

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

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE ANTHONY J. BATTAGLIA, JUDGE PRESIDING

)	CASE NO. 13-MD-02452-AJB
IN RE INCRETIN-BASED THERAPIES,)	
PRODUCTS LIABILITY LITIGATION)	
)	
)	
)	
-----)	SAN DIEGO, CALIFORNIA
)	SEPTEMBER 23, 2014
)	10:06 A.M.
AS TO ALL RELATED AND MEMBER CASES)	
_____)	

REPORTER'S TRANSCRIPT OF PROCEEDINGS
RE: CASE MANAGEMENT CONFERENCE

OFFICIAL REPORTER: JEANNETTE N. HILL, C.S.R.
U.S. COURTHOUSE,
333 WEST BROADWAY, RM 420
SAN DIEGO, CALIFORNIA 92101
(619) 702-3905

REPORTED BY STENOTYPE, TRANSCRIPT PRODUCED BY COMPUTER

SEPTEMBER 23, 2014

1 TELEPHONIC APPEARANCES:

2 FOR PLAINTIFFS:

3 THOMAS J. PREUSS, ESQ.
4 WAGSTAFF & CARTMELL LLP
5 4740 GRAND AVENUE, SUITE 300
6 KANSAS CITY, MISSOURI 64112

7 MICHAEL K. JOHNSON, ESQ.
8 JOHNSON BECKER PLLC
9 33 SOUTH SIXTH STREET, SUITE 4530
10 MINNEAPOLIS, MINNESOTA 5402

11 HUNTER J. SHKOLNIK, ESQ.
12 NAPOLI BERN RIPKA SHKOLNIK & ASSOCIATES
13 111 CORPORATE DRIVE, SUITE 225
14 LADERA RANCH, CALIFORNIA 92694

15 RYAN L. THOMPSON, ESQ.
16 WATTS GUERRA, LLP
17 5250 PRUE ROAD, SUITE 525
18 SAN ANTONIO, TEXAS 78240

19 JACOB W. PLATTENBERGER, ESQ.
20 TOR HOERMAN LAW LLC
21 234 S. WABASH AVENUE, 7TH FLOOR
22 CHICAGO, ILLINOIS 60604

23 MAXWELL S. KENNERLY, ESQ.
24 THE BEASLEY FIRM LLC
25 1125 WALNUT STREET
PHILADELPHIA, PA 19107

17 TELEPHONIC APPEARANCES:

18 FOR THE DEFENDANTS:

19 HEIDI LEVINE, ESQ.
20 MATTHEW HAMILTON, ESQ.
21 LEEANNE MANCARI, ESQ.
22 DLA PIPER LLP (US)
23 1251 AVENUE OF THE AMERICAS
24 NEW YORK NEW YORK 10020-1104

25 DOUGLAS R. MARVIN, ESQ.
ANA REYES, ESQ.
WILLIAMS & CONNOLLY LLP
725 TWELFTH STREET, N.W.
WASHINGTON, D.C. 20005

NINA GUSSACK, ESQ.
PEPPER HAMILTON, LLP
620 EIGHTH AVENUE
NEW YORK, NEW YORK 10018

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

CYNTHIA MERRILL, ESQ.
O'MELVENY & MEYERS LLP
400 SOUTH HOPE STREET
LOS ANGELES, CALIFORNIA 90071

1 SAN DIEGO, CALIFORNIA; TUESDAY, SEPTEMBER 23, 2014; 10:06 A.M.

2 **DEPUTY CLERK:** CALLING MATTER TWO ON CALENDAR, CASE
3 13MD2452, IN RE INCRETIN MIMETICS PRODUCTS LIABILITY
4 LITIGATION, ON FOR MOTION HEARING.

5 **THE COURT:** ALL RIGHT. GOOD MORNING, FOLKS. AND WE
6 ARE HERE TO TALK ABOUT THE COMPELLING OF ADDITIONAL CUSTODIAL
7 FILES. WHO DO WE HAVE THAT IS GOING TO BE SPEAKING ON BEHALF
8 OF THE PLAINTIFFS HERE?

9 **MR. PREUSS:** YOUR HONOR, THIS IS T.J. PREUSS,
10 P-R-E-U-S-S, FOR THE PLAINTIFFS.

11 **THE COURT:** SO YOU WILL BE TAKING THE LEADING OAR.
12 IS THERE ANY OTHER PLAINTIFFS' LAWYERS THAT WANT TO
13 NOTE THEIR APPEARANCE?

14 **MR. JOHNSON:** YES, YOUR HONOR. THIS IS MICHAEL
15 JOHNSON, ALSO ON BEHALF OF THE PLAINTIFFS. I MAY INTERJECT AT
16 SOME POINT.

17 **THE COURT:** OKAY. AND ANYBODY ELSE ON THE PHONE ON
18 THE PLAINTIFFS' SIDE THAT MAY WISH TO MAKE THEIR APPEARANCE?

19 **MR. SHKOLNIK:** YOUR HONOR, THIS IS HUNTER SHKOLNIK ON
20 BEHALF OF PLAINTIFFS, AS WELL. GOOD MORNING.

21 **THE COURT:** GOOD MORNING, MR. SHKOLNIK.

22 **MR. THOMPSON:** GOOD MORNING, YOUR HONOR. RYAN
23 THOMPSON ON BEHALF OF PLAINTIFFS.

24 **THE COURT:** THANKS, MR. THOMPSON.

25 AND WHO ELSE?

SEPTEMBER 23, 2014

1 **MR. PLATTENBERGER:** GOOD MORNING, YOUR HONOR. JACOB
2 PLATTENBERGER ON BEHALF OF THE PLAINTIFFS.

3 **THE COURT:** IS THERE ANYONE ELSE?

4 **MR. KENNERLY:** GOOD MORNING, YOUR HONOR. MAX
5 KENNERLY ON BEHALF OF THE PLAINTIFFS, AS WELL.

6 **THE COURT:** DOES THAT COMPLETE THE CIRCUIT ON THE
7 PLAINTIFFS' SIDE? IT SOUNDS LIKE. AND THEN -- I'M SORRY. WAS
8 SOMEBODY GOING TO SAY SOMETHING?

9 **MR. JOHNSON:** I'M SORRY, YOUR HONOR. YES, YOUR
10 HONOR. THIS IS MIKE JOHNSON. I DIDN'T MEAN TO TALK OVER YOU.
11 I BELIEVE THAT COMPLETES IT FOR THE PLAINTIFFS' SIDE.

12 **THE COURT:** AND THEN WHO IS HERE FOR MERCK TODAY?

13 **MR. MARVIN:** GOOD MORNING, YOUR HONOR. DOUGLAS
14 MARVIN AND ANA REYES.

15 **THE COURT:** THANK YOU, FOLKS.

16 AND THEN HOW ABOUT ON NOVO'S BEHALF?

17 **MS. LEVINE:** GOOD MORNING, YOUR HONOR. THIS IS HEIDI
18 LEVINE. I WILL BE TAKING THE LEAD FOR THE ARGUMENT TODAY ON
19 BEHALF OF BOTH MERCK AND NOVO, ALTHOUGH MERCK IS FREE TO WEIGH
20 IN IF NEEDED. AND MY COLLEAGUE, LEANNE MANCARI, IS ALSO WITH
21 ME FROM NOVO.

22 **THE COURT:** ANY OF THE OTHER DEFENSE COUNSEL ON THAT
23 WOULD LIKE TO ADD THEIR APPEARANCES TO THE RECORD, OR DOES THAT
24 COMPLETE IT?

25 **MS. GUSSACK:** NINA GUSSACK AND MATT HAMILTON FOR ELI

1 LILY.

2 **MS. MERRILL:** GOOD MORNING, YOUR HONOR. THIS IS
3 CYNTHIA MERRILL FOR AMYLIN PHARMACEUTICALS.

4 **THE COURT:** OKAY. I UNDERSTAND IT'S ALL LILY AND
5 AMYLIN'S FAULT THAT MERCK AND NOVO HAVEN'T GIVEN UP ENOUGH
6 DATA?

7 (LAUGHTER)

8 I JUST WANTED TO SEE IF YOU'RE PAYING ATTENTION.
9 ANYBODY ELSE?

10 ALL RIGHT. IT LOOKS LIKE WE'RE GOOD FOR THE MOMENT.
11 LET'S START TALKING ABOUT NOVO. AND I THINK THERE IS SOME
12 GLOBAL CONCERNS AND CONSIDERATIONS. BUT I THINK THE MOST
13 EFFECTIVE WAY TO REALLY RESOLVE THE ISSUE WOULD BE TO TALK
14 ABOUT EACH OF THESE INDIVIDUALS SPECIFICALLY IN TERMS OF THE
15 NEED, FROM A DISCOVERY STANDPOINT, THE SCOPE, WITH REGARD TO
16 THE LIMITED SCOPE, THE RELATIVE DUPLICATION, IF ANY, AND THINGS
17 LIKE THAT. I THINK THAT WOULD BE MOST EFFECTIVE.

18 AND SO NOVO, IN THE RESPONSE -- I'LL START WITH YOU
19 FOLKS BECAUSE YOU OUTLINED WHO THESE PEOPLE WERE AND WHERE
20 OVERLAPS OR DUPLICATION WOULD COME, IN A PRETTY THOROUGH SENSE.
21 AND SO LET'S START THERE.

22 AND LET'S START WITH, I GUESS, MR. PYKE AND
23 MR. HELLER. THEY'RE BOTH KIND OF GROUPED TOGETHER AT NOVO'S
24 DENMARK FACILITY. AND THE PREMISE THAT NOVO IS ADVANCING
25 HERE -- NOT TO SPEAK FOR YOU, BUT I WILL -- IS THAT MS. KNUDSEN

1 AND SO FORTH IS LIKELY GOING TO BE THE FOCUS OF THE SAME, IF
2 NOT ALL THE SAME, INFORMATION. AND THERE IS LITTLE TO BE ADDED
3 BY EXPANDING THE SCOPE TO INCLUDE PYKE AND/OR HELLER.

4 DID I CHARACTERIZE THAT PRETTY WELL, MS. LEVINE, OR
5 DID I BUTCHER IT?

6 **MS. LEVINE:** YOUR HONOR, YOU DID CHARACTERIZE IT VERY
7 WELL. THEY ARE BOTH WITHIN DR. KNUDSEN'S DEPARTMENT. THEY
8 CO-AUTHORED THE VERY ARTICLE FROM JANUARY OF THIS YEAR THAT THE
9 PLAINTIFFS FOCUS WHY THEY NEED -- WHY THEY SAY THEY NEED THESE
10 FILES.

11 IN FACT, DR. KNUDSEN WAS THE PRINCIPAL AUTHOR AND IS
12 REALLY THE CENTRAL FIGURE IN THE PRECLINICAL AREA FOR THE
13 DRUGS. SHE HAS BEEN THE CENTER OF THE DRUG'S DEVELOPMENT FROM
14 THE TIME IT WAS BORN THROUGH TO TODAY. AND THE PLAINTIFFS HAVE
15 HAD HER FILES SINCE JUNE AND HAVE NOT YET DEPOSED DR. KNUDSEN,
16 BUT WILL BE DOING SO IN ABOUT TWO WEEKS.

17 IN FACT, IF I ALSO MAY ADD -- I'M SORRY, YOUR
18 HONOR -- THAT IN THE NEGOTIATIONS AND DISCUSSIONS WITH THE
19 PLAINTIFFS, PLAINTIFFS ACKNOWLEDGED THAT AS BETWEEN PYKE AND
20 HELLER THAT THEY MAY BE DUPLICATIVE OF EACH OTHER AND NOT JUST
21 OF DR. KNUDSEN. THEY ACKNOWLEDGED THAT. SO I THINK THAT THERE
22 IS SOME -- WE'VE ALSO PRODUCED, IN ADDITION TO DR. KNUDSEN, TWO
23 OTHER CUSTODIANS FROM DENMARK THAT ARE IN THE PRECLINICAL
24 DEPARTMENT AND DEAL WITH VICTOZA.

25 SO OUT OF OUR TEN FILES WE'VE PRODUCED, THREE ARE

1 FROM PRECLINICAL. AND WE FEEL THAT THESE TWO ADDITIONS ARE
2 JUST DUPLICATIVE AND UNNECESSARY AND REALLY TAKE AWAY FROM THE
3 TIME AND RESOURCES THAT WOULD BE BETTER SPENT DEALING WITH THE
4 DATA THAT PLAINTIFFS' EXPERTS CLAIM THEY NEED, RATHER THAN
5 DEPARTURE AND, YOU KNOW, STARTING TO PRODUCE NEW FILES TODAY,
6 THREE WEEKS BEFORE THE END OF THE DEPOSITION PERIOD.

7 OKAY. WELL, THANK YOU.

8 **THE COURT:** SO, MR. PREUSS, FROM THE PLAINTIFFS'
9 STANDPOINT, THE PLAINTIFFS HAVE SOME CONCERNS. THEY FEEL THERE
10 MAY LIKELY BE SOME THINGS; THERE OUGHT TO BE SOME THINGS; THERE
11 COULD BE SOME THINGS. I DIDN'T GET A FEELING OF ANY PRECISE
12 INFORMATION THAT EITHER PYKE OR HELLER WOULD PROVIDE THAT
13 KNUDSEN, AS THE HEAD OF THE DEPARTMENT OR THE HEAD PERSON,
14 WOULDN'T BE ABLE TO PROVIDE DISCOVERY ON ON THE LIMITED SCOPE
15 THAT WE'RE ON AT THIS POINT. SO EDUCATE ME, SIR, AS TO WHAT
16 I'M MISSING THERE.

17 **MR. PREUSS:** SURE, YOUR HONOR. I WOULD BE HAPPY TO
18 ADDRESS THAT. DRS. PYKE AND HELLER ADDRESS A CLINICAL ISSUE
19 THAT YOU HEARD DEFENDANT NOVO NORDISK RAISE AT SCIENCE DAY.
20 AND THAT WAS THROUGH RESEARCH -- HISTOLOGY RESEARCH ABOUT
21 STAINING AND WHETHER OR NOT THEY WERE GLP-1 RECEPTORS IN THE
22 PANCREATIC DUCTS. THE STAINING THAT WAS USED IN THAT STUDY WAS
23 A STAIN DEVELOPED AND DESIGNED BY NOVO NORDISK, INCLUDING
24 DRS. HELLER AND PYKE.

25 WE BELIEVE THIS IS AN ISSUE THAT WE ARE GOING TO

1 CONTINUE TO HEAR IN THE LITIGATION FROM THE DEFENDANTS. IT'S
2 AN ISSUE THAT WE NEED TO EXPLORE IN DETAIL IN ORDER TO ADDRESS
3 IT FULLY.

4 DR. LOTTE KNUDSEN IS THE HEAD OF THE DEPARTMENT IN
5 WHICH DRS. HELLER AND PYKE SIT. BUT OUR EXPLORATION OF
6 DR. KNUDSEN'S FILES DOES NOT GIVE US THE DETAILS THAT WE FEEL
7 WE NEED TO FULLY HASH OUT OUR POSITION.

8 DR. HELLER AND DR. PYKE WERE THE HANDS-ON RESEARCHERS
9 BEHIND THIS HISTOLOGY AND STAINING ISSUE. EVEN THOUGH
10 DR. KNUDSEN IS THE HEAD OF THE DEPARTMENT, SHE IS NOT GOING TO
11 BE PRIVY TO -- OR HER CUSTODIAL FILE IS NOT GOING TO HAVE ALL
12 THE DETAILS IN IT THAT THE GROUND-LEVEL SCIENTISTS, SUCH AS
13 DRS. HELLER AND PYKE, WOULD HAVE.

14 AND THAT IS REALLY WHAT WE ARE HONING IN ON, YOUR
15 HONOR, IS TO GET HELLER AND PYKE'S FILES SO THAT WE CAN REALLY
16 HONE IN AND ADDRESS THE DETAILS OF THEIR RESEARCH.

17 **THE COURT:** THE DETAILS OF THEIR RESEARCH IN WHAT
18 RESPECT? I MEAN, WE'RE TALKING, AT THIS STAGE, ABOUT,
19 ESSENTIALLY, WHAT TESTS WERE PERFORMED, WHAT RESULTS WERE
20 ACHIEVED, AND WHAT THEY ESSENTIALLY CONNOTE IN TERMS OF
21 CAUSATION. AND SO GETTING INTO SORT OF THE MINUTIAE, NOT TO BE
22 PEJORATIVE ABOUT IT -- BUT INTO THE DETAILS OF WHAT THEY MIGHT
23 HAVE DONE STEP-BY-STEP, WHY IS THAT NECESSARY IF IT IS THE
24 CONCLUSION -- AT THIS POINT -- IF IT IS THE CONCLUSIONS THAT WE
25 ULTIMATELY WORK OFF WITH REGARD TO THE ISSUES OF GENERAL

1 CAUSATION?

2 **MR. PREUSS:** SURE, YOUR HONOR. AND FIRST I WOULD
3 LIKE TO STEP BACK A BIT AND ADDRESS IT. WHAT OUR EXPERTS AND
4 WHAT WE'RE DOING IN THIS CASE IS OUR EXPERTS ARE ENGAGING IN A
5 SYMPTOMATIC ANALYSIS TO DETERMINE WHETHER THESE DRUGS ARE
6 CAPABLE OF CAUSING PANCREATIC CANCER. AND ALTHOUGH THE DATA
7 AND THE CONCLUSIONS, THE STUDY RESULTS THEMSELVES ARE
8 IMPORTANT, WELL, JUST AS IMPORTANT, IF NOT MORE IMPORTANT, IS
9 WHAT IS BEHIND THOSE RESULTS: THE STUDY METHODS AND THE STUDY
10 DESIGN, THE BIAS, AND THE LIMITATIONS BEHIND THE CONCLUSIONS
11 THAT WE'RE TALKING ABOUT HERE.

12 AND IN THIS INSTANCE, IT'S DRS. HELLER AND PYKE WHO
13 WERE BEHIND THE DYEING OF THE HISTOLOGY STUDY THAT WE ARE
14 TALKING ABOUT, WITH RESPECT TO THE STAIN ISSUE AND THE GLP-1
15 RECEPTORS ON THE PANCREATIC DUCTS. THEY ARE THE ONES WHO
16 DESIGNED THOSE STUDIES.

17 WE ALSO KNOW -- WHAT WE CAN TELL RIGHT NOW FROM THE
18 DOCUMENTS WE DO HAVE -- THAT DR. PYKE AND/OR DR. HELLER
19 ACTUALLY HAD SOME FINDINGS THAT DIFFER FROM DR. KNUDSEN'S
20 ULTIMATE CONCLUSION ON THIS ISSUE. AND WE BELIEVE THAT THE
21 FILE WOULD HAVE MORE INFORMATION ABOUT WHAT THOSE DIFFERENCES
22 OF OPINIONS WERE AND WHAT THE BASES OF THEIR OPINIONS WERE
23 THAT -- THAT AT LEAST AT ONE POINT DIFFERED FROM THEIR
24 SUPERIOR, DR. KNUDSEN.

25 **THE COURT:** OKAY. WELL, MS. LEVINE, YOU WANT TO MAKE

1 ANY REPLY AT ALL?

2 WELL, LET ME BACK UP, FIRST. MR. PREUSS, THE
3 STATEMENT WAS MADE THAT PYKE AND HELLER MAY DUPLICATE, AND THAT
4 WAS ATTRIBUTED TO THE PLAINTIFFS. DO YOU AGREE AT THIS POINT
5 THAT YOU NEED BOTH, OR IS ONE OR THE OTHER GOING TO SUFFICE IN
6 TERMS OF THIS LEVEL OF INQUIRY YOU'RE SEEKING?

7 **MR. PREUSS:** SURE, YOUR HONOR. I DO BELIEVE THAT
8 THEIR FILES WILL OVERLAP QUITE A BIT. I DON'T THINK THEY ARE
9 GOING TO BE COMPLETELY DUPLICATIVE, BUT I DO BELIEVE THE FILES
10 OF DR. PYKE AND HELLER WILL OVERLAP QUITE A BIT.

11 WE ARE HAPPY TO START WITH ONE. IF WE WERE ALLOWED
12 TO JUST HAVE ONE FILE, OUR PREFERENCE WOULD BE TO START WITH
13 DR. PYKE'S FILE.

14 **THE COURT:** LET'S GO TO MS. LEVINE FOR ANY REPLY YOU
15 WOULD LIKE TO MAKE.

16 **MS. LEVINE:** THANK YOU, YOUR HONOR. JUST QUICKLY.
17 THE PUBLICATION ON WHICH THE PLAINTIFFS RELY WAS SENT OUT IN
18 JANUARY. SCIENCE DAY WAS THE FIRST WEEK OF FEBRUARY. MANY,
19 MANY MONTHS AGO. WE ARE IN SEPTEMBER -- THE END OF SEPTEMBER.
20 AND WE HAVE THREE WEEKS LEFT FOR DEPOSITIONS IN THESE CASES.

21 CLEARLY, THESE FILES WILL NOT BE USED AT THE
22 DEPOSITIONS IN THE NEXT THREE WEEKS. AND PLAINTIFFS HAVE NOT
23 INDICATED THAT THEY WANTED TO DEPOSE THESE WITNESSES FOR
24 GENERAL CAUSATION PURPOSES WITHIN THE DEADLINE. AND I THINK
25 THAT WE ARE GETTING FAR ASTRAY FROM THE NARROW SCOPE OF THIS

1 DISCOVERY.

2 THEY HAVE THE DATA, AND THEY HAVE DR. KNUDSEN'S
3 FILES. AND THEY HAVE NOT YET ASKED DR. KNUDSEN WHAT
4 DR. KNUDSEN KNOWS ABOUT THE HISTOLOGY SLIDES AND THE LIKE. AND
5 I JUST THINK WE NEED -- OUR OPINION IS WE NEED TO REALLY FOCUS
6 ON WHAT IS NEEDED AT THIS POINT TO GET TO WHERE THE COURT WANTS
7 TO BE, AND FOCUS ON THE DATA ITSELF. AND SO I THINK THIS IS
8 UNNECESSARY FOR US TO SPEND OUR TIME PRODUCING ADDITIONAL FILES
9 AT THIS LATE STAGE.

10 **THE COURT:** OKAY. WELL, AND JUST AS AN UNDERScore,
11 IF WE FIND THERE IS ADDITIONAL DATA REQUIRED, WE MAY HAVE TO
12 ALTER DATES. AND I KNOW THERE HAS BEEN SOME DISCUSSION, AND
13 WE'LL DISCUSS THAT TO SOME DEGREE ON OCTOBER 9TH, I THINK.

14 BUT HERE IS MY READ ON THIS. I THINK IT'S PREMATURE
15 TO EXPAND THE SCOPE OF THE DEPOSITIONS WITH REGARD TO PYKE AND
16 HELLER, SPECIFICALLY. I THINK WE NEED TO SEE WHAT
17 DR. KNUDSEN -- IS IT DOCTOR? -- OR MS. KNUDSEN SAYS.

18 **MS. LEVINE:** YES.

19 **THE COURT:** AND TO THE EXTENT SHE IS UNABLE TO BE
20 FAIRLY DEPOSED ON THE GENERAL CAUSATION ISSUES -- WHICH I THINK
21 IS REALLY THE FOCUS HERE OF WHAT STUDIES WERE DONE AND WHAT THE
22 RESULTS WERE -- TO THE EXTENT THAT SHE WOULD HAVE TO SAY IN HER
23 DEPOSITION: WELL, I WOULD HAVE TO DEFER TO PYKE AND/OR HELLER,
24 OR BE UNAWARE OF SOMETHING THAT HAPPENED IN THE STUDY AND WOULD
25 SAY I JUST DON'T KNOW, WE'D HAVE TO GO TO PYKE OR HELLER -- WE

1 MAY HAVE A FAIR ENOUGH EXAMINATION FOR OUR PURPOSES AT THIS
2 POINT TO THEN MOVE FURTHER FORWARD.

3 IF SHE IS WITHOUT CERTAIN REQUISITE KNOWLEDGE, THEN I
4 THINK WE REOPEN THE ISSUE. BUT FOR NOW, PYKE AND HELLER, I
5 THINK, WOULD BE DUPLICATIVE. WHAT THE PLAINTIFFS ARE FEELING
6 MAY BE THERE, LIKELY SHOULD BE, IS NOT PRECISE ENOUGH TO ORDER
7 THE PRODUCTION OF THAT DATA. RECOGNIZING, ALSO, THAT IT'S
8 LIKELY NOT TO BE AVAILABLE AND USEFUL FOR THE DEPOSITIONS
9 CURRENTLY PLANNED. AND SO LET'S SEE WHAT KNUDSEN SAYS.

10 AND THEN I WILL JUST DENY THE REQUEST AS TO THESE TWO
11 GENTLEMEN WITHOUT PREJUDICE. I MEAN, CERTAINLY, IF THERE WERE
12 INCONSISTENT FINDINGS OR THINGS DONE IN THE STUDY THAT ARE PART
13 OF KNUDSEN'S OVERSIGHT, SHE WOULD BE IN A POSITION TO DISCUSS
14 THOSE. AND IF SHE SAYS WELL, I JUST DON'T KNOW, WE HAVE TO ASK
15 HELLER, THEN WE'LL ASK HELLER. SO I WILL SAY NO AS TO HELLER
16 AND PYKE.

17 AND THEN LET'S MOVE TO HELGE GYDESEN, THE SENIOR
18 EPIDEMIOLOGY SPECIALIST. AND, ONCE AGAIN, THERE IS A CONCERN
19 THAT HER (SIC) FILE LIKELY CONTAINS MORE DETAIL THAN OTHER
20 EPIDEMIOLOGICAL STUDIES OR FILES THAT HAVE BEEN PRODUCED.

21 BUT I WILL LET YOU COUCH YOUR POSITION AGAIN,
22 MS. LEVINE, TO SORT OF START THE BALL ON THIS, AND THEN WE CAN
23 MOVE TO THE PLAINTIFFS' SIDE. SO AS TO GYDESEN, YOUR OBJECTION
24 IS --

25 **MS. LEVINE:** SURE, YOUR HONOR. AND JUST TO BE CLEAR,

1 WHEN PLAINTIFFS RAISED THE REQUEST OVER THE LAST TWO OR SO
2 MONTHS FOR ADDITIONAL FILES AND UP TO 14 CUSTODIANS, WE DID
3 AGREE TO PRODUCE THREE ADDITIONAL CUSTODIANS ABOVE THE SEVEN
4 BECAUSE WE DID FEEL THAT THERE WERE GOOD REASONS TO DO SO. AND
5 SO I JUST WANT THE COURT TO UNDERSTAND THAT. FOR MERCK IT IS
6 THE SAME; THEY PRODUCED ADDITIONAL CUSTODIANS, AS WELL, WHEN
7 ASKED.

8 SO ON GYDESEN, THE ISSUE, REALLY, IS THAT HE HAS A
9 SOMEWHAT LIMITED ROLE WITH VICTOZA. PERIOD. AND WE DO FEEL
10 THAT BECAUSE WE HAVE PRODUCED THE MOST SENIOR PERSON ON THE
11 SCIENCE AND THE MEDICINE IN THE ENTIRE COMPANY, BEING THE CHIEF
12 MEDICAL OFFICER, WHICH WE THOUGHT WAS IMPORTANT TO DO TO SHOW
13 THE COURT AND THE PLAINTIFFS THAT WE WANTED TO HAVE PLAINTIFFS
14 HAVE THE ABILITY TO GET THE RIGHT PEOPLE AT THE TOP, WE DO
15 BELIEVE THAT DR. MOSES, THE CHIEF MEDICAL OFFICER AND SENIOR
16 V.P. IN THE COMPANY, CAN HANDLE THOSE ISSUES AT DEPOSITION AND
17 KNOWS ENOUGH ABOUT THE ISSUES THAT PLAINTIFFS THINK THEY CAN
18 GATHER FROM THE FILES OF GYDESEN, AS WELL AS DR. JASON BRETT,
19 WHO IS ALSO A DOCTOR, AND WORKS WITH MOSES AND IS IN THE
20 MEDICAL AFFAIRS GROUP AND WORKS EXCLUSIVELY ON VICTOZA, AND
21 HAS, AT CERTAIN DIFFERENT POINTS AND TIMES.

22 SO WE JUST FEEL IT'S A DUPLICATIVE FILE. AND SO FOR
23 ALL THE REASONS I ALREADY STATED, WHY WE THINK THAT THE DATA --
24 THE UNDERLYING DATA IS WHAT IS MOST RELEVANT AND NOT THIS
25 WITNESS' FILES.

1 **THE COURT:** OKAY. AND OBVIOUSLY, I THOUGHT THAT
2 HELGE WAS A FEMALE, BUT IT SOUNDS LIKE GYDESEN IS A MAN.

3 **MS. LEVINE:** I THINK SO.

4 **THE COURT:** SO MY APOLOGIES TO HIM.

5 **MS. LEVINE:** NO. NO. IT'S FINE. IT'S DIFFICULT.

6 **THE COURT:** WELL, I'M NOT FAMILIAR WITH THESE
7 EUROPEAN NAMES IN TERMS OF GENDER, OBVIOUSLY. BUT THE
8 STATEMENT IS MADE BY THE PLAINTIFFS -- AND THEY WILL CERTAINLY
9 GET A CHANCE TO WEIGH IN -- THAT MOSES AND BRETT REALLY DEFER
10 TO GYDESEN ON DETAIL- AND DATA-SPECIFIC DECISIONS. AND THIS IS
11 PART OF WHAT THEY'VE GLEANED FROM THE FILES THAT THEY HAVE.

12 AND ARE WE GOING TO FIND THAT THAT IS GOING TO BE
13 THE -- I'M NOT GOING TO INQUIRE AS TO WHAT THEY ARE GOING TO
14 SAY. BUT FROM A CATEGORICAL STANDPOINT, ARE THEY GOING TO BE
15 EXERCISING DEFERENCE IN THEIR DEPOSITION, OR ARE WE GOING TO
16 HAVE TO ASK DR. GYDESEN ABOUT THIS? OR DID THEY, AS THE
17 OVERSIGHT OF THIS OVER THE DURATION, HAVE AN ABILITY TO TESTIFY
18 THOROUGHLY AS TO WHAT HAPPENED DURING GYDESEN'S PERIOD AS THE
19 HEAD OF STATISTICS, OR WHATEVER HE WAS, AND GIVE A FULL BIT OF
20 TESTIMONY? MS. LEVINE?

21 **MS. LEVINE:** I UNDERSTAND YOUR QUESTION, YOUR HONOR.
22 GYDESEN DID NOT DESIGN THE STUDIES. AND STUDY GROUPS EXIST.
23 AND PARTICULARLY AT NOVO -- AND THIS IS GOING TO BE TRUE FOR
24 THE SAFETY COMMITTEE AS IT IS FOR THE STUDY GROUPS -- THE WAY
25 THAT THE COMPANY OPERATES IS BY COMMITTEE AND BY COLLABORATION

1 ON THE COMMITTEE. AND THERE IS NOT ONE PERSON WHO IS
2 RESPONSIBLE FOR DECISIONS OR ANALYSIS OR THE LIKE.

3 AND SO I CAN'T TELL YOU THAT DR. MOSES OR DR. BRETT
4 WILL NEVER DEFER TO ANY OTHER PERSON IN THE COMPANY ON A SINGLE
5 QUESTION THAT THE PLAINTIFFS ASK THEM OVER A COMBINED MANY
6 HOURS OF DEPOSITIONS. AND I DON'T THINK ANYBODY COULD TELL YOU
7 THAT.

8 AND I DON'T THINK THAT THE DISCOVERY PERIOD
9 CONTEMPLATED THAT THE WITNESSES WE -- OR WHOSE FILES WE
10 PRODUCED WOULD BE ABLE TO COVER THE WATERSHED OF EVERY SINGLE
11 POSSIBLE ISSUE PLAINTIFFS MAY RAISE. BUT WE DO FEEL CONFIDENT
12 THAT WE HAVE DESIGNATED THE RIGHT PEOPLE ON THE RIGHT ISSUES,
13 AND ON A VAST MAJORITY OF THE ISSUES.

14 WE, OF COURSE, DIDN'T KNOW EVERY SINGLE ISSUE THE
15 PLAINTIFFS WOULD WANT TO FOCUS ON AT THE TIME THAT WE CAREFULLY
16 SELECTED OUR CUSTODIANS THAT WE WOULD BE PRODUCING, WHICH WE
17 DID. AS OF THE FEBRUARY ORDER, WE PRODUCED THEM IN JUNE. AND
18 NOW THE PLAINTIFFS ARE NARROWING THE ISSUES THEY WANT TO COVER.

19 I BELIEVE -- AND I WOULDN'T BE IN FRONT OF YOU IF I
20 DIDN'T BELIEVE THAT THE WITNESSES WE HAVE WERE THE RIGHT
21 WITNESSES TO COVER THE ISSUES. BUT I AM HAPPY TO DEFER TO THE
22 COURT, IF THE COURT WANTS TO ISSUE A SIMILAR RULING FOR GYDESEN
23 AS YOUR HONOR HAS FOR HELLER AND PYKE.

24 **THE COURT:** WITH THIS COMMITTEE-TYPE STRUCTURE, I
25 THINK THIS REFLECTS ON THIS QUESTION OF MINUTES THAT WERE

1 DETAILED AND KIND OF CAPTURE WHAT WAS GOING ON AT THE TIME.

2 **MS. LEVINE:** CORRECT.

3 **THE COURT:** AND I TAKE IT THAT MOSES AND BRETT WERE
4 NOT ONLY PARTICIPANTS THROUGHOUT THOSE PERIODS OF TIME, BUT
5 PRIVY TO THE MINUTES AND WHAT WAS GOING ON UNDER THEIR
6 DIRECTION OR WITHIN THEIR BAILIWICK AT THE COMPANY, RIGHT?

7 **MS. LEVINE:** I WANT TO MAKE SURE THAT THE RECORD IS
8 CLEAR. SO THERE IS MINUTES FOR THE LIRAGLUTIDE SAFETY
9 COMMITTEE. AND THAT GOES TO ONE OF THE OTHER -- WELL, THE LAST
10 TWO CUSTODIANS AT ISSUE TODAY. GYDESEN IS NOT PART OF THE
11 SAFETY COMMITTEE, NECESSARILY, IN THE MEETING MINUTES WE
12 PRODUCED. BUT THERE ARE DEFINITELY NUMEROUS RECORDS AND
13 DOCUMENTS WE HAVE PRODUCED FROM THE OTHER FILES THAT INVOLVE
14 THE STUDY GROUPS AND THE DECISIONS THAT WERE MADE AND THE
15 UNDERLYING DATA.

16 **THE COURT:** WELL, THANK YOU FOR CLARIFYING THAT.

17 **MS. LEVINE:** I WANTED TO MAKE SURE THERE WAS A
18 DISTINCTION BETWEEN THE SAFETY COMMITTEE AND OTHERS.

19 **THE COURT:** THANK YOU FOR CLARIFYING THAT. I
20 APPRECIATE THAT.

21 WELL, LET'S SWITCH TO THE PLAINTIFFS' SIDE. AND THE
22 SAME QUESTION, YOU KNOW, TURNED AROUND: WHY IS GYDESEN
23 SUPERIOR WITH REGARD TO SOME OF THIS DATA? WHY IS IT SOMETHING
24 THAT THESE DESIGNATED WITNESSES WON'T BE ABLE TO COVER WITH
25 SOME REASONABLE EXPECTATION? SO, MR. PREUSS?

1 **MR. PREUSS:** SURE, YOUR HONOR. THANK YOU. THE SHORT
2 ANSWER IS THAT DR. GYDESEN IS THE ONLY EPIDEMIOLOGIST WHOSE
3 CUSTODIAL FILES WOULD BE PRODUCED. WITHOUT DR. GYDESEN'S
4 CUSTODIAL FILES, WE DON'T HAVE THE EPIDEMIOLOGIST FILE FROM
5 NOVO NORDISK.

6 NOW, WHAT IS THE IMPORTANCE OF AN EPIDEMIOLOGIST AT A
7 COMPANY LIKE NOVO NORDISK WITH RESPECT TO A DRUG LIKE JANUVIA?
8 AND ONE ROLE IS TO LOOK AT POST-MARKETING OBSERVATIONAL
9 STUDIES, AND TO WORK WITH RESEARCH GROUPS AND HEALTH PLANS TO
10 ASSESS PATIENT INFORMATION, LOOKING AT THINGS SUCH AS (PHONE
11 STATIC INTERRUPTION). DR. GYDESEN, I UNDERSTAND, DID THAT.
12 AND HE WAS NOVO NORDISK'S PRIMARY CONTACT, LIAISON WITH THE
13 STUDY CALLED OPTUM INSIGHT, WHICH WE FULLY EXPECT NOVO NORDISK
14 TO DISCUSS IN THIS CASE.

15 HE WOULD RECEIVE INTERIM REPORTS FROM THE OPTUM
16 RESEARCH GROUP. HE WAS THE EPIDEMIOLOGIST AT NOVO NORDISK WHO
17 WAS RESPONSIBLE FOR STUDIES LIKE THIS, INCLUDING OPTUM INSIGHT
18 WHICH WILL BE A STUDY, AND I'M SURE YOU WILL HEAR MORE ABOUT AS
19 WE GO ON IN LITIGATION.

20 IT IS FOR THAT REASON THAT INDIVIDUALS LIKE MOSES AND
21 DR. BRETT MUST DEFER TO DR. GYDESEN BECAUSE DR. GYDESEN IS THE
22 EPIDEMIOLOGIST. AND DR. MOSES AND DR. BRETT'S FILE IS NOT
23 GOING TO COVER WHAT DR. GYDESEN'S FILE WOULD FOR THE EXACT
24 REASON DR. GYDESEN IS AN EPIDEMIOLOGIST. HE HAS A SPECIFIC
25 ROLE WITH RESPECT TO THESE DRUGS. DR. MOSES AND DR. BRETT ARE

1 NOT. THEY MUST DEFER TO HIM ON ISSUES WITH RESPECT TO
2 EPIDEMIOLOGY. AND WITHOUT DR. GYDESEN'S FILE, WE DON'T HAVE
3 ANY EPIDEMIOLOGIST FROM NOVO NORDISK.

4 **THE COURT:** OKAY. SO, MS. LEVINE, ANY RESPONSE ON
5 THAT?

6 **MS. LEVINE:** YES, YOUR HONOR. FIRST OF ALL, WHEN THE
7 REQUEST FOR THIS CUSTODIAL FILE CAME UP IN THE LAST FEW WEEKS,
8 IT WAS THE FIRST TIME THAT NOVO HAD BEEN ASKED TO PRODUCE THE
9 FILES OF AN EPIDEMIOLOGIST, DESPITE THE FACT THAT WE HAD ASKED
10 FOR PLAINTIFFS' INPUT IN THE LIST OF CUSTODIAL FILES TO PRODUCE
11 SINCE FEBRUARY; AND THAT THEY DID NOT WANT TO BE INVOLVED IN
12 THAT. AND WE COULD HAVE DEALT WITH THIS ISSUE SEVEN MONTHS
13 AGO. AND IT IS SOMEWHAT FRUSTRATING TO DEAL WITH THIS WITH
14 THREE WEEKS LEFT IN THE DISCOVERY PERIOD.

15 NEVERTHELESS, DESPITE THE FACT OF WHAT T.J. JUST
16 SAID, WE DO STILL FEEL THAT MOSES AND BRETT -- DRS. MOSES AND
17 BRETT HAVE SUFFICIENT KNOWLEDGE OF THE INFORMATION THAT THEY
18 CAN DISCUSS IT. WHETHER IN PRACTICE THEY DEFERRED ON ISSUES TO
19 HIM, THEY STILL UNDERSTAND WHAT WENT ON AND CAN ANSWER
20 QUESTIONS AND WHY DECISIONS WERE MADE BY A COMMITTEE.

21 IN ADDITION, ON THE OPTUM INSIGHT STUDY, THE
22 PLAINTIFFS RECENTLY SUBPOENAED THE THIRD PARTY THAT DEALT WITH
23 THAT STUDY AND WILL, PRESUMABLY, BE GETTING ADDITIONAL
24 DOCUMENTS ABOVE AND BEYOND WHAT NOVO HAS ALREADY PRODUCED. AND
25 WE DON'T FEEL THAT THE CUSTODIAL FILES THAT HAVE E-MAILS AND

1 THE LIKE ARE WHAT IS RELEVANT FOR THIS INQUIRY. IT'S THE DATA.
2 AND THEY HAVE THE DATA.

3 AND TO THE EXTENT THERE IS DATA -- INTERIM DATA FOR
4 THIS ONGOING STUDY, WE ARE IN THE MIDDLE OF SPEAKING WITH
5 PLAINTIFFS ABOUT THOSE VERY ISSUES. IN FACT, I JUST SPOKE WITH
6 MIKE JOHNSON TWO HOURS AGO ABOUT THAT ISSUE, AND WE'RE LOOKING
7 INTO THAT. AND THAT, AGAIN, IS WHERE I THINK THE PARTIES
8 SHOULD BE SPENDING THEIR TIME AND RESOURCES, ON THE DATA AND
9 NOT THE E-MAILS.

10 **THE COURT:** I DO THINK THAT IT IS THE DATA THAT WILL
11 DRIVE THE CAUSATION ISSUE, WHICH I'M FOCUSING ON PRIMARILY AT
12 THIS POINT. AND MUCH LIKE WITH THE PRIOR DISCUSSION, I THINK
13 WE HAVE TO SEE HOW COMPLETE THE DEPOSITION CAN BE, THE DEGREE
14 TO WHICH MOSES AND/OR BRETT CAN SATISFY THE INQUIRY WITH REGARD
15 TO THE AREAS, AND HAVING MOSES AND/OR BRETT DEPOSED AND THIS
16 PARTICULAR ISSUE HIGHLIGHTED IN TERMS OF EITHER THEIR ABILITY
17 OR INABILITY, AND THE RELATIVE RELEVANCE IN THE OVERALL SCHEME
18 OF THE DISCOVERY AT THIS STAGE LEADS ME TO MAKE A SIMILAR
19 RULING.

20 I WILL DENY AS TO GYDESEN AT THIS POINT. IT SOUNDS
21 LIKE THERE IS THIRD-PARTY INFORMATION THAT MAY SATISFY SOME OF
22 THE DATA CONCERNS IN THE SHORT TERM. WE CAN GET TO GYDESEN
23 SHOULD MOSES AND BRETT BE UNABLE TO ADEQUATELY ADDRESS ISSUES
24 THAT THE COURT CAN LATER DETERMINE RELEVANT, FOCUSING ON THE
25 SPECIFIC QUESTIONS AND ANSWERS DEALING WITH IT IN A GLOBAL

1 SENSE. SO IT'S A TAD HARD TO GET THE ARMS AROUND. SO I'LL
2 DENY AS TO GYDESEN, WITHOUT PREJUDICE.

3 AND THEN LOOKING AT THE DEFENSE BRIEF, WE HAVE
4 KISHORE SAHA, THE SENIOR SAFETY ADVISORY, AND GURLI
5 HEEBOLL-NEILSEN. AND I WON'T EVEN TRY TO GUESS GENDER HERE.
6 BUT AS TO THESE FOLKS, LET ME HAVE YOU, ONCE AGAIN, MS. LEVINE,
7 GIVE US -- CAPSULIZE YOUR OBJECTIONS OR POSITION AND WE CAN
8 FURTHER THE DISCUSSION.

9 **MS. LEVINE:** THANK YOU, YOUR HONOR.

10 **THE COURT:** HOLD ON. WHO WAS THAT?

11 **MR. PREUSS:** YOUR HONOR -- THIS IS T.J., YOUR HONOR.
12 COULD WE GO BACK TO DR. GYDESEN FOR A MINUTE? I WANT TO MAKE
13 ONE CHARACTERIZATION WITH RESPECT TO DR. GYDESEN. AND THE
14 OPTUM INSIGHT STUDY IS JUST AN EXAMPLE OF THE EPIDEMIOLOGY THAT
15 DR. GYDESEN WAS INVOLVED WITH. HE WAS ACTUALLY THE ONE WHO
16 DESIGNED AN EPIDEMIOLOGY STRATEGY PLAN FOR THE STUDY. SO I
17 JUST WANTED TO CLARIFY THAT THE OPTUM INSIGHT WAS JUST AN
18 EXAMPLE OF THE EPIDEMIOLOGY STRATEGY PLAN THAT DR. GYDESEN
19 WOULD BE INVOLVED IN.

20 AND I UNDERSTAND THE THOUGHT PROCESS OF DEFERRING
21 UNTIL AFTER DEPOSITIONS TO SEE IF, FOR EXAMPLE, DR. MOSES AND
22 DR. BRETT CAN SPEAK TO THE ISSUES THAT DR. GYDESEN WOULD SPEAK
23 TO. BUT ON THAT ISSUE, I FEEL LIKE SIMPLY TALKING ABOUT AN
24 EPIDEMIOLOGY STRATEGY PLAN. I'M NOT CERTAIN THAT THERE IS
25 GOING TO BE ANYBODY ELSE BESIDES DR. GYDESEN WHO CAN SPEAK TO

1 SUCH A PLAN, AS HE IS AN EPIDEMIOLOGIST AND THE OTHERS ARE NOT.
2 I JUST WANTED TO MAKE THAT CLEAR.

3 **THE COURT:** I APPRECIATE THE DISTINCTION ON THE
4 THIRD-PARTY STUDY AND THE ROLE OF GYDESEN, BUT I'M GOING TO
5 STICK WITH THE RULING. LET'S SEE IF MOSES AND/OR BRETT CANNOT
6 ADDRESS THE ISSUE IN TERMS OF A DESIGN, THE DATA AND SO FORTH.
7 CLEARLY, IN THEIR ROLES, THEY WOULD BE THE ONES THAT I THINK
8 WHERE THE BUCK WOULD ULTIMATELY STOP IN TERMS OF MUCH OF THIS.
9 SO I THINK WE NEED TO FIND OUT SO WE CAN REFINE THINGS DOWN.

10 IF THERE IS GOING TO BE FURTHER PRODUCTION OR FURTHER
11 DEPOSITIONS, WE CAN THEN FASHION THAT REMEDY WITH SOME GREAT
12 SPECIFICITY, AND THAT WAY NOT LOSE A WHOLE LOT OF TIME. AND IF
13 NOT, THEN WE MOVE ON, EITHER WAY.

14 SO LET'S MOVE TO SAHA AND HEEBOLL-NEILSEN. AND TO
15 SORT OF START THE BALL ROLLING, IT SEEMS LIKE THE DEFENSE
16 OBJECTION IS THESE AREN'T PRIMARY SOURCES FOR THE INFORMATION.
17 THIS IS WHERE THESE MINUTE MEETINGS REALLY ARE THE SORT OF BEST
18 EVIDENCE OF WHAT WENT ON IN THE SAFETY COMMITTEE, THE
19 LIRAGLUTIDE SAFETY COMMITTEE AND WHATEVER ELSE WAS IN PLACE.

20 SO, MS. LEVINE, PLEASE AMPLIFY OR SUPPLEMENT THAT, AS
21 YOU NEED.

22 **MS. LEVINE:** THANK YOU, YOUR HONOR. THAT WAS A GOOD
23 SUMMARY. SAHA IS A MALE AND NEILSEN IS A WOMAN. AND SAHA IS
24 THE CHAIR OF THE SAFETY COMMITTEE. WE HAVE SPOKEN TO HIM, AND
25 HE CONFIRMS THAT EVERYTHING I SAID BEFORE WAS ACCURATE, THAT IT

1 IS A COMMITTEE. DECISIONS ARE MADE BY COMMITTEE. THE
2 SUMMARIES AND THE MEETING MINUTES ARE DETAILED. SOME OF THEM
3 ARE DOZENS OF PAGES EACH. THE ENTIRE FILE WE PRODUCED OF THE
4 MEETING MINUTES, AND THE INFORMATION THAT IS NEEDED IS THERE.

5 SO WE FEEL, YOU KNOW, VERY COMFORTABLE THAT THE -- I
6 MEAN, WE KNOW THAT IF WE PRODUCED FILES FOR EITHER SAHA OR
7 NEILSEN, IT WOULD BE OF NO USE TO THE DEPOSITIONS THAT ARE
8 COMING UP IN THE NEXT THREE WEEKS.

9 WE SIMILARLY FEEL THAT TO THE EXTENT THAT THE
10 PLAINTIFFS THINK THAT THEIR EXPERTS NEED THESE FILED, THEY NEED
11 THE MEETING MINUTES, AND WE PRODUCED THEM. AND SO I DON'T
12 THINK THERE IS UTILITY IN ESSENTIALLY WASTING RESOURCES ON
13 GATHERING THAT INFORMATION FROM DENMARK.

14 AND IN ADDITION, DR. NEILSEN HAS LEFT THE COMPANY
15 SIX -- FIVE YEARS AGO, IN 2009. AND SO OTHER THAN A FEW FILES
16 THAT WE HAVE BEEN ABLE TO FIND, THERE REALLY ISN'T A FILE TO
17 PRODUCE. BUT THE MEETINGS MINUTES ARE ALL PRESERVED AND WERE
18 THERE AND PRODUCED. SO I THINK THAT THAT IS REALLY WHERE WE
19 STAND ON THAT ISSUE.

20 IN ADDITION, AND LASTLY ON THIS ISSUE, WE PRODUCED
21 THE FILES IN JUNE OF THE SAFETY OFFICER FOR VICTOZA IN THE
22 U.S., MICHAEL SACCO. WE OFFERED HIM FOR DEPOSITION, AND THE
23 PLAINTIFFS ELECTED NOT TO TAKE HIS DEPOSITION. AND SO I THINK
24 ON SAFETY, WHILE I UNDERSTAND THAT IT IS, OBVIOUSLY, AN
25 IMPORTANT ISSUE TO THIS LITIGATION, I THINK THAT WE HAVE

1 PRODUCED WHAT WE NEEDED TO AND PLAINTIFFS HAVE WHAT THEY NEED.

2 **THE COURT:** AND EDUCATE ME JUST A TOUCH ON THIS
3 COMMITTEE PROCESS. I HAVE BEEN A MEMBER OF ANY NUMBER OF
4 COMMITTEES AND THEY OPERATE, TYPICALLY, DIFFERENTLY. BUT IS
5 THIS A COMMITTEE STRUCTURE WHERE THEY OPERATE BY CONSENSUS IN
6 TERMS OF WHERE TO GO, THEY OPERATE ON A MAJORITY VOTE, THEY ARE
7 INFORMATIVE ONLY AND SOME SENIOR OFFICIAL MAKES THE ULTIMATE
8 CALL? WITHOUT GETTING TOO ELABORATE, HOW DOES IT WORK, IN A
9 NUTSHELL?

10 **MS. LEVINE:** THEY ACTUALLY OPERATE BY CONSENSUS ON
11 EVERY ISSUE. DESPITE BEING THE CHAIRMAN, SAHA DOES NOT MAKE
12 DECISIONS. HE IS VERY CONSISTENT WITH THAT ANSWER. HE IS NOT
13 THE DECISION-MAKER. HE IS THE COORDINATOR FOR THE COMMITTEE
14 AND THE COMMITTEE IS MADE UP OF THE VARIOUS ASPECTS AND AREAS
15 THAT YOU WOULD OTHERWISE THINK WOULD BE ON SUCH A COMMITTEE,
16 INCLUDING THE PHARMACOVIGILANCE GROUP, THE REGULATORY GROUP,
17 THE MEDICAL AFFAIRS GROUP AND THE LIKE. AND HE ORGANIZES THE
18 ISSUES AND HELPS DECIDE WHAT ISSUES COME UP BECAUSE THEY COME
19 UP AND DOUBLE UP, SO TO SPEAK, THROUGH EACH OF THE VARIOUS
20 DEPARTMENTS.

21 AND THE PLAINTIFFS HAVE ACCESS TO THE FILES OF THE
22 VARIOUS DEPARTMENTS AND THE WITNESSES THERE. AND SO IT JUST
23 WOULD BE IRRELEVANT OR DUPLICATIVE OR UNNECESSARY TO HAVE THAT.

24 **THE COURT:** AND ULTIMATELY --

25 **MS. LEVINE:** AND ALSO, THE PLAINTIFFS DID DEPOSE

1 MR. SACCO. I'M SORRY, YOUR HONOR. THE PLAINTIFFS DEPOSED
2 MICHAEL SACCO, THE SAFETY OFFICER FROM THE U.S., AS A 30(B)(6)
3 WITNESS, AND WAS ABLE TO AND DID ASK QUESTIONS ABOUT HOW THE
4 SAFETY COMMITTEE FUNCTIONS. AND THAT SAFETY COMMITTEE, BY THE
5 WAY, IS LOCATED IN DENMARK AND IS WITH DANISH WITNESSES.

6 **THE COURT:** OKAY. AND, ULTIMATELY, THINGS TRICKLE UP
7 TO THE POINT WHERE MOSES OR MADSEN, THE TWO FOLKS THAT I THINK
8 ARE SET TO BE -- OR AT LEAST MOSES IS GOING TO BE DEPOSED --
9 THAT WOULD BE SOMETHING UNDER HIS ULTIMATE LEADERSHIP OR
10 PURVIEW. OKAY.

11 SO, MR. PREUSS --

12 **MS. LEVINE:** I'M NOT SURE I WOULD SAY IT'S HIS
13 LEADERSHIP. I'M SORRY, YOUR HONOR. I AM NOT SURE AS TO THE
14 LEADERSHIP ON THE SAFETY COMMITTEE, BUT HE CERTAINLY IS ASKED
15 TO WEIGH IN AND UNDERSTANDS WHAT GOES ON THERE AND IS OPEN TO,
16 OBVIOUSLY, BEING QUESTIONED, IF NECESSARY, ON THOSE ISSUES.

17 **THE COURT:** OKAY. MR. PREUSS, YOUR TURN, SIR.

18 **MR. PREUSS:** OKAY. THANK YOU, YOUR HONOR.

19 YOUR HONOR, PART OF THE BASIS FOR THIS REQUEST IS --
20 OBVIOUSLY, A MAJOR PART OF THIS BASIS IS DR. SAHA AND
21 DR. NEILSEN'S INVOLVEMENT WITH THE NOVO SAFETY COMMITTEE. WE
22 HAVE NOW SEEN DOCUMENTS THAT DISCUSS THE SAFETY COMMITTEE, WHAT
23 ITS PURPOSE IS. AND WE DO HAVE MEETING MINUTES FROM SAFETY
24 COMMITTEE MEETINGS.

25 AS THE CHAIR OF THE SAFETY COMMITTEE, WHICH EACH OF

1 THESE INDIVIDUALS WERE, WE WOULD EXPECT THEM TO HAVE
2 INFORMATION IN THEIR FILES THAT WOULD COME TO THEM FROM
3 COLLEAGUES OUTSIDE OF THE CONTEXT OF THE ACTUAL MEETINGS -- NOT
4 JUST IN THE FORM OF MEETING MINUTES -- BUT I'M GOING TO GO TO
5 DR. SAHA ABOUT THE SAFETY ISSUES BECAUSE HE IS THE CHAIR OF THE
6 SAFETY COMMITTEE. WE WOULD EXPECT E-MAILS FROM INDIVIDUAL
7 COLLEAGUES TO THESE DOCTORS, GIVEN THE ROLE AS CHAIRS OF THE
8 SAFETY COMMITTEE.

9 AND WHEN WE GOT INTO THE DOCUMENTS AND WE SAW WHAT
10 THE SAFETY COMMITTEE MINUTES ENTAILED AND THE PURPOSE OF THE
11 SAFETY COMMITTEE, WE WENT BACK TO DR. MIKE SACCO'S 30(B)(6)
12 DEPOSITION. AND HE ACTUALLY REFERENCES EACH OF THESE DOCTORS
13 IN VARIOUS RESPECTS AND IN DEPOSITION, AS WELL.

14 SO IT'S BECAUSE OF HIS TESTIMONY, ALONG WITH THEIR
15 INVOLVEMENT WITH THE SAFETY COMMITTEE, THAT WE BELIEVE THESE
16 ARE IMPORTANT AND NECESSARY CUSTODIAL FILES TO BE PRODUCED.

17 AND JUST BACKING UP A LITTLE BIT. YOU KNOW, THE
18 NUMBER OF FILES -- CUSTODIAL FILES PRODUCED IN THIS CASE IS
19 MUCH SMALLER THAN ANY MDL THAT I HAVE EVER HAD EXPERIENCE IN.
20 AND I THINK TYPICALLY WHEN YOU ARE TALKING ABOUT A
21 PHARMACEUTICAL MDL OF THE MAGNITUDE LIKE THIS, YOU ARE
22 TYPICALLY LOOKING AT A BARE MINIMUM OF 45 TO 50 CUSTODIAL
23 FILES. AND WE'RE NOT GOING TO GET CLOSE TO THAT HERE AT THIS
24 STAGE. AND WE ARE TRYING OUR DARNDDEST TO KEEP THE FILE REQUEST
25 AS LIMITED AS POSSIBLE.

SEPTEMBER 23, 2014

1 AND THAT'S, FRANKLY, ANOTHER REASON WHY WE REQUESTED
2 DR. SAHA AND DR. NEILSEN'S FILES. AS THE CHAIRS OF THE SAFETY
3 COMMITTEE, WE EXPECT THEM TO BE HUBS OF SAFETY INFORMATION FOR
4 VICTOZA AT NOVO NORDISK. AND WE'RE NOT ASKING FOR ALL THE
5 SPOKES OF THAT HUB. WE'RE NOT ASKING FOR ALL THE CUSTODIAL
6 FILES AT THIS POINT, BUT WE WOULD EXPECT, GIVEN THEIR ROLES,
7 THEY WOULD HAVE A COMPLETE SAFETY CODE FILE -- A COMPLETE
8 SAFETY CODE FILE OF VICTOZA.

9 **THE COURT:** IS THERE ANYTHING THAT IS --

10 **MR. KENNERLY:** YOUR HONOR, IF I MAY, THIS IS MAX
11 KENNERLY, ALSO FOR THE PLAINTIFFS. THE ONLY SHORT INTERJECTION
12 I WOULD ADD HERE IS THAT MANY OF THESE SAFETY MINUTES WE DID
13 NOT RECEIVE UNTIL SEPTEMBER 8TH. AND THE ONLY REASON WE GOT
14 THEM IS BECAUSE WE HAD FILED A PRIOR MOTION TO COMPEL. AND SO
15 MUCH OF THIS WE'RE UNPACKING AT THE LAST MINUTE BECAUSE OF WHAT
16 WASN'T PROVIDED TO US, JUST AS A MATTER OF COURSE, WHICH YOU'D
17 THINK IT WOULD BE, FOR GENERAL CAUSATION.

18 SO IN TERMS OF LATENESS AND TIME, MUCH OF THIS HAS
19 NOT BEEN PRODUCED TO US UNTIL LITERALLY THIS MONTH, WHICH IS
20 WHY WE ARE NOW COMING BACK AROUND THROUGH IT.

21 **THE COURT:** I UNDERSTAND. AND I'M MORE FOCUSED ON
22 DISCOVERY NEED, PROPORTIONALITY, COST EFFECTIVENESS,
23 EXPEDITIOUSNESS. AND I UNDERSTAND THERE ARE SOME DYNAMICS
24 HERE, BUT I GUESS THE QUESTION I WOULD ASK OF THE PLAINTIFFS IS
25 IN THE MEETING MINUTES THAT WE HAVE SEEN SO FAR, ARE THERE

1 REFERENCES TO SCIENTIFIC DATA THAT ISN'T OTHERWISE PROVIDED
2 WITHIN THE CONTENT OF THOSE OTHER CUSTODIAN FILES THAT HAVE
3 BEEN PRODUCED? OR ARE WE NOT THERE ENOUGH TO KNOW -- NOT
4 FURTHER ENOUGH THROUGH THEM TO KNOW?

5 **MR. PREUSS:** PART OF THE ISSUE IS WE ARE ONLY GETTING
6 IT AS A GLIMPSE OF WHAT WE SEE RIGHT NOW THROUGH THE FILES WE
7 HAVE RIGHT NOW. WE DON'T KNOW WHAT WE HAVEN'T BEEN PRIVY TO AT
8 THIS POINT. SO BASED ON WHAT WE HAVE SEEN SO FAR -- THE
9 NARROWNESS OF WHAT WE HAVE SEEN SO FAR, YES, IT APPEARS THAT
10 EACH OF THESE INDIVIDUALS HAVE ADDITIONAL ROLES WITH RESPECT TO
11 SAFETY AT NOVO NORDISK.

12 FOR INSTANCE -- AND I THINK THIS IS ADDRESSED IN OUR
13 PAPERS -- DR. NEILSEN AUTHORED AN EARLY RISK MANAGEMENT PLAN
14 FOR VICTOZA. AND AGAIN, THERE IS SOME INDICATIONS THAT NEILSEN
15 AND SAHA ARE RECEIVING INDIVIDUAL E-MAILS FROM THEIR
16 COLLEAGUES.

17 **THE COURT:** WELL, THE E-MAILS ARE PROBLEMATIC BECAUSE
18 THEY AREN'T NECESSARILY GOING TO BE SCIENTIFIC DATA. THEY ARE
19 MUCH MORE ANECDOTAL. AND I THINK THEY REALLY ARE OUTSIDE THE
20 SCOPE OF DISCOVERY I'VE SET.

21 IN ADDITION, THE MANNER IN WHICH THE SAFETY COMMITTEE
22 SEEMS TO OPERATE -- BASED ON WHAT MS. LEVINE SAID -- AND,
23 APPARENTLY, THIS WAS CONFIRMED BY MR. SACCO -- S-A-C-C-O; I
24 DON'T THINK WE SPELLED THAT ONE YET -- WOULD SUGGEST THAT AS A
25 COMMITTEE OPERATING BY CONSENSUS, SOMEONE MIGHT HAVE SOMETHING

1 IN A FILE SOMEWHERE. BUT UNLESS IT GETS TO THE COMMITTEE, IS
2 DISCUSSED AND BECOMES A DIRECTION OR A DECISION BY THE COMPANY,
3 SO TO SPEAK -- I USE THOSE TERMS VERY LITERALLY -- VERY
4 FIGURATIVELY, NOT LITERALLY -- THAT IT REALLY BEGS THE
5 QUESTIONS OF RELEVANCE.

6 HERE, IF THE DEPOSITIONS OF MOSES OR WHOMEVER ELSE
7 THAT IS ASKED ABOUT THIS INFORMATION REVEALS CONTENT IN THE LSC
8 MEETING MINUTES WITH REGARD TO SCIENTIFIC DATA DISCUSSED AND
9 EITHER UTILIZED, DISPATCHED, IGNORED OR WHATNOT, THAT HASN'T
10 BEEN PROVIDED AND COULD NOT BE INQUIRED ABOUT, THEN I WOULD
11 REVISIT THIS. BUT I THINK, UNLIKE THE PRIOR SETS OF WITNESSES,
12 THIS IS MUCH MORE FAR AFIELD.

13 SO I'M GOING TO DENY THE DEPOSITIONS -- OR THE
14 CUSTODIAL FILES, AND EXPAND THE DEPOSITION LIST TO INCLUDE SAHA
15 AND NEILSEN, WITHOUT PREJUDICE TO SOME SPECIFIC SHOWING THAT
16 THERE IS SOMETHING THEY BROUGHT TO THE MEETING THAT HASN'T BEEN
17 CAPTURED IN SOME OTHER DATA, WHICH MEANS IT WILL BE A
18 POST-DEPOSITION EXERCISE. SO THAT WOULD TAKE CARE OF THE NOVO
19 GROUP OF CANDIDATES.

20 AND THEN WE HAVE MERCK, WHERE THERE ARE ANOTHER FIVE
21 PEOPLE THAT ARE IDENTIFIED, IF MY MEMORY IS STILL ANY GOOD.
22 AND LET ME TURN TO THOSE.

23 AND, MS. LEVINE, DID I HEAR YOU SAY YOU ARE GOING TO
24 TAKE THE LEAD, AND THEN, MR. MARVIN AND MS. REYES MIGHT ASSIST,
25 IF NEED BE?

1 MS. LEVINE, DID WE LOSE YOU? HELLO?

2 **MR. MARVIN:** I'M SORRY. I HAD MY PHONE ON MUTE.

3 **THE COURT:** THE QUESTION WAS IS MS. LEVINE GOING TO
4 TAKE THE LEAD ON THESE ISSUES WITH MERCK, AS WELL, WITH YOUR
5 ASSISTANCE, MR. MARVIN?

6 **MR. MARVIN:** NO, YOUR HONOR. I THINK I CAN TAKE THE
7 LEAD ON THE MERCK CUSTODIANS.

8 **THE COURT:** OKAY. AND I HAD A HARDER TIME FERRETING
9 OUT THE ISSUES FOR MERCK, AND I DON'T MEAN THAT IN A CRITICAL
10 WAY; JUST A PRACTICAL. SO I MAY NEED TO ASK YOU A LITTLE BIT
11 MORE ABOUT YOUR RELATIVE POSITIONS HERE. BUT THE FIRST PERSON
12 ON THE BLOCK, SO TO SPEAK, IS CYNTHIA GIRMAN, WHO IS AN
13 EXECUTIVE DIRECTOR AT MERCK IN THE DATA ANALYTICS AND
14 OBSERVATIONAL METHODS UNIT, ETC., EPIDEMIOLOGIST AND
15 BIOSTATISTICIAN WHO HAS LOOKED AT POST-MARKETING EFFECTS OF
16 SITAGLIPTIN.

17 SO THE QUESTION FOR YOU, MR. MARVIN, IS SHE
18 COVERED -- IS HER INFORMATION, HER DATA AND SO FORTH -- IS IT
19 COVERED SOMEWHERE ELSE IN THE PRODUCTION TO DATE AND, IF SO,
20 WHERE? AND IF NOT, WHY SHOULDN'T IT BE?

21 **MR. MARVIN:** WE MIGHT TAKE UP BOTH GIRMAN AND HER
22 COLLEAGUE, WHO ARE BOTH EPIDEMIOLOGISTS, BRODOVICZ.

23 **THE COURT:** THAT WILL BE FINE. GO AHEAD.

24 **MR. MARVIN:** IN THE PLAINTIFFS' MOTION TO COMPEL,
25 THEY POINT TO TWO TOPICS FOR WHICH THEY NEED THE ADDITIONAL

1 CUSTODIANS. ONE IS STUDY DESIGN AND METHODOLOGY, AND THE OTHER
2 IS DATA INTERPRETATION. AND THAT'S ESPECIALLY TRUE WITH
3 RESPECT TO THE TWO EPIDEMIOLOGISTS.

4 AS FOR THE STUDY DESIGN AND METHODOLOGY, THAT IS
5 CONTAINED IN THE PROTOCOLS. AND WE'VE ALREADY PRODUCED THE
6 PROTOCOLS. THEY CAN SEE THERE WHAT THE METHODOLOGY IS.

7 AS FOR DATA INTERPRETATION, THE SAME IS TRUE THERE.
8 WE HAVE PRODUCED THE STUDIES AND THEY CAN SEE THE RESULTS OF
9 THE STUDIES. SO IN BOTH INSTANCES WHERE THEY POINT TO TOPICS
10 FOR WHICH THEY NEEDED ADDITIONAL CUSTODIANS, THAT HAS ALREADY
11 BEEN PROVIDED IN THE STUDIES THAT THEY HAVE.

12 NOW, AS TO WHO CAN SPEAK TO THOSE SAME ISSUES, AS
13 WELL AS THE ISSUES THAT BOTH OF THE EPIDEMIOLOGISTS WOULD
14 CONSIDER, THAT WOULD BE SAM ENGEL, WHOSE FILE HAS BEEN
15 PRODUCED, AS WELL AS KEITH KAUGHMAN, RICH CLAY, AND LOUANN
16 EADER TO AN EXTENT, AS WELL.

17 THE REASON WHY I MENTION DR. ENGEL IS THAT HE IS THE
18 DOCTOR WHO PRESENTED TO THE NATIONAL INSTITUTES OF HEALTH
19 SESSION WHICH WAS HELD IN 2013, WHICH WAS ATTENDED BY THE
20 LEADING SCIENTISTS IN THE COUNTRY, WHERE THEY INDICATED THAT
21 THEY WERE LOOKING AT ANY LINK BETWEEN PANCREATIC CANCER AND
22 INCRETIN-BASED THERAPIES.

23 AND THAT WAS THE WORKSHOP WHICH THE FDA ATTENDED, AS
24 WELL, AND PRESENTED, AND IT WAS THE NATIONAL INSTITUTE OF
25 DIABETES AND DIGESTIVE AND KIDNEY DISEASES, AND THE NATIONAL

1 CANCER INSTITUTE, ALL AT THIS MEETING AT NIH. SAM ENGEL WAS
2 THE ONE WHO MADE THE PRESENTATION TO THAT GROUP. AND AS A
3 CONSEQUENCE, HE IS STEEPED IN THE CLINICAL STUDIES AND THE
4 OTHER STUDIES THAT HAVE BEEN CONDUCTED BY THE COMPANY, AND
5 WOULD BE IN A POSITION TO ANSWER MANY OF THE QUESTIONS THAT WE
6 THINK COULD BE ADDRESSED BY THE EPIDEMIOLOGISTS.

7 I ALSO WANT TO POINT OUT THAT HE, ALONG WITH RICH
8 CLAY AND LOUANN EADER, WERE MEMBERS OF THE RISK MANAGEMENT
9 SAFETY TEAM. AND THAT IS ANOTHER AREA WHERE THE PLAINTIFFS
10 HAVE SAID THAT THEY NEED BOTH OF THE EPIDEMIOLOGISTS,
11 DR. GIRMAN AND DR. BRODOVICZ. DR. ENGEL IS ALSO A MEMBER OF
12 THAT SAME COMMITTEE AND WOULD BE ABLE TO ADDRESS ISSUES THAT
13 ARISE THERE. AND IN FACT, THERE ARE SEVERAL OTHER CUSTODIANS
14 FOR WHOM WE'VE PRODUCED DOCUMENTS, INCLUDING RICH CLAY AND
15 LOUANN EADER, WHO ARE ALSO MEMBERS OF THAT RISK MANAGEMENT
16 SAFETY TEAM.

17 I ALSO WANT TO POINT OUT THAT WE HAVE PRODUCED
18 DOCUMENTS FROM THE CUSTODIANS WHO WERE SELECTED BY THE
19 PLAINTIFFS AND TO WHICH WE AGREED AS BEING THOSE WHO WERE MOST
20 KNOWLEDGEABLE ABOUT THE VARIOUS AREAS, FROM ANIMAL STUDIES TO
21 CLINICAL STUDIES, TO OBSERVATIONAL STUDIES, TO ADVERSE EVENTS,
22 TO REGULATORY SUBMISSIONS.

23 AND IN PRODUCING THE CUSTODIAL FILES FOR THE TEN --
24 NOT EIGHT AS THE PLAINTIFFS HAVE INDICATED IN THEIR BRIEF -- AS
25 TO TEN CUSTODIANS, WE HAVE ALREADY PRODUCED, FROM THOSE

1 CUSTODIANS, 4,600 DOCUMENTS WHERE DR. GIRMAN WAS A "TO,"
2 "FROM," OR "COPY," AS WELL AS 3,700 DOCUMENTS INVOLVING
3 BRODOVICZ.

4 SO THE PLAINTIFFS ALREADY HAVE DOCUMENTS --
5 SUBSTANTIAL NUMBERS OF DOCUMENTS THAT WOULD BE IN BOTH OF THOSE
6 FILES. WOULD THERE BE MORE? YEAH, I DO BELIEVE THERE WOULD BE
7 MORE. BUT NOW THE PLAINTIFFS ARE ASKING US TO GO THROUGH THE
8 LABORIOUS PROCESS OF LOOKING THROUGH THE FILES OF THOSE
9 ADDITIONAL CUSTODIANS, TO SEE WHAT MORE THERE MIGHT BE.

10 AND AS MS. LEVINE STATED, AT THIS STAGE WE THINK THAT
11 THE FOCUS SHOULD BE MORE ON THE DATA AND THE STUDIES. AND IN
12 THE EVENT THAT THERE ARE GAPS THAT THOSE THAT ARE ALREADY
13 SCHEDULED FOR DEPOSITIONS CANNOT BRIDGE OR CANNOT ADDRESS, THEN
14 WE CERTAINLY CAN REVISIT, AS YOUR HONOR HAS SUGGESTED, THE
15 ADDITIONAL CUSTODIANS THAT THE PLAINTIFFS ARE SEEKING HERE.

16 **THE COURT:** NOW, WHEN YOU SAY THAT ENGEL AND OTHERS
17 COULD ADDRESS THE ISSUES OF CONCERN TO AN EPIDEMIOLOGIST -- I
18 MAY NOT HAVE QUOTED YOU DIRECTLY -- ARE WE TALKING ABOUT ISSUES
19 THAT WOULD CONCERN AN EPIDEMIOLOGIST WITH REGARD TO THE DATA
20 THAT GIRMAN AND BRODOVICZ INTERPRETED WITH REGARD TO WHAT WORK
21 WAS DONE ON BEHALF OF MERCK? ARE WE GETTING THAT SPECIFIC?

22 **MR. MARVIN:** NOT THAT SPECIFIC. AS MS. LEVINE SAID,
23 IN TERMS OF LOOKING OR CONSIDERING WHAT QUESTIONS MIGHT BE
24 ASKED AT A DEPOSITION AND WHAT A PARTICULAR WITNESS CAN
25 ADDRESS, YOU KNOW, I'M NOT IN A POSITION, AS SHE WAS, TO BE

1 ABLE TO SAY THAT EVERY SINGLE QUESTION COULD BE ADDRESSED BY
2 DR. ENGEL THAT WOULD NOT BE PUT TO EITHER OF THE TWO
3 EPIDEMIOLOGISTS. BUT I DO THINK THAT DR. ENGEL WOULD BE IN
4 POSITION BECAUSE HE IS SO STEEPED IN THE STUDIES AND THIS
5 PARTICULAR ISSUE THAT I WOULD EXPECT HIM TO BE ABLE TO ADDRESS
6 MOST OF THOSE QUESTIONS, IF NOT ALL.

7 **THE COURT:** AND WHEN HE SPOKE TO THE NIH IN 2013,
8 PRESUMABLY THE BACKGROUND THAT HE WAS WORKING OFF OF WOULD HAVE
9 INCLUDED THE DATA THAT CAME OUT OF GIRMAN AND BRODOVICZ IN
10 THEIR WORK?

11 **MR. MARVIN:** MOST DEFINITELY, YES. AND I'M SORRY. I
12 SHOULD ALSO INCLUDE KEITH KAUGHMAN AS ANOTHER PERSON WHOSE
13 DEPOSITION IS SCHEDULED, WHO WOULD BE ABLE TO ADDRESS SOME OF
14 THE SAME KIND OF QUESTIONS THAT WE WOULD EXPECT TO BE PUT TO
15 EITHER OF THE TWO EPIDEMIOLOGISTS.

16 **THE COURT:** AND ONE LAST QUESTION AND I WILL TURN IT
17 OVER TO THE PLAINTIFFS. EADER, THAT IS E-A-D-E-R, FOR THE
18 RECORD?

19 **MR. MARVIN:** YES, IT IS.

20 **THE COURT:** I JUST WANT TO MAKE SURE WE HAVE THE
21 SPELLING SOMEWHERE IN THE RECORD. OKAY.

22 SO GOING BACK TO THE PLAINTIFFS' SIDE, NOW FOCUSING
23 ON GIRMAN AND BRODOVICZ, WHAT WOULD YOU LIKE TO ADD, THEN,
24 MR. PREUSS?

25 **MR. PREUSS:** YES. THANK YOU, YOUR HONOR.

1 **MR. MARVIN:** SORRY, YOUR HONOR. IF I MAY INTERJECT.
2 MS. REYES IS -- WHEN I SPOKE ABOUT LOUANN EADER, SHE IS IN
3 REGULATORY AFFAIRS. BUT WHEN I WAS SPEAKING TO HER, I WAS
4 TALKING ABOUT HER ROLE AS ALSO BEING A MEMBER OF THE RISK
5 MANAGEMENT SAFETY TEAM AND NOT PARTICULARLY WITH RESPECT TO THE
6 CLINICAL STUDIES.

7 **THE COURT:** OKAY. THANK YOU FOR THAT
8 CHARACTERIZATION.

9 WITH THAT, THEN, MR. PREUSS, GO AHEAD.

10 **MR. PREUSS:** THANK YOU, YOUR HONOR.

11 FIRST OF ALL, WITH RESPECT TO WHAT OTHERS MAY COVER
12 IN THEIR DEPOSITIONS, I WOULD BE HAPPY TO TAKE THE DEPOSITIONS
13 AND MAKE A DETERMINATION OF WHO WE MIGHT NEED AFTER THOSE
14 DEPOSITIONS. BUT THE PLAINTIFFS FEEL THAT WE ARE IN A POSITION
15 THAT TIME IS NOT GOING TO ALLOW FOR THAT.

16 AND IT'S AN ISSUE THAT WE REASONABLY EXPECT TO BE
17 COVERED BY A FUTURE DEPOSITION, OR IS AN AREA OR SUBJECT MATTER
18 OR DEPARTMENT WHO WE THINK WOULD BE COVERED BY A CUSTODIAN WE
19 ALREADY HAD OR A FUTURE DEPOSITION. AND, FRANKLY, WE HELD OFF
20 ON THOSE REQUESTS.

21 BUT HERE AGAIN, WE'RE TALKING ABOUT EPIDEMIOLOGISTS.
22 JUST LIKE DR. GYDESEN WITH NOVO, THERE ARE NO EPIDEMIOLOGIST
23 CUSTODIAL FILES THAT HAVE BEEN PRODUCED FOR MERCK. AND THE
24 EPIDEMIOLOGISTS ARE GOING TO BE THE ONES WHO KNOW ABOUT THE
25 EPIDEMIOLOGY. I DON'T KNOW HOW ANYONE ELSE, INCLUDING

1 DR. ENGEL, CAN SPEAK TO THE SPECIFICS WITH RESPECT TO
2 EPIDEMIOLOGY.

3 ALSO, GOING BACK A BIT. THEIR ORIGINAL FILE
4 PRODUCTION -- CUSTODIAL FILE PRODUCTION WAS CONTEMPLATED TO BE
5 AN INITIAL PRODUCTION. THAT IS HOW IT WAS ADDRESSED IN THE ESI
6 PROTOCOL. THAT WASN'T TO BE THE END-ALL/BE-ALL. I THINK BOTH
7 PARTIES EXPECTED ADDITIONAL CUSTODIAL FILES TO BE PRODUCED,
8 WHICH IS COMMON IN THE CASES LIKE THESE.

9 YOU GET AN ORIGINAL ROUND OF CUSTODIAL FILES, YOU
10 HAVE PLANS TO REVIEW THOSE FILES. AND DURING THEIR REVIEW THEY
11 LEARN OF ADDITIONAL RELEVANT AND IMPORTANT WITNESSES IN THOSE
12 FILES, AND ADDITIONAL REQUESTS ARE MADE AT THAT TIME. SO THAT
13 IS THE PROCESS WE ARE ENGAGING IN RIGHT NOW. AND, OBVIOUSLY,
14 THERE MAY BE ADDITIONAL NEEDS THAT PLAINTIFFS RECEIVE AS THE
15 DEPOSITIONS CONTINUE, AS WELL.

16 **THE COURT:** AND I UNDERSTAND THAT, BUT GO AHEAD.

17 **MR. PREUSS:** WITH RESPECT TO DRS. GIRMAN AND
18 BRODOVICZ, AGAIN, I THINK IT'S IMPORTANT -- NOT ONLY
19 EPIDEMIOLOGY DATA THAT WAS PRODUCED FROM CERTAIN STUDIES --
20 WHETHER DR. ENGEL OR OTHERS COULD SEE OR INTERPRET AND TALK
21 ABOUT THAT DATA -- BUT FROM THE FOREFRONT OF THOSE STUDIES,
22 WHAT HAPPENED BEFORE THOSE STUDIES.

23 AND THERE IS A LOT OF DESIGN AND INFLUENCE THAT GOES
24 INTO EACH OF THESE STUDIES. YOU HAVE TO KEEP IN MIND THAT THE
25 DEFENDANTS HAVE DRIVEN THE SCIENCE ON THESE DRUGS FOR A NUMBER

1 OF YEARS. AND THE PLAINTIFFS HAVE A RIGHT, WE BELIEVE, TO
2 DISCOVER WHETHER THE SCIENCE, BY DESIGN, OVERLOOKED OR
3 TRIVIALIZED THE PANCREATIC CANCER RISK. AND SO WE ARE ALSO
4 TALKING ABOUT THE FRONT END OF THESE STUDIES IN THAT RESPECT.

5 WITH REGARD TO DR. GIRMAN, WE KNOW FROM WHAT WE CAN
6 SEE AT THIS POINT -- AND WE DON'T BELIEVE THIS IS THE ONLY
7 CONTACT OR THE ONLY EXAMPLE OF THIS -- BUT DR. GIRMAN HAD
8 DISCUSSIONS WITH EXTERNAL RESEARCHERS ABOUT EPIDEMIOLOGY
9 STUDIES WITH RESPECT TO VICTOZA, WITH RESPECT TO PANCREATIC
10 CANCER. AND SOME OF THAT IS DISCUSSED IN OUR PAPERS.

11 WE ASSUME, BASED ON WHAT WE SEE AT THIS POINT IN THE
12 LIMITED DOCUMENTS WE HAVE, THAT THOSE DISCUSSIONS EVOLVE AROUND
13 THE DESIGN AND PROTOCOL OF THE EPIDEMIOLOGY STUDIES. IS IT A
14 GOOD IDEA TO SAY AT THIS POINT OR NOT? WHAT FACTORS WENT INTO
15 THOSE DESIGNS IS IMPORTANT BECAUSE, AGAIN, OUR EXPERTS ARE
16 TRYING TO ANALYZE NOT ONLY THE DATA, BUT EVERY PIECE OF DATA
17 THAT HAD A WEIGHT AFFORDED TO IT. AND THEY ARE TRYING TO
18 ANALYZE AND WEIGH THAT DATA IN A SYSTEMATIC FASHION TO
19 ULTIMATELY DETERMINE THE ULTIMATE QUESTION: ARE THESE DRUGS
20 CAPABLE OF CAUSING PANCREATIC CANCER?

21 DR. GIRMAN HAS CONTACT WITH EXTERNAL RESEARCHERS.
22 AND WE BELIEVE DR. GIRMAN HAS INFORMATION IN HIS CUSTODIAL
23 FILES ABOUT DESIGN METHODOLOGY WITH RESPECT TO EPIDEMIOLOGY
24 STUDIES.

25 AND DR. BRODOVICZ, THE SAME. WE KNOW HE IS INVOLVED

1 IN OTHER OBSERVATIONAL STUDIES AND LOOKED AT DIFFERENT
2 HEALTHCARE DATABASES TO DETERMINE WHICH WOULD BE THE BEST TO
3 STUDY. AND IT BEGS THE QUESTION: WHY WERE CERTAIN DATABASES
4 STUDIED AND WHY WEREN'T OTHERS STUDIES? WHY WAS THE DECISION
5 MADE NOT TO STUDY CERTAIN DATABASES?

6 THOSE RESEARCH METHODS ARE POTENTIALLY EVEN MORE
7 IMPORTANT TO THE CASE, IN OUR EXPERTS' OPINIONS, THAN THE DATA
8 THAT ULTIMATELY IS PRODUCED FROM THOSE STUDIES. AND THAT'S,
9 AGAIN, THE BASIS FOR OUR REQUEST FOR DR. GIRMAN AND
10 DR. BRODOVICZ FILES.

11 **THE COURT:** MAYBE IT'S AN OVERSIMPLISTIC QUESTION, SO
12 FORGIVE ME IN ADVANCE. BUT THE STUDY WAS DESIGNED WITH CERTAIN
13 WEIGHTS GIVEN TO WHATEVER, AND CERTAIN DECISIONS TO STUDY
14 CERTAIN POPULATIONS OR VARIABLES OR WHATNOT. AND THAT'S WHAT
15 THE DEFENDANTS ESSENTIALLY DID. THEY, THROUGH THEIR EMPLOYEES
16 OR CONSULTANTS, DESIGN A STUDY.

17 AND WITH THAT STUDY THEY COLLECT DATA. AND THE DATA
18 IS WHAT WE'RE WORKING OFF OF NOW. A CRITICISM OF THE STUDY
19 CONTOURS OR THE PROTOCOLS UTILIZED WOULD BE SOMETHING AN EXPERT
20 COULD OPINE ON WITH TRAINING IN THE FIELD. AND SO IT SEEMS TO
21 ME THAT WE ARE GETTING FAR AFIELD OF THIS. BUT MAYBE I'M
22 MISSING SOMETHING, SO YOU CAN TRY TO HELP ME ON THAT POINT.

23 **MR. PREUSS:** SURE. AND A COUPLE OF THINGS. FIRST OF
24 ALL, IT'S NOT ONLY THE STUDY -- DESIGNS OF THE STUDIES THAT
25 ULTIMATELY WENT FORWARD AND PRODUCED DATA, BUT ALSO IT'S STUDY

1 DESIGNS THAT WERE CONTEMPLATED AND POTENTIALLY NEVER FOLLOWED
2 UP ON WHICH WOULD HAVE -- IF THOSE STUDIES WOULD HAVE GONE
3 FORWARD, WOULD HAVE BEEN THE BETTER DESIGN, THE ULTIMATE
4 APPROACH TO ANSWER THE QUESTION AT HAND.

5 **THE COURT:** HOW DO WE KNOW THAT? ARE WE SAYING THAT
6 THEN WE'RE GOING TO TAKE THESE ALTERNATE METHODS AND RERUN THE
7 DATA THROUGH ALTERNATE METHODS AND HAVE SOME COMPARATIVE
8 ANALYSIS THAT IS GOING TO SHOW SOMETHING ENTIRELY DIFFERENT?

9 I MEAN, ISN'T THAT WHERE YOU WOULD BE GOING, TO SAY
10 THERE IS ANOTHER METHOD, LET'S RERUN EVERYTHING THROUGH THAT
11 SCREENING DEVICE OR THAT MATRIX AND SEE WHAT WE COME UP WITH?

12 **MR. PREUSS:** POTENTIALLY, IF CERTAIN FACTORS WERE
13 EXCLUDED FROM THE STUDY DESIGN, EXPERTS COULD BE ABLE TO COME
14 IN AND SAY IF THOSE FACTORS WERE CONSIDERED, I DO BELIEVE THAT
15 THIS STUDY WOULD HAVE RENDERED A DIFFERENT RESULT -- RESULTS.
16 CERTAINLY.

17 **THE COURT:** OKAY.

18 **MR. PREUSS:** AND THOSE DESIGNS, THOSE ARE THE SORTS
19 OF THINGS THAT ARE GOING TO BE PICKED OUT IN THE CUSTODIAL
20 FILES, AND SPECIFICALLY FROM E-MAILS FROM THESE CUSTODIANS WHO
21 ARE REQUESTING, INTERNAL COLLEAGUES THROUGH EXTERNAL
22 RESEARCHERS. AND THEN ALL --

23 **THE COURT:** I UNDERSTAND -- GO AHEAD. YOU FINISH.

24 **MR. PREUSS:** ALSO, WITH RESPECT TO STUDIES THAT WENT
25 FORWARD, IT IS IMPORTANT TO KNOW WHY THE DECISION IS MADE TO

1 SET THE PROTOCOL THE WAY IT ULTIMATELY MOVED FORWARD, VERSUS
2 OTHER METHODS AND PROTOCOLS THAT MAY HAVE BEEN CONSIDERED. AND
3 AGAIN, THAT GOES TO THOSE DESIGNS BY DESIGN THAT OVERLOOKED OR
4 TRIVIALIZED THE PANCREATIC CANCER RISKS ASSOCIATED WITH THESE
5 DRUGS.

6 **THE COURT:** OKAY. WELL, I APPRECIATE THE
7 CHARACTERIZATION. SO THANK YOU.

8 SO, MR. MARVIN, WHAT ABOUT THAT? YOU GIVE UP? JUST
9 KIDDING. MR. MARVIN?

10 **MR. MARVIN:** NO, YOUR HONOR, I DON'T. I THINK YOUR
11 HONOR PUT YOUR FINGER ON THE PULSE WHEN YOU ASKED ABOUT THE
12 HYPOTHETICAL STUDIES THAT MIGHT OR MIGHT NOT BE UNDERTAKEN.
13 THAT IS EXACTLY WHAT THEY ARE, HYPOTHETICALS. AND, YOU KNOW,
14 WHETHER THERE IS ANOTHER DESIGN OR ANOTHER STUDY, WHAT COULD
15 HAVE BEEN DONE UNDER THAT STUDY, WHAT KIND OF DATA WOULD HAVE
16 BEEN PRODUCED IS REALLY ALL SPECULATION. AND IT STRIKES ME
17 THAT WE ARE GOING FAR AFIELD IN TERMS OF WHAT DOES THE DATA
18 REALLY SHOW, IF INSTEAD WE ARE TALKING ABOUT SPECULATING WHAT
19 DATA MIGHT BE FROM SOME DIFFERENT OR OTHER TYPE OF STUDY.

20 **THE COURT:** OKAY.

21 **MR. JOHNSON:** YOUR HONOR, THIS IS --

22 **THE COURT:** WHO IS SPEAKING? GO AHEAD.

23 **MR. JOHNSON:** YOUR HONOR, I'M SORRY. THIS IS MIKE
24 JOHNSON. I JUST WANT TO INTERJECT FOR A BRIEF MOMENT AND JUST
25 GIVE THE COURT A CONCRETE EXAMPLE OF WHY CUSTODIAL FILES ARE

1 IMPORTANT AND WHY THEY SHOULDN'T BE UNDERVALUED. AS YOU WILL
2 RECALL WHEN THE DEFENDANTS BROUGHT THEIR PREEMPTION MOTION, WE
3 RESPONDED WITH A RULE 56(D) AFFIDAVIT. AND IN THAT AFFIDAVIT
4 WE SAID HERE IS AN EXAMPLE OF WHY GETTING TO THE BOTTOM OF DATA
5 IS IMPORTANT. AND WE FOUND A LONG-TERM PATIENT IN AN AMYLIN
6 STUDY THAT HAD BEEN EXCLUDED FROM THE RESULTS OF THAT STUDY.

7 AND THERE IS ROBUST E-MAIL DIALOGUE BETWEEN THE
8 COMPANY AND THE PERSON IN CHARGE OF THE STUDY ABOUT WHETHER OR
9 NOT THAT PERSON SHOULD BE IN. ULTIMATELY, IT WAS CONCLUDED
10 THAT THAT PERSON SHOULD BE OUT OF THE STUDY.

11 AND, YOUR HONOR, I WILL TELL YOU -- AND I'M NOT THE
12 PERSON THAT FOUND THAT -- BUT MY RECOLLECTION FROM PUTTING THAT
13 MOTION TOGETHER AND SPENDING SOME TIME WITH THAT STORY LINE IS
14 THAT STORY LINE WAS FIRST RESOLVED OUT OF THE E-MAILS THAT CAME
15 OUT THE CUSTODIAL FILES. AND IF WE WERE TALKING ABOUT DATA AND
16 DATA ONLY, THAT PATIENT, WHO WE BELIEVE IS A CRITICAL PART OF
17 THE SCORING -- AND PARTICULARLY IF THERE IS A FEW MORE OF THEM
18 IT BECOMES EVEN MORE CRITICAL -- WITHOUT THE ABILITY TO GET TO
19 THOSE E-MAILS, WE MAY NEVER KNOW ABOUT THAT PATIENT. WE WOULD
20 CERTAINLY NEVER KNOW ABOUT WHY THEY WERE EXCLUDED.

21 AND SO THE WHOLE POINT IS THAT IT ISN'T ENOUGH TO
22 JUST SAY WELL, HERE IS YOUR DATA. WE HAVE TO LOOK AT HOW THAT
23 DATA CAME TO BE AND WHAT WAS EXCLUDED. THE DATA ITSELF,
24 WITHOUT LOOKING AT THE INTERNAL INTERPRETATION AND HOW IT WAS
25 DERIVED, IS PRETTY MEANINGLESS.

1 AND AGAIN, THE RULE, THE EXAMPLES -- THE CONCRETE
2 EXAMPLES WE HAVE SHOWN YOU, THAT WE OUTLINED IN THAT RULE 56(D)
3 AFFIDAVIT, WOULD EVOLVE, IN LARGE PART, TO CUSTODIAL FILES AND
4 E-MAIL EXCHANGES. SO I DIDN'T MEAN TO STOMP ON A LOT OF THE
5 ARGUMENTS, BUT I JUST WANTED TO GIVE THE COURT A CONCRETE
6 EXAMPLE OF THE VALUE OF THOSE CUSTODIAL FILES AND WHY SAYING,
7 YOU KNOW, YOU'RE GETTING TOO FAR AFIELD FROM THE DATA, AND WHY
8 IT MATTERS AND WHY IT MATTERS IN THIS CASE.

9 **THE COURT:** BUT ISN'T IT THE STUDY DESIGN THAT WILL
10 ESTABLISH WHAT GOES IN AND WHAT GOES OUT FROM A CATEGORICAL
11 STANDPOINT, AND WHERE CRITICISM FROM AN EXPERT'S VIEW MIGHT
12 OCCUR?

13 I MEAN, YOU'RE DEALING WITH YES, THIS IS THE ANECDOTE
14 OF AN E-MAIL THAT TALKS ABOUT SOMEBODY THAT WASN'T IN AND
15 SOMEBODY THINKS THAT THEY COULD HAVE BEEN. BUT THE CRITERIA ON
16 WHICH THEY WERE IN OR OUT MUST HAVE BEEN DICTATED BY THE STUDY
17 PROTOCOL, I WOULD THINK. AND THAT WOULD BE THE EVIDENCE THAT
18 WOULD BE SUGGESTIVE OF INADEQUACY OR UNFAIRLY BIASED DATA
19 RESULTS, WOULDN'T IT?

20 **MR. JOHNSON:** YOUR HONOR, THANK YOU. AND THAT'S A
21 GOOD QUESTION. SO WE HAVE A PROTOCOL, RIGHT? AND WE CAN LOOK
22 AT THE PROTOCOL BLINDLY, BUT WITHOUT KNOWING HOW THAT PROTOCOL
23 WAS APPLIED TO THE PARTICIPANTS IN THAT STUDY, WE DON'T HAVE A
24 LOT OF GUIDANCE FROM JUST THE PROTOCOL. AND AGAIN, THAT
25 MISSING PATIENT, LOOKING AT THE PROTOCOL ITSELF, DOESN'T TELL

1 US THAT HE WAS EXCLUDED. IT DOESN'T TELL US WHY HE WAS
2 EXCLUDED. AND SO WE'RE MISSING, WITHOUT THOSE E-MAILS -- AND
3 AGAIN, WE ATTACHED A GOOD NUMBER OF THEM IN THE RULE 56(D)
4 AFFIDAVIT -- WE JUST DON'T KNOW THE BACKGROUND STORY.

5 SO NO, THE PROTOCOL ITSELF WOULDN'T NECESSARILY BE
6 ENOUGH TO ALERT US OF THE PATIENT. AND IT WOULDN'T ANSWER THE
7 QUESTION AS TO WHY HE WAS OR WASN'T INCLUDED. IN THIS CASE,
8 NOT INCLUDED IN THE STUDY.

9 **THE COURT:** I SEE YOUR POINT. SO LET ME TURN TO
10 MR. MARVIN. HOW DO WE ACCOUNT FOR THAT POTENTIAL PROBLEM THAT
11 WE ARE EITHER LEAVING OUT DATA THAT OUGHT TO BE CONSIDERED AS
12 RELEVANT OR THAT WE DON'T HAVE ANYONE SCHEDULED THAT CAN TALK
13 ABOUT APPLICATION OF THE PROTOCOL TO THE STUDY SUBJECTS?

14 **MR. MARVIN:** BUT WE DO HAVE PEOPLE WHOSE CUSTODIAL
15 RECORDS HAVE ALREADY BEEN PRODUCED, WHO CAN TALK ABOUT THE
16 METHODOLOGY AND HOW THE STUDY WAS CONDUCTED.

17 YOU KNOW, I MENTIONED BEFORE DR. ENGEL AND
18 DR. KAUGHMAN, WHO HAVE BEEN INTIMATELY INVOLVED IN THE CLINICAL
19 STUDIES, TO BE ABLE TO ADDRESS THOSE ISSUES.

20 AND AS I MENTIONED BEFORE, WHILE THE CUSTODIAL
21 DOCUMENTS WERE PRODUCED FOR THE TEN CUSTODIANS, THE FACT IS --
22 IS THAT THOSE CUSTODIAL FILES CONTAIN E-MAILS FROM VARIOUS
23 PEOPLE WITHIN THE COMPANY.

24 I THINK THAT IT'S SAFE TO SAY THAT WITH EVERY ONE OF
25 THE DEFENDANTS AND PHARMACEUTICAL COMPANIES IN GENERAL,

1 E-MAILS, AS WE CAN ALL SEE, INCLUDE LOTS OF RECIPIENTS WITHIN
2 THE COMPANY BECAUSE IT IS A COLLABORATIVE EFFORT.

3 AND, AGAIN, WE ARE IN A SITUATION WHERE WE ARE
4 DEALING WITH SPECULATION AS TO WHAT MIGHT BE, RATHER THAN
5 GETTING TO THE DEPOSITIONS -- NONE OF WHICH HAVE BEEN TAKEN OF
6 MERCK YET -- TO IDENTIFY WHERE THERE ARE ANY GAPS OR WHERE
7 THERE ARE ANY OTHER AVENUES THAT NEED TO BE EXPLORED.

8 **THE COURT:** YES. I FEAR I HAVE TO AGREE. FROM THE
9 PLAINTIFFS' STANDPOINT, I HAVE TO AGREE WITH THE DEFENSE.
10 WE'RE SPECULATING THAT THERE MAY BE SOMETHING OUT THERE. IT
11 SOUNDS LIKE WE HAVE TWO, IF NOT MORE, PEOPLE THAT ARE
12 RECOGNIZED LECTURERS IN THE FIELD PRIVY TO THE DATA, PRIVY TO
13 THE PROTOCOL AND ITS APPLICATION, AND SO FORTH, THAT ARE YET TO
14 BE DEPOSED.

15 TO EXPAND THE UNIVERSE -- AND ESPECIALLY TO EXPAND
16 THE UNIVERSE BEYOND THE QUESTION OF DATA, WHICH WAS THE FOCUS
17 THAT THE COURT HAS IMPOSED UPON ALL OF YOU, RECOGNIZING THAT
18 DOWN THE ROAD, DEPENDING ON HOW THINGS SHAKE OUT ON PREEMPTION,
19 AND AS THINGS SHAKE OUT IN TERMS OF THE BRIEFING OR ABILITY TO
20 ADDRESS ARGUMENTS ON GENERAL CAUSATION OR THEREAFTER, SOME OF
21 THESE MAY BECOME MUCH MORE RELEVANT WHEN WE GET INTO OTHER
22 QUESTIONS THAT GO TO ULTIMATE LIABILITY. BUT CAUSATION,
23 GENERAL CAUSATION, IS JUST ONE PIECE.

24 AND I AM NOT CONVINCED THAT GIRMAN AND BRODOVICZ WILL
25 HAVE THE CRITICAL NEED THAT THE PLAINTIFFS SUGGEST, BUT I WILL

1 DENY THEIR ADDITIONAL PRODUCTION OR DEPOSITION. AND IF THERE
2 IS A GAP THAT COMES UP WITH ENGEL AND COMPANY THAT CAN BE
3 ARTICULATED SPECIFICALLY, THEN WE'LL REVISIT IT AND ALLOW TIME
4 FOR THAT TO FOLLOW THROUGH.

5 WE HAVE THREE MORE, SO LET'S TAKE KATZEFF NEXT. OR
6 TO THE EXTENT THAT KATZEFF CAN BE GROUPED WITH SOMEBODY ELSE,
7 MR. MARVIN, YOU TELL ME. BUT KATZEFF, GLOBAL DIRECTOR OF
8 SCIENTIFIC AFFAIRS IN THE DIABETES GROUP. HOW ARE WE OTHERWISE
9 ACCOMMODATING PLAINTIFFS' CONCERNS, AS EXPRESSED IN THEIR BRIEF
10 IN THIS REGARD?

11 **MR. MARVIN:** YOUR HONOR, I THINK I AM GOING TO BE
12 REPEATING MYSELF ON THOSE THAT REMAIN. WHAT THE PLAINTIFFS SAY
13 ABOUT DR. KATZEFF IS SOME OF WHAT THEY HAVE ALREADY -- SOME OF
14 THE POINTS THAT THEY HAVE ALREADY MADE. THEY SAY THAT THEY
15 WOULD LIKE HIS CUSTODIAL FILE BECAUSE HE WAS CONTACTED BY
16 EXTERNAL INVESTIGATORS WITH RESEARCH PROPOSALS; AND THAT HE, IN
17 ANOTHER INSTANCE, MET WITH INDEPENDENT RESEARCHERS TO DISCUSS
18 DATA GENERATED BY A COMPETITOR OF DRUG IN ANIMALS. IT'S REALLY
19 THE SAME POINT THAT WE HAVE BEEN MAKING. IT APPEARS THAT WHAT
20 THE PLAINTIFFS ARE SEEKING HERE ARE OTHER DESIGNS, OTHER
21 STUDIES THAT HAVE NOT BEEN DONE AND WONDERING WHAT WOULD HAPPEN
22 IF THOSE STUDIES WERE DONE, AND WHAT DATA MIGHT BE -- MIGHT
23 COME OUT OF THOSE STUDIES.

24 SO, YOU KNOW, WITH DR. KATZEFF, IN PARTICULAR, WHILE
25 DR. ENGEL, DR. KAUGHMAN, DR. CLAY, WHOSE FILES HAVE ALREADY

1 BEEN PRODUCED, AND WHOSE DEPOSITIONS HAVE NOT YET TAKEN PLACE,
2 THEY CAN TESTIFY ABOUT WHAT WAS DONE. AND AS TO WHAT IS
3 STILL -- WHAT HASN'T BEEN DONE WITH RESPECT TO PARTICULAR
4 STUDIES OR PARTICULAR DESIGNS, AGAIN, IS ONE OF THOSE AREAS
5 THAT DOESN'T REALLY GO TO THE ISSUE OF GENERAL CAUSATION -- OR
6 PREEMPTION, FOR THAT MATTER.

7 **THE COURT:** OKAY. WELL, MR. PREUSS, WE'LL TURN THE
8 TABLE OVER TO YOU AGAIN.

9 **MR. PREUSS:** THANK YOU, YOUR HONOR. AS OUR PAPERS
10 SUGGEST, DR. KATZEFF IS ANOTHER MERCK RESEARCHER WHO WE BELIEVE
11 HAD CONTACTS AND DISCUSSIONS WITH EXTERNAL RESEARCHERS, BUT
12 HERE WITH RESPECT TO ANIMAL STUDIES.

13 AND LIKE THE OTHER CUSTODIANS WE HAVE TALKED ABOUT
14 TODAY, WE DON'T KNOW EXACTLY WHAT THOSE DISCUSSIONS WERE OR
15 WHERE SPECIFICALLY THE DISCUSSIONS LED. BUT BEING THAT WE ARE
16 IN THE DISCOVERY PHASE, WE WHOLEHEARTEDLY BELIEVE THAT THESE
17 FILES ARE REASONABLE AND CALCULATED TO MOVE TO THE DISCOVERY OF
18 ADMISSIBLE EVIDENCE.

19 HERE, DR. KATZEFF HAD CONTACTS WITH EXTERNAL
20 INVESTIGATORS ABOUT THE PRECLINICAL ANIMAL STUDIES. FOR THE
21 SAME REASONS WE DISCUSSED WITH THE EPIDEMIOLOGIST CUSTODIANS
22 PREVIOUSLY, WE BELIEVE THAT THOSE FILES ARE RELEVANT TO THIS
23 PHASE OF THE CASE.

24 AND, ADDITIONALLY, WITH DR. KATZEFF, ALONG WITH ALL
25 THESE OTHER RESEARCHER CUSTODIANS THAT WE'RE TALKING ABOUT, NOT

1 ONLY THE EXTERNAL DISCUSSIONS WITH EXTERNAL RESEARCHERS, BUT
2 IT'S ALSO INTERNALLY THE INTERPRETATIONS OF THE STUDY DATA:
3 HOW MERCK AND NOVO NORDISK, WHEN WE'RE TALKING ABOUT THEIR
4 CUSTODIANS -- HOW THESE RESEARCHERS TOOK THE DATA AND
5 INTERPRETED IT. AND, ULTIMATELY, YOU KNOW, CAME UP WITH THE
6 FINAL REPORT OF THAT DATA. HOW WAS THAT DATA INTERPRETED
7 INTERNALLY?

8 SO IT'S NOT ONLY THE EXTERNAL FACTION OF IT, BUT IT'S
9 ALSO INTERNALLY THE INTERPRETATION WHEN WE'RE TALKING ABOUT THE
10 RESEARCHER CUSTODIANS, LIKE DR. KATZEFF AND THE OTHERS WE'VE
11 TALKED ABOUT TODAY.

12 **THE COURT:** OF COURSE, THAT PRESUPPOSED THAT
13 DR. FOLLI, F-O-L-L-I, WHO CONDUCTED THE STUDY ON BABOONS, HIS
14 DATA WAS ULTIMATELY SHARED AND MERCK USED IT IN SOME FORM OR
15 FASHION. AND I DON'T HEAR THAT THAT HAS BEEN EVIDENCED, AS
16 YET, IN ANY OF THE DATA THAT HAS BEEN PROVIDED WITH THE
17 40-SOME-ODD FILES, OR HOW IT'S CHARACTERIZED IN TERMS OF WHAT'S
18 BEEN GIVEN.

19 SO I DO THINK WE ARE HIGHLY ON A SPECULATIVE FIELD
20 HERE. I DON'T AGREE THAT IT'S LIKELY TO LEAD TO DISCOVERY OF
21 ADMISSIBLE EVIDENCE, WITHOUT SOME INDICATION THAT MERCK HAS
22 USED THIS DATA. AND SO IF ENGEL, KAUGHMAN, CLAY OR SOMEBODY
23 ELSE IS GOING TO EVIDENCE THAT, INDEED, IT IS INTEGRATED IN THE
24 DATA SOMEWHERE AND CAN POINT IT OUT AND ADEQUATELY DISCUSS IT,
25 FINE. IF NOT, IT'S SOMETHING THAT COULD BE REVISITED. BUT IF

1 IT WASN'T USED, I DON'T SEE HOW IT BECOMES RELEVANT ON THE
2 LIMITED SCOPE OF GENERAL CAUSATION. SO I WILL DENY KATZEFF
3 WITHOUT PREJUDICE.

4 NANCY THORNBERRY IS NEXT, THE BIOCHEMIST, WHO I THINK
5 IS CHARACTERIZED AS BEING INVOLVED WITH ALL ASPECTS OF
6 DEVELOPING JANUVIA. INDEED, SHE WAS EVEN REFERENCED IN TERMS
7 OF THE CONNECTION WITH DR. FOLLI AND THE KATZEFF DISCUSSION.

8 SO GIVEN HER ROLE IN TERMS OF THIS OVERALL
9 INVOLVEMENT, MR. MARVIN, HOW ARE WE OTHERWISE ACCOUNTING FOR
10 THE BODY OF INFORMATION SHE MAY HAVE RELATIVE TO THE SCIENTIFIC
11 DATA?

12 **MR. MARVIN:** YOUR HONOR, NANCY THORNBERRY IS ONE OF
13 THE SCIENTISTS WHO WORKED ON THIS DISCOVERY OF JANUVIA IN THE
14 '90S. AND SHE DID CONTINUE TO PLAY A ROLE IN JANUVIA AND
15 JANUMET, BUT AT HIGHER LEVELS, AND TOOK ON OTHER
16 RESPONSIBILITIES FOR OTHER PRODUCTS AS THE YEARS WENT BY, TO
17 THE POINT WHERE SHE BECAME THE SENIOR VICE PRESIDENT OF THE
18 DIABETES AND ENDOCRINOLOGY DEPARTMENT, WHICH HAD THE
19 RESPONSIBILITY WITH RESPECT TO A NUMBER OF DIABETES PRODUCTS
20 THAT WERE EITHER ON THE MARKET OR IN DEVELOPMENT.

21 THE POINT, THOUGH, IS THAT SHE WAS SEEING THE
22 INFORMATION WITH RESPECT TO CLINICAL STUDIES, ANIMAL STUDIES,
23 AND ADVERSE EVENTS MORE AT THE 30,000-FOOT LEVEL. AND THE
24 PEOPLE ON THE LIST THAT THE PLAINTIFFS PROVIDED TO US, WHICH
25 DOES NOT INCLUDE NANCY THORNBERRY, BUT WE HAPPEN TO AGREE WITH

1 THEM THAT THAT LIST WAS REPRESENTATIVE OF THOSE WHO DID HAVE
2 THE KNOWLEDGE AND WHO ARE MORE ON THE GROUND LEVEL.

3 AND SO THE PEOPLE THAT WE HAVE MENTIONED BEFORE, THE
4 SCIENTISTS WHO WERE WORKING ON THESE MATTERS ON A DAY-BY-DAY
5 BASIS AND WITH MUCH MORE DETAILED INFORMATION, WERE THE ONES
6 WHO WOULD BE ABLE TO ADDRESS THE SAME KIND OF ISSUES THAT
7 MS. THORNBERRY MIGHT BE ABLE TO ADDRESS, BUT WITH MUCH MORE
8 DETAIL AND, YOU KNOW, WITH MUCH MORE CONTEXT.

9 SO, YOU KNOW, I ALSO DO WANT TO POINT OUT THAT AS IN
10 OTHER INSTANCES, MANY OF THE E-MAILS ON WHICH SHE WAS EITHER
11 THE RECIPIENT OR SENDER OR COPIED HAVE ALREADY BEEN PRODUCED.

12 YOU KNOW, THERE ARE OVER 4,000 E-MAILS THAT HAVE BEEN
13 PRODUCED RELATING TO -- INVOLVING DR. THORNBERRY. WHICH,
14 AGAIN, SHOWS THAT IT'S A COLLEGIAL PROCESS THAT IS UNDERTAKEN
15 WITH RESPECT TO THE STUDIES OF THE ISSUES THAT ARE BEFORE THE
16 COURT.

17 SO FOR THE SAME REASONS THAT WE HAVE DISCUSSED IN THE
18 PAST WITH THE OTHER INSTANCES, THE CUSTODIANS WHOSE FILES HAVE
19 ALREADY BEEN PRODUCED AND WHO ARE ALREADY SCHEDULED FOR
20 DEPOSITIONS WOULD BE ABLE TO ADDRESS THE KINDS OF TOPICS THAT
21 WE WOULD EXPECT THE PLAINTIFFS WOULD BE INTERESTED IN WITH
22 RESPECT TO MS. THORNBERRY.

23 **THE COURT:** OKAY. AND THEN, MR. PREUSS, I WILL LET
24 YOU RESPOND BECAUSE THIS ONE IS A LITTLE MORE UNCLEAR TO ME,
25 BUT GO AHEAD.

SEPTEMBER 23, 2014

1 **MR. PREUSS:** SURE, YOUR HONOR. DR. THORNBERRY, WE
2 BELIEVE, YOUR HONOR, IS THE SINGLE MOST KNOWLEDGEABLE PERSON
3 ABOUT JANUVIA. WE ARE SOMEWHAT SURPRISED THAT WE DIDN'T LEARN
4 ABOUT HER FROM MERCK COUNSEL WHEN WE INITIALLY WERE TALKING
5 ABOUT THE DISCUSSIONS OF CUSTODIAL FILES.

6 AS MR. MARVIN JUST INDICATED, SHE HAS KNOWLEDGE ABOUT
7 ALL ASPECTS OF JANUVIA, WHETHER IT'S CLINICAL TRIALS, ANIMAL
8 TRIALS, ADVERSE EVENTS. SHE IS THE SINGLE MOST KNOWLEDGEABLE
9 PERSON ABOUT THIS DRUG.

10 AND EARLIER ON IN TODAY'S HEARING WE WERE TALKING
11 ABOUT WE HAVE THE FILES FROM SOMEONE IN THE LEAD OF THE
12 DEPARTMENT; OUR CLIENT IS ENTITLED TO THE GROUND-LEVEL
13 RESEARCHERS, THE RESEARCHERS WHO ARE WORKING ON THE DRUGS ON A
14 DAY-BY-DAY BASIS. NOW WE ARE HEARING THE OPPOSITE: THAT NANCY
15 THORNBERRY IS TOO HIGH UP AND WE ALREADY HAVE THE DATABASES.
16 AND I WOULD SUGGEST THE DEFENDANTS CAN'T HAVE THEIR CAKE AND
17 EAT IT, TOO. SIMPLY PUT, NANCY THORNBERRY IS THE SCIENTIFIC
18 FOUNDER OF JANUVIA AND HAS MORE INFORMATION ABOUT THE SAFETY OF
19 THE DRUG THAN ANY OTHER CUSTODIAN AT MERCK.

20 **THE COURT:** BUT HER KNOWLEDGE AS TO THAT WOULD BE
21 DERIVATIVE OF THE REPORTS COMING UP THE CHAIN FROM GROUND
22 LEVEL, SO TO SPEAK?

23 **MR. PREUSS:** I DON'T THINK NECESSARILY THAT IS THE
24 CASE, YOUR HONOR. AS THE FOUNDER, I THINK SHE WAS INTIMATELY
25 INVOLVED IN EVERY ASPECT OF THE DRUG. I BELIEVE HER KNOWLEDGE

1 INGESTS RECEIVING THE COURSE UP THE CHAIN. SHE WAS THE
2 SCIENTIFIC FOUNDER OF THIS DRUG AND INTIMATELY INVOLVED FROM
3 EACH ASPECT OF IT.

4 **THE COURT:** I THINK SHE IS DISTINGUISHABLE FROM SOME
5 OF THE OTHERS WHO WERE DEPARTMENT HEADS, AS OPPOSED TO, LIKE,
6 THE GODMOTHER OF JANUVIA, BUT TO THE 30,000-FOOT LEVEL. AND I
7 WOULD SUGGEST, BECAUSE I THINK THIS IS A PRETTY NEBULOUS
8 REQUEST, THAT TO THE EXTENT THAT THE WITNESSES THAT HAVE BEEN
9 IDENTIFIED AND WILL BE DEPOSED RELIED UPON HER, OR LEAD TO SOME
10 DEFERENCE TO HER OR HER DIRECTION ON SOMETHING, THAT MIGHT
11 REOPEN THE QUESTION TO A DEPOSITION.

12 AT THIS POINT I THINK IT'S UNLIKE THE DEPARTMENT HEAD
13 TYPE OF CATEGORY. IT'S MORE AKIN TO AN APEX DEPOSITION. AND I
14 THINK WE WILL BE PROBABLY WELL-SERVED BY THE GROUP THAT HAS
15 BEEN IDENTIFIED SO FAR.

16 AND WITHOUT PREJUDICE, I WILL DECLINE TO ORDER HER
17 PRODUCTION FOR HER FILES OR HER DEPOSITION AT THIS POINT.

18 LET'S TALK ABOUT THE LAST GUY, BEI ZHANG, Z-H-A-N-G.
19 AND, MR. MARVIN, STARTING WITH THE DEFENSE, AS I UNDERSTAND IT,
20 LANKAS' FILES HAVE BEEN PRODUCED AND HE HAS BEEN IN THE GUN
21 SIGHTS. BUT HE LEFT THE COMPANY IN '06, WHEREAS ZHANG COVERS A
22 MUCH GREATER PERIOD. IN THIS INSTANCE, ARE WE GOING TO BE
23 LEAVING SOME YEARS OFF THE TABLE IF WE LIMIT OURSELVES TO
24 LANKAS?

25 **MR. MARVIN:** I DON'T THINK SO, YOUR HONOR. ACTUALLY,

1 DR. ZHANG LEFT THE COMPANY IN 2010 AND IS NOW IN CHINA, WORKING
2 FOR LILY. SO HE HAS REALLY HAD NO INVOLVEMENT AT MERCK SINCE
3 2010.

4 **THE COURT:** BUT WHO IS GOING TO MAKE UP THE GAP
5 BETWEEN '06 AND 2010, AND THEN FROM 2010 TO FEBRUARY OF 2014,
6 WHEN WE HAVE SORT OF CUT OFF THE PERIOD OF REVIEW HERE?

7 I MEAN, YOU'RE GIVING THEM LANKAS, AND HE GOES UP TO
8 '06. SO WHAT HAS HAPPENED SINCE, THAT MIGHT BE SIMILARLY
9 RELEVANT DURING THESE LATER TIME PERIODS? OR ASKED ANOTHER
10 WAY, WHO IS SERVING IN THIS ROLE NOW?

11 **MR. MARVIN:** MY UNDERSTANDING IS THAT -- I NEED TO
12 CHECK WITH MY COLLEAGUE -- DR. ZHANG WAS INVOLVED IN THE ANIMAL
13 STUDIES. AND RICH CLAY IS THE MERCK SCIENTIST TO WHOM HE WOULD
14 HAVE REPORTED OR WOULD HAVE BEEN MORE -- HAVE MORE OF A GREATER
15 KNOWLEDGE WITH RESPECT TO THE ANIMAL STUDIES.

16 I HAVE TO ADMIT THAT I NEED TO LEARN MORE ABOUT THE
17 TIME PERIOD THAT YOU HAVE IDENTIFIED. BUT I DO KNOW, ALSO,
18 THAT DR. CLAY'S DEPOSITION IS SCHEDULED THIS WEEK. AND I
19 BELIEVE HE WOULD BE IN A POSITION TO ADDRESS THE ISSUES
20 RELATING TO TRANSGENIC RATS, HIP RATS, AND THE CHOICE OF LAB
21 ANIMALS THAT DR. ZHANG WOULD BE FAMILIAR WITH.

22 **THE COURT:** OKAY. WELL, LET ME ASK YOU, MR. PREUSS.
23 I MEAN, MAYBE I MISINTERPRETED YOUR REQUEST BECAUSE LANKAS WAS
24 THE PRE-APPROVAL ANIMAL STUDIES. AND THEN WE'VE GOT ZHANG WHO
25 FOLLOWS. I'M NOT QUITE SURE HE WAS DOING THE SAME THING. IT

1 SOUNDS LIKE HE WAS DEALING WITH ANIMALS, FROM PAGE SIX,
2 LINE 20, OF YOUR DOCUMENT 606.

3 BUT, I MEAN, DO THEY CONNECT SEQUENTIALLY OR AT LEAST
4 TOPICALLY? AND WHAT DO WE DO AFTER 2010, IF ANYTHING?

5 **MR. PREUSS:** SURE, YOUR HONOR. WELL, ACTUALLY,
6 DR. LANKAS' FILE HASN'T BEEN PRODUCED, EITHER. WHAT WE ARE
7 SEEING HERE IS AN ATTEMPT TO TRY TO BE AS SELECTIVE AS
8 POSSIBLE. SO WE ARE LOOKING FOR AND SEEING THE NEED FOR
9 INDIVIDUALS IN THE CLINICAL SIDE OF THINGS.

10 INITIALLY, YOUR HONOR, IN NEGOTIATIONS WITH MERCK
11 ABOUT ADDITIONAL FILES, WE IDENTIFIED DR. LANKAS, BUT THEN WE
12 REALIZED DR. LANKAS WAS NO LONGER WITH THE COMPANY, SHORTLY
13 AFTER JANUVIA'S MARKETING APPROVAL. SO WE DECIDED TO REQUEST
14 DR. ZHANG INSTEAD BECAUSE HE WAS THERE FOR A LONGER PERIOD OF
15 TIME -- COVERED A LONGER PERIOD OF TIME.

16 BUT FRANKLY, PLAINTIFFS BELIEVE THAT WE ARE ENTITLED
17 TO BOTH OF THESE FILES. BUT AGAIN, WE ARE TRYING TO BE
18 SELECTIVE. THAT IS WHY WE REQUESTED DR. ZHANG'S FILE.

19 I WOULD JUST BACK UP A LITTLE BIT. IN GOING BACK TO
20 OUR INITIAL REQUEST, IF YOU THINK ABOUT THE KNOWLEDGE THAT
21 LANKAS HAD WHEN WE MADE OUR INITIAL CUSTODIAL FILE REQUEST, IT
22 WAS VERY LIMITED. IT WAS BASED ON A 30(B)(6) DEPOSITION OR
23 TWO, FOR THE DEFENDANTS.

24 SO FOR INSTANCE, WE PROBABLY DIDN'T KNOW ABOUT
25 DR. ZHANG OR DR. LANKAS AFTER THOSE DEPOSITIONS. WE CERTAINLY

1 DIDN'T KNOW ABOUT DR. THORNBERRY. WE WOULDN'T KNOW ABOUT ANY
2 OF THESE CUSTODIANS WHO WEREN'T IDENTIFIED BY THE DEONENTS,
3 WHO WAS PRODUCED BY THE DEFENDANTS FOR THE 30(B)(6) DEPOSITION.
4 SO WE WERE OPERATING UNDER VERY LITTLE INFORMATION AT THE TIME
5 THAT WE MADE THESE INITIAL CUSTODIAL FILE REQUESTS AND DURING
6 ITS INFANCY.

7 **THE COURT:** AND I APPRECIATE THAT. THAT IS CERTAINLY
8 PART OF WHY I KEEP SAYING IF THE DEPOSITION PROCESS HERE YIELDS
9 SOME GAPS OR WE SHOW SOME INEFFICIENCIES IN GETTING THE
10 APPROPRIATE DATA DISCLOSED AND DISCOVERED, I WOULD REVISIT THE
11 ISSUES BECAUSE I AM SENSITIVE TO THE PROCESS.

12 BUT LET ME GO BACK TO MR. MARVIN. MR. CLAY, WHO IS
13 SORT OF IN THE ROLE OF DEALING WITH THE ANIMAL STUDIES, DOES
14 HIS CUSTODIAL FILE INCLUDE THE DATA THAT LANKAS AND ZHANG WOULD
15 HAVE THEN WORKED WITH OVER THE COLLECTIVE NINE TO TEN YEARS
16 THAT THE TWO OF THEM WERE ON THE JOB?

17 **MR. MARVIN:** YES, IT WOULD, YOUR HONOR.

18 **THE COURT:** OKAY. SO I GUESS THERE WOULD BE A BROKEN
19 RECORD HERE. LET'S SEE HOW CLAY'S DEPOSITION GOES. THE DATA
20 SHOULD BE IN HIS FILE, WE'RE TOLD. IF IT APPEARS THERE IS
21 GAPS, WE CAN REVISIT THAT. IF IT APPEARS THAT CLAY IS UNABLE
22 TO ADDRESS SOME OF THESE PRE-APPROVAL ANIMAL STUDIES THAT
23 LANKAS AND ZHANG OR EITHER OF THEM OR BOTH WERE INVOLVED IN,
24 THEN WE MAY HAVE TO REVISIT IT. AND THAT IS GOING TO CAUSE
25 SOME CHANGE IN SCHEDULING.

1 BUT I THINK WE ARE SO CLOSE NOW TO HEARING WHAT CLAY
2 CAN SHARE, WE CAN REALLY IDENTIFY WITH SOME PRECISION WHAT, IF
3 ANYTHING, IS FURTHER NEEDED.

4 SO I'M GOING TO DENY ZHANG AND LANKAS WITHOUT
5 PREJUDICE. LET'S GET THE DEPOSITION UNDERWAY AND THEN FOCUS ON
6 ANY OF THESE GAPS OR PROBLEMS. AND WITH A SPECIFIC SHOWING, WE
7 CAN ACCOMMODATE THE NEED.

8 SO THAT WOULD TAKE CARE OF THOSE, THE MERCK
9 DEPOSITIONS. AND MUCH LIKE THE NOVO ONES, WE'RE GOING TO LEAVE
10 THE DOOR OPEN ON A SPECIFIC SHOWING OF SOME INADEQUACY,
11 INEFFICIENCY OR GAP.

12 LET ME THEN MOVE, AS A LAST TOPIC, TO OUR CURRENT
13 SETTING FOR SEPTEMBER 29TH, NEXT MONDAY, FOR ANOTHER
14 DISCUSSION. WE HAVE TWO ITEMS, AT LEAST, THAT ARE SET THAT
15 DAY: FOREIGN REGULATORY COMMUNICATIONS, FOREIGN FILES, WRITTEN
16 RESPONSES, TO BE VERY GENERAL.

17 I HAVE A DRUG TRIAL THAT IS STARTING THAT MORNING AND
18 SO I AM GOING TO HAVE A CONFLICT. I KNOW WE DON'T NECESSARILY
19 HAVE EVERYBODY THAT WILL BE INVOLVED ON THE 29TH, BUT I WANT TO
20 SEE IF EACH SIDE CAN BE EMISSARIES TO THEIR COLLEAGUES AND FIND
21 OUT IF WE -- I JUST NEED A COUPLE DAYS TO TRY THIS CASE. I AM
22 WONDERING IF WE COULDN'T DO OCTOBER 2ND AT 10:00 TO ADDRESS THE
23 ISSUES OTHERWISE SET FOR 9/29.

24 AND I DON'T KNOW IF YOU FOLKS KNOW RIGHT NOW IF THAT
25 IS JUST A DEAD-ON-ARRIVAL DATE OR NOT. BUT IF NOT, PERHAPS YOU

SEPTEMBER 23, 2014

1 CAN CHECK WITH YOUR COLLEAGUES AND CALL US BACK AND TELL LEX,
2 MY LAW CLERK, IT'S A GO. AND IF NOT, WE CAN FIND ANOTHER DATE
3 TO ADDRESS THAT.

4 SO FIRST QUESTION: WOULD OCTOBER 2ND AT 10:00 A.M.
5 WORK AS AN ALTERNATIVE, AS FAR AS WE KNOW, WITH YOU FOLKS?

6 **MR. MARVIN:** YOUR HONOR, WILL THAT BE A TELEPHONIC
7 HEARING, AGAIN?

8 **THE COURT:** YES. WE'RE GOING TO DO THESE TELEPHONIC
9 SO YOU DON'T HAVE TO FLY OUT HERE FOR THESE. YOU CAN BE TAKING
10 DEPOSITIONS ON THE SIDE.

11 **MR. MARVIN:** YES. THAT WOULD WORK FOR MERCK.

12 **MS. LEVINE:** FOR AMYLIN, WE WOULD NEED TO GET BACK TO
13 YOU TO CONFIRM.

14 **THE COURT:** OKAY. FAIR ENOUGH.

15 AND HOW ABOUT LILY?

16 **MR. HAMILTON:** ALSO, YOUR HONOR, WE WILL CONFIRM AND
17 GET BACK TO YOU.

18 **THE COURT:** AND THEN FROM THE PLAINTIFFS' SIDE, WILL
19 YOU NEED TO CHECK WITH THE GROUP AND SEE?

20 **MR. JOHNSON:** YOUR HONOR, THIS IS MIKE JOHNSON. I AM
21 REASONABLY CERTAIN THAT WE CAN MAKE THAT DATE WORK. IF I COULD
22 ASK TO CONFIRM WITH THE GROUP AND GET BACK PROMPTLY?

23 **THE COURT:** OF COURSE. THAT IS THE WHOLE POINT. IF
24 IT'S DEAD ON ARRIVAL, I WILL TRY TO WORK SOMETHING ELSE. RUN
25 THAT UP THE FLAGPOLE AND CONFIRM WITH LEX OF THE COURT HERE.

1 AND WITH MY APOLOGIES, THERE IS NO WAY TO WORK THEM BOTH IN AT
2 THE SAME TIME. IT'S A SPEEDY TRIAL ACT ISSUE AND THE CASE HAS
3 GOT TO START AT 9:00 THAT MORNING.

4 SO CHECK WITH YOUR FOLKS. GO AHEAD AND CONFIRM.
5 WE'LL ADJUST TO SUIT YOUR SCHEDULE SO THE RIGHT PEOPLE CAN BE
6 HERE AT THE TIME. WE'LL LET THE RECORD ON THIS SPEAK FOR THE
7 DAY.

8 I WON'T ISSUE A DETAILED RULING. WE'LL HAVE THE
9 MINUTES REFLECT THAT THE MOTION TO COMPEL THE PRODUCTION OF THE
10 ADDITIONAL CUSTODIANS IS DENIED WITHOUT PREJUDICE. AND THEN
11 WE'LL LOOK FORWARD TO THE NEXT ISSUE WHEN WE NEXT SPEAK.

12 SO LET US KNOW ABOUT THAT DATE CHANGE. OTHERWISE,
13 THANK YOU ALL FOR YOUR TIME. I KNOW I HAVE TAKEN UP ALMOST A
14 COUPLE HOURS HERE, BUT I WANTED TO GO THROUGH EVERYBODY IN
15 DETAIL, TO BE CLEAR AND RULE ACCORDINGLY.

16 SO THANK YOU FOLKS VERY MUCH, AND WE'LL TALK TO YOU
17 SOON.

18 **MS. LEVINE:** THANK YOU, YOUR HONOR.

19 **MR. JOHNSON:** THANK YOU, YOUR HONOR.

20 **MR. PREUSS:** THANK YOU, YOUR HONOR.

21 **MR. MARVIN:** THANK YOU, YOUR HONOR.

22

23

24

25

///

1 (PROCEEDINGS CONCLUDED AT 11:45 A.M.)

2 CERTIFICATION

3 I HEREBY CERTIFY THAT I AM A DULY APPOINTED,
4 QUALIFIED AND ACTING OFFICIAL COURT REPORTER FOR THE UNITED
5 STATES DISTRICT COURT; THAT THE FOREGOING IS A TRUE AND CORRECT
6 TRANSCRIPT OF THE PROCEEDINGS HAD IN THE AFOREMENTIONED CAUSE
7 ON SEPTEMBER 23, 2014; THAT SAID TRANSCRIPT IS A TRUE AND
CORRECT TRANSCRIPTION OF MY STENOGRAPHIC NOTES; AND THAT THE
8 FORMAT USED HEREIN COMPLIES WITH THE RULES AND REQUIREMENTS OF
9 THE UNITED STATES JUDICIAL CONFERENCE.

8 DATED: SEPTEMBER 25, 2014, AT SAN DIEGO, CALIFORNIA.

9 S/N _____
10 JEANNETTE N. HILL, OFFICIAL REPORTER, CSR NO. 11148

11
12
13
14
15
16
17
18
19
20
21
22
23
24
25