

Exhibit 1

(Hearing) (Hardeman) Hearing (Hardeman v Monsanto Co.) 4/7/2016 10:02:00 AM

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
BEFORE THE HONORABLE VINCE CHHABRIA

EDWIN HARDEMAN,)
)
PLAINTIFF,)
)
VS.) NO. C 3:16-CV-00525-VC
)
MONSANTO COMPANY AND JOHN)
DOES 1-50,)
) SAN FRANCISCO, CALIFORNIA
DEFENDANTS.) THURSDAY
) APRIL 7, 2016

_____)
TRANSCRIPT OF PROCEEDINGS OF THE OFFICIAL ELECTRONIC SOUND
RECORDING 10:02 A.M. - 10:38 A.M.

APPEARANCES:

FOR PLAINTIFF ANDRUS WAGSTAFF, PC
7171 W. ALASKA DRIVE
LAKEWOOD, COLORADO 80226
BY: DAVID J. WOOL, ESQUIRE

FOR DEFENDANTS HOLLINGSWORTH, LLP
1350 I STREET NW
WASHINGTON, D.C. 20005
BY: ERIC G. LASKER, ESQUIRE

REPORTED BY: JOAN MARIE COLUMBINI, CSR #5435, RPR
RETIRED OFFICIAL COURT REPORTER, USDC

(Hearing) (Hardeman) Hearing (Hardeman v Monsanto Co.) 4/7/2016 10:02:00 AM

1 THURSDAY, APRIL 7 , 2016 10:02 A.M.

2 PROCEEDINGS

3 ---000---

4 THE CLERK: CALLING CASE NUMBER 16-CV-00525, HARDEMAN
5 VERSUS MONSANTO COMPANY, ET AL.

6 COUNSEL, PLEASE STEP FORWARD AND STATE YOUR
7 APPEARANCES FOR THE RECORD.

8 MR. LASKER: ERIC LASKER FOR THE DEFENDANT
9 NOVARTIS -- I MEAN MONSANTO. SORRY.

10 THE COURT: HARD TO KEEP THOSE COMPANIES STRAIGHT.

11 MR. WOOL: AND DAVID WOOL FOR THE PLAINTIFF, EDWARD
12 HARDEMAN.

13 THE COURT: GOOD MORNING. SO I GUESS I THINK THAT
14 PERHAPS YOUR STRONGEST ARGUMENT AT THE PLEADING STAGE, ANYWAY,
15 WHICH I THINK YOU PROBABLY STILL LOSE ON --

16 MR. LASKER: YES.

17 THE COURT: -- IS YOUR ARGUMENT THAT THE EPA HAS
18 DETERMINED THAT ROUNDUP OR -- WHAT'S THE CHEMICAL CALLED?

19 MR. LASKER: GLYPHOSATE.

20 THE COURT: -- GLYPHOSATE DOESN'T CAUSE CANCER.

21 AND, I MEAN, I THINK -- I THINK YOU TEND TO OVERSTATE
22 A LITTLE BIT SOME OF THE STATEMENTS THAT EPA HAS MADE ABOUT
23 GLYPHOSATE, BUT MORE IMPORTANTLY, SOME OF THE LESS EQUIVOCAL
24 STATEMENTS THAT THE EPA HAS MADE ABOUT GLYPHOSATE DON'T COME IN
25 THE CONTEXT OF IMPLEMENTING OR INTERPRETING FIFRA.

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1 AND SO I'M NOT SURE HOW THOSE STATEMENTS COULD
2 HAVE -- COULD GIVE RISE TO FIFRA PREEMPTION. I SORT OF THINK
3 IT MIGHT BE DIFFERENT -- IT WAS CURIOUS. HAS ANYBODY -- I
4 WOULD THINK IN A SITUATION LIKE THIS THAT SOME INTEREST GROUP
5 WOULD GO TO EPA AND PETITION EPA TO REQUIRE MONSANTO TO PUT A
6 WARNING ON ITS LABEL ABOUT ROUNDUP BEING CARCINOGENIC.

7 AND I WOULD THINK THAT IF THAT HAPPENED AND EPA SAID,
8 NO, YOU KNOW, WE'VE LOOKED AT THE EVIDENCE, AND WE MADE A
9 DETERMINATION THAT MONSANTO DOESN'T NEED TO PUT THAT TYPE OF
10 LABEL ON ITS -- ON ROUNDUP, THEN, AT LEAST POTENTIALLY, I MIGHT
11 EVEN SAY PROBABLY, THAT WOULD CREATE A PREEMPTION PROBLEM FOR
12 THE PLAINTIFFS. BUT IT DOESN'T SEEM TO ME THAT IN -- AT LEAST
13 IN THE MATERIAL YOU SUBMITTED TO US ABOUT WHAT EPA HAS SAID
14 ABOUT GLYPHOSATE AND ROUNDUP -- AND/OR ROUNDUP, THAT YOU HAVE
15 ANYTHING LIKE THAT HERE. SO I DON'T SEE HOW THERE WOULD BE
16 FIFRA PREEMPTION.

17 MR. LASKER: WELL, YOUR HONOR, I THINK THAT ACTUALLY
18 WE HAVE SUBMITTED SOMETHING THAT'S VERY SIMILAR TO THAT. AND
19 IF YOU LOOK AT, IN PARTICULAR, THE DOCUMENTS WE ATTACHED FOR
20 JUDICIAL NOTICE -- AND THIS WILL BE SPECIFICALLY WITH RESPECT
21 TO -- I'M SORRY -- THE 2002 REGULATORY FINDING, AND THAT WOULD
22 BE IN OUR NOTICE.

23 THE COURT: EXHIBIT C?

24 MR. LASKER: I BELIEVE IT'S C, YES.

25 THE COURT: NO, NO. THAT WAS FOR 2004.

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1 MR. LASKER: NO. I'M SORRY. IT'S EXHIBIT B.

2 THE COURT: EXHIBIT B.

3 MR. LASKER: "B" AS IN BOY.

4 THE COURT: OKAY.

5 MR. LASKER: AND IF YOU LOOK AT THE SECOND PAGE IN
6 THAT DOCUMENT ON THE LEFT-HAND SIDE, THE TOP, RESPONSE TO
7 COMMENTS.

8 THE COURT: RIGHT.

9 MR. LASKER: THERE IS DISCUSSION OF THE NORTHWEST
10 COALITION FOR ALTERNATIVES TO PESTICIDES, AND THIS IS ONE OF
11 THOSE GROUPS THAT YOU -- OF THE TYPE YOU WERE TALKING ABOUT
12 THAT HAS BEEN ARGUING ABOUT CARCINOGENICITY OF GLYPHOSATE AND
13 ROUNDUP FOR MANY YEARS, BACK INTO THE 1990S.

14 AND IN CONNECTION WITH THIS REGULATORY ACTION -- AND
15 JUST TO STEP BACK, WHEN THE EPA'S REQUIREMENT TO LOOK AT THE
16 SAFETY OF GLYPHOSATE IN CONNECTION WITH RESIDUES IS ALSO -- IT
17 IS DONE THROUGH THE FDA REGULATIONS, BUT THEN ALSO FEEDS INTO
18 WHETHER YOU CAN LABEL THE PRODUCT UNDER FIFRA.

19 THE COURT: OKAY. BUT THIS REGULATION -- I'M
20 SORRY -- I MEAN, I -- I'M SORRY TO INTERRUPT YOU, BUT I --

21 MR. LASKER: SURE.

22 THE COURT: I JUST WANT TO SORT OF ESTABLISH AT THE
23 OUTSET THAT THIS -- THIS RULE INVOLVES IMPLEMENTATION OF THE
24 FOOD, DRUG, AND COSMETIC ACT, AND TOLERANCES OF GLYPHOSATE IN
25 VARIOUS CONTEXTS UNDER THE FOOD, DRUG, AND COSMETIC ACT.

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1 SO I'M STILL INTERESTED IN YOU POINTING ME TO THE
2 LANGUAGE IN THIS RULE THAT SORT OF STANDS FOR THE PROPOSITION
3 THAT THE EPA'S MADE A FINAL DETERMINATION THAT GLYPHOSATE IS
4 NOT CARCINOGENIC. BUT EVEN IF YOU POINT ME TO THAT, I REALLY
5 WONDER IF A RULE ENACTED PURSUANT TO THE FOOD, DRUG, AND
6 COSMETIC ACT COULD SERVE AS THE BASIS FOR A CONCLUSION THAT A
7 STATE LAW CLAIM IS PREEMPTED BY FIFRA.

8 MR. LASKER: RIGHT. I UNDERSTAND, YOUR HONOR.

9 AND I THINK THE CONNECTION THERE, YOUR HONOR, IS THAT
10 EPA, ALTHOUGH IT -- ALTHOUGH THE REGULATION DOES COME IN UNDER
11 THE FDA, UNDER THE FOOD, DRUG, AND COSMETIC ACT, THE STATUTE
12 HAS PROVIDED THAT INSTEAD EPA MAKES THAT ASSESSMENT BECAUSE
13 IT'S EPA THAT THEN WILL BE MAKING REGULATORY DETERMINATIONS
14 WITH RESPECT TO THE PESTICIDE, INCLUDING THE LABELING
15 DETERMINATIONS.

16 AND AS YOU POINTED OUT, YOUR HONOR, IT'S WELL
17 ESTABLISHED EPA HAS APPROVED THE LABEL OF ALL THE ROUNDUP
18 PRODUCTS FOR 25 YEARS, INCLUDING AS RECENTLY AS THIS PAST YEAR.
19 AND THEY ARE REQUIRED, UPON APPROVING THE LABEL, TO MAKE A
20 SAFETY AND HEALTH ASSESSMENT, AND THAT HAS TO BE INCORPORATED
21 IN THE LABEL.

22 THE COURT: THEN YOU GET BACK TO THE FIFRA STATUTE,
23 WHICH SAYS THAT EPA APPROVAL DOESN'T PRECLUDE A LAWSUIT BY A
24 PRIVATE ENTITY FOR VIOLATION OF THE STATUTE.

25 MR. LASKER: WELL, NO, I DON'T THINK IT SAYS THAT.

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1 WHAT THE STATUTE SAYS --

2 THE COURT: OR BATES INTERPRETATION OF THE STATUTE.

3 MR. LASKER: WHAT THE STATUTE STATES IS THAT

4 REGISTRATION ALONE IS NOT A DEFENSE, BECAUSE THERE'S A

5 CONTINUING OBLIGATION.

6 BUT IT ALSO STATES THAT APPROVAL --

7 THE COURT: DOES IT SAY BECAUSE THERE'S A CONTINUING

8 OBLIGATION, OR DOES IT JUST SAY BECAUSE THERE'S A DEFENSE, AND

9 THEN YOU'VE ADDED THE WORD -- IT JUST SAYS IT'S NOT A DEFENSE,

10 AND YOU'VE ADDED THE WORDS, "BECAUSE THERE'S A CONTINUING

11 OBLIGATION."

12 MR. LASKER: WELL, THAT IS HOW BATES INTERPRETS IT

13 WHEN BATES TALKS ABOUT THE FACT THAT THERE IS CONTINUING

14 OBLIGATIONS ON THE APPLICANT THAT GIVES RISE TO THE MISBRANDING

15 STANDARD. THAT'S HOW IT'S INTERPRETED IN BATES. AND WHAT

16 FIFRA STATUTE STATES IS THAT UNLESS THERE IS A REVOCATION

17 PROCEEDING GOING ON, THE APPROVAL REMAINS PRIMA FACIE EVIDENCE

18 OF APPROVAL. SO THERE'S THIS UNDERSTANDING THAT WHAT THE

19 OBLIGATION IS, WHICH MAKES SENSE, IS THAT --

20 THE COURT: AND SO MAYBE THE APPROVAL, GIVEN IT'S

21 PRIMA FACIE EVIDENCE OF LEGITIMACY OR PRIMA FACIE EVIDENCE THAT

22 THE LABEL DOESN'T VIOLATE THE FIFRA STATUTE, MAYBE THAT'S GOING

23 TO BE VERY HELPFUL FOR YOU AT SUMMARY JUDGMENT. BUT I DON'T

24 SEE, WHEN GIVEN THEIR ALLEGATIONS, WHICH WE HAVE TO ACCEPT AS

25 TRUE, I DON'T SEE HOW THAT HELPS YOU AT THE PLEADING STAGE.

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1 MR. LASKER: WELL, YOUR HONOR, I WOULD SAY THAT IT IS
2 PRIMA FACIE EVIDENCE THAT IT CONTINUES TO BE VALID. WHEN THERE
3 IS AN APPROVAL OF THE LABEL AT THE TIME OF THE APPROVAL,
4 THOUGH, EPA CANNOT APPROVE A LABEL AND WILL NOT APPROVE A LABEL
5 UNLESS IT DETERMINES THAT LABEL DOES NOT CONSTITUTE
6 MISBRANDING.

7 SO THERE'S TWO POSSIBLE SCENARIOS HERE.

8 YOU COULD HAVE A SCENARIO WHERE A LABEL WAS APPROVED.
9 AS OF THE TIME IT WAS APPROVED, EPA DETERMINES THAT'S NOT
10 MISBRANDING, AND THAT FINDING REMAINS PRIMA FACIE EVIDENCE
11 GOING FORWARD.

12 BUT IN THIS SITUATION, WE ARE FACED WITH EPA APPROVAL
13 OF THE LABEL THAT POSTDATES THE EXPOSURE, THAT POSTDATES THE
14 INJURY, AND AS OF THE DATE OF THOSE APPROVALS, EPA HAS MADE THE
15 DETERMINATION THIS LABEL IS NOT -- IS NOT MISBRANDED. SO AS OF
16 THE TIME --

17 THE COURT: AND THAT'S PRIMA FACIE EVIDENCE THAT IT'S
18 NOT A VIOLATION. I MEAN, I THINK THAT'S THE ANSWER. IT'S
19 PRIMA FACIE EVIDENCE, BUT IT'S NOT -- IT'S NOT PROOF THAT IT'S
20 NOT A VIOLATION. IT'S NOT --

21 MR. LASKER: WELL --

22 THE COURT: I MEAN --

23 MR. LASKER: I GUESS I WOULD DIFFER, YOUR HONOR. IT
24 GOES BACK TO SOME OF THE ANALYSES I KNOW THAT YOU'VE MADE IN
25 SOME OTHER CASES WITH PREEMPTION. THE ISSUE IS WHETHER OR NOT

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1 THE REQUIREMENT THAT WOULD BE IMPOSED UNDER STATE LAW HERE IS
2 DIFFERENT OR IN ADDITION TO FEDERAL REQUIREMENTS UNDER -- UNDER
3 FIFRA. AND SO THERE WOULD HAVE TO BE A FINDING HERE THAT IT IS
4 MISBRANDING UNDER THE FIFRA STATUTE.

5 THE COURT: AND YOU AGREE IT CAN HAPPEN EVEN WHEN THE
6 EPA HAS APPROVED A LABEL, RIGHT? YOU HAVE TO AGREE WITH THAT.

7 MR. LASKER: I WOULD NOT AGREE THAT IT CAN HAPPEN AS
8 OF THE TIME OF EPA APPROVES THE LABEL.

9 THE COURT: WHAT ABOUT THE NEXT DAY?

10 MR. LASKER: IF IT'S NEXT DAY, YES, IF THERE'S MORE
11 INFORMATION THAT'S COME FORWARD.

12 BUT WHAT WE HAVE HERE IS A LABEL THAT WAS APPROVED
13 AFTER ALL THE EXPOSURE TOOK PLACE.

14 THE COURT: SEE, I DON'T THINK THAT'S WHAT THAT
15 LANGUAGE IN THE STATUTE MEANS. I MEAN, I DON'T -- WHERE IN THE
16 STATUTE -- WHERE IN THE STATUTE OR WHERE IN BATES DOES IT SAY
17 THAT IT'S ONLY THAT -- THAT APPROVAL OF A LABEL IS A DEFENSE
18 FOR ANYTHING THAT HAPPENED PRIOR TO APPROVAL OF THE LABEL?

19 MR. LASKER: YOUR HONOR --

20 THE COURT: WHERE DOES IT SAY THAT IN BATES OR IN THE
21 STATUTE?

22 MR. LASKER: YOUR HONOR, AGAIN, I WOULD CITE TO 40
23 CFR SECTION 152.112(F), WHICH IS A STATUTORY PROVISION --

24 THE COURT: SAY IT ONE MORE TIME.

25 MR. LASKER: I'M SORRY. 40 CFR SECTION 152.112(F).

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1 THE COURT: OKAY.

2 MR. LASKER: AND THE STATEMENT THERE IS THAT:

3 (AS READ) "IF THE AGENCY HAS

4 DETERMINED THAT THE PRODUCT IS NOT MISBRANDED

5 AS THAT TERM IS DEFINED IN FIFRA AND ITS

6 LABELING AND PACKAGING COMPLY WITH THE

7 APPLICABLE REQUIREMENTS OF THE ACT."

8 NOW, THAT IS EPA'S DETERMINATION THAT.

9 THE COURT: COULD YOU READ -- COULD YOU READ THAT --

10 MR. LASKER: SURE.

11 THE COURT: -- ONE MORE TIME.

12 MR. LASKER: "EPA WILL APPROVE A PESTICIDE

13 APPLICATION ONLY IF 'THE AGENCY' HAS DETERMINED THAT

14 THE PRODUCT IS NOT MISBRANDED AS THAT TERM IS DEFINED

15 IN FIFRA, AND ITS LABELING AND PACKAGING COMPLY WITH

16 THE APPLICABLE REQUIREMENTS OF THE ACT."

17 AND THAT'S THE KEY TERM HERE.

18 THE COURT: RIGHT. BUT I GUESS THE STATUTE

19 CONTEMPLATES THAT EVEN IF THE AGENCY APPROVES A LABEL, SOMEONE

20 CAN STILL BRING SUIT TO SAY THAT THE LABEL IS -- INVOLVES

21 MISBRANDING, SO --

22 MR. LASKER: I WOULD NOT AGREE WITH SOMEBODY CAN

23 BRING SUIT. IT ALLOWS EPA TO COME BACK AND MAKE A

24 DETERMINATION. THERE'S NOTHING IN THE STATUTE THAT SAYS A

25 PLAINTIFF --

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1 THE COURT: BUT IT SAYS THE APPROVAL IS NOT A
2 DEFENSE. RIGHT? SO THE FEDS COULD SUE DIRECTLY UNDER FIFRA
3 OR -- AND WE KNOW BECAUSE OF THE PREEMPTION PROVISION THAT
4 PRIVATE INDIVIDUALS CAN SUE UNDER STATE LAW.

5 MR. LASKER: BUT THERE WOULD HAVE TO BE A FEDERAL
6 REQUIREMENT -- ONCE EPA HAS MADE -- AND, AGAIN, THE LANGUAGE IS
7 A REQUIREMENT -- EPA HAS MADE THIS DETERMINATION THAT THE LABEL
8 COMPLIES WITH THE REQUIREMENTS OF THE ACT -- AND THIS IS AFTER
9 THE EXPOSURE HERE.

10 AND PLAINTIFFS ARE ALLEGING AT THAT TIME, NO, THAT
11 VIOLATES STATE LAW, THE REQUIREMENTS OF STATE LAW, WHEN EPA, A
12 FEDERAL AGENCY, HAS DETERMINED IT DOES NOT VIOLATE THE
13 REQUIREMENTS OF THIS ACT. THAT'S WHERE YOU HAVE -- WHERE YOU
14 HAVE A CONFLICT. AND THAT'S EXACTLY THE CONFLICT THAT IS SET
15 FORTH IN THE PREEMPTION PROVISION.

16 IF THAT WERE NOT THE CASE, THEN THERE WOULD NOT BE
17 ANY REQUIREMENTS UNDER THE ACT AT ALL. YOU WOULD NEVER HAVE
18 PREEMPTION. WE KNOW THAT'S WRONG. BATES CLEARLY MAKES CLEAR
19 THERE ARE CLAIMS THAT WILL BE PREEMPTED.

20 SO THAT ARGUMENT, YOUR HONOR, IT PROVES TOO MUCH. IT
21 BASICALLY TAKES PREEMPTION OUT OF THE PICTURE ALL TOGETHER, AND
22 THAT'S CLEARLY CONTRARY TO WHAT BATES HOLDS.

23 THE COURT: I MEAN, THE LABEL THAT WAS APPROVED IN
24 BATES, I MEAN, WOULDN'T THAT -- WOULDN'T THE SAME ARGUMENT
25 APPLY THAT UNDER THE REGULATION THAT YOU JUST CITED TO ME, THAT

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1 EPA MADE A DETERMINATION THAT THE LABEL DIDN'T VIOLATE THE ACT,
2 AND, THEREFORE, THERE COULD NOT BE -- WOULDN'T THE SUPREME
3 COURT HAVE HAD TO CONCLUDE THAT THE STATE LAW CLAIM IN THAT
4 CASE WAS PREEMPTED BASED ON THE REGULATION YOU JUST CITED TO
5 ME?

6 MR. LASKER: WELL, WHAT THE SUPREME COURT IS REMANDED
7 ON THAT QUESTION, BECAUSE THE EVIDENCE HADN'T -- THE ARGUMENT
8 HADN'T BEEN PRESENTED. ON THE FAILURE-TO-WARN CLAIM, THE --
9 AND ON THE FRAUD -- MISREPRESENTATION CLAIM, THE SUPREME COURT
10 REMANDED --

11 THE COURT: NO. THE COURT REMANDED ON THE SCOPE OF
12 THE STATE LAW CLAIM, LIKE HOW BROAD IS THE STATE LAW CLAIM AND
13 DOES IT EXCEED THE SCOPE OF FIFRA. IT DIDN'T REMAND ON THE
14 QUESTION OF WHETHER THAT REGULATION THAT YOU QUOTED TO ME
15 REQUIRES A CONCLUSION THAT THE STATE LAW CLAIMS ARE PREEMPTED.

16 I THINK THE ARGUMENT THAT YOU JUST MADE TO ME IS
17 DIRECTLY CONTRARY TO BATES, BECAUSE THE SUPREME COURT IN BATES
18 WOULD HAVE HAD TO APPLY YOUR REGULATION TO CONCLUDE THAT THE
19 LABEL IN BATES WAS -- WAS CONSISTENT WITH FIFRA AND THEN THE
20 STATE LAW CLAIM ATTACKING IT WAS PREEMPTED. RIGHT?

21 MR. LASKER: IT WOULD HAVE, YOUR HONOR, IF IT WERE
22 REPRESENTED TO THE SUPREME COURT, AS THERE IS IN THIS CASE,
23 THAT EPA HAD REVIEWED THE LABEL, REVIEWED THE ISSUE, THE
24 LABELING CLAIM AT ISSUE IN THAT CASE, WHICH THE SUPREME COURT
25 HELD IN BATES WAS -- HAD NOT HAPPENED BECAUSE IT WAS AN

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1 EFFICACY CLAIM, AND EPA DOES NOT DO EFFICACY ISSUES. THAT WAS
2 PART OF THE BATES FINDING AS WELL.

3 BUT IF THERE HAD BEEN A RECORD IN BATES THAT EPA HAD
4 REVIEWED THIS LABELING CLAIM AND HAD APPROVED IT, THEN, YES,
5 YOUR HONOR, I THINK UNDER BATES, THAT CASE, THE CLAIM WOULD
6 HAVE BEEN PREEMPTED. THE SUPREME COURT DID NOT HAVE THAT
7 RECORD.

8 THE COURT: HOW DID THE LABEL EXIST IF EPA HADN'T
9 REVIEWED AND APPROVED IT?

10 MR. LASKER: WELL, THE ISSUE IN -- THE LABEL WAS
11 APPROVED AT SOME POINT IN TIME, BUT THE QUESTION IS: WHAT IS
12 WITHIN THE SCOPE OF WHAT EPA HAS IMPOSED AS REQUIREMENTS UNDER
13 THAT LABEL? OKAY?

14 SO EPA DOES NOT REVIEW -- SO, FOR EXAMPLE, YOU DEALT
15 WITH ISSUES, FOR EXAMPLE, ON WHETHER OR NOT A PRODUCT IS ALL
16 NATURAL, RIGHT? UNDER THE FOOD, AND, DRUG, AND COSMETIC ACT.
17 AND IF THE FDA DOESN'T REACH THAT ISSUE, THEN THERE IS NO FDA
18 FINDING -- THEY'VE APPROVED THE LABEL, BUT THEY DON'T ADDRESS
19 THAT ISSUE OF ALL NATURAL, THEY DON'T REACH THAT ISSUE, AND,
20 THEREFORE, THERE'S NO FEDERAL REQUIREMENT.

21 HERE WE'RE DEALING WITH A SITUATION THAT IS SQUARELY
22 WITHIN THE SCOPE OF WHAT THE EPA IS DETERMINING. WHETHER OR
23 NOT THERE IS A CANCER RISK IS SPECIFICALLY PART OF EPA'S CHARGE
24 IN APPROVING THE LABELING. AND SO THAT IS SOMETHING THAT THEY
25 DIRECTLY ADDRESS AND HAVE DIRECTLY ADDRESSED REPEATEDLY.

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1 AND, ALSO -- AND WE'LL GET BACK TO THIS, YOUR HONOR,
2 IN RESPONSE TO A CITIZEN PETITION, ARGUMENT FROM THIS NORTHWEST
3 COALITION IN WHICH THAT GROUP BROUGHT TOGETHER -- BROUGHT
4 FORWARD ALL THE EVIDENCE THAT THEY ARGUED POINTED TO
5 CARCINOGENICITY. EPIDEMIOLOGY STUDIES, YOU KNOW, TOXICOLOGY
6 STUDIES, ALL THE EVIDENCE, THEY SAID, EPA, LOOK AT THIS, THIS
7 SHOWS IT'S A CARCINOGEN, AND EPA LOOKED AT IT AND SAID, NO, IT
8 DOESN'T, WE DISAGREE WITH YOU. SO THE EXACT SORT OF FACT
9 PATTERN YOU WERE SAYING.

10 AND IN THIS CASE, BECAUSE THE PLAINTIFF IS ALLEGING
11 EXPOSURES FROM 1980'S FORWARD, THAT EPA DETERMINATION IN 2002
12 POSTDATED, AT LEAST AS FAR AS WE KNOW, ALL THE EXPOSURES IN
13 THIS CASE.

14 SO THERE IS A SPECIFIC EPA FINDING UNLIKE IN BATES,
15 UNLIKE IN THE ALL NATURAL --

16 THE COURT: WHERE'S THE FINDING IN EXHIBIT B?

17 MR. LASKER: OKAY. SO IF WE GO TO EXHIBIT B, THERE
18 ARE A NUMBER OF DISCUSSIONS. SO IF YOU GO TO THE THIRD PAGE
19 THEN -- OR, ACTUALLY, ON THE SAME PAGE. WE'LL START ON THE
20 SAME THAT YOU WERE --

21 THE COURT: IS THIS WHOLE THING ABOUT GLYPHOSATE?

22 MR. LASKER: YES.

23 THE COURT: OKAY. THIS WHOLE THING IS ABOUT
24 GLYPHOSATE?

25 MR. LASKER: YES.

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1 THE COURT: ALL RIGHT.

2 MR. LASKER: AND IT IS FOR A VARIETY OF DIFFERENT

3 USES. IN GRASS, ACTUALLY.

4 SO THE ISSUE ON -- FEDERAL REGISTER AT 60935, THE

5 SAME PAGE WE WERE ON.

6 THE COURT: OKAY.

7 MR. LASKER: BUT NOW WE'RE IN THE RIGHT-HAND COLUMN.

8 THE COURT: OKAY.

9 MR. LASKER: THE VERY RIGHT-HAND SIDE COLUMN.

10 THERE IS AN ISSUE OF GENOTOXICITY AND MUTAGENICITY.

11 AND THE PLAINTIFFS IN THIS CASE POINT TO GENOTOXICITY AS PART

12 OF THEIR EVIDENCE THAT'S IN THEIR COMPLAINT -- OF VARIOUS

13 STUDIES.

14 AND SO THE COMMENT IS THE NORTHWEST COALITION END CAP

15 ARGUMENTS ABOUT HOW THERE ARE ALL THESE OTHER STUDIES THAT

16 POINT TO GENOTOXICITY. AND IF YOU GO DOWN THE LIST AND IF YOU

17 KEEP READING DOWN THIS COLUMN, IT'S THE SAME STUDIES, MANY OF

18 THE SAME STUDIES THAT ARE EVEN MENTIONED IN THE COMPLAINT IN

19 THIS CASE, THAT THE -- THAT END CAP SAYS: THIS SHOWS

20 GENOTOXICITY.

21 AND EPA GOES THROUGH ALL OF THOSE STUDIES AND EXPLAIN

22 WHY THEY REJECT THE ARGUMENT THAT THIS -- THAT THIS SHOWS

23 GENOTOXICITY, WHICH END CAP AND PLAINTIFFS HERE ARGUE IS

24 EVIDENCE ALSO OF CARCINOGENICITY.

25 LET ME KNOW WHEN YOU'RE DONE. I'LL TAKE YOU TO THE

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1 NEXT SECTION.

2 THE COURT: GIVE ME ONE QUICK SECOND.

3 MR. LASKER: OKAY.

4 THE COURT: I MEAN, IF YOU LOOK -- IF YOU LOOK AT THE
5 PARAGRAPH, THE FINAL PARAGRAPH IN SECTION 2, IT SEEMS TO BE
6 SAYING THAT, YOU KNOW, THESE STUDIES HAVE NOT DONE ENOUGH TO
7 ALLOW US TO CONCLUDE THAT ROUNDUP MIGHT BE CARCINOGENIC, BUT IS
8 THERE A DEFINITIVE -- IS THERE A DEFINITIVE STATEMENT --

9 MR. LASKER: YES, YOUR HONOR.

10 THE COURT: -- BY THE EPA THAT IT'S NOT CARCINOGENIC?

11 MR. LASKER: YES, YOUR HONOR. IN THIS DOCUMENT ON
12 PAGE 60943, IN THE TABLE, THE BOTTOM BLOCK TO THE RIGHT --

13 THE COURT: NO EVIDENCE OF CARCINOGENICITY.

14 MR. LASKER: NO EVIDENCE OF CARCINOGENICITY.

15 THE COURT: BUT TO SAY NO EVIDENCE, I MEAN, THAT SORT
16 OF BEGS THE QUESTION, RIGHT? I MEAN, IT DEPENDS ON THE QUALITY
17 OF THE STUDIES. I MEAN, THERE COULD BE NO EVIDENCE OF -- THAT
18 SOMETHING CAUSES CANCER BECAUSE WE HAVEN'T HAD THE TIME TO DO
19 SUFFICIENT LONGITUDINAL STUDIES YET. THERE COULD BE -- OR IT
20 COULD BE THERE'S NO EVIDENCE AFTER COMBING THROUGH, YOU KNOW, A
21 BUNCH OF RELIABLE DATA.

22 SO THAT STATEMENT ON ITS OWN -- YOU KNOW, IN ADDITION
23 TO THE FACT THAT IT'S IN A DOCUMENT THAT IS IMPLEMENTING OR
24 ADMINISTERING A DIFFERENT STATUTE --

25 MR. LASKER: RIGHT.

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1 THE COURT: -- YOU KNOW, AT LEAST BEGS THE QUESTION A
2 LITTLE BIT, YOU KNOW.

3 MR. LASKER: YES, YOUR HONOR, ALTHOUGH I WOULD SAY
4 THAT THE ISSUE IS NOT -- AND THE REASON WE'RE SUBMITTING THIS
5 IS NOT THAT EPA HAS ESTABLISHED THAT GLYPHOSATE CANNOT CAUSE
6 CANCER. WE BELIEVE THAT'S TRUE AND THE SCIENCE WILL SHOW THAT.

7 THE ISSUE HERE, THOUGH, IS: IS THERE EVIDENCE BY
8 WHICH EPA WOULD REQUIRE A LABEL, AND IF EPA SAYS THERE'S NO
9 EVIDENCE THAT WILL MAKE US A REQUIRE A LABEL, THERE'S NO
10 SUFFICIENT EVIDENCE FOR US TO MAKE THIS FINDING, THAT'S THE
11 ISSUE HERE. IT DOESN'T HAVE TO BE EPA SAYING IT CANNOT --

12 THE COURT: HAS ANYBODY GONE -- HAS THERE BEEN ANY
13 PROCEEDING IN EPA WHERE SOMEBODY'S GONE AND SAID, YOU NEED TO
14 MAKE MONSANTO LABEL IT ITS PRODUCT AS CARCINOGENIC?

15 MR. LASKER: WELL, THAT HAS HAPPENED ORIGINALLY IN
16 THE ORIGINAL REGISTRATION WHERE THEY WENT THROUGH THAT PROCESS

17 THE COURT: IN THE WHAT?

18 MR. LASKER: IN THE ORIGINAL REGISTRATION WHEN THEY
19 WENT THROUGH THAT PROCESS.

20 THERE'S AN ONGOING REVIEW RIGHT NOW, YOUR HONOR, IN
21 WHICH EPA IS ALSO LOOKING AT THAT, AND THE OTHER REGULATORY
22 AGENCIES AROUND THE WORLD HAVE BEEN LOOKING AT THAT.

23 THE COURT: THERE'S AN ONGOING REVIEW WITHIN EPA OF
24 WHETHER ROUNDUP IS CARCINOGENIC?

25 MR. LASKER: YEAH, THAT'S GOING ON RIGHT NOW. IT'S

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1 NOT -- IT'S NOT --

2 THE COURT: IF THEY'D ALREADY CONCLUDED IT'S NOT
3 CARCINOGENIC, WHY WOULD THEY BE IN THE MIDDLE OF A REVIEW TO
4 DECIDE WHETHER ROUNDUP IS CARCINOGENIC?

5 MR. LASKER: IT'S PART OF THE STATUTE, AND IT'S NOT
6 SPECIFIC TO GLYPHOSATE, YOUR HONOR. ALL PESTICIDES ARE GOING
7 THROUGH A REREVIEW PROCESS. THEY HAVE TO GO THROUGH IT AT A
8 CERTAIN PERIOD OF TIME. AND SO GLYPHOSATE IS IN THAT PROCESS
9 NOW, AS IT'S NOT UNIQUE TO GLYPHOSATE.

10 THE COURT: AND IT'S -- IS THAT SORT OF IN THE FIFRA
11 CONTEXT?

12 MR. LASKER: YES.

13 THE COURT: OR IN THE CONTEXT OF HOW PEOPLE SHOULD BE
14 LABELING THESE PRODUCTS?

15 MR. LASKER: THAT IS IN THE FIFRA CONTEXT.

16 BUT, AGAIN, YOUR HONOR, EVERY TIME THAT MONSANTO
17 FORMULATES A NEW PRODUCT -- AND THIS MAKES THIS DIFFERENT, FOR
18 EXAMPLE, A PHARMACEUTICAL. YOU HAVE A PHARMACEUTICAL, YOU GET
19 LABEL APPROVAL, IT'S A ONE-TIME DEAL.

20 WITH ROUNDUP, EVERY TIME THEY CHANGE THE
21 FORMULATION -- AND THEY'VE DONE THIS DOZENS OF TIMES -- THEY
22 HAVE TO SUBMIT AN APPLICATION TO EPA TO GET APPROVAL OF THE NEW
23 LABEL. AND TO THE EXTENT EPA REQUIRES ANY ADDITIONAL SAFETY
24 INFORMATION WITH RESPECT TO THAT FORMULATION, IT HAS TO SUBMIT
25 NEW SAFETY INFORMATION. EPA HAS TO MAKE ANOTHER FINDING THAT

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1 THIS LABEL IS -- MEETS THE FIFRA REQUIREMENTS. AND THAT'S BEEN
2 HAPPENING, AS WE'VE SAID, DOZENS OF TIMES. HAPPENED AS
3 RECENTLY AS 2005 THE LAST TIME, JUST BY COINCIDENCE.

4 SO EPA IS CONTINUING TO MAKE THESE FINDINGS IN THE
5 LABELING CONTEXT SPECIFICALLY AND HAS BEEN, YOU KNOW, FOR 25
6 YEARS, WELL AFTER ANY OF THE EXPOSURES IN THIS CASE.

7 AND THAT IS -- AGAIN, EPA HAS -- THE ISSUE HERE, YOUR
8 HONOR, IS EPA MAKES THOSE LABELING DETERMINATIONS, MAKES THOSE
9 LABELING DETERMINATIONS UNDER FIFRA, IN THE CONTEXT OF HAVING
10 LOOKED AT THE SCIENTIFIC EVIDENCE WITH RESPECT TO GLYPHOSATE
11 AND CANCER AGAIN AND AGAIN AND AGAIN OVER 25 YEARS.

12 NOW, I RECOGNIZE, YOUR HONOR, THE POINT YOU'RE TRYING
13 TO MAKE -- THAT YOU'RE MAKING ABOUT WHETHER OR NOT EPA WAS
14 LOOKING AT THE CANCER EVIDENCE IN THESE INDIVIDUAL INSTANCES IN
15 THE CONTEXT OF A FIFRA OR IN THE CONTEXT OF FDCA.

16 BUT EPA CANNOT MAKE A LABELING DETERMINATION AND
17 APPROVE A LABEL IN 2015 BASED UPON ITS SCIENTIFIC EVALUATION OF
18 GLYPHOSATE AND APPROVE THAT LABEL WITHOUT A CANCER WARNING IF
19 EPA DETERMINES THAT THERE SHOULD BE A REQUIREMENT OF A CANCER
20 WARNING.

21 THE COURT: AND I HAVE TO TELL YOU THAT ON A -- ON AN
22 INTUITIVE LEVEL, ON A COMMON SENSE LEVEL, I THINK YOUR ARGUMENT
23 HAS A LOT OF FORCE. IT'S NOT AS IF THE ALLEGATION THAT ROUNDUP
24 CAUSES CANCER IS A BIG SECRET OR SOMETHING. AND EVEN IF
25 SOMEBODY HASN'T SPECIFICALLY PETITIONED THE EPA TO REQUIRE

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1 MONSANTO TO CHANGE THE LABEL ON ITS ROUNDUP PRODUCT, ASSUMING
2 SUCH A PROCESS EXISTS, IT'S NOT LIKE THE PEOPLE AT EPA HAVE
3 THEIR HEAD IN THE SAND TO THIS ISSUE, AND THEY'VE -- YOU KNOW,
4 THEY'VE CONTINUED TO APPROVE THE LABEL, NOTWITHSTANDING THAT.
5 AND I THINK, AS A COMMONSENSE MATTER, LIKE THAT TELLS US A LOT.

6 BUT YOU HAVE THE STATUTE THAT SAYS, YOU KNOW, THAT
7 THE APPROVAL OF A LABEL ISN'T A DEFENSE, AND IT'S -- YOU KNOW,
8 LIKE I SAID, I THINK THIS IS GOING TO HELP YOU A TREMENDOUS
9 AMOUNT AT SUMMARY JUDGMENT, AND, YOU KNOW, MY SENSE IS THAT
10 THEY HAVE A -- YOU KNOW, THEY -- THEY'RE GOING TO HAVE A NUMBER
11 OF PRETTY BIG PROBLEMS AS THIS CASE GOES FORWARD, BUT I JUST --
12 I'M NOT SEEING HOW -- I'M JUST NOT -- I'M NOT SEEING HOW IT
13 COULD BE DISMISSED AT THIS STAGE.

14 MR. LASKER: WELL, YOUR HONOR, LET ME SUGGEST IN THE
15 GITSON CASE WHERE YOU ARE FACED WITH OBVIOUSLY A DIFFERENT
16 QUESTION --

17 THE COURT: WHICH CASE?

18 MR. LASKER: THE GITSON, THE GITSON VERSUS TRADER'S
19 JOES CASE THAT YOU DECIDED ON THE ISSUE OF SOY MILK AND WHETHER
20 OR NOT THE CLAIM A LABEL SHOULD NOT SAY SOY MILK BECAUSE THAT'S
21 DECEPTIVE.

22 I DON'T BELIEVE.

23 THE COURT: I'M SEARCHING IN MY BRAIN TO TRY TO
24 FIGURE OUT HOW THAT CASE IS RELEVANT TO THIS CASE.

25 MR. LASKER: WELL, YOUR HONOR, I'D SAY THIS, BECAUSE

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1 THERE WASN'T ANY FDA FINDING. THERE WAS A QUESTION OF WHETHER
2 OR NOT THAT LABEL OR THAT CLAIM WOULD BE VIOLATION OF A
3 FEDERAL --

4 THE COURT: YEAH, BUT THAT'S A TOTALLY DIFFERENT
5 STANDARD, AND IT'S A DIFFERENT STATUTE, AND THE QUESTION IS
6 WHETHER ANY CONSUMER WOULD BELIEVE THAT SOY MILK COMES FROM A
7 COW. AND THE CONCLUSION AT THE PLEADING STAGE WAS THAT, NO,
8 YOU KNOW, IT'S IMPLAUSIBLE TO BELIEVE THAT SOMEBODY WOULD
9 BELIEVE THAT SOY MILK COMES FROM A COW BASED ON THE FACT THAT
10 IT CONTAINS THE WORD "MILK" IN IT.

11 WHAT DOES THAT HAVE TO DO WITH ANY OF THIS?

12 MR. LASKER: I RECOGNIZE THAT, YOUR HONOR. BUT YOUR
13 HONOR, YOU DID NOT GO TO THE FRAUDULENT CLAIM STATUTE, YOU
14 STOPPED BEFORE THEN AND SAID FIRST QUESTION IS PREEMPTION. THE
15 ONLY POINT HERE AS TO HOW I THINK IT'S RELEVANT IS THAT IT
16 INFORMS THE DECISION, WOULD THE FEDERAL GOVERNMENT VIEW THIS AS
17 BEING VIOLATIVE OF A FEDERAL REQUIREMENT.

18 THE STATUTE THERE IS SOMEWHAT DIFFERENT LANGUAGE, BUT
19 IT'S --

20 THE COURT: BUT THAT'S NOT THE QUESTION. I MEAN,
21 THAT'S ACTUALLY NOT THE PREEMPTION QUESTION, WOULD THE FEDERAL
22 GOVERNMENT VIEW THIS AS VIOLATIVE OF A REQUIREMENT. THAT'S NOT
23 THE QUESTION THAT I HAVE TO ANSWER.

24 MR. LASKER: WELL, YOUR HONOR, I SUBMIT THAT IT IS,
25 BECAUSE IF A STATE --

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1 THE COURT: THE QUESTION IS WHETHER FEDERAL LAW
2 PREVENTS A PRIVATE INDIVIDUAL FROM BRINGING A STATE LAW CAUSE
3 OF ACTION ALLEGING THAT A LABEL VIOLATES THE FEDERAL
4 REQUIREMENT. AND THE QUESTION IS WHETHER -- IS THERE ANYTHING
5 THAT HAS THE FORCE OF LAW THAT PREVENTS THE PRIVATE INDIVIDUAL
6 FROM PURSUING THAT STATE LAW CLAIM.

7 MR. LASKER: YES, YOUR HONOR. I WOULD SUBMIT THAT
8 WHAT PREVENTS IT IS WHAT IS MEANT BY THE FEDERAL REQUIREMENT.
9 HOW DO YOU DETERMINE -- WHAT BATES SAID IS THAT YOU HAVE TO
10 LOOK NOT ONLY AT THE REGULATIONS THEMSELVES, BUT THE ACTIONS
11 THAT GIVE CONTENT TO THOSE REGULATIONS IN THE INDIVIDUAL
12 INSTANCE.

13 SO IF YOU'RE LOOKING AT WHAT ACTIONS GIVE CONTENT TO
14 THAT, IT HAS BE -- I DON'T KNOW WHAT ELSE IT COULD BE -- BUT
15 THE FEDERAL REGULATORY DETERMINATIONS ABOUT WHAT REQUIREMENTS
16 ARE IMPOSED UPON THAT MANUFACTURER.

17 IF YOU SEPARATE OUT THE QUESTION OF WHAT A FEDERAL
18 THE REQUIREMENT IS FROM WHAT THE FEDERAL AGENCY HAS DETERMINED
19 THEN YOU WOULD NEVER HAVE PREEMPTION. THE WHOLE IDEA OF
20 PREEMPTION, EVERY CASE YOU LOOK AT, IF YOU LOOK AT CASES THAT
21 DEAL WITH FEDERAL PREEMPTION IN THE EXPRESS PREEMPTION CONTEXT,
22 IF IT'S UNDER THE MEDICAL DEVICE ACT, IF IT'S UNDER THE
23 (UNINTELLIGIBLE) ACT, IT'S ALWAYS SAYING, OKAY, WELL, WHAT HAS
24 EPA OR WHAT HAS FDA SAID WITH RESPECT TO THIS PRODUCT? WHAT
25 HAVE THEY IMPOSED AS REQUIREMENTS? THAT'S ALWAYS THE ANALYSIS

(Hearing) (Hardeman) Hearing (Hardeman v Monsanto Co.) 4/7/2016 10:02:00 AM

1 THAT IS CONDUCTED BECAUSE THAT --

2 THE COURT: NO. THE STATUTE SAYS IT'S NOT A DEFENSE.

3 THE APPROVAL OF A LABEL ISN'T A DEFENSE. I MEAN, THAT'S THE

4 THING THAT YOU -- I MEAN, THAT'S THE ELEPHANT IN THE ROOM FOR

5 YOU, I THINK, YOU KNOW.

6 MR. LASKER: YES, YOUR HONOR. I WOULD SUBMIT IT DOES

7 NOT MAKE SENSE TO READ THAT PROVISION. THERE'S TWO -- THERE'S

8 TWO WAYS YOU COULD READ THAT.

9 THE COURT: DOESN'T MAKE SENSE TO READ THAT PROVISION

10 AS BEING IN THE STATUTE?

11 MR. LASKER: NO, IT CERTAINLY IS IN THE STATUTE. THE

12 STATUTE PROVIDES ONCE YOU HAVE A LABEL, YOU DON'T HAVE A

13 DEFENSE GOING FORWARD, YOU HAVE A CONTINUING OBLIGATION. AND

14 BATES TALKS ABOUT THE FACT YOU HAVE A CONTINUING OBLIGATION TO

15 MAKE SURE YOU DON'T VIOLATE THE MISBRANDING STATUTE.

16 IF IT WERE NOT -- IF IT WERE THE CASE THAT APPROVAL

17 OF THE REGISTRATION PROHIBITS A MISBRANDING CLAIM --

18 THE COURT: WHERE'S THE LANGUAGE IN BATES THAT YOU

19 CLAIM STANDS FOR THE PROPOSITION THAT IT'S NOT A DEFENSE TO

20 WHAT YOU DO GOING FORWARD?

21 MR. LASKER: IF YOU GIVE ME A MOMENT, YOUR HONOR?

22 THE COURT: YEAH. AND THEN WE CAN WRAP UP AFTER

23 THAT.

24 MR. LASKER: YEAH.

25 SO, YOUR HONOR, BATES, 544 U.S. AT 4040 STATES, QUOTE

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1 --

2 THE COURT: WAIT. HOLD ON. LET ME GET THERE.

3 MR. LASKER: I'M SORRY.

4 THE COURT: OKAY. WHAT PARAGRAPH?

5 MR. LASKER: I'M ACTUALLY LOOKING AT THE PLAINTIFF'S

6 OWN BRIEF. I DON'T HAVE THIS IN -- LET ME PULL OUT

7 THE (UNINTELLIGIBLE) AS WELL.

8 I'M SORRY, YOUR HONOR. IT SEEMS TO BE THE

9 PLAINTIFF'S HAVE CITED TO PAGE 440. I'M TRYING TO FIND OUT

10 WHERE IT IS ON THE PAGE. HERE IT IS. I'M SORRY. IT'S ON PAGE

11 439.

12 THE COURT: OKAY.

13 MR. LASKER: IT WAS -- IT'S ON -- ON 438, ACTUALLY.

14 SO IF YOU'RE LOOKING AT THE PUBLISHED OPINION, THE PAGES THAT

15 HAVE -- THAT STARTS IN THE LEFT-HAND COLUMN ON THE RIGHT TOP,

16 PERIOD, QUOTATION MARK, YOU SEE THE TOP OF THE COLUMN. I'M NOT

17 SURE WHAT YOUR PUBLICATION IS, BUT THE SENTENCE STARTS "BECAUSE

18 IT IS UNLAWFUL..."

19 THE COURT: OKAY.

20 MR. LASKER: "BECAUSE IT IS UNLAWFUL UNDER THE

21 STATUTE TO SELL A PESTICIDE THAT IS REGISTERED BUT

22 NONETHELESS MISBRANDED, MANUFACTURERS HAVE A

23 CONTINUING OBLIGATION TO ADHERE TO FIFRA'S LABELING

24 REQUIREMENTS."

25 THE COURT: THAT'S YOUR AUTHORITY FOR THE PROPOSITION

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1 THAT THE PROVISION IN THE STATUTE THAT SAYS APPROVAL IS NOT A
2 DEFENSE IS ONLY FOR -- ONLY APPLIES TO WHAT THE COMPANY DOES
3 AFTER APPROVAL OF THE LABEL?

4 MR. LASKER: THEY CITE -- THE SUPREME COURT CITES
5 RIGHT AFTER THAT TO THE SECTIONS AT ISSUE DEALING WITH WHETHER
6 OR NOT APPROVAL IS A DEFENSE TO MISBRANDING. AND THE SUPREME
7 COURT INTERPRETS THAT AS BEING PLACED IN THE STATUTE BECAUSE
8 THE APPLICANT HAS A CONTINUING OBLIGATION. THAT'S HOW THE
9 SUPREME COURT -- THAT'S HOW THE SUPREME COURT UNDERSTANDS THAT
10 PROVISION --

11 THE COURT: OKAY.

12 MR. LASKER: -- I WOULD SUBMIT.

13 THE COURT: ALL RIGHT. I UNDERSTAND YOUR ARGUMENTS.

14 MR. LASKER: AND IT THEN TALKS ABOUT EPA -- THE
15 REGISTRANT'S CONTINUING REPORTING OBLIGATIONS THEREAFTER THAT
16 FOLLOW AFTER THE REGISTRATION.

17 SO THE SUPREME COURT IS TALKING ABOUT THIS VERY
18 PROVISION IN THE CONTEXT OF YOUR CONTINUING OBLIGATIONS: YOU
19 CAN'T COUNT ON THE FACT THAT WE HAVE APPROVED YOUR LABEL AT ONE
20 POINT IN TIME TO SAY IT'S NOT MISBRANDED GOING FORWARD; YOU
21 HAVE OBLIGATIONS THAT CONTINUE, AND YOU CAN'T BRING THIS UP AS
22 A DEFENSE.

23 NOW IT'S A PRIME FACE DEFENSE IF WE HAD NOT BROUGHT A
24 CANCELLATION ACTION.

25 THE COURT: IT WOULD HAVE BEEN PRETTY EASY TO WRITE

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1 THE STATUTE THAT WAY, WOULDN'T IT? I MEAN, IT WOULD HAVE BEEN
2 PRETTY EASY TO SAY, YOU KNOW, YOU HAVE A CONTINUING OBLIGATION
3 TO MAKE SURE THAT YOUR PRODUCT IS NOT MISLABELED, AND IF IT
4 BECOMES MISLABELED AFTER APPROVAL, THE FACT THAT IT WAS
5 MISLABELED IS NOT A DEFENSE -- I MEAN, THE FACT IT WAS APPROVED
6 IS NOT A DEFENSE TO A CLAIM THAT IT WAS MISLABELED.

7 MR. LASKER: WELL, YOUR HONOR, I WOULD SUBMIT THAT IF
8 YOU READ THAT WHOLE CLAUSE WHERE IT SAYS IT'S NOT A DEFENSE,
9 THE WHOLE POINT ABOUT IT'S PRIMA FACIE UNLESS EPA HAS BROUGHT A
10 CANCELLATION ACTION IS TALKING ABOUT EPA SUBSEQUENTLY --

11 THE COURT: OKAY.

12 MR. LASKER: -- LOOKING AT WHAT'S HAPPENED
13 AFTERWARDS.

14 THE COURT: I THINK I HAVE A PRETTY GOOD
15 UNDERSTANDING OF YOUR ARGUMENTS. I'LL THINK ABOUT IT A LITTLE
16 BIT MORE AND ISSUE A WRITTEN ORDER --

17 MR. WOOL: OKAY.

18 THE COURT: -- SHORTLY.

19 MR. LASKER: AND, YOUR HONOR, THERE IS ALSO
20 SEPARATELY -- AND I THINK I RECOGNIZE WHERE THIS MAY BE GOING,
21 BUT IN THE VERY IMMEDIATE TERM, YOUR COURT HAS AN ORDER WITH
22 RESPECT TO DISCOVERY 26(F), AND WE HAVE MOVED TO PUT A HOLD ON
23 THAT UNTIL THERE'S A RULING THAT COMES DOWN --

24 THE COURT: I'LL ISSUE A RULING BY TOMORROW.

25 MR. LASKER: OKAY.

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1 THE COURT: AND THE DISCOVERY STAY WILL BE LIFTED.

2 MR. LASKER: OKAY. AND THEN, YOUR HONOR, YOU HAVE

3 A -- THERE ARE SOME DEADLINES THAT ARE IMPOSED, AND WE WOULD

4 ASK THAT THE DEADLINES SHOULD AT LEAST PROVIDE SOME

5 ADDITIONAL TIME, BECAUSE I THINK WE'RE FACING A DEADLINE WITHIN

6 THE NEXT WEEK OR WEEK AND A HALF FROM NOW ON. I THINK THE

7 DEADLINES --

8 THE COURT: CASE MANAGEMENT CONFERENCE, YOU MEAN?

9 MR. LASKER: THE DEADLINES WE HAVE IN THE ORDER ARE

10 FOR A MEET AND CONFER BY APRIL 13TH.

11 THE COURT: YEAH.

12 MR. LASKER: AND A DEADLINE FOR 26(F) CONFERENCE BY

13 APRIL 12TH.

14 THE COURT: WHAT'S WRONG WITH THAT?

15 MR. LASKER: WELL, YOUR HONOR, WE WOULD ASK FOR SOME

16 ADDITIONAL TIME, BUT IT'S OBVIOUSLY YOUR DISCRETION.

17 THE COURT: WHY? WHY? I MEAN I ISSUE MY RULINGS

18 QUICKLY. YOU'RE GOING TO GET YOUR RULING QUICKLY.

19 MR. LASKER: OKAY.

20 THE COURT: YOU DON'T NEED ADDITIONAL TIME. WE'LL

21 HAVE A CASE MANAGEMENT CONFERENCE, WHAT? IN A COUPLE OF WEEKS

22 FROM NOW, I BELIEVE.

23 MR. LASKER: IT'S ON MAY 3RD.

24 THE COURT: OKAY. GOOD.

25 MR. LASKER: THANK YOU, YOUR HONOR.

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1 THE COURT: WE'LL TALK TO YOU THEN. THANKS.

2 MR. WOOL: THANK YOU, YOUR HONOR.

3 (PROCEEDINGS ADJOURNED AT 10:38 A.M.)

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I CERTIFY THAT THE FOREGOING IS A TRUE AND CORRECT TRANSCRIPT, TO THE BEST OF MY ABILITY, OF THE ABOVE PAGES OF THE OFFICIAL ELECTRONIC SOUND RECORDING PROVIDED TO ME BY THE U.S. DISTRICT COURT, NORTHERN DISTRICT OF CALIFORNIA, OF THE PROCEEDINGS TAKEN ON THE DATE AND TIME PREVIOUSLY STATED IN THE ABOVE MATTER.

I FURTHER CERTIFY THAT I AM NEITHER COUNSEL FOR, RELATED TO, NOR EMPLOYED BY ANY OF THE PARTIES TO THE ACTION IN WHICH THIS HEARING WAS TAKEN; AND, FURTHER, THAT I AM NOT FINANCIALLY NOR OTHERWISE INTERESTED IN THE OUTCOME OF THE ACTION.

JOAN MARIE COLUMBINI

APRIL 19, 2016