, 11:5, 11:19, 11:21, 11:25, 19:8, 19:18, 22:3 **motions** [1] - 6:18 **move** [1] - 5:23 **MR** [2] - 11:9, 17:22 **MS** [9] - 3:18, 3:24,

3:15, 3:16, 3:21, 4:3, 4:13, 11:5, 11:19, 11:21, 11:25, 19:8, 19:18, 22:3 **motions** [1] - 6:18 **move** [1] - 5:23 **MR** [2] - 11:9, 17:22 **MS** [9] - 3:18, 3:24,

3:15, 3:16, 3:21, 4:3, 4:13, 11:5, 11:19, 11:21, 11:25, 19:8, 19:18, 22:3 **motions** [1] - 6:18 **move** [1] - 5:23 **MR** [2] - 11:9, 17:22 **MS** [9] - 3:18, 3:24,

4:2, 5:9, 7:15, 18:14, 21:13, 30:17, 30:18 **must** [4] - 5:15, 6:6,

4:2, 5:9, 7:15, 18:14, 21:13, 30:17, 30:18 **must** [4] - 5:15, 6:6,

16:7, 29:12 **N**

16:7, 29:12 **N**

16:7, 29:12 **N**

**name** [2] - 19:17, 29:5 **narrow** [1] - 26:7 **nature** [1] - 18:19 **necessarily** [1] - 21:10 **necessitated** [1] -

**name** [2] - 19:17, 29:5 **narrow** [1] - 26:7 **nature** [1] - 18:19 **necessarily** [1] - 21:10 **necessitated** [1] -

**name** [2] - 19:17, 29:5 **narrow** [1] - 26:7 **nature** [1] - 18:19 **necessarily** [1] - 21:10 **necessitated** [1] -

13:16 **negligence** [3] - 8:13,

13:16 **negligence** [3] - 8:13,

13:16 **negligence** [3] - 8:13,

8:14, 25:18 **negligent** [6] - 9:15,

8:14, 25:18 **negligent** [6] - 9:15,

8:14, 25:18 **negligent** [6] - 9:15,

23:24, 24:9, 25:20, 25:24, 27:11 **never** [2] - 6:8, 13:20 **nevertheless** [1] -

23:24, 24:9, 25:20, 25:24, 27:11 **never** [2] - 6:8, 13:20 **nevertheless** [1] -

23:24, 24:9, 25:20, 25:24, 27:11 **never** [2] - 6:8, 13:20 **nevertheless** [1] -

23:24, 24:9, 25:20, 25:24, 27:11 **never** [2] - 6:8, 13:20 **nevertheless** [1] -

23:24, 24:9, 25:20, 25:24, 27:11 **never** [2] - 6:8, 13:20 **nevertheless** [1] -

28:9 **New** [5] - 3:19, 13:6,

28:9 **New** [5] - 3:19, 13:6,

28:9 **New** [5] - 3:19, 13:6,

13:14, 19:10, 20:15 **Ninth** [1] - 21:21 **noises** [1] - 28:5 **non** [5] - 7:4, 8:8,

13:14, 19:10, 20:15 **Ninth** [1] - 21:21 **noises** [1] - 28:5 **non** [5] - 7:4, 8:8,

13:14, 19:10, 20:15 **Ninth** [1] - 21:21 **noises** [1] - 28:5 **non** [5] - 7:4, 8:8,

13:14, 19:10, 20:15 **Ninth** [1] - 21:21 **noises** [1] - 28:5 **non** [5] - 7:4, 8:8,

18:1, 29:2, 29:16 **non-compliance** [2] -

18:1, 29:2, 29:16 **non-compliance** [2] -  
18:1, 29:2, 29:16 **non-compliance** [2] -  
18:1, 29:2, 29:16 **non-compliance** [2] -  
18:1, 29:2, 29:16 **non-compliance** [2] -

29:2, 29:16 **non-conforming** [1] -  
29:2, 29:16 **non-conforming** [1] -  
29:2, 29:16 **non-conforming** [1] -  
29:2, 29:16 **non-conforming** [1] -

18:1 **non-existent** [1] - 7:4 **non-specific** [1] - 8:8 **note** [2] - 10:10, 11:20 **noted** [5] - 6:6, 14:22, 23:5,  
28:11, 28:19 **nothing** [1] - 8:1 **noting** [1] - 18:8 **notwithstanding** [2] -  
18:1 **non-existent** [1] - 7:4 **non-specific** [1] - 8:8 **note** [2] - 10:10, 11:20 **noted** [5] - 6:6, 14:22, 23:5,  
28:11, 28:19 **nothing** [1] - 8:1 **noting** [1] - 18:8 **notwithstanding** [2] -  
18:1 **non-existent** [1] - 7:4 **non-specific** [1] - 8:8 **note** [2] - 10:10, 11:20 **noted** [5] - 6:6, 14:22, 23:5,  
28:11, 28:19 **nothing** [1] - 8:1 **noting** [1] - 18:8 **notwithstanding** [2] -  
18:1 **non-existent** [1] - 7:4 **non-specific** [1] - 8:8 **note** [2] - 10:10, 11:20 **noted** [5] - 6:6, 14:22, 23:5,  
28:11, 28:19 **nothing** [1] - 8:1 **noting** [1] - 18:8 **notwithstanding** [2] -  
18:1 **non-existent** [1] - 7:4 **non-specific** [1] - 8:8 **note** [2] - 10:10, 11:20 **noted** [5] - 6:6, 14:22, 23:5,  
28:11, 28:19 **nothing** [1] - 8:1 **noting** [1] - 18:8 **notwithstanding** [2] -  
18:1 **non-existent** [1] - 7:4 **non-specific** [1] - 8:8 **note** [2] - 10:10, 11:20 **noted** [5] - 6:6, 14:22, 23:5,  
28:11, 28:19 **nothing** [1] - 8:1 **noting** [1] - 18:8 **notwithstanding** [2] -  
18:1 **non-existent** [1] - 7:4 **non-specific** [1] - 8:8 **note** [2] - 10:10, 11:20 **noted** [5] - 6:6, 14:22, 23:5,  
28:11, 28:19 **nothing** [1] - 8:1 **noting** [1] - 18:8 **notwithstanding** [2] -

16:19, 28:7 **Number** [1] - 28:23 **number** [6] - 4:8, 7:23,  
16:19, 28:7 **Number** [1] - 28:23 **number** [6] - 4:8, 7:23,  
16:19, 28:7 **Number** [1] - 28:23 **number** [6] - 4:8, 7:23,  
16:19, 28:7 **Number** [1] - 28:23 **number** [6] - 4:8, 7:23,  
16:19, 28:7 **Number** [1] - 28:23 **number** [6] - 4:8, 7:23,

8:1, 11:11, 13:16, 14:20  
8:1, 11:11, 13:16, 14:20  
8:1, 11:11, 13:16, 14:20  
8:1, 11:11, 13:16, 14:20  
8:1, 11:11, 13:16, 14:20

○  
○  
○  
○  
○

**obligation** [1] - 30:14 **obligations** [1] - 9:23 **obliged** [1] - 3:9 **obtained** [3] - 24:18,  
**obligation** [1] - 30:14 **obligations** [1] - 9:23 **obliged** [1] - 3:9 **obtained** [3] - 24:18,  
**obligation** [1] - 30:14 **obligations** [1] - 9:23 **obliged** [1] - 3:9 **obtained** [3] - 24:18,  
**obligation** [1] - 30:14 **obligations** [1] - 9:23 **obliged** [1] - 3:9 **obtained** [3] - 24:18,  
**obligation** [1] - 30:14 **obligations** [1] - 9:23 **obliged** [1] - 3:9 **obtained** [3] - 24:18,  
**obligation** [1] - 30:14 **obligations** [1] - 9:23 **obliged** [1] - 3:9 **obtained** [3] - 24:18,  
**obligation** [1] - 30:14 **obligations** [1] - 9:23 **obliged** [1] - 3:9 **obtained** [3] - 24:18,  
**obligation** [1] - 30:14 **obligations** [1] - 9:23 **obliged** [1] - 3:9 **obtained** [3] - 24:18,

24:21, 25:6 **obvious** [1] - 24:23 **obviously** [4] - 4:13, 5:6, 11:20, 21:16 **OF** [1] - 3:5 **offer** [1] - 29:21  
**often** [1] - 4:24 **old** [1] - 13:19 **once** [1] - 16:2 **One** [4] - 7:24, 23:23,



24:21, 25:6 **obvious** [1] - 24:23 **obviously** [4] - 4:13, 5:6, 11:20, 21:16 **OF** [1] - 3:5 **offer** [1] - 29:21  
**often** [1] - 4:24 **old** [1] - 13:19 **once** [1] - 16:2 **One** [4] - 7:24, 23:23,  
24:21, 25:6 **obvious** [1] - 24:23 **obviously** [4] - 4:13, 5:6, 11:20, 21:16 **OF** [1] - 3:5 **offer** [1] - 29:21  
**often** [1] - 4:24 **old** [1] - 13:19 **once** [1] - 16:2 **One** [4] - 7:24, 23:23,  
24:21, 25:6 **obvious** [1] - 24:23 **obviously** [4] - 4:13, 5:6, 11:20, 21:16 **OF** [1] - 3:5 **offer** [1] - 29:21  
**often** [1] - 4:24 **old** [1] - 13:19 **once** [1] - 16:2 **One** [4] - 7:24, 23:23,  
24:21, 25:6 **obvious** [1] - 24:23 **obviously** [4] - 4:13, 5:6, 11:20, 21:16 **OF** [1] - 3:5 **offer** [1] - 29:21  
**often** [1] - 4:24 **old** [1] - 13:19 **once** [1] - 16:2 **One** [4] - 7:24, 23:23,  
24:21, 25:6 **obvious** [1] - 24:23 **obviously** [4] - 4:13, 5:6, 11:20, 21:16 **OF** [1] - 3:5 **offer** [1] - 29:21  
**often** [1] - 4:24 **old** [1] - 13:19 **once** [1] - 16:2 **One** [4] - 7:24, 23:23,

25:24, 27:18 **one** [18] - 4:22, 6:22,  
25:24, 27:18 **one** [18] - 4:22, 6:22,  
25:24, 27:18 **one** [18] - 4:22, 6:22,  
25:24, 27:18 **one** [18] - 4:22, 6:22,  
25:24, 27:18 **one** [18] - 4:22, 6:22,

6:24, 7:16, 7:23, 8:1, 8:6, 15:15, 16:1, 16:24, 17:17, 20:11, 21:23, 22:11, 24:9, 24:14  
**one-by-one** [1] - 7:16 **ones** [1] - 12:19 **opinion** [6] - 7:6,  
6:24, 7:16, 7:23, 8:1, 8:6, 15:15, 16:1, 16:24, 17:17, 20:11, 21:23, 22:11, 24:9, 24:14  
**one-by-one** [1] - 7:16 **ones** [1] - 12:19 **opinion** [6] - 7:6,  
6:24, 7:16, 7:23, 8:1, 8:6, 15:15, 16:1, 16:24, 17:17, 20:11, 21:23, 22:11, 24:9, 24:14  
**one-by-one** [1] - 7:16 **ones** [1] - 12:19 **opinion** [6] - 7:6,  
6:24, 7:16, 7:23, 8:1, 8:6, 15:15, 16:1, 16:24, 17:17, 20:11, 21:23, 22:11, 24:9, 24:14  
**one-by-one** [1] - 7:16 **ones** [1] - 12:19 **opinion** [6] - 7:6,  
6:24, 7:16, 7:23, 8:1, 8:6, 15:15, 16:1, 16:24, 17:17, 20:11, 21:23, 22:11, 24:9, 24:14  
**one-by-one** [1] - 7:16 **ones** [1] - 12:19 **opinion** [6] - 7:6,  
6:24, 7:16, 7:23, 8:1, 8:6, 15:15, 16:1, 16:24, 17:17, 20:11, 21:23, 22:11, 24:9, 24:14  
**one-by-one** [1] - 7:16 **ones** [1] - 12:19 **opinion** [6] - 7:6,

13:11, 21:22, 26:6, 26:14, 29:22 **opinions** [2] - 7:7,  
13:11, 21:22, 26:6, 26:14, 29:22 **opinions** [2] - 7:7,  
13:11, 21:22, 26:6, 26:14, 29:22 **opinions** [2] - 7:7,  
13:11, 21:22, 26:6, 26:14, 29:22 **opinions** [2] - 7:7,  
13:11, 21:22, 26:6, 26:14, 29:22 **opinions** [2] - 7:7,

12:18 **opportunity** [1] -  
12:18 **opportunity** [1] -  
12:18 **opportunity** [1] -  
12:18 **opportunity** [1] -  
12:18 **opportunity** [1] -

22:21 **opposed** [1] - 11:1 **opposes** [1] - 3:16 **opposition** [1] - 9:11 **order** [1] - 30:5 **Osteonics** [2] - 3:7,  
22:21 **opposed** [1] - 11:1 **opposes** [1] - 3:16 **opposition** [1] - 9:11 **order** [1] - 30:5 **Osteonics** [2] - 3:7,  
22:21 **opposed** [1] - 11:1 **opposes** [1] - 3:16 **opposition** [1] - 9:11 **order** [1] - 30:5 **Osteonics** [2] - 3:7,  
22:21 **opposed** [1] - 11:1 **opposes** [1] - 3:16 **opposition** [1] - 9:11 **order** [1] - 30:5 **Osteonics** [2] - 3:7,  
22:21 **opposed** [1] - 11:1 **opposes** [1] - 3:16 **opposition** [1] - 9:11 **order** [1] - 30:5 **Osteonics** [2] - 3:7,  
22:21 **opposed** [1] - 11:1 **opposes** [1] - 3:16 **opposition** [1] - 9:11 **order** [1] - 30:5 **Osteonics** [2] - 3:7,  
22:21 **opposed** [1] - 11:1 **opposes** [1] - 3:16 **opposition** [1] - 9:11 **order** [1] - 30:5 **Osteonics** [2] - 3:7,  
22:21 **opposed** [1] - 11:1 **opposes** [1] - 3:16 **opposition** [1] - 9:11 **order** [1] - 30:5 **Osteonics** [2] - 3:7,  
22:21 **opposed** [1] - 11:1 **opposes** [1] - 3:16 **opposition** [1] - 9:11 **order** [1] - 30:5 **Osteonics** [2] - 3:7,

11:4 **ousted** [1] - 29:10 **outset** [1] - 4:5  
11:4 **ousted** [1] - 29:10 **outset** [1] - 4:5  
11:4 **ousted** [1] - 29:10 **outset** [1] - 4:5

**outside** [1] - 10:9 **overall** [1] - 9:18 **overview** [1] - 7:11 **own** [2] - 19:12, 21:16  
**outside** [1] - 10:9 **overall** [1] - 9:18 **overview** [1] - 7:11 **own** [2] - 19:12, 21:16  
**outside** [1] - 10:9 **overall** [1] - 9:18 **overview** [1] - 7:11 **own** [2] - 19:12, 21:16  
**outside** [1] - 10:9 **overall** [1] - 9:18 **overview** [1] - 7:11 **own** [2] - 19:12, 21:16

**outside** [1] - 10:9 **overall** [1] - 9:18 **overview** [1] - 7:11 **own** [2] - 19:12, 21:16  
**outside** [1] - 10:9 **overall** [1] - 9:18 **overview** [1] - 7:11 **own** [2] - 19:12, 21:16  
**outside** [1] - 10:9 **overall** [1] - 9:18 **overview** [1] - 7:11 **own** [2] - 19:12, 21:16  
**outside** [1] - 10:9 **overall** [1] - 9:18 **overview** [1] - 7:11 **own** [2] - 19:12, 21:16  
**outside** [1] - 10:9 **overall** [1] - 9:18 **overview** [1] - 7:11 **own** [2] - 19:12, 21:16

**P**  
**P**  
**P**  
**P**

**page** [3] - 23:15, 23:17, 23:20 **pages** [1] - 4:23 **papers** [2] - 18:16,  
**page** [3] - 23:15, 23:17, 23:20 **pages** [1] - 4:23 **papers** [2] - 18:16,  
**page** [3] - 23:15, 23:17, 23:20 **pages** [1] - 4:23 **papers** [2] - 18:16,  
**page** [3] - 23:15, 23:17, 23:20 **pages** [1] - 4:23 **papers** [2] - 18:16,  
**page** [3] - 23:15, 23:17, 23:20 **pages** [1] - 4:23 **papers** [2] - 18:16,  
**page** [3] - 23:15, 23:17, 23:20 **pages** [1] - 4:23 **papers** [2] - 18:16,  
**page** [3] - 23:15, 23:17, 23:20 **pages** [1] - 4:23 **papers** [2] - 18:16,  
**page** [3] - 23:15, 23:17, 23:20 **pages** [1] - 4:23 **papers** [2] - 18:16,

19:3 **paragraphs** [2] - 27:8,  
19:3 **paragraphs** [2] - 27:8,  
19:3 **paragraphs** [2] - 27:8,  
19:3 **paragraphs** [2] - 27:8,  
19:3 **paragraphs** [2] - 27:8,  
27:13 **parallel** [18] - 11:15,  
27:13 **parallel** [18] - 11:15,  
27:13 **parallel** [18] - 11:15,  
27:13 **parallel** [18] - 11:15,  
27:13 **parallel** [18] - 11:15,  
27:13 **parallel** [18] - 11:15,

12:3, 12:15, 12:22, 13:2, 13:6, 14:12, 14:15, 15:6, 16:4, 16:7, 18:15, 18:17, 18:18, 18:19,  
18:22, 18:24, 21:25 **Parker** [1] - 12:14 **parrot** [1] - 8:2 **parroting** [1] - 11:1 **part** [5] - 5:11, 5:14,  
18:5, 27:5, 29:18 **particular** [5] - 9:4,  
12:3, 12:15, 12:22, 13:2, 13:6, 14:12, 14:15, 15:6, 16:4, 16:7, 18:15, 18:17, 18:18, 18:19,  
18:22, 18:24, 21:25 **Parker** [1] - 12:14 **parrot** [1] - 8:2 **parroting** [1] - 11:1 **part** [5] - 5:11, 5:14,  
18:5, 27:5, 29:18 **particular** [5] - 9:4,  
12:3, 12:15, 12:22, 13:2, 13:6, 14:12, 14:15, 15:6, 16:4, 16:7, 18:15, 18:17, 18:18, 18:19,  
18:22, 18:24, 21:25 **Parker** [1] - 12:14 **parrot** [1] - 8:2 **parroting** [1] - 11:1 **part** [5] - 5:11, 5:14,  
18:5, 27:5, 29:18 **particular** [5] - 9:4,  
12:3, 12:15, 12:22, 13:2, 13:6, 14:12, 14:15, 15:6, 16:4, 16:7, 18:15, 18:17, 18:18, 18:19,  
18:22, 18:24, 21:25 **Parker** [1] - 12:14 **parrot** [1] - 8:2 **parroting** [1] - 11:1 **part** [5] - 5:11, 5:14,  
18:5, 27:5, 29:18 **particular** [5] - 9:4,  
12:3, 12:15, 12:22, 13:2, 13:6, 14:12, 14:15, 15:6, 16:4, 16:7, 18:15, 18:17, 18:18, 18:19,  
18:22, 18:24, 21:25 **Parker** [1] - 12:14 **parrot** [1] - 8:2 **parroting** [1] - 11:1 **part** [5] - 5:11, 5:14,  
18:5, 27:5, 29:18 **particular** [5] - 9:4,  
12:3, 12:15, 12:22, 13:2, 13:6, 14:12, 14:15, 15:6, 16:4, 16:7, 18:15, 18:17, 18:18, 18:19,  
18:22, 18:24, 21:25 **Parker** [1] - 12:14 **parrot** [1] - 8:2 **parroting** [1] - 11:1 **part** [5] - 5:11, 5:14,  
18:5, 27:5, 29:18 **particular** [5] - 9:4,





7:20, 8:10, 8:24, 10:14, 10:16, 10:18, 19:23, 24:15 **PMA-approved** [1] -  
6:9 **point** [6] - 5:24, 6:5, 8:25, 21:1, 21:19, 23:12 **points** [1] - 20:11 **position** [2] - 11:12,  
22:12 **possible** [1] - 17:17 **post** [1] - 6:25 **post-Riegel** [1] - 6:25 **potential** [1] - 18:17 **practice**  
[4] - 7:13,  
15:24, 19:8, 22:24 **practices** [2] - 15:18,  
15:23 **pre** [3] - 24:1, 24:19,  
25:6 **pre-market** [3] - 24:1,  
24:19, 25:6 **precedent** [9] - 15:9,  
19:13, 19:16, 19:24, 20:17, 21:9, 21:12, 21:17, 30:11 **precise** [1] - 8:16 **precisely** [4] - 7:20,  
9:4, 9:12, 22:8 **preempted** [22] - 7:22, 8:17, 9:1, 9:2, 9:14, 13:1, 13:2, 14:1, 14:13, 14:16, 15:7,  
15:19, 19:15, 22:8, 25:8, 25:20, 27:9, 27:15, 27:19, 27:20, 28:10, 28:20 **preemption** [26] -  
4:12, 6:12, 6:19, 8:6, 8:7, 8:12, 8:20, 10:2, 10:5, 10:6, 10:16, 10:22, 12:10, 12:21, 13:20,  
14:2, 14:3, 14:8, 15:2, 15:12, 15:21, 16:1, 16:4, 20:7, 22:10, 26:17

4:18, 6:20 **preemptive** [2] - 25:3,  
26:7 **preexisting** [1] - 19:13 **prejudice** [1] - 14:18

**prepared** [2] - 3:16,

23:11 **present** [3] - 3:14,

3:22, 13:4 **presented** [1] - 30:1 **pretty** [1] -

**private** [5] - 9:20,

**problem** [1] - 9:24 **problems** [3] - 9:25,

12:3, 17:9 **proceed** [2] - 3:11, 4:1 **proceedings**

29:4, 30:19 **process** [7] - 5:3,

5, 24:1, 24:15 **processes** [1] - 24:20 **product** [25] - 5:16, 6:15, 6:16,  
10:14, 10:15, 10:18, 11:14, 12:4, 12:11, 12:18, 16:12, 16:13, 17:2,  
24:14, 24:21, 27:7 **products** [2] - 15:17,

17:1 **program** [1] - 26:21 **promptly** [1] - 22:25

14:6, 16:14 **Protection** [4] - 9:9, 14:9, 24:6,

**provided** [1] - 11:24 **provides** [3] - 15:11,

15:15, 28:2 **provisions** [1] - 29:3 **published** [1]

15:16, 17:23 **pursue** [3] - 10:3,

10:4, 10:7 **pursuing** [1] - 19:7 **put** [3] - 5:6,

27:3 **putting** [1] - 22:16

Q  
Q  
Q

**questions** [1] - 7:14 **quite** [1] - 14:25 **quotation** [2] - 23:16,

**questions** [1] - 7:14 **quite** [1] - 14:25 **quotation** [2] - 23:16,

**questions** [1] - 7:14 **quite** [1] - 14:25 **quotation** [2] - 23:16,

23:18 **quote** [4] - 26:8,

23:18 **quote** [4] - 26:8,

26:10, 29:3, 29:6

26:10, 29:3, 29:6

R

**R**  
**R**

**raised** [1] - 20:12 **rather** [1] - 29:1 **read** [10] - 7:3, 7:17,  
**raised** [1] - 20:12 **rather** [1] - 29:1 **read** [10] - 7:3, 7:17,  
**raised** [1] - 20:12 **rather** [1] - 29:1 **read** [10] - 7:3, 7:17,

9:19, 10:24, 11:10, 16:1, 23:3, 23:4, 25:3, 25:7 **reading** [1] - 21:6 **reads** [2] - 26:16,  
9:19, 10:24, 11:10, 16:1, 23:3, 23:4, 25:3, 25:7 **reading** [1] - 21:6 **reads** [2] - 26:16,  
9:19, 10:24, 11:10, 16:1, 23:3, 23:4, 25:3, 25:7 **reading** [1] - 21:6 **reads** [2] - 26:16,  
9:19, 10:24, 11:10, 16:1, 23:3, 23:4, 25:3, 25:7 **reading** [1] - 21:6 **reads** [2] - 26:16,

28:25 **ready** [1] - 3:11 **really** [5] - 8:13, 9:8,  
28:25 **ready** [1] - 3:11 **really** [5] - 8:13, 9:8,  
28:25 **ready** [1] - 3:11 **really** [5] - 8:13, 9:8,  
28:25 **ready** [1] - 3:11 **really** [5] - 8:13, 9:8,

9:20, 15:8, 25:7 **reason** [1] - 14:23 **reasonable** [1] - 23:10 **reasoning** [3] -  
6:14,

9:20, 15:8, 25:7 **reason** [1] - 14:23 **reasonable** [1] - 23:10 **reasoning** [3] -  
6:14,

9:20, 15:8, 25:7 **reason** [1] - 14:23 **reasonable** [1] - 23:10 **reasoning** [3] -  
6:14,

21:11, 21:15 **reasons** [3] - 10:22,  
21:11, 21:15 **reasons** [3] - 10:22,  
21:11, 21:15 **reasons** [3] - 10:22,

11:3, 30:4 **recalled** [2] - 10:11,  
11:3, 30:4 **recalled** [2] - 10:11,  
11:3, 30:4 **recalled** [2] - 10:11,

10:15 **receive** [1] - 25:12 **received** [1] - 10:10 **recess** [2] - 3:9, 30:16  
**recognize** [1] - 12:14 **recognized** [7] - 12:2, 12:21, 13:1, 14:11, 14:15, 15:5, 16:24

**recognizing** [1] - 16:3 **recourse** [2] - 26:10,  
10:15 **receive** [1] - 25:12 **received** [1] - 10:10 **recess** [2] - 3:9, 30:16

**recognize** [1] - 12:14 **recognized** [7] - 12:2, 12:21, 13:1, 14:11, 14:15, 15:5, 16:24  
**recognizing** [1] - 16:3 **recourse** [2] - 26:10,

10:15 **receive** [1] - 25:12 **received** [1] - 10:10 **recess** [2] - 3:9, 30:16  
**recognize** [1] - 12:14 **recognized** [7] - 12:2, 12:21, 13:1, 14:11, 14:15, 15:5, 16:24

**recognizing** [1] - 16:3 **recourse** [2] - 26:10,  
10:15 **receive** [1] - 25:12 **received** [1] - 10:10 **recess** [2] - 3:9, 30:16

**recognize** [1] - 12:14 **recognized** [7] - 12:2, 12:21, 13:1, 14:11, 14:15, 15:5, 16:24  
**recognizing** [1] - 16:3 **recourse** [2] - 26:10,

10:15 **receive** [1] - 25:12 **received** [1] - 10:10 **recess** [2] - 3:9, 30:16  
**recognize** [1] - 12:14 **recognized** [7] - 12:2, 12:21, 13:1, 14:11, 14:15, 15:5, 16:24

**recognizing** [1] - 16:3 **recourse** [2] - 26:10,  
10:15 **receive** [1] - 25:12 **received** [1] - 10:10 **recess** [2] - 3:9, 30:16

**recognize** [1] - 12:14 **recognized** [7] - 12:2, 12:21, 13:1, 14:11, 14:15, 15:5, 16:24  
**recognizing** [1] - 16:3 **recourse** [2] - 26:10,

10:15 **receive** [1] - 25:12 **received** [1] - 10:10 **recess** [2] - 3:9, 30:16  
**recognize** [1] - 12:14 **recognized** [7] - 12:2, 12:21, 13:1, 14:11, 14:15, 15:5, 16:24

**recognizing** [1] - 16:3 **recourse** [2] - 26:10,  
26:20 **reference** [3] - 7:24,

26:20 **reference** [3] - 7:24,  
26:20 **reference** [3] - 7:24,

23:22, 26:12 **referenced** [2] - 23:4,  
23:22, 26:12 **referenced** [2] - 23:4,

24:5 **referencing** [1] - 24:6 **regard** [2] - 15:20,  
24:5 **referencing** [1] - 24:6 **regard** [2] - 15:20,

24:5 **referencing** [1] - 24:6 **regard** [2] - 15:20,

22:1 **regulate** [1] - 18:6 **regulation** [1] - 8:8 **Regulations** [1] -

22:1 **regulate** [1] - 18:6 **regulation** [1] - 8:8 **Regulations** [1] -

22:1 **regulate** [1] - 18:6 **regulation** [1] - 8:8 **Regulations** [1] -

22:1 **regulate** [1] - 18:6 **regulation** [1] - 8:8 **Regulations** [1] -

15:21 **reject** [1] - 7:8 **rejected** [1] - 8:16 **relate** [2] - 10:6, 25:9 **related** [6] -

4:3,

15:21 **reject** [1] - 7:8 **rejected** [1] - 8:16 **relate** [2] - 10:6, 25:9 **related** [6] -

4:3,

15:21 **reject** [1] - 7:8 **rejected** [1] - 8:16 **relate** [2] - 10:6, 25:9 **related** [6] -

4:3,

15:21 **reject** [1] - 7:8 **rejected** [1] - 8:16 **relate** [2] - 10:6, 25:9 **related** [6] -

4:3,

25:10, 25:15, 26:5, 27:7, 28:9

25:10, 25:15, 26:5, 27:7, 28:9

**relates** [3] - 15:17,

**relates** [3] - 15:17,

**relates** [3] - 15:17,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

27:6, 27:12 **relating** [1] - 28:4 **relevant** [1] - 10:12 **relied** [1] - 14:25 **remove** [1] - 26:10 **render** [1] -  
29:22 **repaid** [1] - 18:4 **repeated** [1] - 23:15 **replace** [1] - 18:4 **replead** [2] - 14:6,

14:8 **report** [1] - 9:22 **reporting** [1] - 6:3 **represented** [2] - 3:12,

14:8 **report** [1] - 9:22 **reporting** [1] - 6:3 **represented** [2] - 3:12,

14:8 **report** [1] - 9:22 **reporting** [1] - 6:3 **represented** [2] - 3:12,

3:13 **request** [3] - 17:15,

3:13 **request** [3] - 17:15,

3:13 **request** [3] - 17:15,

3:13 **request** [3] - 17:15,

22:2, 30:3 **require** [1] - 28:13 **required** [1] - 29:15 **requirement** [3] -

22:2, 30:3 **require** [1] - 28:13 **required** [1] - 29:15 **requirement** [3] -

22:2, 30:3 **require** [1] - 28:13 **required** [1] - 29:15 **requirement** [3] -

22:2, 30:3 **require** [1] - 28:13 **required** [1] - 29:15 **requirement** [3] -

22:2, 30:3 **require** [1] - 28:13 **required** [1] - 29:15 **requirement** [3] -

22:2, 30:3 **require** [1] - 28:13 **required** [1] - 29:15 **requirement** [3] -

15:17, 25:10, 26:23 **requirement's** [1] -

15:17, 25:10, 26:23 **requirement's** [1] -

15:17, 25:10, 26:23 **requirements** [1] -  
15:17, 25:10, 26:23 **requirements** [1] -

28:13 **requirements** [16] -  
28:13 **requirements** [16] -  
28:13 **requirements** [16] -  
28:13 **requirements** [16] -  
28:13 **requirements** [16] -

6:3, 8:6, 8:10, 11:12, 14:12, 15:12, 15:13, 15:16, 15:19, 17:10, 18:7, 26:5, 26:20, 26:24, 27:3,  
28:12 **requires** [2] - 11:2,  
6:3, 8:6, 8:10, 11:12, 14:12, 15:12, 15:13, 15:16, 15:19, 17:10, 18:7, 26:5, 26:20, 26:24, 27:3,  
28:12 **requires** [2] - 11:2,  
6:3, 8:6, 8:10, 11:12, 14:12, 15:12, 15:13, 15:16, 15:19, 17:10, 18:7, 26:5, 26:20, 26:24, 27:3,  
28:12 **requires** [2] - 11:2,  
6:3, 8:6, 8:10, 11:12, 14:12, 15:12, 15:13, 15:16, 15:19, 17:10, 18:7, 26:5, 26:20, 26:24, 27:3,  
28:12 **requires** [2] - 11:2,  
6:3, 8:6, 8:10, 11:12, 14:12, 15:12, 15:13, 15:16, 15:19, 17:10, 18:7, 26:5, 26:20, 26:24, 27:3,  
28:12 **requires** [2] - 11:2,  
6:3, 8:6, 8:10, 11:12, 14:12, 15:12, 15:13, 15:16, 15:19, 17:10, 18:7, 26:5, 26:20, 26:24, 27:3,  
28:12 **requires** [2] - 11:2,

28:14 **research** [1] - 13:24 **resolved** [1] - 20:2 **respect** [1] - 21:8 **respectfully** [1] -  
28:14 **research** [1] - 13:24 **resolved** [1] - 20:2 **respect** [1] - 21:8 **respectfully** [1] -  
28:14 **research** [1] - 13:24 **resolved** [1] - 20:2 **respect** [1] - 21:8 **respectfully** [1] -  
28:14 **research** [1] - 13:24 **resolved** [1] - 20:2 **respect** [1] - 21:8 **respectfully** [1] -  
28:14 **research** [1] - 13:24 **resolved** [1] - 20:2 **respect** [1] - 21:8 **respectfully** [1] -  
28:14 **research** [1] - 13:24 **resolved** [1] - 20:2 **respect** [1] - 21:8 **respectfully** [1] -

17:15 **respond** [1] - 18:13 **restrain** [1] - 29:4 **results** [1] - 22:13 **retains** [1] - 5:24 **reviewed** [2] - 23:2,  
17:15 **respond** [1] - 18:13 **restrain** [1] - 29:4 **results** [1] - 22:13 **retains** [1] - 5:24 **reviewed** [2] - 23:2,  
17:15 **respond** [1] - 18:13 **restrain** [1] - 29:4 **results** [1] - 22:13 **retains** [1] - 5:24 **reviewed** [2] - 23:2,  
17:15 **respond** [1] - 18:13 **restrain** [1] - 29:4 **results** [1] - 22:13 **retains** [1] - 5:24 **reviewed** [2] - 23:2,  
17:15 **respond** [1] - 18:13 **restrain** [1] - 29:4 **results** [1] - 22:13 **retains** [1] - 5:24 **reviewed** [2] - 23:2,  
17:15 **respond** [1] - 18:13 **restrain** [1] - 29:4 **results** [1] - 22:13 **retains** [1] - 5:24 **reviewed** [2] - 23:2,  
17:15 **respond** [1] - 18:13 **restrain** [1] - 29:4 **results** [1] - 22:13 **retains** [1] - 5:24 **reviewed** [2] - 23:2,

23:5 **revisit** [1] - 20:1 **Riegel** [31] - 4:18, 6:6,  
23:5 **revisit** [1] - 20:1 **Riegel** [31] - 4:18, 6:6,  
23:5 **revisit** [1] - 20:1 **Riegel** [31] - 4:18, 6:6,  
23:5 **revisit** [1] - 20:1 **Riegel** [31] - 4:18, 6:6,

6:10, 6:11, 6:19, 6:25, 8:15, 8:22, 9:5, 9:12, 11:13, 12:3, 12:7, 12:13, 12:16, 15:7, 16:2, 16:6,  
19:11, 19:22, 20:6, 21:22, 22:9, 25:1, 25:3, 25:12, 26:6, 27:10, 27:15, 28:10 **risks** [2] - 5:17,  
5:20 **roundly** [1] - 6:25 **rule** [2] - 22:25, 29:25 **ruling** [1] - 30:4 **running** [1] - 28:13  
6:10, 6:11, 6:19, 6:25, 8:15, 8:22, 9:5, 9:12, 11:13, 12:3, 12:7, 12:13, 12:16, 15:7, 16:2, 16:6,  
19:11, 19:22, 20:6, 21:22, 22:9, 25:1, 25:3, 25:12, 26:6, 27:10, 27:15, 28:10 **risks** [2] - 5:17,  
5:20 **roundly** [1] - 6:25 **rule** [2] - 22:25, 29:25 **ruling** [1] - 30:4 **running** [1] - 28:13  
6:10, 6:11, 6:19, 6:25, 8:15, 8:22, 9:5, 9:12, 11:13, 12:3, 12:7, 12:13, 12:16, 15:7, 16:2, 16:6,  
19:11, 19:22, 20:6, 21:22, 22:9, 25:1, 25:3, 25:12, 26:6, 27:10, 27:15, 28:10 **risks** [2] - 5:17,  
5:20 **roundly** [1] - 6:25 **rule** [2] - 22:25, 29:25 **ruling** [1] - 30:4 **running** [1] - 28:13  
6:10, 6:11, 6:19, 6:25, 8:15, 8:22, 9:5, 9:12, 11:13, 12:3, 12:7, 12:13, 12:16, 15:7, 16:2, 16:6,  
19:11, 19:22, 20:6, 21:22, 22:9, 25:1, 25:3, 25:12, 26:6, 27:10, 27:15, 28:10 **risks** [2] - 5:17,  
5:20 **roundly** [1] - 6:25 **rule** [2] - 22:25, 29:25 **ruling** [1] - 30:4 **running** [1] - 28:13  
6:10, 6:11, 6:19, 6:25, 8:15, 8:22, 9:5, 9:12, 11:13, 12:3, 12:7, 12:13, 12:16, 15:7, 16:2, 16:6,  
19:11, 19:22, 20:6, 21:22, 22:9, 25:1, 25:3, 25:12, 26:6, 27:10, 27:15, 28:10 **risks** [2] - 5:17,  
5:20 **roundly** [1] - 6:25 **rule** [2] - 22:25, 29:25 **ruling** [1] - 30:4 **running** [1] - 28:13  
6:10, 6:11, 6:19, 6:25, 8:15, 8:22, 9:5, 9:12, 11:13, 12:3, 12:7, 12:13, 12:16, 15:7, 16:2, 16:6,  
19:11, 19:22, 20:6, 21:22, 22:9, 25:1, 25:3, 25:12, 26:6, 27:10, 27:15, 28:10 **risks** [2] - 5:17,





**see** [3] - 4:24, 12:6,  
 27:7 **sample** [1] - 20:23 **satisfied** [1] - 22:13 **scant** [1] - 21:3 **scope** [1] - 26:7 **seated** [1] - 3:3 **second** [1] - 28:2 **Section** [1] - 29:6  
**see** [3] - 4:24, 12:6,  
 27:7 **sample** [1] - 20:23 **satisfied** [1] - 22:13 **scant** [1] - 21:3 **scope** [1] - 26:7 **seated** [1] - 3:3 **second** [1] - 28:2 **Section** [1] - 29:6  
**see** [3] - 4:24, 12:6,  
 27:7 **sample** [1] - 20:23 **satisfied** [1] - 22:13 **scant** [1] - 21:3 **scope** [1] - 26:7 **seated** [1] - 3:3 **second** [1] - 28:2 **Section** [1] - 29:6  
**see** [3] - 4:24, 12:6,  
 27:13 **seek** [2] - 16:7, 29:19 **seeking** [2] - 9:21,  
 27:13 **seek** [2] - 16:7, 29:19 **seeking** [2] - 9:21,  
 27:13 **seek** [2] - 16:7, 29:19 **seeking** [2] - 9:21,  
 27:13 **seek** [2] - 16:7, 29:19 **seeking** [2] - 9:21,  
 27:13 **seek** [2] - 16:7, 29:19 **seeking** [2] - 9:21,  
 27:13 **seek** [2] - 16:7, 29:19 **seeking** [2] - 9:21,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 16:23 **sense** [1] - 19:21 **separate** [1] - 23:14 **set** [4] - 3:5, 11:12,  
 24:24, 27:18 **seven** [3] - 12:1, 12:9,  
 24:24, 27:18 **seven** [3] - 12:1, 12:9,  
 24:24, 27:18 **seven** [3] - 12:1, 12:9,  
 24:24, 27:18 **seven** [3] - 12:1, 12:9,  
 14:21 **several** [2] - 23:5,  
 14:21 **several** [2] - 23:5,  
 14:21 **several** [2] - 23:5,  
 14:21 **several** [2] - 23:5,  
 14:21 **several** [2] - 23:5,  
 23:14 **shall** [1] - 29:5 **Shiley** [5] - 19:17,  
 23:14 **shall** [1] - 29:5 **Shiley** [5] - 19:17,  
 23:14 **shall** [1] - 29:5 **Shiley** [5] - 19:17,  
 23:14 **shall** [1] - 29:5 **Shiley** [5] - 19:17,  
 23:14 **shall** [1] - 29:5 **Shiley** [5] - 19:17,  
 23:14 **shall** [1] - 29:5 **Shiley** [5] - 19:17,  
 23:14 **shall** [1] - 29:5 **Shiley** [5] - 19:17,  
 23:14 **shall** [1] - 29:5 **Shiley** [5] - 19:17,  
 19:24, 20:1, 20:5, 20:16 **shopped** [1] - 15:3 **shopping** [1] - 13:11 **short** [3] - 14:25, 30:2,  
 19:24, 20:1, 20:5, 20:16 **shopped** [1] - 15:3 **shopping** [1] - 13:11 **short** [3] - 14:25, 30:2,  
 19:24, 20:1, 20:5, 20:16 **shopped** [1] - 15:3 **shopping** [1] - 13:11 **short** [3] - 14:25, 30:2,  
 19:24, 20:1, 20:5, 20:16 **shopped** [1] - 15:3 **shopping** [1] - 13:11 **short** [3] - 14:25, 30:2,  
 19:24, 20:1, 20:5, 20:16 **shopped** [1] - 15:3 **shopping** [1] - 13:11 **short** [3] - 14:25, 30:2,  
 19:24, 20:1, 20:5, 20:16 **shopped** [1] - 15:3 **shopping** [1] - 13:11 **short** [3] - 14:25, 30:2,  
 19:24, 20:1, 20:5, 20:16 **shopped** [1] - 15:3 **shopping** [1] - 13:11 **short** [3] - 14:25, 30:2,  
 30:5 **shortcomings** [1] -  
 30:5 **shortcomings** [1] -  
 30:5 **shortcomings** [1] -  
 30:5 **shortcomings** [1] -  
 11:16 **show** [1] - 12:4 **shows** [1] - 27:8 **sides** [2] - 23:2, 30:8 **significance** [3] -  
 11:16 **show** [1] - 12:4 **shows** [1] - 27:8 **sides** [2] - 23:2, 30:8 **significance** [3] -  
 11:16 **show** [1] - 12:4 **shows** [1] - 27:8 **sides** [2] - 23:2, 30:8 **significance** [3] -  
 11:16 **show** [1] - 12:4 **shows** [1] - 27:8 **sides** [2] - 23:2, 30:8 **significance** [3] -  
 11:16 **show** [1] - 12:4 **shows** [1] - 27:8 **sides** [2] - 23:2, 30:8 **significance** [3] -

11:16 **show** [1] - 12:4 **shows** [1] - 27:8 **sides** [2] - 23:2, 30:8 **significance** [3] -  
11:16 **show** [1] - 12:4 **shows** [1] - 27:8 **sides** [2] - 23:2, 30:8 **significance** [3] -  
11:16 **show** [1] - 12:4 **shows** [1] - 27:8 **sides** [2] - 23:2, 30:8 **significance** [3] -  
11:16 **show** [1] - 12:4 **shows** [1] - 27:8 **sides** [2] - 23:2, 30:8 **significance** [3] -  
5:10, 6:10, 21:10 **significant** [1] - 6:5 **similar** [1] - 11:11 **simply** [4] - 8:13,  
5:10, 6:10, 21:10 **significant** [1] - 6:5 **similar** [1] - 11:11 **simply** [4] - 8:13,  
5:10, 6:10, 21:10 **significant** [1] - 6:5 **similar** [1] - 11:11 **simply** [4] - 8:13,  
5:10, 6:10, 21:10 **significant** [1] - 6:5 **similar** [1] - 11:11 **simply** [4] - 8:13,  
5:10, 6:10, 21:10 **significant** [1] - 6:5 **similar** [1] - 11:11 **simply** [4] - 8:13,  
5:10, 6:10, 21:10 **significant** [1] - 6:5 **similar** [1] - 11:11 **simply** [4] - 8:13,  
5:10, 6:10, 21:10 **significant** [1] - 6:5 **similar** [1] - 11:11 **simply** [4] - 8:13,  
14:17, 18:8, 29:12 **six** [1] - 7:2 **slightly** [1] - 24:19 **so-called** [3] - 5:8,  
14:17, 18:8, 29:12 **six** [1] - 7:2 **slightly** [1] - 24:19 **so-called** [3] - 5:8,  
14:17, 18:8, 29:12 **six** [1] - 7:2 **slightly** [1] - 24:19 **so-called** [3] - 5:8,  
14:17, 18:8, 29:12 **six** [1] - 7:2 **slightly** [1] - 24:19 **so-called** [3] - 5:8,  
14:17, 18:8, 29:12 **six** [1] - 7:2 **slightly** [1] - 24:19 **so-called** [3] - 5:8,  
23:6, 24:13 **socket** [1] - 28:3 **sometimes** [1] - 21:7 **somewhat** [1] - 22:2 **sorry** [1] - 8:20 **sort** [2] - 12:6, 22:25 **sought** [1] - 30:3  
**specific** [4] - 8:1, 8:8,  
23:6, 24:13 **socket** [1] - 28:3 **sometimes** [1] - 21:7 **somewhat** [1] - 22:2 **sorry** [1] - 8:20 **sort** [2] - 12:6, 22:25 **sought** [1] - 30:3  
**specific** [4] - 8:1, 8:8,  
23:6, 24:13 **socket** [1] - 28:3 **sometimes** [1] - 21:7 **somewhat** [1] - 22:2 **sorry** [1] - 8:20 **sort** [2] - 12:6, 22:25 **sought** [1] - 30:3  
**specific** [4] - 8:1, 8:8,  
23:6, 24:13 **socket** [1] - 28:3 **sometimes** [1] - 21:7 **somewhat** [1] - 22:2 **sorry** [1] - 8:20 **sort** [2] - 12:6, 22:25 **sought** [1] - 30:3  
**specific** [4] - 8:1, 8:8,  
23:6, 24:13 **socket** [1] - 28:3 **sometimes** [1] - 21:7 **somewhat** [1] - 22:2 **sorry** [1] - 8:20 **sort** [2] - 12:6, 22:25 **sought** [1] - 30:3  
**specific** [4] - 8:1, 8:8,  
23:6, 24:13 **socket** [1] - 28:3 **sometimes** [1] - 21:7 **somewhat** [1] - 22:2 **sorry** [1] - 8:20 **sort** [2] - 12:6, 22:25 **sought** [1] - 30:3  
**specific** [4] - 8:1, 8:8,  
23:6, 24:13 **socket** [1] - 28:3 **sometimes** [1] - 21:7 **somewhat** [1] - 22:2 **sorry** [1] - 8:20 **sort** [2] - 12:6, 22:25 **sought** [1] - 30:3  
**specific** [4] - 8:1, 8:8,

## Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 36 of 37

5

12:20, 25:11 **specifically** [5] - 7:2, 15:22, 16:16, 19:6, 23:22 **spend** [1] - 5:5 **spending** [1] -  
4:23 **spoken** [2] - 30:10,  
30:11 **stand** [1] - 22:4 **standards** [1] - 7:25 **standing** [2] - 18:15,  
29:15 **start** [1] - 24:24 **started** [2] - 3:8, 22:11 **starting** [1] - 23:12 **State** [1] - 26:22 **state** [35] -  
11:14,  
11:15, 12:3, 12:15, 12:22, 12:25, 13:1, 13:7, 13:15, 13:21, 14:3, 14:11, 14:15, 14:16, 15:6,  
15:12, 15:15, 16:4, 16:7, 16:9, 16:18, 16:23, 17:8, 18:6, 18:9, 25:22, 26:19, 26:22, 27:1,  
27:17, 28:12, 28:20 **statement** [2] - 11:23,  
12:9 **statements** [2] - 27:6,  
27:24 **States** [5] - 11:13,  
24:25, 29:6, 30:10 **statute** [1] - 26:3 **statutory** [1] - 16:15 **step** [1] - 4:12 **still** [2] - 6:9, 11:11  
**stops** [1] - 9:1 **strict** [2] - 25:17,  
25:23 **Stryker** [1] - 14:11 **submit** [9] - 4:15, 8:11, 9:7, 9:24, 10:11, 12:1, 18:23, 20:8, 22:6  
**submitted** [1] - 6:17 **subsequent** [1] - 20:4 **substantially** [1] -  
15:13 **substantive** [2] - 9:8,  
21:22 **sue** [1] - 29:10 **suffered** [1] - 18:6 **sufficiently** [2] -  
14:19, 15:6 **suggest** [1] - 22:4 **suggesting** [2] - 21:14, 21:17 **suggestions** [1] -  
29:24 **suing** [1] - 23:18 **suit** [1] - 29:2 **sum** [1] -

:5 supplemental [2] -

6:17, 23:6 **Supreme** [12] - 4:22,

2:12, 13:13, 16:3, 21:6, 24:25, 28:21, 30:10 **surgery** [1] - 18:4

26:4 **System** [2] - 4:4, 4:6

26:18 **test** [1] - 25:18 **testing** [1] - 25:24 **THE** [10] - 3:3, 3:8,

7:20, 18:12, 20:25, 22:22 **theme** [1] - 23:15 **they've** [1] - 7:5 **Third** [5] -

16 **Three** [6] - 8:19, 24:2, 24:4, 26:1, 27:20, 27:22 **tied** [4] - 19:16,

22:19, 24:8 **time-intensive** [1] -

5:2 **today** [3] - 11:16, 13:4,

22:4 **took** [1] - 29:18 **top** [2] - 7:1, 10:4 **topic** [1] -

12,

13:17, 19:5 **tort-based** [1] - 12:10 **touches** [1] -

5:22, 15:24 **Trident** [9] - 4:4, 4:6, 6:15, 12:11, 12:18, 13:13, 16:11,

13:15 **tried** [1] - 20:21 **troubling** [1] - 22:5 **true** [1] - 20:14 **try** [2] - 8:5,

**trying** [2] - 17:6, 18:6 **turn** [5] - 3:22, 23:12, 23:22, 26:5, 27:21 **turning** [1] - 6:15 **twenty** [1] -  
15:15 **twenty-one** [1] - 15:15 **Two** [3] - 23:23, 25:25,

**trying** [2] - 17:6, 18:6 **turn** [5] - 3:22, 23:12, 23:22, 26:5, 27:21 **turning** [1] - 6:15 **twenty** [1] -  
15:15 **twenty-one** [1] - 15:15 **Two** [3] - 23:23, 25:25,

**trying** [2] - 17:6, 18:6 **turn** [5] - 3:22, 23:12, 23:22, 26:5, 27:21 **turning** [1] - 6:15 **twenty** [1] -  
15:15 **twenty-one** [1] - 15:15 **Two** [3] - 23:23, 25:25,

27:18 **Twombly** [3] - 7:4,

27:18 **Twombly** [3] - 7:4,

27:18 **Twombly** [3] - 7:4,

10:21, 11:1 **type** [5] - 8:16, 19:24,

10:21, 11:1 **type** [5] - 8:16, 19:24,

26:2, 27:9, 27:14 **types** [1] - 25:8 **U**

26:2, 27:9, 27:14 **types** [1] - 25:8 **U**

26:2, 27:9, 27:14 **types** [1] - 25:8 **U**

**U.S** [1] - 16:3 **ultimately** [2] - 20:1,

**U.S** [1] - 16:3 **ultimately** [2] - 20:1,

**U.S** [1] - 16:3 **ultimately** [2] - 20:1,

21:16 **umbrella** [1] - 26:2 **under** [8] - 9:23, 10:2, 12:3, 16:15, 18:6, 18:8,  
24:15, 26:2 **undergo** [1] - 18:4 **unfair** [3] - 15:18,

21:16 **umbrella** [1] - 26:2 **under** [8] - 9:23, 10:2, 12:3, 16:15, 18:6, 18:8,  
24:15, 26:2 **undergo** [1] - 18:4 **unfair** [3] - 15:18,

21:16 **umbrella** [1] - 26:2 **under** [8] - 9:23, 10:2, 12:3, 16:15, 18:6, 18:8,  
24:15, 26:2 **undergo** [1] - 18:4 **unfair** [3] - 15:18,

15:22, 15:24 **unfortunately** [1] -

15:22, 15:24 **unfortunately** [1] -

17:2 **Uniform** [1] - 24:5 **uniform** [1] - 15:25 **United** [5] - 11:13,

17:2 **Uniform** [1] - 24:5 **uniform** [1] - 15:25 **United** [5] - 11:13,

17:2 **Uniform** [1] - 24:5 **uniform** [1] - 15:25 **United** [5] - 11:13,  
17:2 **Uniform** [1] - 24:5 **uniform** [1] - 15:25 **United** [5] - 11:13,  
17:2 **Uniform** [1] - 24:5 **uniform** [1] - 15:25 **United** [5] - 11:13,

24:25, 29:5, 29:6, 30:9 **unless** [1] - 22:7 **unsafe** [1] - 6:7 **up** [7] - 5:20, 10:1,  
24:25, 29:5, 29:6, 30:9 **unless** [1] - 22:7 **unsafe** [1] - 6:7 **up** [7] - 5:20, 10:1,  
24:25, 29:5, 29:6, 30:9 **unless** [1] - 22:7 **unsafe** [1] - 6:7 **up** [7] - 5:20, 10:1,

10:20, 11:18, 16:1, 18:25, 27:8 **urge** [1] - 7:7 **V**

10:20, 11:18, 16:1, 18:25, 27:8 **urge** [1] - 7:7 **V**

10:20, 11:18, 16:1, 18:25, 27:8 **urge** [1] - 7:7 **V**

10:20, 11:18, 16:1, 18:25, 27:8 **urge** [1] - 7:7 **V**

10:20, 11:18, 16:1, 18:25, 27:8 **urge** [1] - 7:7 **V**

**Van** [6] - 3:6, 14:24,

**Van** [6] - 3:6, 14:24,

17:13, 23:16, 23:18, 28:5 **various** [1] - 21:2 **versus** [3] - 3:6, 13:5,  
17:13, 23:16, 23:18, 28:5 **various** [1] - 21:2 **versus** [3] - 3:6, 13:5,  
17:13, 23:16, 23:18, 28:5 **various** [1] - 21:2 **versus** [3] - 3:6, 13:5,

14:11 **view** [4] - 10:22,

14:11 **view** [4] - 10:22,

14:11 **view** [4] - 10:22,

26:14, 28:21, 29:23 **vigilant** [2] - 6:4, 6:5 **violate** [3] - 16:17,

26:14, 28:21, 29:23 **vigilant** [2] - 6:4, 6:5 **violate** [3] - 16:17,

26:14, 28:21, 29:23 **vigilant** [2] - 6:4, 6:5 **violate** [3] - 16:17,

18:8 **violates** [4] - 11:14,

18:8 **violates** [4] - 11:14,

18:8 **violates** [4] - 11:14,

16:8, 16:18 **violation** [4] - 6:2,

16:8, 16:18 **violation** [4] - 6:2,

16:8, 17:11, 18:9 **violations** [4] - 23:17,

16:8, 17:11, 18:9 **violations** [4] - 23:17,

23:19, 29:4, 29:10

23:19, 29:4, 29:10

23:19, 29:4, 29:10

**W**

**W**

**W**

**wants** [4] - 15:8, 18:3,

**wants** [4] - 15:8, 18:3,

**wants** [4] - 15:8, 18:3,

22:11, 22:13 **warrantees** [1] - 8:18 **warranties** [2] - 9:3,

22:11, 22:13 **warrantees** [1] - 8:18 **warranties** [2] - 9:3,

22:11, 22:13 **warrantees** [1] - 8:18 **warranties** [2] - 9:3,

22:11, 22:13 **warrantees** [1] - 8:18 **warranties** [2] - 9:3,

22:11, 22:13 **warrantees** [1] - 8:18 **warranties** [2] - 9:3,  
22:11, 22:13 **warrantees** [1] - 8:18 **warranties** [2] - 9:3,  
22:11, 22:13 **warrantees** [1] - 8:18 **warranties** [2] - 9:3,  
13:8 **warranty** [22] - 8:21, 14:4, 14:9, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 24:3, 25:17, 25:25, 27:1,  
27:2, 27:19, 27:21, 27:23, 28:4, 28:8, 28:15 **weeks** [1] - 21:20 **weigh** [1] - 5:21 **withdraw** [1] -  
6:6 **words** [2] - 8:2, 16:10 **writing** [1] - 22:7  
13:8 **warranty** [22] - 8:21, 14:4, 14:9, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 24:3, 25:17, 25:25, 27:1,  
27:2, 27:19, 27:21, 27:23, 28:4, 28:8, 28:15 **weeks** [1] - 21:20 **weigh** [1] - 5:21 **withdraw** [1] -  
6:6 **words** [2] - 8:2, 16:10 **writing** [1] - 22:7  
13:8 **warranty** [22] - 8:21, 14:4, 14:9, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 24:3, 25:17, 25:25, 27:1,  
27:2, 27:19, 27:21, 27:23, 28:4, 28:8, 28:15 **weeks** [1] - 21:20 **weigh** [1] - 5:21 **withdraw** [1] -  
6:6 **words** [2] - 8:2, 16:10 **writing** [1] - 22:7  
13:8 **warranty** [22] - 8:21, 14:4, 14:9, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 24:3, 25:17, 25:25, 27:1,  
27:2, 27:19, 27:21, 27:23, 28:4, 28:8, 28:15 **weeks** [1] - 21:20 **weigh** [1] - 5:21 **withdraw** [1] -  
6:6 **words** [2] - 8:2, 16:10 **writing** [1] - 22:7  
13:8 **warranty** [22] - 8:21, 14:4, 14:9, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 24:3, 25:17, 25:25, 27:1,  
27:2, 27:19, 27:21, 27:23, 28:4, 28:8, 28:15 **weeks** [1] - 21:20 **weigh** [1] - 5:21 **withdraw** [1] -  
6:6 **words** [2] - 8:2, 16:10 **writing** [1] - 22:7  
13:8 **warranty** [22] - 8:21, 14:4, 14:9, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 24:3, 25:17, 25:25, 27:1,  
27:2, 27:19, 27:21, 27:23, 28:4, 28:8, 28:15 **weeks** [1] - 21:20 **weigh** [1] - 5:21 **withdraw** [1] -  
6:6 **words** [2] - 8:2, 16:10 **writing** [1] - 22:7  
13:8 **warranty** [22] - 8:21, 14:4, 14:9, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 24:3, 25:17, 25:25, 27:1,  
27:2, 27:19, 27:21, 27:23, 28:4, 28:8, 28:15 **weeks** [1] - 21:20 **weigh** [1] - 5:21 **withdraw** [1] -  
6:6 **words** [2] - 8:2, 16:10 **writing** [1] - 22:7  
13:8 **warranty** [22] - 8:21, 14:4, 14:9, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 24:3, 25:17, 25:25, 27:1,  
27:2, 27:19, 27:21, 27:23, 28:4, 28:8, 28:15 **weeks** [1] - 21:20 **weigh** [1] - 5:21 **withdraw** [1] -  
6:6 **words** [2] - 8:2, 16:10 **writing** [1] - 22:7  
13:8 **warranty** [22] - 8:21, 14:4, 14:9, 19:9, 19:15, 19:18, 20:7, 20:18, 24:2, 24:3, 25:17, 25:25, 27:1,  
27:2, 27:19, 27:21, 27:23, 28:4, 28:8, 28:15 **weeks** [1] - 21:20 **weigh** [1] - 5:21 **withdraw** [1] -  
6:6 **words** [2] - 8:2, 16:10 **writing** [1] - 22:7

**Y**  
**Y**  
**Y**

**year** [3] - 5:2, 13:19,  
**year** [3] - 5:2, 13:19,  
**year** [3] - 5:2, 13:19,

14:25 **years** [1] - 4:21 **yesterday** [2] - 13:9,  
14:25 **years** [1] - 4:21 **yesterday** [2] - 13:9,  
14:25 **years** [1] - 4:21 **yesterday** [2] - 13:9,  
14:25 **years** [1] - 4:21 **yesterday** [2] - 13:9,  
14:25 **years** [1] - 4:21 **yesterday** [2] - 13:9,

19:3  
19:3  
19:3

19:3

19:3

Case 2:09-cv-00078-SEH Document 39 Filed 05/14/10 Page 37 of 37