

BEFORE THE
INTELLECTUAL PROPERTY TASK FORCE
OF THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

LOCATION: AS INDICATED IN THE AGENDA

DATE: NOVEMBER 18, 2008
2 P.M.

REPORTER: BETH C. DRAIN, CSR
CSR. NO. 7152

BRS FILE NO. : 83085

BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

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NOVEMBER 18, 2008; 2 P.M.

CHAIRMAN PENHOET: . . . ED PENHOET, CHAIR OF THIS COMMITTEE. I'M JOINED IN SAN FRANCISCO BY JEFF SHEEHY, ANOTHER MEMBER OF THE COMMITTEE, AND I THINK YOU ALL HEARD WHO WAS ON THE PHONE. WE HAVE A SMALL AUDIENCE HERE IN SAN FRANCISCO OF INTERESTED PARTIES. SO HOPEFULLY WE'LL HEAR SOMETHING FROM THEM GOING FORWARD.

I THINK YOU'VE ALL BEEN INFORMED WHAT THE GENERAL PURPOSE OF THIS MEETING AND SOME SUBSEQUENT MEETING WILL BE, WHICH IS PRIMARILY TO ENGAGE IN A MERGER OF THE TWO DOCUMENTS THAT WE HAVE CREATED -- WELL, THE TWO SETS OF RULES THAT WE'VE CREATED IN THE PAST REGARDING INTELLECTUAL PROPERTY. SO JUST TO REMIND YOU, WE STARTED BY TRYING TO DEFINE A SET OF INTELLECTUAL PROPERTY POLICIES FOR THE NOT-FOR-PROFIT SECTOR SINCE THAT'S WHERE WE MADE OUR FIRST GRANTS. THAT WAS FOLLOWED BY A SIMILAR EXERCISE FOR THE FOR-PROFIT SECTOR.

WHEN WE FINISHED THOSE TWO PROJECTS, WE REALIZED A COUPLE OF THINGS. FIRST OF ALL, THAT LEAVING THE PAYBACK PROVISIONS ASIDE, THE REST OF THE POLICIES FOR THE TWO WERE VERY SIMILAR. AND WE THOUGHT ON THAT BASIS, AT LEAST, THAT IT MADE SENSE

BARRISTERS' REPORTING SERVICE

1 FOR US THAT WE SHOULD COMBINE THESE INTO A SINGLE
2 INTELLECTUAL PROPERTY POLICY WITH THE EXCEPTION THAT
3 EMBODIED IN THE SINGLE POLICY WOULD BE TWO DIFFERENT
4 PAYBACK PROVISIONS, SO THOSE PARTS ARE MAINTAINED.
5 BUT WITH RESPECT TO ALL OTHER ASPECTS OF WHAT WE'VE
6 BEEN TALKING ABOUT AND ACTUALLY HAVE IN PLACE TODAY,
7 IT'S LARGELY THE SAME AS WHAT WE'VE HAD BEFORE.

8 BUT IN LOOKING THROUGH THE MATERIALS AND
9 LOOKING THROUGH THE DOCUMENTS AND THEN ALSO GETTING
10 SOME CONTINUOUS FEEDBACK FROM OUR VARIOUS
11 STAKEHOLDERS IN THIS PROCESS, WE ALSO UNDERSTOOD
12 THAT THERE WERE CERTAIN ELEMENTS OF OUR PRIOR
13 EFFORTS WHICH WERE AMBIGUOUS, NO. 1; AND SECOND OF
14 ALL, EMBEDDED IN THAT AMBIGUITY WERE SOME FEATURES
15 THAT MIGHT, IN FACT, DISCOURAGE COLLABORATION,
16 ESPECIALLY BETWEEN GROUPS WHICH ARE CIRM-FUNDED AND
17 NOT FUNDED BY CIRM.

18 AND SO WHILE WE WERE DOING THIS
19 PROMULGATION PROCESS, SO TO SPEAK, WE WANTED TO ALSO
20 DO A CLEANUP ON WHAT WE HAD DONE BEFORE AND TRY TO
21 LOOK CAREFULLY AT THIS WHOLE ISSUE OF, YOU KNOW, IN
22 THE COLLABORATIVE SETTING IN THE ONE CIRCUMSTANCE
23 ARE OUR COLLABORATORS OBLIGATED ESSENTIALLY BUY INTO
24 OUR INTELLECTUAL PROPERTY POLICIES AND UNDER WHAT
25 CIRCUMSTANCES ARE THEY NOT OBLIGATED TO FOLLOW OUR

BARRISTERS' REPORTING SERVICE

1 PROCESSES.

2 SO WE SPENT A FAIR AMOUNT OF TIME ON THAT
3 ISSUE, TALKED TO A NUMBER OF DIFFERENT GROUPS ABOUT
4 THIS, INCLUDING LAST FRIDAY THE INVITATION OF WENDY
5 STREITZ, WHO IS HERE WITH US TODAY. WE MET WITH ALL
6 OF -- NOT ALL OF, BUT THE REPRESENTATIVES OF THE
7 LICENSING OFFICES FROM ALL TEN UC CAMPUSES THAT WERE
8 HAVING THEIR ANNUAL MEETING. AND SO WE, NANCY KOCH,
9 SCOTT TOCHER, AND I, MADE A PRESENTATION TO THIS
10 GROUP, AND WE HAD A PRETTY VIGOROUS DIALOGUE WITH
11 THEM ABOUT THE ISSUES AROUND THIS.

12 AND, WENDY, WE WANT TO THANK YOU FOR YOUR
13 INVITATION, BUT ALSO A GOOD DISCUSSION WITH YOUR
14 GROUP GOING FORWARD.

15 I THINK MAYBE EVERYBODY IS ON THE PHONE,
16 SO MELISSA REMINDS ME THAT WE NEED TO DO AN OFFICIAL
17 ROLL CALL. SO WHY DON'T YOU DO THAT NOW, MELISSA,
18 AND THEN WE'LL PROCEED FORWARD.

19 MS. KING: ABSOLUTELY. BEFORE I DO THAT,
20 I JUST ALSO WANTED TO CHECK AND MAKE SURE,
21 ANTOINETTE, DID YOU MAKE IT ONTO THE CALL?

22 SPEAKER*: YES, I'M HERE.

23 MS. KING: SUSAN BRYANT. MICHAEL
24 GOLDBERG. TED LOVE. HE'S GOING TO BE A LITTLE
25 LATE. ED PENHOET.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN PENHOET: HERE.

2 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.

3 I KNOW HE'S GOING TO BE A LITTLE LATE. JEANNIE

4 FONTANA WILL BE A LITTLE LATE. DUANE ROTH.

5 MR. ROTH: HERE.

6 MS. KING: JEFF SHEEHY.

7 MR. SHEEHY: HERE.

8 MS. KING: OSWALD STEWARD.

9 DR. STEWARD: HERE.

10 MS. KING: THANK YOU.

11 CHAIRMAN PENHOET: GOOD. ANTOINETTE,
12 SINCE YOU'RE ON THE PHONE, WE WOULD LIKE TO TAKE
13 THIS OPPORTUNITY TO THANK YOU AND YOUR COLLEAGUES AT
14 FOLEY AND LARDNER FOR THE EFFORTS THAT YOU HAVE MADE
15 ON OUR BEHALF. ANTOINETTE HAS BEEN WORKING WITHOUT
16 COMPENSATION PRO BONO FOR US AND IS DOING A
17 MARVELOUS JOB. SO IT'S REALLY NICE TO HAVE AN
18 INDEPENDENT SET OF INTELLIGENT AND WELL EDUCATED
19 EARS OUT THERE LISTEN TO US AS WE GO THROUGH THESE
20 THINGS. SO WE'RE ALL VERY DEEPLY APPRECIATIVE OF
21 YOUR EFFORTS, ANTOINETTE. THANK YOU.

22 MS. KONSKI: THANK YOU. IT WAS OUR
23 PLEASURE.

24 CHAIRMAN PENHOET: AND HOPEFULLY WILL
25 CONTINUE TO BE YOUR PLEASURE.

BARRISTERS' REPORTING SERVICE

1 SO WE ARE ON THE FIRST SLIDE, WHICH IS, AS
2 I SAID, THE GOAL FOR THIS MEETING, SO THE PRIMARY
3 EMPHASIS THAT WE'RE PLACING ON THIS DISCUSSION IS
4 CONSOLIDATION FOR THOSE; BUT AS YOU WILL SEE, THERE
5 ARE SOME OTHER ELEMENTS THAT HAVE COME UP IN THIS
6 PROCESS.

7 SO WE WANT TO HAVE A DISCUSSION ABOUT THE
8 CONSOLIDATION AND CLARIFY CERTAIN POINTS. I WANT TO
9 EMPHASIZE THAT WE ARE NOT INTENDING TO REOPEN THE
10 ENTIRE PROCESS. WE'RE TAKING WHAT EXISTS. WE'RE,
11 IN SOME CASES, FOR THE MOST PART, CLARIFYING
12 AMBIGUITIES WHICH EXIST, AND, AS I SAID,
13 PARTICULARLY WITH REGARD TO COLLABORATION GOING
14 FORWARD. I THINK MANY OF YOU KNOW THAT SEVERAL
15 PEOPLE HERE HAVE BEEN BUSY FORGING COLLABORATIONS
16 BETWEEN THE CIRM AND VARIOUS ENTITIES AROUND THE
17 WORLD.

18 AND, IN FACT, I UNDERSTAND OUR ESTEEMED
19 LEADER, ALAN TROUNSON, IS CURRENTLY ON HIS WAY BACK
20 FROM JAPAN. THERE WAS A MEETING HERE EARLY IN THE
21 WEEK WITH A JAPANESE DELEGATION THAT ENDED UP IN A
22 DECISION TO DO A COLLABORATION. SO ALAN HAD TO FLY
23 TO JAPAN FOR A SIGNING CEREMONY AND SOME TEA, I
24 SUPPOSE. AND HE'S CURRENTLY ON HIS WAY BACK.

25 BUT, YOU KNOW, THE LIST OF PEOPLE WHO ARE

BARRISTERS' REPORTING SERVICE

1 NOW FORMALLY COLLABORATING WITH CIRM, WHATEVER THAT
2 TURNS OUT TO MEAN IN PRACTICE, INCLUDE MRC IN THE
3 UNITED KINGDOM, THE STATE OF VICTORIA IN AUSTRALIA,
4 NOW THE JAPANESE GOVERNMENT, THE CANADIAN STEM CELL
5 CANCER CONSORTIUM, JDRF, AND I DON'T KNOW IF I
6 MISSED ANY OTHERS, BUT IT'S QUITE A SIGNIFICANT
7 GROUP WHO WOULD LIKE TO WORK WITH US, WHICH IS
8 GREAT.

9 AS WE HAVE DONE BEFORE, THOUGH, BY
10 ESSENTIALLY REVISITING THIS WHOLE PACKAGE OF THINGS,
11 WE WILL HAVE TO SUBMIT, AT THE CONCLUSION OF OUR
12 WORK, ANOTHER SET OF PRINCIPLES TO BE APPROVED BY
13 THE OAL. AND ACCORDING TO THAT POLICY, WE WILL HAVE
14 A NUMBER OF OPPORTUNITIES FOR PEOPLE TO COMMENT BOTH
15 IN TODAY'S MEETING AND GOING FORWARD. AS WE DEVELOP
16 THESE, WE ARE NOT ONLY OBLIGATED, BUT LOOK FORWARD
17 TO HAVING FURTHER DISCUSSIONS ON SPECIFIC ITEMS
18 ASSOCIATED WITH OUR NEW FILING.

19 SO TODAY'S MEETING IS THE FIRST IN WHAT
20 WE'D EXPECT TO BE A SERIES. I THINK WE HAVE TO
21 REMIND EVERYBODY WHAT WE WENT THROUGH BEFORE. WE
22 WILL HAVE THIS MEETING; WE WILL COME OUT OF THIS
23 MEETING WITH A REVISED DOCUMENT PROBABLY. WE
24 WILL -- AND THERE ARE SOME AREAS WHERE I'LL POINT
25 OUT TO YOU WHERE ACTUALLY WE NEED SOME REVISION OF

BARRISTERS' REPORTING SERVICE

1 WHAT WE HAVE IN FRONT OF US TODAY. WE THEN WILL --
2 WHEN WE AS A GROUP, OUR COMMITTEE, IS COMFORTABLE
3 WITH THE DOCUMENT, WE RETAKE IT TO THE BOARD FOR
4 THEIR CONSIDERATION. AFTER THEIR APPROVAL, THEN WE
5 ENTER INTO THE APA PROCESS.

6 MR. TOCHER: ACTUALLY, ED, YOU DESCRIBED
7 VERY WELL WHAT THE PROCESS WE'VE ALWAYS FOLLOWED.
8 IT'S ACTUALLY PROPOSED TO DO SOMETHING SLIGHTLY
9 DIFFERENT WITH THE PROCESS THIS TIME. WE WENT TO
10 THE ICOC FIRST FOR CONCEPT APPROVAL TO ASK THAT THE
11 PROJECT BE LOOKED AT BY THE TASK FORCE. BECAUSE WE
12 ARE HOPING TO HAVE THIS WRAPPED UP IN TIME FOR OUR
13 DISEASE TEAM GRANTS WHEN THEY'RE AWARDED IN THE
14 MIDDLE OF NEXT YEAR AND A LITTLE AFTER THE MIDDLE OF
15 NEXT YEAR, THE DANCE IS SLIGHTLY DIFFERENT.

16 SO WHAT WE'LL DO IS COMING OUT OF THIS
17 MEETING, WE HOPE TO HAVE A DOCUMENT THAT WE CAN
18 NOTICE WITH THE OFFICE OF ADMINISTRATIVE LAW. WE'LL
19 BRING IT BACK TO THE ICOC TO LET THEM KNOW THIS IS
20 THE LANGUAGE THAT IS CIRCULATING RIGHT NOW THAT
21 WE'RE GETTING FEEDBACK ON. WE'LL DO IN THAT
22 JANUARY. BUT THIS ALLOWS US TO AT LEAST GET A JUMP
23 START ON GETTING THE FEEDBACK ON THE DIFFERENT
24 CONCEPTS.

25 AND SO IT WILL COME BACK TO THE TASK FORCE

BARRISTERS' REPORTING SERVICE

1 AND THE ICOC FOR FINAL APPROVAL BEFORE IT GOES BACK
2 TO THE OAL PROCESS FOR FINAL APPROVAL.

3 CHAIRMAN PENHOET: OKAY.

4 MR. TOCHER: AND SO I GUESS IF I COULD
5 JUST INTERJECT SOMETHING, THE PRIMARY PURPOSE, I
6 THINK, FOR US AS STAFF TO GET FROM THIS MEETING IS
7 APPROVAL OF OR GUIDANCE ON THE CONCEPTS AS WE GO
8 THROUGH THEM AND AS WE GO THROUGH THE PRESENTATION.
9 LESS SO AT THIS MOMENT ABOUT SPECIFIC WHERE THE
10 COLONS ARE AND THAT SORT OF THING, WHICH WE HOPE TO
11 GET BEFORE WE FINALIZE IT. THAT'S THE POINT OF THE
12 45-DAY PROCESS. AND WE DON'T WANT TO SHORTCUT THAT;
13 BUT WITH THE TIME THAT WE HAVE, WE WOULD LIKE TO
14 FOCUS ON THE CONCEPTS FIRST.

15 CHAIRMAN PENHOET: YES. IT'S NOT MEANT TO
16 BE A DRAFTING SESSION.

17 MR. TOCHER: THAT'S RIGHT.

18 CHAIRMAN PENHOET: SO WE'LL -- ALTHOUGH
19 SUGGESTIONS WILL CERTAINLY BE WELCOME.

20 MR. TOCHER: THAT'S RIGHT.

21 CHAIRMAN PENHOET: I THINK THE NEXT SLIDE
22 IN YOUR SERIES JUST REVIEWS THE BIDDING. IN TERMS
23 OF HISTORY, WE FINALIZED THE FIRST NOT-FOR-PROFIT
24 REGULATIONS IN JUNE OF 2007. LITTLE LESS THAN A
25 YEAR LATER THE FOR-PROFITS WERE FINALIZED IN MARCH

BARRISTERS' REPORTING SERVICE

1 OF THIS YEAR. OUR TARGET FOR COMPLETING THIS
2 EXERCISE, WHICH IS THE CONSOLIDATION OF THE TWO, IS
3 IN MARCH 2009.

4 AND THEN WE ALSO HAVE TALKED ABOUT THE
5 LOAN PROGRAM GOING FORWARD, AND THAT PROCESS IS
6 PROCEEDING APACE, BUT I THINK THE VIEW CURRENTLY IS
7 THAT THERE MAY BE SOME SIGNIFICANT DIFFERENCES
8 BETWEEN THE GRANTS PROGRAM AND THE LOAN PROGRAM WITH
9 RESPECT TO IP POLICY DEPENDING ON THE KIND OF LOAN
10 THAT PEOPLE ENGAGE FROM US.

11 NANCY, I DON'T KNOW IF YOU JUST WANT TO
12 GIVE US ANY KIND OF A PREVIEW OF THAT. I KNOW
13 YOU'VE BEEN WORKING ON IT.

14 MS. KOCH: YOU'RE RIGHT. THERE WILL BE
15 OVERLAP IN IP ISSUES BETWEEN THE ANTICIPATED LOAN
16 PROGRAM AND THE NORMAL GRANT PROGRAM. SO THE
17 CONCEPT HERE WAS TO COME TO THE IP TASK FORCE AND
18 THINK ABOUT THE IP REGULATIONS AND SUCH IN A GRANTS
19 CONTEXT. AND AFTER WE GET THE FEELING FROM THE
20 COMMITTEE OF WHAT'S APPROPRIATE, WE WILL THEN
21 UNDERTAKE TO DRAFT FOR THE LOANS PROGRAM AN IP
22 POLICY, BUT WE DIDN'T WANT TO START DOWN THAT ROAD
23 UNTIL WE HAD SOME GUIDANCE FROM THE COMMITTEE AND
24 THE DIRECTION WE'RE HEADING.

25 MR. ROTH: LET ME JUST CLARIFY. THIS LOAN

BARRISTERS' REPORTING SERVICE

1 PROGRAM SAYS ICOC CONSIDERATION DECEMBER 2009?

2 MS. KOCH: YES. I THINK, DUANE, YOU'RE
3 RIGHT. WHEN THIS SLIDE WAS CREATED, THAT WAS THE
4 ANTICIPATED DATE. I THINK NOW IT WILL GO UP FOR
5 ICOC CONSIDERATION IN JANUARY OF 2009.

6 MR. ROTH: EITHER 2008 OR --

7 MS. KOCH: DECEMBER 2008.

8 MR. ROTH: IT SHOULD BE EIGHT, I THINK.

9 MR. TOCHER: JUST THE MONTH AND YEAR ONLY.

10 MR. ROTH: AND, ED, JUST FROM NANCY, MAYBE
11 AN OVERVIEW OF WHY THE IP POLICY WOULD BE INVOLVED
12 IN THE LOAN PROGRAM.

13 MS. KOCH: BECAUSE I THINK, DUANE, THE
14 CONCEPT, AS I UNDERSTAND IT, IS THAT THE REVENUE
15 SHARING RESPONSIBILITY THAT A TAKER OF A LOAN WOULD
16 HAVE WOULD BE DIFFERENT THAN WHAT A GRANT RECIPIENT
17 WOULD HAVE.

18 MR. ROTH: BUT THEY OWN THE IP. THEY'RE
19 TAKING A LOAN.

20 MS. KOCH: THAT'S RIGHT.

21 MR. ROTH: SO I DON'T SEE HOW THE IP EVEN
22 COMES IN UNDER THE LOAN PROGRAM.

23 CHAIRMAN PENHOET: YOU KNOW, THAT IS
24 SOMETHING THAT I THINK THAT ICOC WILL HAVE TO
25 DEBATE. I HAVE ALWAYS -- I'LL GIVE YOU A PERSONAL

BARRISTERS' REPORTING SERVICE

1 VIEW ON THAT. MY PERSONAL VIEW IS IF THERE'S A FULL
2 RECOURSE LOAN TO AN ORGANIZATION WHICH HAS THE
3 WHEREWITHAL TO QUALIFY FOR A TYPICAL COMMERCIAL
4 LOAN, I.E., THEY'RE CREDITWORTHY AND COULD BORROW
5 THE MONEY ELSEWHERE, MAYBE SOME OF OUR IP POLICIES
6 MIGHT BE OVERREACHING. THAT'S ONE POSSIBILITY.

7 AT THE OTHER EXTREME, IF IT'S A
8 NONRECOURSE LOAN THAT FOR ALL OTHER INTENTS AND
9 PURPOSES LOOKS AN AWFUL LOT LIKE A GRANT, IT SEEMS
10 TO ME THAT ONE COULD ARGUE THAT UNDER THOSE
11 CIRCUMSTANCES -- AND, DUANE, I'M NOT CLEAR IN MY OWN
12 MIND YET WHAT THE WHOLE SPECTRUM IS OF THE TYPES OF
13 LOANS WE INTEND TO MAKE IN THIS FIELD ARE. YOU ARE
14 CORRECT THAT THEY WILL OWN THE IP, BUT GRANTEES ALSO
15 OWN THE IP, BY THE WAY. WE HAVE NO OWNERSHIP OF IP
16 AT CIRM. THAT WAS ONE OF THE FIRST FUNDAMENTAL
17 PRINCIPLES THAT WE RESOLVED.

18 BUT, AGAIN, I THINK HOW THIS IS GOING TO
19 WORK OUT IN THE LOAN -- THIS EVOLVED. I THINK EVEN
20 YOUR POSITION, IF I REMEMBER A YEAR OR SO AGO,
21 DUANE, WAS THE SAME RULES SHOULD APPLY TO THE LOAN
22 PROGRAM.

23 MR. ROTH: ED, ONLY IN TERMS OF THE
24 COVENANTS. ONLY IN TERMS OF THE COVENANTS. WE
25 NEVER DISCUSSED IF A COMPANY IS TAKING A LOAN OUT,

BARRISTERS' REPORTING SERVICE

1 WHETHER IT'S RECOURSE OR NONRECOURSE, AND GIVING US
2 WARRANTS ON TOP OF AN INTEREST PAYMENT, I NEVER
3 BELIEVED THAT THEY WOULD OWE THE STATE ANYTHING BACK
4 IN TERMS OF A ROYALTY.

5 MS. KOCH: NO. NO. NO. THAT'S RIGHT.
6 AND THAT'S WHAT I MEAN IN TERMS OF THE REVENUE
7 SHARING BEING DIFFERENT IN THE LOAN CONTEXT AND THE
8 GRANT CONTEXT. BUT, DUANE, FOR INSTANCE, ONE THING
9 THAT WE DID DISCUSS WAS IN THE EVENT THAT WE HAD A
10 BORROWER WHO WAS GOING TO GO UNDER AND THERE MIGHT
11 BE SOME PROVISIONS THAT REQUIRE THEM TO GIVE US
12 NOTICE AND TO DO THEIR BEST TO PRESERVE THE IP SO
13 THAT WE COULD GET IT INTO SOMEONE ELSE'S HANDS, I
14 IMAGINE WE'LL HAVE TO DRAFT SOME REGULATIONS WITH
15 REGARD TO THAT.

16 MR. ROTH: SO THAT I'M FINE WITH. BUT
17 WHAT I'M NOT IS THE IDEA THAT THERE'S SOMEHOW ON TOP
18 OF ALL THE OTHER CONDITIONS OF THE LOAN --

19 MS. KOCH: NO. NO. I'M WITH YOU ON THAT.
20 BUT THE THINKING WAS THE EASIEST WAY TO DRAFT THOSE
21 WOULD BE TO USE THE SAME TYPES OF DEFINITIONS AND
22 SUCH THAT WE'RE PROPOSING FOR THE CONSOLIDATED IP
23 REGULATIONS HERE.

24 MR. ROTH: ALL RIGHT. SO THE PURPOSE, ED,
25 IN MAKING THESE COMMENTS IS I DON'T WANT TO CONFUSE

BARRISTERS' REPORTING SERVICE

1 PEOPLE. THEY'RE ALREADY TENSE ENOUGH OUT THERE
2 ABOUT THE LOAN PROGRAMS. AND IF WE START TALKING
3 ABOUT HAVING TO CONSOLIDATE, AND THERE WAS EVEN ONE
4 OF THE STAFFERS FOR ONE OF THE LEGISLATORS WHO WE
5 HAD TO GO THROUGH WITH THIS AND EXPLAIN WHY THE
6 STATE WOULD NOT GET A ROYALTY ON LOANS, MONEY USED
7 FOR LOANS. SO I JUST DIDN'T WANT TO CONFUSE THAT.

8 IN TERMS OF THE, YOU KNOW, THE DUTIES TO
9 PERFORM AND AFFORDABILITY AND ACCESS RATHER, THOSE
10 THINGS ALL WILL APPLY. AND WHAT NANCY IS TALKING
11 ABOUT WILL APPLY IF SOMEBODY GOES UNDER AND THERE'S
12 IP LEFT OVER, HOW DO WE DISPOSE OF THAT?

13 CHAIRMAN PENHOET: ED, WELL, THEN I
14 MISUNDERSTOOD YOUR COMMENT. THAT'S WHAT I BELIEVED
15 ALL ALONG. SO, IN FACT, WE MAY END UP WITH ONE SET
16 OF RULES FOR ALL ORGANIZATIONS WHICH TAKE FUNDING
17 FROM US WITH RESPECT TO ACCESS, MARCH-IN, AND ALL
18 THE OTHER NONFINANCIAL ASPECTS OF THIS TRANSACTION,
19 BUT THE PAYBACK PROVISIONS WOULD BE THERE WOULD BE
20 THREE DIFFERENT PAYBACKS. IF YOU TAKE A LOAN, YOU
21 PAY BACK THE LOAN. IF YOU TAKE A GRANT, YOU WILL
22 PAY BACK NOTHING. AND IF YOU'RE A NOT-FOR-PROFIT,
23 YOU PAY US OUT OF YOUR LICENSING REVENUES. AND IF
24 YOU'RE A FOR-PROFIT, YOU PAY US ACCORDING TO THE
25 SCHEDULE WE'VE ALREADY ARTICULATED. THAT'S

BARRISTERS' REPORTING SERVICE

1 PROBABLY -- THAT WOULD BE THE SIMPLEST OUTCOME FOR
2 THIS.

3 MS. KOCH: THAT'S RIGHT.

4 CHAIRMAN PENHOET: THAT'S WHAT I
5 UNDERSTOOD YOU TO MEAN BEFORE. OKAY.

6 MS. KING: WHO JUST JOINED A MOMENT AGO?

7 DR. LOVE: TED, MELISSA.

8 CHAIRMAN PENHOET: OKAY. SO I THINK THESE
9 GOVERNING PRINCIPLES ARE KNOWN TO ALL. WE DON'T
10 HAVE TO GO THROUGH THEM. BUT THIS NEXT SLIDE IS AN
11 IMPORTANT ONE TO EMPHASIZE THE AREAS WHERE WE REALLY
12 DON'T EXPECT TO CHANGE THESE MAJOR COMPONENTS.

13 SO WE SAID IN THE BEGINNING THE FIRST
14 DOLLAR OF CIRM FUNDING TRIGGERED THE OBLIGATIONS.
15 THE REVENUE SHARING RATES WERE ESTABLISHED OR THE
16 FINANCIAL PAYBACK GENERALLY WAS ESTABLISHED FOR BOTH
17 THE FOR-PROFIT AND NOT-FOR-PROFIT EARLY ON IN THE
18 PROCESS. AND I BELIEVE PEOPLE HAVE COME TO ACCEPT
19 THAT AS A REALITY OF THIS.

20 WE DON'T INTEND TO MODIFY THE ACCESS PLAN
21 OR PRICING REQUIREMENTS.

22 WE BELIEVE THE CORNERSTONE OF OUR WHOLE
23 POLICY IS THAT THE GRANTEES OR RECIPIENTS OF LOANS
24 OWN THE INTELLECTUAL PROPERTY, NOT CIRM.

25 AND THEN WE HAVE A NUMBER OF OTHER

BARRISTERS' REPORTING SERVICE

1 REQUIREMENTS IN THE STRUCTURE. INVENTION AND
2 LICENSING REPORTING, OBVIOUSLY NECESSARY FOR US TO
3 FOLLOW WHAT'S GOING ON IN THE FIELD. PUBLICATION
4 REQUIREMENTS, THE BIOMEDICAL MATERIALS REQUIREMENTS.
5 WE HAD A LOT OF BACK AND FORTH WITH INDUSTRY,
6 ESPECIALLY WITH INVITROGEN AND OTHERS, BUT I THINK
7 WE HAVE A CURRENT SITUATION WHICH PARTIES HAVE ALL
8 AGREED THIS IS AT LEAST WORKABLE WHETHER THEY'RE ALL
9 COMPLETELY HAPPY WITH IT OR NOT.

10 PATENT OWNERSHIP AND PROSECUTION COSTS
11 WE'VE DEALT WITH. THE ABILITY OF GRANTEES TO
12 LICENSE AND THE PREFERENCE FOR NONEXCLUSIVE
13 LICENSES, AGAIN, WE'VE LEFT THAT UP TO THE GRANTEES.

14 THE ACCESS PLAN, IT'S ONE PIECE. WE DON'T
15 PROPOSE TO CHANGE IT, BUT, YOU KNOW, WE CONTINUE TO
16 HAVE QUESTIONS ABOUT WHETHER IT SHOULD BE DEFINED
17 NOW OR DEFINED LATER. THE BULK OF THE OPINION STILL
18 RESIDES ON THE LATTER; THAT IS, IT'S HARD TO
19 ANTICIPATE TEN YEARS IN ADVANCE WHAT SUCH A PROGRAM
20 COULD BE. SO RELIANCE ON THE STATE OF THE ART, IF
21 YOU WILL, AT THE TIME. ALTHOUGH WE HAVE HAD SOME
22 SUGGESTIONS THAT IT MIGHT BE HELPFUL TO PUT IN SOME
23 LANGUAGE SUCH AS PERMISSION TO GO FORWARD WITH THIS
24 ACCESS PLAN WOULD NOT BE UNREASONABLY WITHHELD. AND
25 WE'RE NOT EXACTLY SURE HOW WORKABLE THAT IS, BUT

BARRISTERS' REPORTING SERVICE

1 THAT IS A SUGGESTION THAT CAME OUT OF THE MEETING WE
2 HAD WITH THE UC LICENSING PEOPLE LAST WEEK.

3 I THINK WHAT PEOPLE ARE AFRAID OF OUT
4 THERE IS THAT WE'LL BE UNREASONABLE WITH RESPECT TO
5 THESE ACCESS PLANS. AND SO THE ONLY QUESTION IS HOW
6 TO PUT SOME TEETH IN THE COMPARISON OF WHAT A
7 COMPANY PROPOSES TO US TO DO AND ITS COMPATIBILITY,
8 IF YOU WILL, OF THE STATE-OF-THE-ART OF THAT AT THE
9 TIME.

10 JEFF, YOU'VE DONE THIS IN THE PAST, AND WE
11 DON'T HAVE TO TAKE THE WHOLE ISSUE UP NOW, BUT AT
12 LEAST --

13 MR. SHEEHY: RIGHT. AND I THINK, YOU
14 KNOW, GOING BACK TO OUR ORIGINAL INTENT, I THINK THE
15 IDEA WAS THAT COMPANIES MAKE AN EFFORT TO DO
16 SOMETHING AND RECOGNIZE THAT THERE ARE PEOPLE IN
17 CALIFORNIA WHO KNOW WE'VE PUT MONEY ASIDE, AND
18 PEOPLE MAY NOT HAVE ACCESS. THE INTENT WASN'T TO
19 TRY TO COVER EVERYONE. AND WE ALL RECOGNIZE THAT WE
20 HAVE NO IDEA WHAT THE POTENTIAL THERAPY OR WHAT HAVE
21 YOU WOULD LOOK LIKE OR HOW IT WILL BE DELIVERED.
22 AND SO IT WAS MORE OF A STATEMENT OF REALLY -- WELL,
23 I LIKE THAT DUANE KEEPS USING THE WORD "COVENANT,"
24 THAT THIS WAS AN AWARENESS THAT WHEN YOU TOOK MONEY
25 FROM CIRM, YOU WERE ENTERING INTO A COVENANT WITH

BARRISTERS' REPORTING SERVICE

1 THE PEOPLE OF CALIFORNIA TO RECOGNIZE THAT THERE WAS
2 A LARGER OBLIGATION THAN WHAT YOU MIGHT SIMPLY HAVE
3 IN A COMMERCIAL RELATIONSHIP.

4 AND SO I DON'T THINK WE INTEND EVER TO BE
5 ONEROUS ON THIS AS WE CERTAINLY DON'T WANT TO
6 INTERFERE WITH COMPANIES BEING ABLE TO DEVELOP
7 PRODUCTS OR BE ABLE TO GET THEM INTO THE MARKETPLACE
8 OR TO MAKE REASONABLE RATES OF RETURN.

9 BUT YOU LOOK AT INDUSTRY STANDARD NOW,
10 MOST COMPANIES DO RECOGNIZE A MORAL OBLIGATION TO
11 MAKE AT LEAST TO A HANDFUL OF PATIENTS AT A MINIMUM
12 THE PRODUCTS THAT THEY DEVELOP THAT THEY CAN SAVE
13 SOMEONE'S LIFE. AND WE LIVE IN AN IMPERFECT
14 HEALTHCARE SYSTEM. MAYBE OUR CURRENT PRESIDENT --
15 THIS MIGHT NOT EVEN BE AN ISSUE WITH THE -- CROSS
16 YOUR FINGERS.

17 MR. ROTH: JEFF, HE'S NOT PRESIDENT YET.

18 MR. SHEEHY: BUT AGAIN, IT'S ABOUT A
19 COVENANT. IT'S ABOUT A COMMITMENT TO TRY AND TO
20 MAKE A GOOD-FAITH EFFORT, AND I DON'T THINK ANY OF
21 US WANT TO HURT THE FOLKS THAT ARE TRYING TO DEVELOP
22 THESE PRODUCTS.

23 MR. ROTH: ED, I WOULD ADD TO THAT THAT
24 THE ACCESS PLAN, I THINK THE WORDING GOES SOMETHING
25 ALONG THE LINES THAT IT'S APPROPRIATE FOR THE SCOPE

BARRISTERS' REPORTING SERVICE

1 AND SIZE OF THE COMPANY.

2 CHAIRMAN PENHOET: IT DOES.

3 MR. ROTH: AND SO THAT'S THE KEY. WE'RE
4 NOT GOING TO ASK A COMPANY WITH THEIR VERY FIRST
5 PRODUCT TO HAVE A PFIZER OR A JOHNSON & JOHNSON TYPE
6 ACCESS PLAN, BUT SOMETHING THAT'S APPROPRIATE THAT
7 CAN COVER AS MANY AS WE POSSIBLY CAN THAT'S
8 REASONABLE, I THINK, WOULD BE ACCEPTABLE.

9 CHAIRMAN PENHOET: YEAH. WELL, I THINK
10 THE CONCERN IS TO MAKE SURE THAT THE COMPARATORS ARE
11 DEEMED VALID, THAT WE DON'T TRY TO MOVE BEYOND WHAT
12 THE STATE OF THE ART AT THE TIME IS. AND SO WE'VE
13 BEEN STRUGGLING A LITTLE BIT AMONG OURSELVES TO TRY
14 USE SOME LANGUAGE WE COULD INSERT THAT PLACES AN
15 AFFIRMATIVE OBLIGATION ON US TO MAKE SURE THAT WE
16 DON'T GO BEYOND THE THEN EXISTING STANDARD IN THE
17 INDUSTRY WITH THESE CAVEATS IN PLACE.

18 AND PEOPLE'S CONCERNS, FRANKLY, WERE
19 ELEVATED WHEN THE WHOLE NOTION OF HAVING A PUBLIC
20 MEETING TO DISCUSS THIS WAS INSERTED FAIRLY LATE IN
21 THE PROCESS AT A BOARD MEETING.

22 MR. ROTH: AND THAT WAS NOT PICKED UP
23 THOUGH, RIGHT? WE'RE NOT SUGGESTING WE'D DO THAT.

24 CHAIRMAN PENHOET: NO. IT'S IN THE
25 REGULATIONS NOW BECAUSE IT WAS BROUGHT UP, NOT BY

BARRISTERS' REPORTING SERVICE

1 THIS COMMITTEE, BUT AT THE BOARD LEVEL.

2 MR. TOCHER: THE ICOC ALREADY APPROVED
3 THAT AS PART OF ITS LEGISLATIVE EFFORTS TO DEAL WITH
4 LEGISLATION ON THE ISSUE.

5 MR. ROTH: I HOPE I VOTED AGAINST THAT.

6 CHAIRMAN PENHOET: WELL, AS I SAY, I THINK
7 IT'S POSSIBLE THAT WE COULD DRAFT SOME LANGUAGE.
8 MAYBE WE'LL DEAL WITH THE ISSUE NOW. SHOULD WE
9 CRAFT SOME LANGUAGE AROUND THIS ISSUE THAT
10 ESSENTIALLY HOLDS US RESPONSIBLE FOR NOT GOING
11 BEYOND WHAT THE STATE OF THE ART IN THE FIELD IS AT
12 THE TIME?

13 MR. SHEEHY: I THINK I WOULD SUPPORT THAT
14 BECAUSE I DO THINK, YOU KNOW -- AND I PERSONALLY
15 FELT THAT THE PUBLIC HEARING WAS NOT A BAD IDEA IN
16 ORDER TO REACH SOME ACCOMMODATION WITH THE
17 LEGISLATURE. SO I AM KIND OF GLAD THAT, EVEN THOUGH
18 THAT PARTICULAR BILL IS NOT IN FORCE, WE DID REACH
19 OUT TO THE LEGISLATURE AND TRY TO ACCOMMODATE THEIR
20 CONCERN.

21 BUT THEN I DO THINK, I AGREE WITH ED, THAT
22 IT MAY BE INCUMBENT ON US NOW TO LET FOLKS INVOLVED
23 IN OUR PROCESS KNOW THEY'RE NOT GOING TO GET
24 STAMPEDED AT A PUBLIC HEARING INTO SOMETHING THAT'S
25 BEYOND WHAT WE ORIGINALLY INTENDED. SO IF THERE'S A

BARRISTERS' REPORTING SERVICE

1 WAY TO ARTFULLY CRAFT LANGUAGE. AND OUR ATTORNEYS
2 ARE FABULOUS. I'VE JUST BEEN READING THROUGH THIS
3 THE LAST COUPLE OF DAYS, AND THIS IS JUST AN
4 INCREDIBLE WORK PRODUCT. I DON'T THINK WE COULD ASK
5 FOR ANYTHING -- THIS HAS JUST BEEN TREMENDOUS.
6 SO --

7 CHAIRMAN PENHOET: YEAH, NANCY AND SCOTT
8 AND ANTOINETTE HAVE DONE A VERY NICE JOB. FABULOUS.

9 MS. KOCH: WOULD IT BE HELPFUL FOR ME TO
10 JUST READ ALOUD WHAT THE EXISTING REGULATION SAYS
11 ABOUT THIS --

12 CHAIRMAN PENHOET: YES, PLEASE DO.

13 MS. KOCH: -- SO YOU HAVE IT IN YOUR MIND?
14 IT SAYS IN OUR MEETING FROM 100407(A)(2), FOR THOSE
15 OF YOU WHO HAVE IT, THE ACCESS PLAN MUST BE
16 CONSISTENT WITH INDUSTRY STANDARDS AT THE TIME OF
17 COMMERCIALIZATION, ACCOUNTING FOR THE SIZE OF THE
18 MARKET FOR THE DRUG AND THE RECOURSE OF THE GRANTEE
19 OR ITS EXCLUSIVE LICENSEE.

20 CHAIRMAN PENHOET: SO THE WORD "MUST" PUTS
21 AN OBLIGATION ON OUR SIDE TO MAKE SURE THAT IT
22 ADHERES TO THAT. SO IF SOMEONE DECIDES THEY WANT TO
23 GET OUT IN FRONT ON THIS ISSUE IN SOME MEANINGFUL
24 WAY, THAT THE PROTECTION A COMPANY WOULD HAVE IS THE
25 WORD "MUST"; IS THAT RIGHT?

BARRISTERS' REPORTING SERVICE

1 MS. KOCH: I THINK --

2 CHAIRMAN PENHOET: I'M NOT A LAWYER. OR
3 ANTOINETTE IF YOU WANT TO WEIGH IN.

4 MS. KOCH: I THINK IF I WERE A GRANTEE
5 SEEKING PERMISSION TO COMMERCIALIZE AND GET APPROVAL
6 FOR AN ACCESS PLAN, I WOULD FOCUS ON THE WORD
7 "CONSISTENT WITH INDUSTRY STANDARD" AS SETTING WHAT
8 THE BASELINE IS AND SAYING THAT CIRM WOULD NOT HAVE
9 THE RIGHT TO IMPOSE SOMETHING IN EXCESS OF INDUSTRY
10 STANDARDS. BUT IF A PARTICULAR GRANTEE WANTED TO DO
11 SOMETHING ABOVE AND BEYOND, THEY'D CERTAINLY BE FREE
12 TO DO SO.

13 BUT WE CAN LOOK AT SOME LANGUAGE TO
14 ENFORCE THAT CONCEPT.

15 MR. SHEEHY: MAYBE THAT LAST PHRASE WHERE
16 YOU'VE STIPULATED THAT CIRM WOULD NOT BE ABLE TO
17 ENFORCE A STRICTER PROVISION. YOU KNOW, AND WE DO
18 HAVE PEOPLE FOR INDUSTRY HERE. I MEAN IF THAT'S
19 SOMETHING THAT ALLEVIATES SOME CONCERNS.

20 CHAIRMAN PENHOET: CAN I HAVE OTHER
21 FEEDBACK FROM OTHER BOARD MEMBERS? TED OR --

22 MS. KING: I THINK FRANCISCO PRIETO JUST
23 JOINED.

24 DR. PRIETO: YES, I DID.

25 CHAIRMAN PENHOET: THANK YOU.

BARRISTERS' REPORTING SERVICE

1 DR. LOVE: I THINK THAT THAT IS
2 REASSURING, THAT WE WOULDN'T BE IN A POSITION TO TRY
3 TO IMPOSE A STANDARD THAT'S BEYOND THE INDUSTRY
4 STANDARD. SO I THINK THAT SOUNDED VERY ATTRACTIVE
5 TO ME.

6 MR. TOCHER: ED, THIS IS SCOTT. ONE OF
7 THE THINGS THAT I KNOW WE'VE HEARD SOMETIME FROM THE
8 REGULATED COMMUNITY AND IT CAME UP AGAIN LAST WEEK
9 SPEAKING TO THE UC FOLKS IS ANOTHER WAY OF, I THINK,
10 WHAT WE'RE TRYING TO DO IS GIVE FOLKS REASSURANCE IS
11 TO TRY TO DO A BETTER JOB OF SPELLING OUT WHAT THE
12 COMPONENTS OF THE PLAN ARE. SO THAT FOLKS KNOW WHEN
13 THEY'RE INSIDE THE BOX OR OUTSIDE THE BOX. AND THIS
14 IS NOT NEW. THIS IS SOMETHING WE WENT OVER AND OVER
15 TIME AND TIME AGAIN FOR OVER A YEAR WHEN WE WERE
16 DEVELOPING THE REGULATIONS.

17 THAT'S SOMETHING ELSE THAT KIND OF WENDY
18 STREITZ HAS SPOKEN ABOUT AT THE LAST MEETING LAST
19 WEEK, THAT THERE ARE OTHER FOLKS IN HER COMMUNITY
20 WHO ARE GOING TO BE TAKING A LOOK AT THAT AND MAYBE
21 OFFERING US SUGGESTIONS ON HOW WE CAN BETTER FLESH
22 OUT WHAT THE PARTICULARS OF THE PLAN WOULD BE. AND
23 THAT WOULD BE PROBABLY GO A LONG WAY IF WE COULD PUT
24 THAT INTO THE REGULATIONS SO THAT THEY KNEW WHAT
25 THEY WOULD BE BEING JUDGED AGAINST.

BARRISTERS' REPORTING SERVICE

1 MR. ROTH: SCOTT, I DON'T KNOW HOW YOU DO
2 THAT WHEN YOU'D HAVE NO IDEA WHAT THOSE PLANS ARE
3 GOING TO LOOK LIKE IN TEN YEARS.

4 MR. TOCHER: NO. NO. I DON'T THINK IT
5 WOULD SAY ANYTHING LIKE PERCENTAGES OR THAT SORT OF
6 THING, BUT JUST WHAT THE GENERAL AREAS ARE OF WHAT
7 AND ACCESS PLAN SHOULD EVEN BE ADDRESSING.

8 CHAIRMAN PENHOET: I THINK THE ONUS WILL
9 BE ON CIRM AT THE TIME TO ACTUALLY DEFINE THOSE
10 TERMS -- THAT SITUATION. SOMEBODY WILL HAVE TO THE
11 HOMEWORK TO DEFINE WHAT THE STATE OF THE ART IN THE
12 INDUSTRY IS TO HAVE AS A COMPARATOR. WELL, MAYBE
13 WE'LL SIC OUR LAWYERS ON THIS ISSUE AND SEE
14 WHAT -- WENDY, DO YOU WANT TO -- WELL, LET ME GO
15 THROUGH. ANY OTHER BOARD MEMBERS HAVE A COMMENT ON
16 THIS ISSUE?

17 MR. ROTH: ED, I'VE MADE MINE, BUT I JUST
18 I WANT TO CLARIFY. IS THERE A REQUIREMENT FOR A
19 PUBLIC HEARING IN THE PLAN NOW?

20 CHAIRMAN PENHOET: THERE IS. AND IT WAS
21 INTRODUCED AS IN THE -- WHAT SHOULD I SAY -- IN THE
22 TOTALLY USELESS HOPE THAT IT WOULD ACTUALLY
23 FORESTALL THE KUEHL BILL FROM -- YOU KNOW, IF WE
24 MADE ENOUGH COMPROMISES. SO WE ENDED UP MAKING THE
25 COMPROMISES, AND THE KUEHL BILL PASSED ANYWAY.

BARRISTERS' REPORTING SERVICE

1 MR. ROTH: AND I'M GOING TO REPEAT AGAIN I
2 REALLY DON'T LIKE THAT CLAUSE. I THINK IT CAN BE SO
3 ABUSIVE AND THERE WOULD BE PROPRIETARY INFORMATION,
4 AND YOU'RE GOING TO PUT A COMPANY OUT IN FRONT OF --
5 I THINK YOU'RE GOING TO PUT THEM IN A VERY DIFFICULT
6 POSITION, AND I DON'T THINK THAT'S NECESSARY. I
7 THINK WE CAN HAVE THAT DISCUSSION; AND IF THERE'S AN
8 ISSUE, THEN WE HAVE OTHER MEANS THAT WE CAN TAKE, I
9 THINK, TO GET THAT OUT. BUT I'M -- I REALLY DON'T
10 KNOW HOW THAT WOULD WORK, PUBLIC HEARING.

11 DR. PRIETO: PUBLIC HEARING ON THE ACCESS
12 PLANS?

13 CHAIRMAN PENHOET: YES.

14 MR. ROTH: ON THE INDIVIDUAL ACCESS PLAN.

15 CHAIRMAN PENHOET: WHEN A COMPANY BRINGS A
16 PRODUCT TO MARKET, THEY WOULD HAVE TO APPEAR IN A
17 MEETING TO WHICH THE PUBLIC COULD PARTICIPATE AND
18 DESCRIBE THEIR ACCESS PLAN. AND PRESUMABLY THE CIRM
19 STAFF INVOLVED WOULD BE PRESENT IN THE SAME MEETING,
20 AND THERE WOULD BE SOME DISCUSSION ABOUT IT. WELL,
21 THIS IS ONE WE WOULD HAVE TO TAKE BACK TO THE BOARD
22 BECAUSE IT WAS INTRODUCED AT A BOARD MEETING.

23 DR. PRIETO: I WOULD PRESUME THAT --

24 MR. ROTH: PUBLIC HEARING.

25 MR. TOCHER: NO. THE PUBLIC HEARING IS

BARRISTERS' REPORTING SERVICE

1 ALREADY A COMPONENT NOW.

2 CHAIRMAN PENHOET: I UNDERSTAND. IF
3 SOMEBODY WANTS TO REMOVE IT.

4 MR. TOCHER: OH, THAT'S CORRECT. YEAH.
5 YOU WOULD HAVE TO GO THROUGH THE NOTICE PROCESS
6 AGAIN. AND AS YOU SAID, IT'S JUST SOMETHING THAT
7 WAS ARRIVED AT WITH THE LEGISLATURE IN MIND.

8 DR. PRIETO: I WOULD JUST ANSWER THAT
9 CONCERN ABOUT THE PROPRIETARY INFORMATION. I WOULD
10 THINK THAT ANY COMPANY, YOU KNOW, ANY REASONABLY
11 CAUTIOUS COMPANY WOULD BE CAREFUL NOT TO REVEAL
12 ANYTHING WITHIN THIS PLAN ITSELF THAT WOULD
13 JEOPARDIZE THEIR OWN SITUATION.

14 MR. ROTH: SO I'M NOT THINKING NOW ABOUT
15 PROPRIETARY IN TERMS OF SECRET. I'M TALKING ABOUT
16 THINGS LIKE WHAT ARE YOU REALLY DOING ON YOUR ACCESS
17 PLAN? HOW MUCH MONEY ARE YOU GOING TO DEDICATE
18 THERE AND WHAT IS IT? AND IF I'M A COMPETITOR THAT
19 DOESN'T HAVE TO DEAL WITH THIS, HOW AM I TO RESPOND
20 TO THAT TO GET MARKET SHARE OR TO PUT MORE ONEROUS
21 ON THE COMPANY TO HAVE TO GIVE MORE AWAY? THOSE
22 KIND OF THINGS THAT, I THINK, THEY'LL BE CANDID WITH
23 YOU IN A CLOSED MEETING, BUT I THINK THEY DON'T
24 NECESSARILY WANT EVERYBODY IN THE WORLD TO KNOW WHAT
25 THEY'RE ACCESS PLAN MIGHT BE.

BARRISTERS' REPORTING SERVICE

1 DR. PRIETO: I DON'T KNOW. I MEAN AS THEY
2 CURRENTLY EXIST, YOU KNOW, IN THE PHARMACEUTICAL
3 INDUSTRY, IT'S NOT DIFFICULT TO GET THE DETAILS OF
4 THAT. I DON'T KNOW ABOUT HOW MUCH MONEY ANYBODY IN
5 A COMPANY PUTS INTO IT UNDER QUALIFYING RULES AND SO
6 ON. I'D HAVE TO ASK THE PEOPLE IN OUR PRACTICE WHO
7 HELP PATIENTS NEGOTIATE THROUGH THESE, SO I DON'T
8 KNOW HOW MUCH OF THAT IS PUBLIC.

9 DR. LOVE: I THINK FROM MY PERSPECTIVE, IT
10 WOULDN'T BOTHER ME THAT MUCH TO DO THIS. IN FACT, I
11 THINK ONE OF THE ATTRACTIVE THINGS, IF YOU ARE SO
12 FORTUNATE TO HAVE A PRODUCT THAT YOU COULD SELL, BE
13 ABLE TO GET OUT THERE AND TOUT THE FACT THAT YOU ARE
14 PROUD THAT YOU'RE ABLE TO MAKE IT ACCESSIBLE TO
15 PEOPLE THAT MIGHT NOT OTHERWISE HAVE ACCESS TO THE
16 PRODUCT, WHATEVER THOSE CONFIDENTIAL INFORMATION, I
17 THINK WE WOULDN'T BE IN A POSITION TO MAKE PEOPLE
18 SHARE INFORMATION THAT THAT'S CONFIDENTIAL, BUT I
19 THINK WE COULD EXPECT PEOPLE TO SHOW UP AT THESE
20 MEETINGS AND DESCRIBE THE PLAN TO THE EXTENT THAT
21 IT'S APPROPRIATE THAT THEY BE TRANSPARENT.

22 SO I DON'T THINK IT WOULD BOTHER ME THAT
23 MUCH TO DO THIS.

24 CHAIRMAN PENHOET: OKAY. AS A FIRST
25 APPROACH, LET'S TRY TO LOOK AT THE LANGUAGE AND MAKE

BARRISTERS' REPORTING SERVICE

1 SURE THAT THE STATE HAS AN AFFIRMATIVE OBLIGATION
2 NOT TO GO BEYOND THE STATE OF THE ART AT THE TIME.
3 DO WE HAVE CONSENSUS AROUND THAT POINT OF VIEW?

4 MR. ROTH: YES.

5 CHAIRMAN PENHOET: ANYBODY DISAGREE?
6 WENDY STREITZ WANTS TO MAKE A COMMENT. THE MIC IS
7 OVER HERE.

8 MS. STREITZ: I'M WENDY STREITZ FROM THE
9 UNIVERSITY OF CALIFORNIA SYSTEM. A COUPLE THINGS.
10 ONE IS I THINK THE PUBLIC HEARING REQUIREMENT
11 IS -- I KNOW IT'S IN THE FOR-PROFIT POLICY. I DON'T
12 BELIEVE IT'S IN THE NONPROFIT POLICY RIGHT NOW.

13 AND JUST TO BE CLEAR FROM THE ACADEMIC
14 COMMUNITY, OUR CONCERN IS ENTIRELY WHETHER ANY OF
15 THE PROVISIONS IN HERE ARE ONEROUS ENOUGH TO PREVENT
16 INDUSTRY FROM TAKING OUR INVENTIONS AND RUNNING WITH
17 THEM. THAT WOULD BE THE WORST SCENARIO FOR US AND
18 THE WORST SCENARIO FOR CIRM.

19 I DON'T KNOW -- AND I GIVE YOU THAT WHAT
20 WAS REFERRED TO AS THE UC SYSTEMWIDE MEETING IS NOT
21 NECESSARILY UNIVERSAL VIEW OF THE UC SYSTEM, THAT WE
22 NEED TO DEFINE PARAMETERS UP FRONT FOR SOMETHING
23 THAT MAY NOT HAPPEN FOR ANOTHER FIVE OR TEN YEARS.
24 I THINK THE CONCERN IS NOT SO MUCH THE LANGUAGE THAT
25 TALKS ABOUT THE PLAN BEING CONSISTENT WITH INDUSTRY

BARRISTERS' REPORTING SERVICE

1 STANDARDS, BLAH, BLAH, BLAH, BUT THAT IT BE SUBJECT
2 TO THE APPROVAL OF CIRM AFTER A PUBLIC HEARING. AND
3 I THINK IT WAS THAT -- THE CONTROL OF THE APPROVAL
4 THAT WE WERE CONCERNED WOULD SCARE COMPANIES AWAY.
5 AND THE SUGGESTION WAS THAT WE JUST ADD A CLARIFIER
6 THAT THAT APPROVAL WOULD NOT BE UNREASONABLY
7 WITHHELD.

8 DR. PRIETO: I HAVE A QUESTION. I WONDER
9 IF IT'S THE FRUIT OF CIRM-FUNDED RESEARCH, WHO ELSE
10 WOULD APPROVE IT?

11 MS. STREITZ: OH, I'M NOT SAYING THAT.
12 BUT CIRM IS THE OBVIOUS BODY TO APPROVE IT. IT'S
13 JUST THAT THE CONCERN THAT WAS EXPRESSED WAS THAT IT
14 WOULD BE DIFFICULT FOR US TO LICENSE A TECHNOLOGY TO
15 A COMPANY AND FOR THEM TO INVEST POSSIBLY HUNDREDS
16 OF MILLIONS OF DOLLARS IN GETTING IT READY FOR
17 MARKET WHEN AT THE LAST MINUTE THE SITUATION IS
18 COMPLETELY OUT OF THE COMPANY'S CONTROL AND
19 COMPLETELY OUT OF OTHER CONTROL BECAUSE THERE'S A
20 THIRD ENTITY THAT COULD VETO THE WHOLE THING. AND I
21 THINK JUST THE REASSURANCE THAT THE APPROVAL WOULD
22 NOT BE UNREASONABLY WITHHELD WOULD GO A LONG WAY.

23 CHAIRMAN PENHOET: THAT MIGHT BE A SIMPLE
24 FIX TO THIS DOCUMENT.

25 MR. VALENCIA: JOHN VALENCIA WITH THE

BARRISTERS' REPORTING SERVICE

1 WILKE FLEURY FIRM IN SACRAMENTO. AS MANY OF YOU
2 KNOW, WHEN I HAD A REPRESENTATION FOR THE CALIFORNIA
3 HEALTHCARE INSTITUTE, WHICH IS NOT CURRENT, WE
4 CONTRIBUTED SUBSTANTIALLY IN THIS AREA. I WANT TO
5 ECHO WENDY'S OBSERVATIONS, ED, AND DUANE'S, BUT I
6 THINK THERE'S SOME PROPENSITY TO MAKE THIS A LITTLE
7 MORE COMPLICATED THAN IT REALLY IS.

8 IF YOU LOOK AT THE PROGRAMS THAT EXIST
9 TODAY, AND I THINK DR. PRIETO CAME CLOSEST TO IT IN
10 THE DISCUSSION SO FAR, PATIENT ASSISTANCE PROGRAMS,
11 ACCESS PROGRAMS, HAVE CERTAIN BASIC INDICIA.
12 OTHERWISE THEY DON'T WORK. YOU HAVE TO HAVE AN
13 ELIGIBILITY STANDARD. AND THAT FUNDAMENTALLY IS
14 THIS: PATIENTS NEED TO MEET A CERTAIN PROFILE; AND
15 THEN TO THE EXTENT THAT MY CLIENTS IN TRADITION
16 PHARMA MAKE THOSE PROGRAMS AVAILABLE, UNLESS IT WERE
17 TO BANKRUPT THE COMPANY, THEY'RE ESSENTIALLY WITHOUT
18 LIMIT FOR THE DURATION OF THE PATIENT'S NEED.

19 EVEN IN CHRONIC CARE CASES, SO LONG AS THE
20 PATIENT MEETS THE PROFILE, MOST, UNLIKE GOVERNMENT,
21 AND I'LL CONTRAST PRIVATE SECTOR PATIENT ASSISTANCE
22 PROGRAMS WITH MEDI-CAL, FOR EXAMPLE, MOST DON'T EVEN
23 RECERTIFY PATIENT ELIGIBILITY. AND MOST HAVE NO
24 INDEPENDENT CERTIFICATION TO MY KNOWLEDGE; WHEREAS,
25 YOU CONSTANTLY MUST REAPPLY AND RECERTIFY YOUR

BARRISTERS' REPORTING SERVICE

1 ELIGIBILITY WITH MEDI-CAL OR ADAP, FOR EXAMPLE, AIDS
2 DRUG ASSISTANCE PROGRAM. THAT'S FUNDAMENTALLY THE
3 ONUS THAT GOVERNMENT PUTS ON YOU. I'M UNAWARE OF
4 VERY MANY COMPANIES THAT EVEN APPROACH THAT.

5 THE COMMENTS ABOUT CLARITY, I, FRANKLY,
6 FROM AN ATTORNEY'S PERSPECTIVE AND FROM AN
7 ADVOCATE'S PERSPECTIVE, NOT UNREASONABLY WITHHELD IS
8 PURE SUBJECTIVE JUDGMENT. IF YOU -- WHEN THE TIME
9 IS RIGHT, AND I THINK IT IS PREMATURE NOW, IF YOU
10 ASSESS INDUSTRY STANDARDS WHEN YOU EVEN GET MUCH
11 CLOSER TO COMMERCIALIZATION, AND TAKE A LOOK AT
12 WHETHER OR NOT TODAY'S ROUGH INDUSTRY STANDARD, I
13 HESITATE EVEN TO CHARACTERIZE THAT, THAT INITIAL
14 PATIENT ELIGIBILITY IS ASSESSED AT 300 PERCENT OF
15 FEDERAL POVERTY LEVEL. WELL, WHO KNOWS WHAT THE
16 STANDARD WILL BE? BUT WITHIN THAT, COMPANIES WILL
17 VARY FROM AS GENEROUS AS 150 PERCENT, WHICH IS
18 ACTUALLY MEDI-CAL'S ELIGIBILITY THRESHOLD, ON UP TO
19 A LITTLE MORE PENURIOUS LITTLE TIGHTER 400, 450
20 PERCENT.

21 A LOT OF IT REALLY WILL DEPEND ON THE
22 COMPANY. THAT'S THE INDIVIDUAL STATUS OF THE
23 COMPANY, THE NATURE OF THE PRODUCTS THEY HAVE. SO I
24 THINK IF YOU RESOLVE TO IDENTIFY SOME OBJECTIVE
25 CRITERIA, WHICH SHOULDN'T BE TOO TERRIBLY DIFFICULT,

BARRISTERS' REPORTING SERVICE

1 AS A FLOOR, TO BORROW FROM TED' S PERSPECTIVE, FROM
2 DR. LOVE' S PERSPECTIVE, IF YOU ESTABLISH A FLOOR
3 THAT IS AN APPROXIMATION OF WHERE INDUSTRY IS AT THE
4 TIME, YOU SHOULD BE FINE. AS LONG AS YOU DON' T THEN
5 DENY COMPLIANCE ONCE YOU HAVE ENTITIES THAT ARE
6 GRANTEES STEP TO THE PLATE AND SAY WE HIT YOUR
7 FLOOR, WE HIT YOUR MINIMUM THRESHOLD IF A GOOD
8 APPROXIMATION OF WHAT EXISTS IN INDUSTRY STANDARDS.
9 THANK YOU.

10 CHAIRMAN PENHOET: ARE THERE ANY -- OH, WE
11 HAD ONE MORE COMMENT.

12 MR. STRATTON: I' M KEN STRATTON. I' M
13 GENERAL COUNSEL OF STEM CELLS, INC. JUST A COUPLE
14 OF QUICK THOUGHTS.

15 FIRST OFF, I REALLY APPRECIATE ALL THE
16 EFFORTS THAT HAVE GONE INTO WORKING ON THESE
17 REGULATIONS. CLEARLY TREMENDOUS AMOUNT OF WORK FROM
18 CIRM AND MANY OF THE PEOPLE AFFILIATED WITH CIRM. I
19 LOOK FORWARD TO LOOKING THROUGH THEM IN MORE DETAIL
20 COMING UP.

21 I' M VERY HEARTENED BY JEFF SHEEHY' S
22 COMMENTS EARLIER ABOUT THE COVENANT. I THINK ON
23 BEHALF OF INDUSTRY, THAT' S WHAT I' VE ALWAYS HEARD.
24 THERE IS AN INTEREST AND A WILLINGNESS TO ACCEPT A
25 COVENANT OF TAKING THE CIRM PUBLIC MONEY COMES WITH

BARRISTERS' REPORTING SERVICE

1 IT CERTAIN OBLIGATIONS TO MAKE THE PRODUCTS
2 GENERALLY AVAIL ABLE OR AVAI LABLE AT PRICING FOR
3 THOSE WHO ARE DI SADVANTAGED WITH IN CALI FORNIA.

4 THERE ARE A COUPLE OF CONCERNS THAT WE' VE
5 ALWAYS HAD, AND THEY' RE A MATTER OF PUBLIC RECORD IN
6 OUR LETTERS, BUT JUST TO HIGHLIGHT A COUPLE OF
7 THINGS.

8 FIRST, THE INDUSTRY STANDARD PUBLIC ACCESS
9 REQUIREMENTS THAT INDUSTRY TAKES ON VOLUNTARILY IS A
10 VERY DIFFERENT SORT OF THING THAN STANDARDS THAT ARE
11 IMPOSED UPON US BY REGULATION OR STATUTE. STATUTES,
12 REGULATIONS DON' T TEND TO MOVE VERY MUCH. AND
13 WHATEVER ACCESS PLAN IS ADOPTED AT THE TIME OF THE
14 GRANT OR THE TIME OF RECEIVING FUNDS, BY THE TIME OF
15 COMMERCIALIZATION, WE WORRY THAT THEY WILL BE RIGID
16 AND THEY' LL BE RIGIDLY APPLIED AGAINST US WHILE
17 COMPETITORS ARE ALLOWED TO CHANGE THEIR ACCESS PLANS
18 TO MEET WHATEVER COMMERCIAL PRESSURES THEY HAVE TO
19 RESPOND TO.

20 SO WHAT WE DO ABOUT THE RIGIDITY OF THE
21 ACCESS PLAN? FRANKLY, ABOUT A YEAR AGO WE PROPOSED
22 CERTAIN SAFETY NETS FOR THE REGULATIONS TO TRY TO
23 GIVE US SOME ADDITIONAL COMFORT THAT THERE' S CERTAIN
24 BASELINE FLOORS THAT WE WILL NOT BE FORCED TO GO
25 BELOW. ONE WAS WE SHOULD NEVER BE FORCED TO SELL

BARRISTERS' REPORTING SERVICE

1 THE PRODUCT AT A LOSS. THAT'S A LOSING PROPOSITION
2 FOR US. IT WORRIES US TREMENDOUSLY THAT SOME THIRD
3 PARTIES, NOT THE CIRM, BUT PATIENT ADVOCATE GROUPS,
4 PLAINTIFF'S ATTORNEY SOMEDAY WILL FORCE US TO TRY TO
5 SELL THE PRODUCT AT A LOSS. SO THE REGULATIONS CAN
6 CLEARLY CREATE THAT. THAT WOULD BE AN ADVANTAGE.

7 ANOTHER SAFETY NET CLEARLY IS IF WE ARE
8 NOT COMMERCIALIZING THE PRODUCT, DON'T USE THESE
9 REGULATIONS TO FORCE US TO SELL IN CALIFORNIA FOR
10 EVER. RIGHT. THERE ARE MANY REASONS WHY WE MAY NOT
11 BE INTERESTED IN COMMERCIALIZING OR CONTINUING TO
12 SELL A PRODUCT. IT MAY BE OUTMODED. IT MAY BE
13 POTENTIALLY RISKY. IT MAY BE UNCOMPETITIVE FOR A
14 VARIETY OF REASONS. SO DO NOT USE A PUBLIC ACCESS
15 REQUIREMENT, WHICH IS A LAUDABLE INTEREST, A
16 LAUDABLE DESIRE, TO FORCE THE COMPANY TO BE AT A
17 COMMERCIAL DISADVANTAGE.

18 AND, FRANKLY, THAT IS WHY WE'VE ALWAYS
19 REQUESTED THAT THE PUBLIC ACCESS PLAN BE SOMETHING
20 THAT WE COULD ESTABLISH FROM THE GET-GO. BECAUSE IF
21 WE HAVE CERTAINTY AND WE KNOW WHAT THE PLAN WILL
22 REQUIRE FROM US, ON DAY ONE WHEN WE TAKE MONEY FROM
23 THE CIRM, THEN WE CAN TELL OUR BOARD, WE CAN TELL
24 OUR INVESTORS, WE CAN TELL OUR POTENTIAL PARTNERS
25 WHAT THE ULTIMATE REQUIREMENT WILL BE FOR US AND OUR

BARRISTERS' REPORTING SERVICE

1 PRODUCTS.

2 CHAIRMAN PENHOET: KEN, MAY I ASK YOU A
3 QUESTION TO FOLLOW UP ON YOUR COMMENT.

4 MR. STRATTON: OH, PLEASE.

5 CHAIRMAN PENHOET: WITH RESPECT TO -- DO
6 YOU BELIEVE THAT THE CURRENT LANGUAGE COULD FORCE
7 YOU TO CONTINUE TO PROVIDE ACCESS TO A DRUG OR
8 THERAPY OF WHATEVER KIND EVEN THOUGH YOU HAD STOPPED
9 COMMERCIAL ACTIVITIES ASSOCIATED WITH THAT PRODUCT?

10 MR. STRATTON: THE LANGUAGE AS DERIVED OR
11 THE LANGUAGE THAT IT EXISTED BEFORE TODAY?

12 CHAIRMAN PENHOET: WELL, EITHER --

13 MR. STRATTON: LANGUAGE BEFORE TODAY, I'VE
14 BEEN AN ATTORNEY FOR ABOUT 15 YEARS, AND, FRANKLY, I
15 WOULD --

16 CHAIRMAN PENHOET: DON'T TELL ME THAT. IT
17 MAKES ME FEEL OLDER. BUT GO AHEAD.

18 MR. STRATTON: SO I WOULD TAKE IT IF THERE
19 IS A SUBSTANTIAL THERAPY ON THE LINE AND PEOPLE NEED
20 THE TREATMENT, IF I WERE A PLAINTIFF'S ATTORNEY FOR
21 A PATIENT ADVOCACY GROUP, I WOULD TURN TO THAT
22 LANGUAGE IN A HEARTBEAT. WHETHER WE'LL WIN, I DON'T
23 KNOW. BUT, FRANKLY, MY COMPANY WOULD PREFER NOT TO
24 HAVE TO LITIGATE THAT TEN YEARS DOWN THE ROAD.

25 CHAIRMAN PENHOET: I DON'T THINK THAT WAS

BARRISTERS' REPORTING SERVICE

1 OUR INTENT, SO WE'LL TRY TO LOOK AT THE LANGUAGE.

2 DON, DON REED.

3 MR. REED: DON REED. THIS IS JUST A
4 REMINDER THAT THIS THURSDAY, TWO DAYS FROM NOW, IS
5 THE FIRST MEETING OF THE LITTLE HOOVER COMMISSION.
6 YOU MIGHT REMEMBER THAT. IT SPRANG FROM THE SB
7 1565. IT WAS A RECOMMENDATION THAT THE EFFICIENCY
8 GROUP CALLED THE LITTLE HOOVER COMMISSION STUDY THE
9 ICOC AND PRESENT POSSIBLE LEGISLATION TO DEAL WITH
10 ANY REAL OR PERCEIVED CONFLICTS OF INTEREST. THIS
11 COULD BE ALL KINDS OF MAJOR CHANGES. THIS IS THIS
12 THURSDAY AT ROOM 4203 AT THE STATE CAPITOL.

13 I THINK IT'S REALLY IMPORTANT THAT IT BE
14 WATCHED. THE WAY WE'RE WORKING THINGS OUT NOW IS
15 THE CONFLICT, EVERYBODY CONCERNED IS TALKING ABOUT
16 IT. IT'S BEING WRESTLED BACK AND FORTH IN THE LIGHT
17 OF DAY. I HATE THE THOUGHT OF THE ENTIRE STRUCTURE
18 OF THE ICOC BEING POSSIBLY POLITICIZED, AND THERE'S
19 NO TELLING WHAT COULD HAPPEN. THIS IS AN IMPORTANT
20 THING. I HOPE EVERYBODY CAN COME AND BRING THE
21 FAMILY.

22 CHAIRMAN PENHOET: THANK YOU. WELL, DON,
23 THAT REMINDS ME THAT I SHOULD SHARE WITH ALL OF YOU
24 IN CASE YOU MISSED IT FOR SOME REASON, THAT I AM
25 CURRENTLY AN INDUSTRY REPRESENTATIVE, NO LONGER THE

BARRISTERS' REPORTING SERVICE

1 VICE CHAIR. SO YOU CAN TAKE THAT INTO YOUR
2 CONSIDERATION IF THERE'S ANYTHING I SAID, I SUPPOSE.

3 DO WE HAVE ANY COMMENTS FROM THE PUBLIC
4 ELSEWHERE IN THE SYSTEM? OKAY. WELL, I THINK WE'VE
5 HEARD SEVERAL IMPORTANT POINTS. I THINK WE HAVE
6 PROBABLY CONSENSUS AROUND, KEN'S CONCERNS
7 NOTWITHSTANDING, IF WE LEAVE IT AT THE TIME OF
8 COMMERCIALIZATION THAT THERE'S SOME PROTECTIVE
9 LANGUAGE EMBEDDED IN THIS THAT SAYS WE WON'T TRY TO
10 BREAK NEW GROUND WITH RESPECT TO THIS ISSUE. I
11 DON'T KNOW HOW IT WILL COME OUT YET. EVERYBODY
12 AGREE WITH THAT GENERAL STATEMENT?

13 MR. ROTH: YES.

14 DR. PRIETO: YES.

15 CHAIRMAN PENHOET: ALL RIGHT. WE HAVE
16 AGREEMENT HERE AS WELL. ALL RIGHT. THEN WE'LL MOVE
17 ON.

18 THE NEXT SLIDE JUST SORT OF GOES THROUGH
19 THE MAJOR ISSUES WE'RE GOING TO COVER IN THE REST OF
20 THE PRESENTATION. THE CONSOLIDATION HAS BEEN DONE
21 LARGELY, AS I SAID, TO HARMONIZE OUR POLICIES AND
22 ELIMINATE DISCREPANCIES. THIS BECOMES -- YOU KNOW,
23 MAYBE THIS IS THE CENTRAL THEME OF OUR WHOLE
24 DISCUSSION TODAY. AS WE CONTEMPLATE THE DISEASE
25 TEAMS AND REALIZE WE'RE GOING TO HAVE COLLABORATIONS

BARRISTERS' REPORTING SERVICE

1 BETWEEN COMPANIES AND UNIVERSITIES, ANY AMBIGUITY ON
2 WHETHER WHICH RULES APPLY WOULD BE A NEGATIVE IN
3 TERMS OF THEIR FRUITFUL COLLABORATION. SO THAT'S A
4 CASE WHERE THEY'RE BOTH INSIDE. INSIDE IN THE SENSE
5 THAT THEY BOTH HAVE TAKEN CIRM FUNDING, THEY'RE
6 WORKING ON ONE PROJECT TOGETHER, ETC. SO WE HAVE TO
7 MAKE SURE THAT WE'RE NOT SETTING UP CONFLICTS FOR
8 TWO GRANTEES THAT COME FROM OUR TWO DIFFERENT
9 WORLD'S WORKING ON THE SAME PROJECT.

10 IN ADDITION TO THAT, AS I SAID BEFORE,
11 WE'RE NOW CONTEMPLATING A NUMBER OF COLLABORATIONS
12 WITH OUTSIDE PARTIES WHO ARE NOT TAKING OUR FUNDING
13 YET. THEY'RE COLLABORATING ON PROJECTS, AND THAT'S,
14 I THINK, AN ISSUE WE HADN'T REALLY THOUGHT THROUGH
15 VERY CAREFULLY THE FIRST ROUND. AND SO SOME OF
16 WHICH WE'RE GOING TO DO TODAY IS THAT.

17 BUT MAYBE THE CLEANUP ISSUES ARE THE MOST
18 STRAIGHTFORWARD IN A WAY. AND WE'LL GET TO THOSE, I
19 THINK, AT THE END, BUT DIVE INTO THIS WHOLE
20 CONSOLIDATION ISSUE RIGHT NOW. I THINK THAT THAT
21 SLIDE IS PRETTY OBVIOUS IN TERMS OF WHAT WE'RE
22 TRYING TO DO.

23 MR. TOCHER: FOR THE RECORD, ED, YOU'RE
24 LOOKING AT A SLIDE TITLED ISSUE 1, CONSOLIDATION?

25 CHAIRMAN PENHOET: YES.

BARRISTERS' REPORTING SERVICE

1 MR. TOCHER: OKAY.

2 CHAIRMAN PENHOET: SO, YOU KNOW, IT'S A
3 PRETTY DECLARATIVE, SIMPLE STATEMENT. ARE THERE ANY
4 QUESTIONS FROM ANYONE ABOUT WHAT WE'RE DOING WITH
5 RESPECT TO THIS? THE DETAILS ARE IMPORTANT
6 OBVIOUSLY.

7 THE NEXT SLIDE, IF WE COULD GO TO IT THEN,
8 IS ONLY THE GRANTEE BOUND BY CIRM REGULATIONS?

9 DR. STEWARD: EXCUSE ME, ED. COULD YOU
10 JUST GIVE THE SLIDE NUMBER FOR THOSE OF US WHO ARE
11 TRYING TO FOLLOW ALONG HERE?

12 MR. TOCHER: SLIDE NO. 8.

13 DR. STEWARD: THANK YOU.

14 CHAIRMAN PENHOET: SLIDE 8, ISSUE 2.

15 DR. STEWARD: OKAY. THANK YOU.

16 CHAIRMAN PENHOET: ALL CIRM-FUNDED
17 RESEARCHERS BOUND EQUALLY. AND I WANT TO BEGIN THIS
18 DISCUSSION BY, WELL, NOT EXACTLY APOLOGIZING, BUT
19 TRYING TO CLARIFY ONE THING FOR YOU. WE HAVE USED
20 THE WORD "COLLABORATOR" IN THE CURRENT VERSION OF
21 THE DOCUMENT IN TWO DIFFERENT SENSES OF THAT WORD.
22 OKAY. ONE IS THE GANG THAT'S WORKING INSIDE A GRANT
23 FUNDED BY US WHO IS NOT A PI, BUT ALL THE OTHER
24 PEOPLE ASSOCIATED WITH IT, THE PEOPLE WORKING IN THE
25 PI'S LAB, THE PEOPLE, THE TECHNICIANS, ALL OF THE

BARRISTERS' REPORTING SERVICE

1 PEOPLE WHO ARE CIRM-FUNDED HEADED BY THE
2 INVESTIGATOR, THE PRINCIPAL INVESTIGATOR OR
3 CO-PRINCIPAL INVESTIGATOR.

4 BUT THERE'S A SECOND MEANING OF THE TERM
5 "COLLABORATOR," WHICH IS PEOPLE WORKING ON A PROJECT
6 WITH CIRM-FUNDED GRANTEES WHO ARE NOT THEMSELVES
7 RECEIVING ANY FUNDS FROM US, BUT STILL MIGHT BE
8 COLLABORATING ON A PROJECT, SHARING INFORMATION,
9 TOOLS, WHATEVER IT IS, AND WORKING ALONGSIDE
10 ESSENTIALLY TRYING TO FURTHER THE INTERESTS OF THE
11 PROJECT, WHATEVER IT IS.

12 WE WILL PROBABLY CHANGE, AND WE GOT SOME
13 GOOD ADVICE FROM PEOPLE AT UC ABOUT WHAT THEY CALL
14 PEOPLE WHO WORK IN A LAB WHO ARE NOT THE PI OR
15 CO-PI. WE'LL PROBABLY CHANGE THE TERMS
16 "COLLABORATOR" IN THIS AGREEMENT AND DIVIDE IT INTO
17 TWO PARTS. WE WILL COME UP WITH A NEW TERM FOR THE
18 CIRM-FUNDED TEAM.

19 LET ME REMIND YOU THE GRANTEE IS TYPICALLY
20 THE INSTITUTION. SO GRANTEE WOULD BE UCSF. WORKING
21 AT THE GRANTEE INSTITUTION WOULD BE A PRINCIPAL
22 INVESTIGATOR AND/OR ANY CO-PRINCIPAL INVESTIGATORS.

23 MR. TOCHER: I'M JUST GOING TO SKIP AHEAD
24 TO A SLIDE THAT MIGHT SHOW WHAT YOU'RE TALKING ABOUT
25 THERE. ON THE LEFT. FOR THOSE OF YOU ON THE

BARRISTERS' REPORTING SERVICE

1 PHONE --

2 DR. PRIETO: THE OTHER DECK?

3 MR. TOCHER: RIGHT. IT'S THE FIRST SLIDE
4 OF THE OTHER DECK.

5 CHAIRMAN PENHOET: THAT'S PRETTY HARD TO
6 GET TO. LET'S COME BACK TO IT, SCOTT.

7 MR. TOCHER: YOU WERE GOING THERE, AND I
8 THOUGHT MAYBE --

9 CHAIRMAN PENHOET: I KNOW. BUT LET'S COME
10 BACK TO IT. THE QUESTION THAT WE'RE LOOKING AT NOW
11 IS ONLY THE GRANTEE BOUND BY CIRM REGULATIONS. SO
12 I'M JUST TRYING TO GIVE YOU A LITTLE PERSPECTIVE OF
13 WHERE WE'RE GOING WITH THIS DISCUSSION. AND THE
14 ANSWER IS NO. THE GRANTEE AND ITS COLLABORATORS AND
15 EXCLUSIVE LICENSEES ARE ALL BOUND. IN THE SENSE OF
16 THIS SLIDE, THE COLLABORATOR MEANS SOMEBODY WORKING
17 AT THAT INSTITUTION OR ANYBODY ELSE PAID FOR BY CIRM
18 FUNDS. THAT'S THIS MEANING OF COLLABORATOR.

19 SO WE'LL DISCUSS LATER WHERE THE VARIOUS
20 DIVISIONS OF AND WHERE TO DRAW SOME LINES WITH
21 RESPECT TO COLLABORATION GOING FORWARD. AND WE ARE
22 GOING TO CHANGE THE NAME OF THESE PEOPLE WHO WORK
23 FOR A PI TO SOME OTHER NAME OTHER THAN COLLABORATOR
24 BECAUSE IT GETS CONFUSING, AND IT'S NOT THE USUAL
25 SENSE WHICH PEOPLE THINK ABOUT WHEN YOU TALK ABOUT

BARRISTERS' REPORTING SERVICE

1 COLLABORATION. AND IT'S INCONSISTENT WITH THE,
2 QUOTE, UNQUOTE, COLLABORATION AGREEMENTS WE'RE NOW
3 BUSY MAKING WITH PEOPLE AROUND THE WORLD. SO WE
4 HAVE A DIFFERENT TERM TO DESCRIBE THIS.

5 SO TO BE CLEAR, THIS DESCRIPTION OF
6 COLLABORATOR CURRENTLY IN YOUR DOCUMENT AND SIGNED
7 HERE IS ANYBODY WORKING ON THE PROJECT, THE WHOLE
8 GANG OF PEOPLE WORKING ON A PROJECT, UNDER THE
9 SUPERVISION OF A PI OR CO-PI WITHIN THE FRAMEWORK OF
10 CIRM FUNDING. OKAY.

11 MS. KOCH: AND WHETHER THERE IS A GRANTEE
12 INSTITUTION OR NOT.

13 CHAIRMAN PENHOET: YEAH. IF THEY'RE BEING
14 PAID WITH CIRM FUNDS UNDER THE DIRECTION OF A PI --

15 MS. KOCH: WENDY, TAKE YOUR POINT, IF YOU
16 HAD A UCSF COLLABORATION WITH COMPANY A AND THEY
17 WERE ALL RECEIVING CIRM FUNDS, THEY WOULD ALL FALL
18 WITHIN THIS BUCKET OF FOLKS WHO ARE OBLIGATED UNDER
19 THE CIRM INTELLECTUAL PROPERTY REGULATIONS.

20 CHAIRMAN PENHOET: NOW, WHY HAVE WE SPENT
21 A LOT OF TIME THINKING ABOUT THIS ISSUE? BECAUSE WE
22 HAVE A LOT OF CONCERN ABOUT THE FACT THAT IF THESE
23 REGULATIONS ARE PERCEIVED TO BE OVERREACHING, AND
24 ANYONE WHO GETS CLOSE TO A CIRM-FUNDED GRANT BECOMES
25 STUCK AS A RESULT OF DOING IT, IT COULD BE A BAR TO

BARRISTERS' REPORTING SERVICE

1 COLLABORATION. NOT COLLABORATION ASSISTANCE, BUT
2 COLLABORATION WITH THIRD PARTIES NOT FUNDED BY CIRM.

3 AND THE LAST THING WE WANT TO DO, I THINK,
4 IS DISCOURAGE THOSE COLLABORATIONS. WE'RE PUTTING A
5 LOT OF EFFORT INTO COMING UP WITH WAYS TO TRY TO
6 ENCOURAGE COLLABORATION OUTSIDE THE NARROW CONFINES
7 OF OUR CIRM-FUNDED PEOPLE.

8 SO WE'VE NOW, YOU KNOW, FOCUSED ON THIS
9 DISTINCTION, AND WE'LL GET INTO THE DETAILS LATER,
10 BUT THE FIRST PIECE IS TO UNDERSTAND THAT PEOPLE WHO
11 ARE INSIDE THE TENT BEING FUNDED BY CIRM WORKING FOR
12 A PI, EVERY ONE OF THEM HAS THESE OBLIGATIONS.

13 NOW, IT WILL COME -- ONE OF THE PLACES
14 THIS COMES INTO PLAY IS IN THE DEFINITION OF WHEN
15 THEY OWE US SOMETHING. AND THEN LATER ON WE'LL TALK
16 ABOUT WHETHER IT BE LANGUAGE IN BAYH-DOLE, WHICH WE
17 NEED TO BE CONSISTENT WITH, WHICH WE WERE NOT, AND
18 IT WILL BECOME OBVIOUS, I THINK, GOING FORWARD.

19 SO THE NEXT SLIDE IN WHOLE OR IN PART
20 ADDRESSES THE QUESTION OF HOW FAR DO THE REGULATIONS
21 GO. AND, NANCY, I'LL JUST TURN IT OVER TO YOU TO
22 DESCRIBE THIS ONE.

23 MS. KOCH: THIS WAS AN AREA WHERE WE
24 PROBABLY GOT THE MOST QUESTIONS FROM FOLKS OUT THERE
25 IN INDUSTRY AND FROM ACADEMIA AS WELL. WE USED THE

BARRISTERS' REPORTING SERVICE

1 LANGUAGE IN WHOLE AND IN PART, I THINK, TO SIGNAL TO
2 THE COMMUNITY THE CONCEPT OF THE FIRST CIRM DOLLAR
3 TRIGGERS THE OBLIGATIONS. BUT WHEN PEOPLE TOOK A
4 LOOK AT INVENTIONS THAT WERE FUNDED IN WHOLE OR IN
5 PART BY CIRM, THEY SAID, WELL, WHAT IF A CIRM
6 RESEARCHER PUBLISHES THEIR DATA AT A POSTER SESSION
7 OR IN A PEER REVIEW JOURNAL OR I JUST MEET THAT
8 RESEARCHER ON THE STREET AND HE OR SHE TELLS ME WHAT
9 THEY'RE DOING, AND IT SPARKS FOR ME, A
10 NON-CIRM-FUNDED RESEARCHER, A SET OF IDEAS WHICH IN
11 TURN LEAD TO NEW INVENTIONS.

12 SO I'VE GOT SOME CONCEPTS BY TALKING TO MY
13 COLLEAGUES OR BY READING A POSTER AT POSTER SESSION
14 OR READING AN ARTICLE. CIRM MIGHT HAVE PAID FOR
15 THOSE CONCEPTS, BUT I DID ADDITIONAL WORK AND I DID
16 NOT RECEIVE ANY CIRM FUNDS AND I WAS NOT PART OF THE
17 CIRM PROJECT TEAM THAT'S FUNDED IN WHOLE AND IN
18 PART.

19 WE, I THINK, BASED ON SOME CONVERSATIONS I
20 HAD WITH YOU, ED, AND IN REVIEWING THE TRANSCRIPT
21 FROM THE EARLIER SESSIONS OF THE INTELLECTUAL
22 PROPERTY TASK FORCE, SAID NO. THE CIRM INTELLECTUAL
23 PROPERTY OBLIGATIONS DO NOT GO THAT FAR. AND SO
24 PART OF WHAT'S EMBEDDED IN THIS PROPOSED DRAFT OF
25 THE REGULATIONS IS A WAY TO SORT OF FEND OFF THOSE

BARRISTERS' REPORTING SERVICE

1 KINDS OF HYPOTHETICALS.

2 ONCE CIRM INFORMATION IS PUT INTO THE
3 PUBLIC DOMAIN AND USED BY SOMEONE WHO DID NOT
4 RECEIVE CIRM FUNDS AND WAS NOT PART OF A CIRM
5 PROJECT TEAM, THEY ARE NOT RESPONSIBLE FOR CIRM IP
6 REGULATIONS. EVEN IF I HADN'T HAD ACCESS TO SOME OF
7 THE RESULTS FROM THE CIRM RESEARCH, THEY COME UP
8 WITH NEW INVENTIONS.

9 CHAIRMAN PENHOET: NOW, THE NEXT SLIDE,
10 AND IT IS IN THE OTHER DECK, IS A PICTORIAL
11 REPRESENTATION OF THE THREE MOST LIKELY KINDS OF
12 ACTIVITIES CONDUCTED WITH CIRM FUNDING.

13 SO THE SIMPLEST CASE IS ON THE LEFT-HAND
14 SIDE. IF WE HAVE A GRANTEE, A PI, EVERYBODY WHO
15 WORKS ON THE PROJECT IS ASSOCIATED WITH THE PI, AND
16 IS PART OF THE CORE TEAM, THEN IT'S A SIMPLE
17 CIRCUMSTANCE. THEY'RE ALL BOUND.

18 WHETHER THEY REDUCE AN INVENTION TO
19 PRACTICE OR, AS NANCY WILL POINT OUT LATER,
20 CONCEIVED OF AN INVENTION WHILE THEY ARE WORKING
21 WITH CIRM FUNDING, THEY'RE BOUND BY OUR REGULATIONS.
22 THE WORD "CONCEIVED" WAS ADDED, AND WE'LL TALK ABOUT
23 IT LATER BECAUSE WE ARE ATTEMPTING TO BE AS
24 COMPATIBLE AS POSSIBLE WITH BAYH-DOLE. THAT IS THE
25 LANGUAGE IN BAYH-DOLE.

BARRISTERS' REPORTING SERVICE

1 THE NEXT CIRCUMSTANCE IS YOU HAVE SOME
2 KIND OF COLLABORATION WITHIN THE UNIVERSITY
3 STRUCTURE, FOR EXAMPLE, A UNIVERSITY AND A COMPANY,
4 BUT THE TOTALITY OF THE PROJECT, BOTH SIDES OF THIS
5 COLLABORATION, ARE FUNDED BY CIRM. OKAY. THEN
6 AGAIN, THEY'RE ALL IN AND MUST MEET THE REGULATIONS.

7 THE THIRD KIND IS THE COMPLICATED KIND,
8 AND HERE'S WHERE WE MAKE A DISTINCTION. SO IF THERE
9 IS A COLLABORATION, AND MANY OF OUR NONSTATE
10 COLLABORATIONS WILL BE OF THIS KIND BECAUSE WE'RE
11 NOT ALLOWED TO FUND OUT-OF-STATE, IF THERE IS A
12 COLLABORATION ON A PROJECT, THEN YOU HAVE, FOR
13 EXAMPLE, A UNIVERSITY, A COMPANY, AND SOME THIRD
14 PARTY FROM SOMEPLACE. IF THE THIRD PARTY IS NOT
15 RECEIVING FUNDING FROM US, THEN WE DO NOT INTEND TO
16 OBLIGATE THAT THIRD PARTY BY VIRTUE SOLELY OF THEIR
17 COLLABORATION WITH A CIRM-FUNDED ENTITY TO BE BOUND
18 BY OUR REGULATIONS.

19 OBVIOUSLY THERE ARE SPECIAL CASES OF THIS,
20 AND WE HAVE TO THINK ABOUT JOINT OWNERSHIP OF
21 INVENTIONS THAT THEY MIGHT MAKE. SO TYPICALLY IN A
22 UNIVERSITY/INDUSTRY RELATIONSHIP, IF PEOPLE FROM
23 BOTH THE COMPANY AND THE UNIVERSITY ARE WORKING ON A
24 PROJECT, TWO PEOPLE ARE INVENTORS OF AN INVENTION,
25 THEN THEY BOTH HAVE THE RIGHT TO PRACTICE THE

BARRISTERS' REPORTING SERVICE

1 INVENTION UNLESS THEY HAVE SOME OTHER AGREEMENT
2 BETWEEN THEMSELVES ABOUT WHAT THEY' RE GOING TO DO
3 WITH THE INVENTION. USUALLY THEY DO HAVE SUCH AN
4 AGREEMENT.

5 IN THAT CASE THE CO-INVENTING PARTIES WILL
6 DECIDE WHAT TO DO; BUT IF THEY' RE BOTH CIRM-FUNDED,
7 IT MEETS ALL THE REQUIREMENTS.

8 MS. KOCH: I THINK THAT' S EXACTLY RIGHT,
9 ED. AND LOOKING AT THIS SLIDE THAT YOU ARE
10 REFERRING TO, OF THE THREE POSSIBILITIES, WHICH IS
11 ONE FUNDED PROJECT WHERE IS THERE IS ONE FUNDED
12 PARTNER AND ONE NONFUNDED PARTNER. THE CIRM
13 INVENTOR COULD BE THE SOLE INVENTION, AND THE
14 BENEFITS OF THAT AND THE OBLIGATIONS UNDER THE REGS
15 WOULD APPLY. IT' S CIRM' S INVENTOR, CIRM' S FUNDS,
16 CIRM' S TOTALLY RESPONSIBLE.

17 ON THE OTHER EXTREME, THE NONFUNDED
18 COLLABORATOR, ALTHOUGH WORKING ON THE PROJECT, BUT
19 NOT RECEIVING CIRM FUNDS, COULD COME UP ON THEIR OWN
20 SOLELY AS AN INVENTOR OF SOMETHING, AND WE WOULD NOT
21 SAY THAT THE CIRM REGULATIONS ATTACH AT THAT POINT.
22 WHY? THEY' RE NOT A CIRM-FUNDED INVENTOR. THERE WAS
23 NO CIRM RESEARCHER THAT CONTRIBUTED TO THAT WORK.

24 BUT IN THE MIDDLE AND PARTNER CASE, WHERE
25 THE INVENTION IS A CO-INVENTION OF A RESEARCHER WHO

BARRISTERS' REPORTING SERVICE

1 WAS CIRM-FUNDED AND A RESEARCHER WHO WAS NOT
2 CIRM-FUNDED, THAT CASE COMES TO THE CIRM-COVERED
3 SIDE (INAUDIBLE) BECAUSE INVENTORS HAVE RIGHTS OF
4 EQUAL EXPLOITATION. AND WE HAVE TO. IN ORDER TO
5 ENSURE THAT OUR ACCESS PLANS AND PRICING
6 RESTRICTIONS AND THE LIKE WORK AND CAN'T BE
7 UNDERCUT, THEY HAVE TO COME ON THIS SIDE OF THE
8 LINE.

9 SO AGAIN, IN SUMMARY, ONE PROJECT, IF A
10 CIRM INVENTOR SOLELY INVENTS SOMETHING, IT FALLS
11 WITHIN THE CIRM REGS. IF THE NONFUNDED PARTNER
12 SOLELY INVENTS SOMETHING, IT'S OUTSIDE OF THE REGS.
13 IN THE IN-BETWEEN CASE OF CO-INVENTION, CIRM'S
14 FUNDED INVENTOR AND THE NON-CIRM-FUNDED INVENTOR
15 CO-INVENT SOMETHING, THAT FALLS WITHIN THE REGS.
16 THAT'S WHAT WE TRIED TO CAPTURE IN THE DRAFT YOU
17 HAVE IN FRONT OF YOU.

18 DR. STEWARD: MAY I ASK A QUESTION
19 RELATING TO EFFORT? SO IT'S THE RULE RATHER THAN
20 THE EXCEPTION IN ACADEMIC SETTINGS THAT PEOPLE,
21 GRADUATE STUDENTS AND KEY PERSONNEL, ARE PAID ONLY
22 PARTIALLY ON ONE PROJECT OR ANOTHER. SO PROBABLY
23 VERY OFTEN YOU ARE GOING TO RUN INTO A SITUATION
24 WHERE PARTICIPANTS, INCLUDING PI'S AND EVERYBODY
25 ELSE THAT'S FUNDED BY CIRM, WILL ALSO BE FUNDED BY

BARRISTERS' REPORTING SERVICE

1 SOMEBODY ELSE PART TIME. HOW DOES THIS -- HOW IS
2 THAT HANDLED?

3 CHAIRMAN PENHOET: WELL, IT DOESN'T GO TO
4 THE -- IF THEY'RE FUNDED -- PRESUMABLY THEY'RE
5 FUNDED BY CIRM TO WORK ON THE CIRM PROJECT. OKAY.
6 IF THEY'RE FUNDED BY ANOTHER PARTY WHO HAS NO
7 INTEREST IN THEIR WORK, NO FINANCIAL INTEREST IN
8 THEIR WORK, WE ASSUME, AND THEY'RE WORKING FULL TIME
9 FOR CIRM, LET'S SAY, I DON'T KNOW, NEXT FEBRUARY
10 THEY GET SOME FEDERAL FUNDING TO FUND THEIR WORK
11 WHICH FALLS UNDER THE UMBRELLA OF THE GRANT WITH US,
12 I THINK THE RESTRICTIONS STILL APPLY. THEY ARE
13 CIRM-FUNDED. SO THEY'RE IN -- BUT THERE ARE MANY
14 CASES WHERE THERE WILL BE PEOPLE WORKING ON THE
15 GRANT WHO ARE NOT FUNDED AT ALL BY CIRM, BUT THEY'RE
16 PART OF THE TEAM.

17 SO THE UNIVERSITY HAS SOME LANGUAGE THAT
18 IT'S GOING TO SHARE WITH US TO DESCRIBE THIS IN ALL
19 THE GRANTS THEY DO WHAT CONSTITUTES PART OF THE
20 TEAM. BECAUSE THERE ARE SOME GRADUATE STUDENTS, IF
21 THEY'RE SUPPORTED BY THE NATIONAL SCIENCE
22 FOUNDATION, WE'RE NOT PAYING THEIR SALARY, BUT WE
23 WILL BE BUYING THE EQUIPMENT, WE'LL BE BUYING THE
24 REAGENTS, SO THEY'RE A PART OF THE TEAM IRRESPECTIVE
25 OF WHERE THEY'RE GETTING THEIR SALARY.

BARRISTERS' REPORTING SERVICE

1 AND, WENDY, MAYBE YOU CAN HELP US WITH
2 THIS ISSUE. I DON'T REMEMBER PRECISELY WHAT YOUR
3 GUYS WERE TELLING US, BUT THERE IS A UNIVERSITY
4 DESCRIPTION FOR THESE PEOPLE.

5 MS. STREITZ: EVERY FUNDED PROJECT HAS A
6 SCOPE OF WORK. SO THE CIRM PROJECT WILL HAVE A
7 SCOPE OF WORK, AND THE FEDERALLY FUNDED PROJECT WILL
8 HAVE A DIFFERENT SCOPE OF WORK. THAT'S THE KEY. SO
9 WHEN YOU LOOK TO WHERE -- WHEN YOU MAKE AN INVENTION
10 AND YOU WANT TO ASSESS WHERE DO THE OBLIGATIONS LIE
11 WITHIN THE SCOPE OF WORK THE INVENTION WAS MADE
12 UNDER, IT LARGELY TRACKS WITH (UNINTELLIGIBLE), BUT
13 YOU'RE RIGHT. SOMETIMES IT DOESN'T, SO WHAT WE'LL
14 LOOK TO WAS WAS THE INVENTION MADE IN THE
15 PERFORMANCE OF THE CIRM SCOPE OF WORK OR IN THE
16 PERFORMANCE OF A DIFFERENT SCOPE OF WORK. AND IT'S
17 THE JOB OF THE PI IN THE LAB TO KEEP THE SCOPES OF
18 WORK SEPARATE SO WE CAN MANAGE OUR OBLIGATION.

19 DR. STEWARD: OKAY. I GUESS I JUST -- I
20 JUST HAD TO SAY IT COULD GET A LITTLE BIT HARD TO DO
21 THAT ESPECIALLY WHEN THERE ARE DIFFERENT SOURCES OF
22 FUNDING, INCLUDING, FOR EXAMPLE, MAYBE PRIVATE
23 FUNDING FOR STEM CELL PROJECTS. THE PRODUCT,
24 WHATEVER IT IS, OR THE INVENTION MIGHT BE HARD TO
25 ASCRIBE. AND I JUST WILL THROW THAT OUT THERE AS A

BARRISTERS' REPORTING SERVICE

1 COMMENT AT THIS POINT.

2 CHAIRMAN PENHOET: WELL, YOU KNOW, I THINK
3 IF YOU GO BACK TO THE FIRST PRINCIPLES, ONE OF THE
4 FIRST PRINCIPLES WAS FIRST DOLLAR IN. SO IF A
5 PROJECT IS FUNDED BY A PRIVATE PARTY AND BY CIRM, I
6 THINK THE CIRM RULES WILL APPLY. SO IF SOMEBODY
7 WANTS TO BE ABSOLUTELY SURE THAT NONE OF THIS -- OF
8 COURSE, THEY'LL HAVE TO SEGREGATE THAT PROJECT FROM
9 THE CIRM-FUNDED PROJECT. HOPEFULLY THAT WON'T
10 HAPPEN TOO OFTEN.

11 DR. PRIETO: ED, A QUESTION. ISN'T THAT
12 THE STANDARD FOR NIH FUNDING, THAT IF YOU ACCEPT \$1
13 OF NIH FUNDING, THEN NIH RULES APPLY?

14 CHAIRMAN PENHOET: THAT'S CORRECT.

15 MS. KOCH: WE DO RECOGNIZE, OF COURSE,
16 PROPORTIONALITY IN THE REVENUE SHARING SIDE. SO --

17 MR. TOCHER: THE LICENSING REVENUE.

18 MS. KOCH: YES, LICENSING REVENUE. SO IF
19 THERE WERE JOINT CONTRIBUTIONS, FOR EXAMPLE, NIH AND
20 CIRM TO AN INVENTION WHERE WE PONIED UP 60 PERCENT
21 OF IT AND NIH PONIED UP 40 PERCENT OF IT, IN THE
22 REVENUE SHARING OBLIGATION, THE OBLIGATIONS WOULD BE
23 DIMINISHED BY 40 PERCENT, REFLECTING CONTRIBUTION
24 FROM ANOTHER SOURCE.

25 CHAIRMAN PENHOET: YOU KNOW, THAT'S NOT

BARRISTERS' REPORTING SERVICE

1 REALLY DIFFERENT THAN WHAT WE'VE BEEN SAYING BEFORE.
2 BUT THE PRIMARY DIFFERENCE IS TO MAKE SURE THAT
3 WE -- THAT OUR RULES ARE NOT INTERPRETED THAT A
4 THIRD PARTY FUNDED BY OTHERS, WE'RE TAKING A PIECE
5 OF A PROJECT, SO TO SPEAK, WON'T BE FOLDED INTO
6 OR BROUGHT UNDER OUR TENT IF THEY RECEIVE NO MONEY
7 FROM US, AND THEY DON'T HAVE A CO-INVENTION WITH US
8 TO EXPLOIT. SO WHATEVER THEY EXPLOIT ON THEIR OWN.

9 NOW, WHAT WE DO KNOW IS THERE WILL BE
10 ALMOST CERTAINLY -- THERE CERTAINLY WILL BE SOME
11 AGREEMENT IN PLACE BETWEEN THESE VARIOUS PARTIES ON
12 THE RIGHT-HAND SIDE HERE AMONG THEMSELVES ABOUT HOW
13 THEY'RE GOING TO DO THIS. SO WE'RE NOT TRYING TO
14 INVADE THAT SPACE. IF THE PEOPLE ON THE LEFT-HAND
15 SIDE ARE UC AND THE PEOPLE ON THE RIGHT-HAND SIDE
16 ARE MERCK & COMPANY IN NEW JERSEY, THEY'RE GOING TO
17 MAKE SOME DEAL WITH EACH OTHER. OKAY. THEY WILL
18 SIMPLY HAVE TO EMBED IN THAT DEAL, IF THEY'RE DOING
19 RESEARCH TOGETHER, UNDER WHAT CIRCUMSTANCES WILL
20 THEY FALL IN THE SCOPE OF THE CIRM AND WHAT
21 CIRCUMSTANCES THEY WON'T.

22 SO WE'RE WORKING HARD TO CLARIFY THIS
23 ISSUE BECAUSE I DO THINK THAT THERE WAS A NOTION
24 FLOATING AROUND, AT LEAST FOR A WHILE, THAT ANYBODY
25 WHO TOUCHED ANYTHING RELATED TO CIRM WAS GOING TO

BARRISTERS' REPORTING SERVICE

1 BE, YOU KNOW, DRAWN UNDER THE TENT. AND THAT WILL
2 DISCOURAGE COLLABORATION. IT'S A VIEW WE'VE HEARD
3 FROM MANY DIFFERENT PEOPLE, INCLUDING KEN STRATTON.
4 SO THAT'S WHAT WE'RE TRYING TO ADDRESS HERE.

5 SO I THINK WE'LL OPEN IT UP FIRST TO
6 QUESTIONS FROM MEMBERS OF THE COMMITTEE.

7 MR. ROTH: ED, I DON'T HAVE ANY. JUST A
8 COMMENT. I THINK IT'S CLEAR, AND THIS CLARIFIES
9 EVEN FURTHER. AND COMPANIES AND INSTITUTIONS DEAL
10 WITH THESE TYPES OF INVENTIONS ALL THE TIME, AND WE
11 SOMEHOW MANAGE TO FIND A WAY THROUGH THEM. SO I
12 THINK IT WILL BE FINE.

13 CHAIRMAN PENHOET: ANY OTHERS COMMENTS
14 FROM THE COMMITTEE?

15 DR. LOVE: I AGREE WITH WHAT DUANE JUST
16 SAID. THIS IS TED.

17 CHAIRMAN PENHOET: OKAY. THEN WHY DON'T
18 WE HEAR FROM THE PUBLIC. WE DO HAVE AN EAGER PUBLIC
19 PARTICIPANT IN SAN FRANCISCO, KEN STRATTON.

20 MR. STRATTON: SO THIS IS KEN STRATTON.
21 THANK YOU. BIG FAN OF CLARITY AND BRIGHT LINE
22 RULES. IT HELPS A LOT.

23 SO LET ME JUST PLAY OUT A FACT PATTERN TO
24 MAKE SURE THAT I UNDERSTAND WHAT THE INTENT IS
25 BEHIND THE DRAFT, SO WHEN I GO BACK AND LOOK AT THE

BARRISTERS' REPORTING SERVICE

1 LANGUAGE, I CAN TRACK IT.

2 AS YOU MAY KNOW, STEM CELLS, INC. HAS
3 SEVERAL BANKS OF PURIFIED HUMAN NEURAL STEM CELLS.
4 NOT TO HAVE FLASKS UPON FLASKS OF REAGENTS THAT ARE
5 READILY AVAILABLE, WE'VE BEEN APPROACHED BY MANY
6 INTERESTED PEOPLE WHO WANT TO DO DIFFERENT KINDS OF
7 RESEARCH ON BOTH THE NEURAL STEM CELLS AND USING THE
8 REAGENTS OF TAGS AS SOME SORT OF PROCESS FOR OTHER
9 KINDS OF STUDIES.

10 SO WE'RE TRYING TO FIGURE OUT WHAT WE CAN
11 PROVIDE TO THEM AS FAR AS SUPPORT WITHOUT TAKING US
12 UNDER THE TENT AND HAVING ALL THE OBLIGATIONS FALL
13 ON US WITHOUT TAKING ANY CIRM MONEY IN EXCHANGE.

14 IF WE PROVIDE THE CELL --

15 CHAIRMAN PENHOET: LET ME STOP YOU THERE.
16 I BELIEVE THAT UNDER THOSE CIRCUMSTANCES -- WE HAVE
17 AN AFFIRMATIVE OBLIGATION ELSEWHERE IN OUR DOCUMENT
18 FOR YOU TO PROVIDE THOSE MATERIALS IF THEY WERE
19 ESSENTIALLY REDUCED TO PRACTICE WITH CIRM FUNDING.
20 YOU HAVE AN AFFIRMATIVE OBLIGATION TO SHARE THOSE
21 WITH THE COMMUNITY. SO I THINK IT WOULD BE
22 INCONSISTENT ON OUR PART TO SAY, BY THE WAY, ANYBODY
23 YOU SHARE THEM WITH WILL BE DRAGGED UNDER THE TENT.
24 SO I DON'T THINK THAT WAS OUR INTENT, BUT WE'LL HAVE
25 TO --

BARRISTERS' REPORTING SERVICE

1 MR. STRATTON: RIGHT. AND THESE ARE
2 PREEXISTING CELLS, THEY HAVE THEM PROTECTED ALREADY,
3 NOT DEVELOPED USING CIRM MONEY. SO IF WE PROVIDE
4 THE CELLS AND REAGENTS TO INVESTIGATORS IN SUPPORT
5 OF THEIR CIRM-FUNDED RESEARCH, IT SOUNDS LIKE WE
6 WOULD FALL OUTSIDE. BUT A QUESTION.

7 MS. KOCH: TAKE IN PIECES. I THINK WHAT
8 HE'S POSITING IS THAT HE IS A MERE SUPPLIER OF A
9 GOOD WHICH IS USED BY A CIRM-FUNDED RESEARCHER.

10 CHAIRMAN PENHOET: BY A NON-CIRM-FUNDED
11 RESEARCHER.

12 MR. STRATTON: NO. CIRM-FUNDED
13 RESEARCHER.

14 CHAIRMAN PENHOET: I'M SORRY.

15 MS. KOCH: HE IS A NON-CIRM-FUNDED
16 SUPPLIER OF A GOOD WHICH IS GOING TO BE USED BY A
17 CIRM-FUNDED RESEARCHER ON A CIRM-FUNDED PROJECT. HE
18 WANTS TO KNOW IF SUPPLYING THOSE CELLS, WHICH WERE
19 NOT PAID FOR BY CIRM IN THE FIRST PLACE, GOING TO
20 DRAG HIS COMPANY INTO THE CIRM REGULATIONS. THAT
21 ALONE. AND I THINK, ED, THAT THE ANSWER TO THAT IS
22 NO, BUT I'D BE INTERESTED TO HEAR IF YOU DISAGREE.

23 CHAIRMAN PENHOET: WELL, PRESUMABLY YOU
24 WILL EMBED SOMETHING IN YOUR MATERIAL TRANSFER
25 AGREEMENT ABOUT WHAT THE OBLIGATIONS OF THE

BARRISTERS' REPORTING SERVICE

1 RECIPIENT ARE TO YOU IN CASE THEY DO SOMETHING OF
2 COMMERCIAL SIGNIFICANCE WITH THOSE CELLS; IS THAT
3 RIGHT?

4 MR. STRATTON: EVERY FACT PATTERN IS
5 DIFFERENT. BUT IF IT'S PROVIDED IN A WAY THAT GIVES
6 US SOME SORT OF THE RIGHTS TO A PRODUCT, PRESUMABLY
7 THAT WOULD BE A CIRM-FUNDED PRODUCT. AND WE WOULD
8 HAVE THIS OBLIGATION TO TRACK.

9 ON THE OTHER HAND, THE PREEXISTING CELLS,
10 BY VIRTUE OF PROVIDING THEM TO CIRM-FUNDED
11 RESEARCHERS, I WOULD ARGUE SHOULDN'T TRIGGER THE
12 OBLIGATIONS FOR THOSE CELLS ABSENT AN ADDITIONAL
13 INVENTION.

14 CHAIRMAN PENHOET: WE AGREE. I THINK WE
15 AGREE. ANYBODY DISAGREE?

16 MR. STRATTON: RIGHT. AND THAT'S VERY
17 MUCH APPRECIATED. AND, FRANKLY, THERE ARE A LOT OF
18 INVESTIGATORS NOW WHO WILL BREATHE A LITTLE EASIER.

19 MONEY IS FUNGIBLE, AND CELLS AND REAGENTS
20 ARE EXPENSIVE. SO IF WE REQUEST COVERING THE COST
21 OF THOSE MATERIALS IN CONNECTION WITH THEIR SUPPLY,
22 DOES THAT BRING US UNDER THE TENT?

23 DR. PRIETO: QUESTION. ARE YOU SIMPLY
24 TALKING ABOUT A STRAIGHTFORWARD, YOU KNOW,
25 VENDOR/BUYER RELATIONSHIP WITH NOTHING DOWNSTREAM?

BARRISTERS' REPORTING SERVICE

1 MR. STRATTON: AS STRAIGHTFORWARD AS YOU
2 CAN IN BIOTECH.

3 DR. PRIETO: OKAY. BECAUSE THEN I WOULD
4 THINK THAT THERE WOULD BE NO WAY THAT WOULD TRIGGER
5 OUR REQUIREMENTS. IT'S ONLY IF YOU ARE -- IF YOU
6 STIPULATE THAT YOU ARE GOING TO BE IN SOME WAY THE
7 BENEFICIARY OF THE FRUITS OF THAT RESEARCH, IF THERE
8 ARE ANY, THEN THAT AGREEMENT WOULD PULL YOU IN. BUT
9 OTHERWISE I WOULDN'T SEE ANY WAY.

10 CHAIRMAN PENHOET: WELL, BUT PRESUMABLY
11 THE CIRM-FUNDED RESEARCHER WILL RECEIVE MATERIALS
12 FROM STEM CELLS, INC., CARRY OUT SOME LINE OF
13 RESEARCH WITH THESE. IF THEY DON'T INVENT ANYTHING
14 OF VALUE DURING THAT TIME, THEN THEY WON'T GET
15 ANYTHING FROM IT. IF THEY DO INVENT SOMETHING OF
16 VALUE, THE VALUE WILL BE -- THEN THE INVENTION WOULD
17 BE LICENSED BACK TO STEM CELLS, INC., AND AT THAT
18 POINT THE INVENTION WOULD BE SUBJECT TO OUR IP
19 REQUIREMENTS. I THINK THAT'S HOW IT WOULD WORK.

20 MS. KOCH: AND THE TERMS OF THE LICENSE
21 BACK WOULD NEED TO BE CONSISTENT WITH OUR IP
22 REQUIREMENTS.

23 CHAIRMAN PENHOET: YES. BUT WE --
24 REMEMBER WE DON'T ENTER INTO THAT. IF WENDY AND KEN
25 SIT DOWN AND WORKOUT A LICENSE AGREEMENTS, WHATEVER

BARRISTERS' REPORTING SERVICE

1 THEY DECIDE. IN THAT CASE, THEN THIS IS A
2 UNIVERSITY THAT'S ON THE OTHER SIDE OF THIS
3 TRANSACTION, THEY'RE THE ONES WHO WOULD HAVE THE
4 OBLIGATION TO SHARE WITH US ANYTHING THEY GOT FROM
5 YOU. THAT'S HOW IT WOULD WORK. BUT THAT LICENSE
6 WOULD HAVE TO EMBED OUR COVENANTS AS WE NOW CALL
7 THEM.

8 MR. STRATTON: THANK YOU.

9 CHAIRMAN PENHOET: BUT, AGAIN, A LOT OF
10 YOU WILL READ THROUGH THESE DOCUMENTS AS THEY EVOLVE
11 WITH AN EYE TOWARDS THE PRINCIPAL THRUST OF WHAT
12 WE'RE TRYING TO DO IN THESE REFINEMENTS, WHICH IS TO
13 NOT CREATE BARRIERS TO COLLABORATION. THAT'S REALLY
14 WHAT, AND WE'RE TRYING TO CLARIFY WHAT'S IN AND
15 WHAT'S OUT FOR THAT REASON.

16 SO DO WE HAVE QUESTIONS -- WELL, FIRST,
17 LET ME ASK IF -- I KEEP ASKING THIS QUESTION. DO WE
18 HAVE ANY MEMBERS OF THE PUBLIC AT ANY OTHER SITE
19 OTHER THAN SAN FRANCISCO?

20 MR. ROTH: NO. THERE'S NONE HERE IN SAN
21 DIEGO.

22 DR. PRIETO: NO.

23 CHAIRMAN PENHOET: WELL, THEN I'LL STOP
24 ASKING FOR PUBLIC COMMENT OUTSIDE.

25 SO LET'S MOVE ON, THEN, TO WHAT WOULD BE

BARRISTERS' REPORTING SERVICE

1 SLIDE -- OKAY -- THIS SLIDE.

2 MR. TOCHER: IT'S SLIDE 10 FOR THOSE OF
3 YOU ON THE PHONE WHO HAVE THE TWO SLIDE
4 PRESENTATIONS SEPARATE. FOR THOSE OF US HERE, IT'S
5 SLIDE 12. FOR THOSE OF YOU ON THE PHONE, 10.

6 MR. ROTH: SO MY SLIDE 10 IS JUST THE
7 ONE-LINE THING?

8 CHAIRMAN PENHOET: NO. IT SHOULD BE ISSUE
9 4, SCOPE.

10 MR. ROTH: OKAY. ALL RIGHT.

11 CHAIRMAN PENHOET: REVENUE SHARING.

12 MR. ROTH: REVENUE SHARING, IT'S SLIDE 11.

13 MR. TOCHER: OH, IT IS.

14 CHAIRMAN PENHOET: SCOTT OR NANCY, YOU
15 WANT TO COMMENT.

16 MS. KOCH: SURE. THE ISSUE HERE WAS THAT
17 IN THE REGS AS ADOPTED, MOST OF THE OBLIGATIONS
18 TRIGGERED OFF LICENSING BASED TRANSACTIONS. AND, OF
19 COURSE, FOLKS TRANSFER VALUE IN INTELLECTUAL
20 PROPERTY BY WAY OF OTHER THAN LICENSES. THERE COULD
21 BE SALES, THERE CAN BE ASSIGNMENTS. AND SO WE ADDED
22 SOME CLARIFICATION TO THE PROPOSED REGS TO MAKE IT
23 CLEAR TO FOLKS THAT, REGARDLESS OF HOW YOU STRUCTURE
24 YOUR DEAL, IF THERE IS -- IF YOU RECEIVE BENEFIT OR
25 CONSIDERATION FROM THE TRANSFER OF INTELLECTUAL

BARRISTERS' REPORTING SERVICE

1 PROPERTY, REGARDLESS OF THE FORMAT OF THE TRANSFER,
2 IT FALLS WITHIN THE INTELLECTUAL PROPERTY
3 REGULATIONS AND OBLIGATIONS.

4 CHAIRMAN PENHOET: THAT SEEMS
5 STRAIGHTFORWARD. WHAT WOULD HAPPEN IN THE CASE OF A
6 SALE OF AN ENTIRE COMPANY? LET'S SAY OUR MERCK-STEM
7 CELLS, INC. EXAMPLE. MERCK DECIDES TO BUY STEM
8 CELLS, INC., AND STEM CELLS, INC. DECIDES TO SELL
9 ITSELF TO MERCK. I WOULD GUESS IN THAT CASE MERCK'S
10 OBLIGATIONS WOULD CONTINUE TO US; IS THAT RIGHT?

11 MS. KOCH: THAT'S RIGHT.

12 MR. ROTH: YEAH. THEY WOULD FOLLOW
13 ANYTHING THAT'S COMMERCIALIZED.

14 CHAIRMAN PENHOET: RIGHT.

15 MR. ROTH: SO IT'S A PRODUCT, NOT -- I
16 THINK THE IP, WHATEVER THAT IP CLAIMS, WHATEVER YOU
17 DID WITH IT IN TERMS OF A LICENSE, IF IT AFFECTS A
18 PRODUCT SALE, THEN IT TRIGGERS -- WELL, THEN THERE
19 WOULD BE MONIES DUE TO THE STATE.

20 DR. LOVE: SO IN OTHER WORDS, WHENEVER YOU
21 ACQUIRE A COMPANY, YOU ACQUIRE ALL OF THE RIGHTS AND
22 OBLIGATIONS.

23 MR. ROTH: CORRECT.

24 CHAIRMAN PENHOET: BUT THEN, BACKING OFF
25 OF THAT, IF MERCK PAID STEM CELLS, INC. \$50 MILLION

BARRISTERS' REPORTING SERVICE

1 FOR RIGHTS TO ITS INTELLECTUAL PROPERTY, SOME OF
2 WHICH WAS FUNDED BY CIRM, WE WOULD HAVE A RIGHT TO
3 SOME FRACTION OF THAT \$50 MILLION ASCRIBABLE TO THAT
4 PART OF THE TRANSFER OF IP ASSETS TO MERCK, WHICH IS
5 ASCRIBABLE AND PROPORTIONAL TO WHAT WE PUT INTO
6 THIS.

7 MS. KOCH: THAT'S RIGHT.

8 MR. ROTH: WELL --

9 CHAIRMAN PENHOET: COULD BE A NEGOTIATION.

10 MR. ROTH: BUT, AGAIN, ED, IT'S A ROYALTY
11 ON A PRODUCT.

12 MS. KOCH: I THINK WHAT HE'S
13 CONTEMPLATING --

14 MR. ROTH: IF THEY USE THE PATENT ON
15 ANYTHING THAT THEY -- THEY ACQUIRE THE PATENT
16 PORTFOLIO, AND THAT PATENT IS CLAIMED ON A PRODUCT
17 THAT WAS FUNDED TO CREATE THAT PATENT, THEN THEY
18 WOULD OWE THE PERCENTAGE ROYALTY THAT THE -- IN A
19 NONPROFIT STATE, THE RESEARCH INSTITUTE LICENSE. IT
20 WON'T GO AWAY BECAUSE SOMEBODY ACQUIRES IT.

21 CHAIRMAN PENHOET: BUT THERE'S A -- I
22 THINK THE MORE I THINK ABOUT THIS, IT'S A LITTLE
23 HAI RY WHEN YOU THINK ABOUT IT. A LICENSE MIGHT IN
24 INVOLVE NO UP-FRONT PAYMENT, OKAY, SIMPLY -- LET'S
25 SAY THE LICENSEE -- THE LICENSOR IS UNIVERSITY OF

BARRISTERS' REPORTING SERVICE

1 CALI FORNIA. SO MERCK LI CENSES FROM UNIVERSITY OF
2 CALI FORNIA CIRM-FUNDED TECHNOLOGY, GENERATES A
3 PRODUCT, AGREES TO PAY UC A 3-PERCENT ROYALTY, AND
4 OUT OF ALL THAT WE GET OUR 25 PERCENT. OKAY. SO
5 THAT' S PRETTY EASY AND CLEAR TO UNDERSTAND.

6 INSTEAD OF THAT, STEM CELLS, INC. DEVELOPS
7 TECHNOLOGY WITH OUR MONEY, AND THEY LI CENSE MERCK,
8 BUT THEY GET A \$50 MILLION FRONT-END PAYMENT AND
9 WHATEVER ROYALTY THEY GET. LET' S SAY THEY GET A
10 10-PERCENT ROYALTY. WE WOULD THEN GET OUR PIECE OF
11 THAT ACTION FROM THE COMPANY, BUT I THINK WHAT WE' RE
12 TRYING TO DO TO CLOSE A LOOPHOLE HERE IS WE ALSO
13 SHOULD GET A PIECE OF THE FRONT-END PAYMENT.

14 MS. KOCH: THAT' S RIGHT.

15 CHAIRMAN PENHOET: IN ADDITION TO GETTING
16 A PIECE OF THE ROYALTY.

17 MR. ROTH: SO, SCOTT, REMIND ME WHAT WE
18 HAVE IN THERE IN TERMS OF WHAT WE CALL REVENUE.

19 MR. TOCHER: WELL, RIGHT NOW IT' S DERIVED
20 FROM LICENSING OF A PATENTED INVENTION. SO HERE IT
21 COULD BE A TRANSFER OF IT OR ASSIGNMENT --

22 CHAIRMAN PENHOET: WE' RE LOOKING FOR THE
23 RELEVANT SECTI ON. BUT THAT' S WHAT WE' RE INTENDING
24 TO CLARIFY HERE.

25 MS. KOCH: THAT' S RIGHT.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN PENHOET: MONEY CAN COME TO OUR
2 GRANTEE IN SEVERAL DIFFERENT FORMS, AND IRRESPECTIVE
3 OF THE RATE, ETC., WHEN MONIES CROSS THE
4 THRESHOLD --

5 MS. KOCH: IT WON'T ALWAYS BE A ROYALTY ON
6 A PATENT OR PATENT INFRINGEMENT CLAIM. DUANE, AS
7 YOU POINT OUT, YOU COULD SELL KNOW-HOW OR YOU COULD
8 SELL A TRADE SECRET, AND YOU COULD GET A LOT OF
9 VALUE FOR THAT. AND OUR POINT IS IF YOU GET THAT
10 KIND OF VALUE IN THAT KIND OF TRANSACTION, WE GET
11 OUR PIECE OF IT.

12 MR. ROTH: SO WE SHOULD GET 25 PERCENT OF
13 WHATEVER THEY GET FOR THAT PARTICULAR ASSET?

14 CHAIRMAN PENHOET: WELL, ADJUSTED FOR --

15 MS. KOCH: FOR EVERYTHING ELSE --

16 CHAIRMAN PENHOET: -- FRACTIONAL --

17 MS. KOCH: -- THAT'S IN THE BASKET OF WHAT
18 THEY SOLD.

19 MR. ROTH: RIGHT. RIGHT.

20 CHAIRMAN PENHOET: IF IT WAS A HUNDRED
21 PERCENT, ALL OUR FUNDING THAT LED TO IT, WE WOULD
22 GET 25 PERCENT. THAT'S RIGHT.

23 MR. TOCHER: THE TERM CURRENTLY USED IS
24 NET LICENSING REVENUE, WHICH IS GROSS REVENUE
25 DERIVED FROM A LICENSE AGREEMENT MINUS THE DIRECT

BARRISTERS' REPORTING SERVICE

1 COSTS INCURRED IN THE PROSECUTION AND PROTECTION OF
2 THE CIRM-FUNDED PATENTED INVENTION.

3 CHAIRMAN PENHOET: SO YOU MUST HAVE A
4 DEFINITION OF NET REVENUE SOMEPLACE.

5 MS. KOCH: AND WE HAVE A DEFINITION OF
6 LICENSING REVENUE, WHICH IS NOW NOT JUST CONSTRAINED
7 TO INCLUDE STRICT LICENSES. IT'S ANY VALUE FROM ANY
8 KIND OF TRANSACTION.

9 CHAIRMAN PENHOET: SO WHERE DO WE FIND THE
10 DEFINITION OF LICENSING REVENUE?

11 MS. KOCH: AS TO THE DEFINITION OF
12 LICENSING REVENUE, 100401(Q).

13 CHAIRMAN PENHOET: 401.

14 MR. TOCHER: MAKE SURE YOU'RE ON THE
15 REDLINE VERSION OF -- NO. I GUESS THAT'S NOT TRUE.
16 YOU COULD BE ON THE CLEAN VERSION AS WELL.

17 MS. KOCH: 100401(Q) IS THE DEFINITION OF
18 LICENSING REVENUE.

19 CHAIRMAN PENHOET: CAN YOU READ THAT TO
20 US, PLEASE.

21 MS. KOCH: SURE. THE CONSIDERATION
22 RENDERED TO AN OWNER OR LICENSEE OF A CIRM-FUNDED
23 INVENTION OR CIRM-FUNDED TECHNOLOGY PURSUANT TO A
24 LICENSE AGREEMENT. AND I'M GOING TO STOP THERE FOR
25 JUST A SECOND TO SAY THAT IT'S PHRASED UP IN TERMS

BARRISTERS' REPORTING SERVICE

1 OF CONSIDERATION AS OPPOSED TO ROYALTY, WHICH
2 OBVIOUSLY CONSIDERATION IS A BROADER TERM. IT'S
3 ALSO FRAMED UP IN TERMS OF CONSIDERATION RECEIVED
4 PURSUANT TO A LICENSE AGREEMENT, WHICH IS ITSELF A
5 DEFINED TERM. AND THAT'S FOUND IN 100401(O), AND
6 THAT DEFINITION IS BROAD ENOUGH TO INCLUDE
7 TRANSACTIONS THAT ARE BEYOND TRADITIONAL LICENSES.
8 AND THEY GO TO SALES AND ASSIGNMENTS AND THE LIKE.
9 SO THAT'S HOW WE'VE --

10 DR. PRIETO: SO THAT WOULD CAPTURE THAT.

11 MR. ROTH: I THINK IT'S COVERED.

12 CHAIRMAN PENHOET: SO DO WE HAVE
13 AGREEMENT -- ANY QUESTIONS FROM THE TASK FORCE? ANY
14 COMMENTS FROM OUR AUDIENCE IN SAN FRANCISCO? WENDY.

15 MS. STREITZ: I HAVE A COUPLE OF COMMENTS.
16 ONE IS THAT THE LANGUAGE SCOTT READ IS FROM THE
17 EXISTING POLICY WHICH DOES NOT INCLUDE THE COST OF
18 OBTAINING AND PROTECTING PATENTS AND REVENUE. SO
19 THE GRANTEE IS ALLOWED TO RECOVER ITS OWN EXPENSES
20 FIRST, AND THEN WHAT'S LEFT IS CONSIDERED REVENUE.
21 THAT CONCEPT HAS GONE AWAY IN THE NEW VERSION. AND
22 I UNDERSTAND THERE ARE SOME ARGUMENTS PRO AND CON.
23 WE HAVE SOME CONCERNS ABOUT THAT.

24 MS. KOCH: SO, WENDY, JUST TO I CAN
25 CLARIFY AND UNDERSTAND YOUR QUESTION, I THINK THE

BARRISTERS' REPORTING SERVICE

1 PROPOSED VERSION THAT WE'RE LOOKING AT TODAY STILL
2 INCLUDES THE 500,000 FREE PERIOD, WHICH I BELIEVE WE
3 CARRIED FORWARD IN PART TO REFLECT THE FACT THAT
4 GRANTEES WOULD HAVE TO PAY PATENT PROSECUTION COSTS
5 AND THE LIKE.

6 ARE YOU -- AND THAT WAS ALSO IN THE
7 EARLIER VERSION. YOU TALKING ABOUT THAT?

8 MS. STREITZ: NO. THE EARLIER VERSION HAS
9 THAT, BUT THE EARLIER VERSION ALSO LET US RECOVER
10 PATENT -- THE COSTS OF MAINTAINING AND PROTECTING
11 PATENTS BEFORE WE STARTED COUNTING TOWARDS THE \$500
12 THRESHOLD. THIS IS A DIFFERENCE IN THE NEW POLICY.
13 I'M POINTING OUT THERE IS A DIFFERENCE.

14 ONE OF THE CONCERNS IS IF IT DOES PERTAIN
15 TO WORLDWIDE PROTECTION, IT CAN EASILY BE A QUARTER
16 OF A MILLION DOLLARS. SO THE \$500 THRESHOLD ONLY
17 COVERS US FOR TO -- IT MAKES UP FOR ONE LOSER, ONE
18 WINNER.

19 CHAIRMAN PENHOET: YEAH. WE GET THIS
20 EFFECT.

21 MS. STREITZ: AND THEN IF YOU ACTUALLY
22 ENFORCE IT, THE LITIGATION COSTS CAN BE EXORBITANT.
23 SO THAT -- THE INABILITY TO RECOVER THOSE EXPENSES
24 IS AN ISSUE. I'M JUST PUTTING IT ON THE TABLE.

25 CHAIRMAN PENHOET: WELL, WE HAVE NOT HAD

BARRISTERS' REPORTING SERVICE

1 ANY DISCUSSION, AND IT MAY HAVE BEEN AN INADVERTENT.
2 WE HAVE NOT DISCUSSED THIS. NET REVENUES WERE NET
3 OF YOUR PATENT PROSECUTION COSTS. I THINK SOME
4 PEOPLE DID POINT OUT, WELL, MAYBE YOU SHOULD COVER
5 THIS UNDER YOUR 500,000, BUT YOU ARE CORRECT.

6 HISTORICALLY, THE 500,000 WAS TO TO SOME
7 DEGREE PROVIDE YOU SOME IMMUNITY FROM ALL THE PATENT
8 FILINGS YOU MADE THAT TURNED OUT TO BE WORTHLESS.

9 MS. KOCH: SO JUST TO CLARIFY AGAIN, IN
10 THE FOR-PROFIT --

11 CHAIRMAN PENHOET: WE HAVE LANGUAGE ABOUT
12 SPECIFIC PATENT COST TO THE LICENSE, NOT ANY OLD
13 PATENT COST THAT WENT IN HERE.

14 MS. KOCH: THERE ARE TWO THINGS WE'RE
15 THINKING ABOUT. ONE IS I THINK THE REGULATIONS
16 SPECIFICALLY SAY THAT THERE'S NOTHING TO STOP
17 WENDY'S ORGANIZATION, FOR INSTANCE, FROM COLLECTING
18 THOSE PROSECUTION AND ENFORCEMENT COSTS FROM THE
19 COLLABORATOR FROM A LICENSEE FROM WHEREVER.

20 SECOND, THE FOR-PROFIT REGULATIONS NEVER
21 HAD THE PROVISION THAT ALLOWED THEM, THE FOR-PROFIT
22 SECTOR, TO DEDUCT THE PATENT PROSECUTION COSTS. SO
23 THIS IS A CONSEQUENCE OF COMBINING OR CONSOLIDATING
24 THE FOR-PROFIT AND NOT-FOR-PROFIT, AND IT'S AN
25 APPROPRIATE THING FOR THE COMMITTEE TO CONSIDER

BARRISTERS' REPORTING SERVICE

1 WHETHER THEY WANT TO CONTINUE TO TREAT THE
2 FOR-PROFITS DIFFERENTLY IN THIS REGARD.

3 CHAIRMAN PENHOET: THE ANSWER TO THAT
4 PROBABLY IS NO BECAUSE I THINK WE WANT TO MAKE
5 THESE -- UNLESS THERE'S SOME GOOD REASON FOR DOING
6 IT, WE WANT TO MAKE THEM AS CONSISTENT AS POSSIBLE.
7 HOWEVER, IT IS IN THE RETURNS PART OF THIS THING,
8 NOT IN THE COVENANTS PART. SO ONE COULD ARGUE IT'S
9 MONEY, NOT COVENANTS RELATED TO THIS ISSUE.

10 MS. STREITZ: MAY I MAKE TWO COMMENTS ON
11 THAT? ONE IS TO RECOVER PATENT EXPENSES FROM OUR
12 LICENSEES. THE PUBLIC WE DON'T ALWAYS SUCCESSFULLY
13 GET LICENSEES. AND THE \$500 THRESHOLD IS TO -- AND
14 YOU DON'T KNOW -- YOU DON'T HAVE A CRYSTAL BALL AT
15 THIS EARLY STAGE TECHNOLOGY, SO YOU DON'T KNOW FOR
16 SURE WHICH INVENTIONS ARE GOING TO BE SUCCESSFUL.
17 SO THE 500 HELPS US INVEST IN THE LOSERS BEFORE WE
18 KNOW ABOUT THE WINNERS. SO THOSE ONES WE'RE NEVER
19 EVER GOING TO BE REIMBURSED FOR.

20 CHAIRMAN PENHOET: WE DID UNDERSTAND THAT.
21 THAT'S WHY THE 500 WAS THERE.

22 MS. STREITZ: AND PATENT EXPENSES ARE A
23 COST OF BUSINESS FOR A BUSINESS. WE DON'T HAVE --
24 UNIVERSITIES DON'T HAVE A FUND SET ASIDE FOR PATENT
25 EXPENSES. SO WE'RE CONSTANTLY PLAYING THIS GAME

BARRISTERS' REPORTING SERVICE

1 ABOUT TRYING TO MAKE UP ON THE WINNERS FOR THE
2 LOSERS. SO THERE IS A DIFFERENCE.

3 CHAIRMAN PENHOET: WELL, I DO THINK THE
4 NOT-FOR-PROFIT POLICY SAID THAT YOU COULD DEDUCT
5 PATENT EXPENSES TO THE DEGREE TO WHICH THEY WERE
6 CLEARLY WITHIN THE SCOPE OF THE LICENSE, NOT ANY
7 OTHER PATENT EXPENSES THAT YOU HAVE. SO THAT
8 WAS -- THAT WAS THE CONCEPT IN THE NOT-FOR-PROFIT
9 REGS.

10 MR. ROTH: YEAH. SO WE WOULDN'T BE PAYING
11 FOR DRY HOLES.

12 CHAIRMAN PENHOET: WE PAY FOR THE DRY
13 HOLES UNDER THE 500,000.

14 MR. ROTH: THEY'RE 500, BUT IF YOU DO IT
15 THE OTHER WAY AROUND, THEN YOU'D BE LIMITED TO THE
16 PATENT YOU'RE ACTUALLY LICENSING.

17 CHAIRMAN PENHOET: THAT'S RIGHT. AND THAT
18 WAS -- THAT IS IN NOT-FOR-PROFIT REGS IS MY
19 RECOLLECTION.

20 MR. TOCHER: TWO POINTS I WANT MAKE.
21 FIRST OF ALL, THE DEFINITION ITSELF IN THE NONPROFIT
22 AGAIN, BECAUSE, AS NANCY JUST NOTED, THIS WAS NEVER
23 A PROVISION OF THE FOR-PROFITS.

24 THE REVENUE SHARING SPEAKS IN ONE
25 PROVISION TO A GRANTEE ORGANIZATION'S SHARE. AND

BARRISTERS' REPORTING SERVICE

1 THIS IS HOW IT DEFINES IT. THE REVENUES RECEIVED BY
2 A GRANTEE ORGANIZATION UNDER A COMMERCIAL LICENSE OF
3 A CIRM-FUNDED PATENTED INVENTION REMAINING AFTER
4 DEDUCTING THE DIRECT COSTS ASSOCIATED WITH PATENTS
5 AND PATENT APPLICATIONS CLAIMING INVENTIONS MADE
6 UNDER CIRM FUNDING AND THE INVENTOR'S SHARE OF THOSE
7 REVENUES. I'M READING FROM SUBDIVISION H.

8 SO THE FIRST POINT I WOULD NOTE IS YOU
9 COULD ARGUE ABOUT WHETHER COSTS ASSOCIATED WITH
10 PATENTS AND PATENT APPLICATIONS WOULD ALSO INCLUDE
11 THE COST OF HAVING TO DEFEND THOSE IN SOME LAWSUITS
12 OR ENFORCEMENT DOWN THE ROAD. BUT THE OTHER POINT I
13 WOULD MAKE IS THAT IN THE ACTUAL REGULATION WHERE
14 THIS TERM IS USED, IT'S NOT USED THROUGHOUT THE
15 REGULATION INVOLVING REVENUE SHARING, BUT ONLY WITH
16 RESPECT TO THE VERY LAST SUBDIVISION WHERE IT TALKS
17 ABOUT THE NONPROFIT GRANTEE MUST USE ITS SHARE ONLY
18 FOR CERTAIN PURPOSES.

19 GRANTEES SHALL APPLY THE GRANTEE
20 ORGANIZATION'S SHARE OF ANY REVENUES, READING FROM
21 SUBDIVISION D OF 308, GRANTEE SHALL APPLY THE
22 GRANTEE ORGANIZATION'S SHARE OF ANY REVENUES EARNED
23 AS A RESULT OF CIRM-FUNDED PATENTED INVENTIONS TO
24 THE SUPPORT OF SCIENTIFIC RESEARCH OR EDUCATION.

25 SO THERE THAT'S THE ONLY PART, THE ONLY

BARRISTERS' REPORTING SERVICE

1 SUBDIVISION WHERE YOU USE THE TERM "GRANTEE
2 ORGANIZATION'S SHARE." AND THERE IT JUST DIRECTS AS
3 TO HOW AND WHAT PURPOSES THE REMAINDER AFTER
4 DEDUCTING THE COST OF THE PATENT AND THE PATENT
5 APPLICATION AND SUCH ARE TO BE USED.

6 WHERE YOU LOOK AT THE SPECIFIC FORMULA IN
7 THE PRECEDING SUBDIVISIONS OF THAT REGULATION THAT
8 LAY OUT WHAT THE FORMULA IS FOR COMPUTING FIRM'S
9 SHARE, THERE IS NO ALLOTMENT BEYOND THAT \$500,000
10 THRESHOLD FOR ENFORCING PATENTS OR FOR PURSUING
11 PATENT COSTS.

12 CHAIRMAN PENHOET: IN THE EQUATION THERE
13 MUST BE AN ALLOTMENT FOR THE INVENTOR'S SHARE.

14 MR. TOCHER: THERE IS FOR THE INVENTOR'S
15 SHARE, THAT'S RIGHT.

16 CHAIRMAN PENHOET: SO OUR DOCUMENT IS
17 AMBIGUOUS.

18 MS. STREITZ: NO. ACTUALLY, IF I MAY, IN
19 308(B) IT TALKS ABOUT -- 308(A) SAYS NET REVENUE IS
20 DEFINED AS GROSS REVENUES MINUS THE DIRECT COST
21 INCURRED IN GENERATION AND PROTECTION OF PATENTS
22 FROM WHICH THE REVENUES ARE RECEIVED.

23 CHAIRMAN PENHOET: IT'S A DEFINED TERM.

24 MR. TOCHER: AS FOLLOWS THOUGH AND THEN IT
25 PROVIDES THE FORMULA.

BARRISTERS' REPORTING SERVICE

1 MS. STREITZ: A IT DOESN' T DO AN AS
2 FOLLOWS.

3 CHAIRMAN PENHOET: ALL RIGHT.

4 MS. STREITZ: I DIDN' T WANT TO GET CAUGHT
5 UP IN THAT.

6 CHAIRMAN PENHOET: WELL, BUT WE HAVE -- I
7 MEAN THIS IS PART OF WHAT WE' RE TRYING TO DO IS
8 CLEAN UP LANGUAGE IN THIS THING. SO I THINK WE HAVE
9 AMBIGUITY AROUND THIS ISSUE NOW. YOU KNOW, I DO
10 THINK THAT WHAT WE WERE TRYING TO GET WAS A CUT OF
11 THE PROFITS. I THINK THAT WAS THE UNDERLYING
12 NOTION. SO CONSISTENT WITH THAT, WE WOULD ALLOW
13 PEOPLE TO DEDUCT EXPENSES OF THEIR PATENT
14 PROSECUTION NARROWLY DEFINED BY THIS. BUT I DON' T
15 KNOW WHAT OTHER MEMBERS OF THE TASK FORCE THINK
16 ABOUT THAT.

17 MR. SHEEHY: I KNOW WE WANT THEM TO AGREE,
18 BUT I ALSO -- YOU KNOW, THERE WAS, I THINK IT WAS
19 PART H WHICH YOU READ, WHAT THE INSTITUTIONS COULD
20 DO WITH THE MONEY WAS DEFINED. THAT COMES CLEAR OUT
21 OF BAYH-DOLE.

22 CHAIRMAN PENHOET: YES, IT IS.

23 MR. SHEEHY: SO THAT' S NO LONGER IN HERE
24 EITHER, RIGHT? YOU KNOW, IT ACTUALLY DOES CREATE A
25 VACUUM FOR REVENUE THAT' S ACQUIRED THROUGH CIRM

BARRISTERS' REPORTING SERVICE

1 FUNDING THAT COULD BE USED DIFFERENTLY THAN REVENUE
2 THAT'S ACQUIRED FROM FUNDING FROM THE NIH. AND THEY
3 CAN -- YOU KNOW, THERE'S A LOT MORE FREEDOM THERE
4 FOR INSTITUTIONS TO USE THAT MONEY FOR WHATEVER;
5 WHEREAS, BAYH-DOLE AND CIRM WERE BOTH CONSISTENT AND
6 REQUIRED TO GO BACK TO EDUCATIONAL RESEARCH, WHICH,
7 GRANTED, ARE TWO OF THE PRIMARY MISSIONS OF BOTH
8 THESE INSTITUTIONS.

9 BUT NOT TO ASCRIBE ANY BASE MOTIVES OR
10 THAT PEOPLE ARE GOING TO USE THIS MONEY FOR ANY
11 OTHER PURPOSE, BUT THAT CONSISTENCY WAS APPRECIATED
12 AT THE TIME. AND I DON'T KNOW MAYBE IF WE NEED TO
13 HAVE ABSOLUTE AGREEMENT BETWEEN NONPROFIT AND
14 FOR-PROFIT BECAUSE I DO REMEMBER A DISCUSSION ON --
15 YOU KNOW, I'M SITTING BACK AT STANFORD AND YOU'RE
16 THERE, AND THEN THE OPL PERSON FROM STANFORD IS
17 THERE, AND YOU'RE BOTH TALKING -- WE'RE HAVING
18 ALMOST THE SAME DISCUSSION. WE SPENT A LOT OF MONEY
19 DEFENDING THESE THINGS, AND, YOU KNOW, WE DID SET
20 THE 500,000 THRESHOLD, BUT THERE WAS ALSO THIS
21 CONCEPT OF NET THAT WAS ALSO THERE.

22 AND I DON'T KNOW. WE MAY WANT TO THINK
23 ABOUT WHETHER WE WANT TO THROW ALL THOSE
24 DISTINCTIONS OUT THE WINDOW JUST TO HAVE AGREEMENT
25 BETWEEN THE TWO POLICIES, ABSOLUTE AGREEMENT. AND

BARRISTERS' REPORTING SERVICE

1 IT MIGHT MAKE SENSE TO DO TO A CARVE-OUT.

2 CHAIRMAN PENHOET: ON THIS ISSUE?

3 MR. SHEEHY: ON THIS -- YEAH.

4 CHAIRMAN PENHOET: WELL, THIS IS IN THE
5 REVENUE CATEGORY. IT'S NOT IN THE REST OF THE
6 COVENANTS CATEGORY.

7 MR. ROTH: ED, JUST TO --

8 MR. SHEEHY: -- ARRANGEMENT IN PLACE FOR
9 FOR-PROFIT, SO WHY NOT HAVE A DIFFERENT REVENUE
10 ARRANGEMENT FOR NOT-FOR-PROFIT?

11 MS. KOCH: THE ONLY THING I'D CALL TO YOUR
12 ATTENTION IS THIS CAN BE A LOT OF MONEY, AS WENDY
13 SAID, ESPECIALLY IF YOU THROW IN THE COST OF
14 PROSECUTING AND DEFENDING PATENTS. DEFENDING,
15 LITIGATING, THAT CAN REALLY ADD UP TO A LOT OF
16 MONEY. AND THAT COULD BE ENOUGH MONEY IN SOME
17 CIRCUMSTANCES TO MAKE THE COLLABORATORS GAME WHO
18 WOULD BE THE GRANTEE, WHO WOULD APPLY.

19 AND BECAUSE ONE MIGHT GAME WHO APPLIES
20 VERSUS WHO OWNS THE PATENT AND THEN WHO ABSORBS THE
21 COSTS OF PROSECUTING AND DEFENDING THE PATENTS. I
22 MEAN THAT WOULD THEN BECOME A VERY INTENSE
23 DISCUSSION AMONG THE COLLABORATORS AND MIGHT INCENT
24 PARTIES ONE WAY OR THE OTHER FOR WHO'S THE GRANTEE.
25 AND WHO'S THE GRANTEE HAS AN IMPACT, MAY HAVE AN

BARRISTERS' REPORTING SERVICE

1 IMPACT, DEPENDING ON WHAT HAPPENS TO THE LOAN
2 POLICY, ABOUT WHETHER FOLKS APPLY FOR LOANS OR FOR
3 GRANTS.

4 THAT'S A WHOLE NOTHER ISSUE FOR US, BUT WE
5 JUST NEED TO THINK ABOUT THIS ISSUE IN THAT CONTEXT.

6 MR. SHEEHY: BUT THE OTHER THING IS THAT
7 WE DO WANT -- IF WE'RE GOING TO GET REVENUE, WE DO
8 WANT TO EMPOWER SOMEONE TO DEFEND THE PATENTS.
9 RIGHT? AND SO IF WE'RE NOT PROVIDING THE MECHANISM,
10 AT LEAST AT THE INSTITUTIONAL LEVEL, AND EVEN IF
11 THEY GAME US ON THIS, YOU KNOW, IF THERE'S REVENUE
12 TO BE HAD BECAUSE WE ENFORCE A PATENT, I DON'T KNOW
13 WHY WE SHOULDN'T BEAR THE COST OF ENFORCING THAT
14 PATENT, SOME OF THE COST. I MEAN I DON'T OBJECT.

15 IF YOU GET TO LICENSE IT, IN OTHER WORDS,
16 I DON'T SEE WHERE THE GAMING REALLY -- I MEAN
17 SOMEBODY HAS GOT TO PAY FOR LICENSING. AND SO IF
18 THEY DECIDE BECAUSE YOU HAVE A FOR-PROFIT AND
19 NOT-FOR-PROFIT, BECAUSE THE FOR-PROFIT CAN COUNT
20 THAT AGAINST THE LICENSING AGREEMENT, I DON'T --
21 WE'RE NOT IN THIS NECESSARILY TO MAKE MONEY. THE
22 QUESTION FROM MY POINT OF VIEW IS WHAT WILL DRIVE A
23 PRODUCT TO DEVELOPMENT? AND THAT'S WHERE -- THE
24 GAMING IS LESS IMPORTANT TO ME TO WHICH IS GOING TO
25 BE MORE CONDUCTIVE TOWARDS GETTING SOMETHING

BARRISTERS' REPORTING SERVICE

1 DEVELOPED FASTER AND INTO PEOPLE'S HANDS.

2 THAT'S MY BIAS TO A FINANCIAL RETURN.

3 WE'VE NEVER GONE INTO THIS WITH FINANCIAL RETURN

4 STRICTLY IN MIND. WE JUST WANTED TO MAKE SURE

5 SOMETHING THAT WAS RECOVERABLE, YOU KNOW, THAT WE

6 DIDN'T SHORTCHANGE THE TAXPAYERS. WE'RE NOT HERE TO

7 MAKE MONEY. WE'RE HERE TO GET PRODUCTS INTO

8 CLINICS.

9 MR. ROTH: ED, SO I JUST WANT TO REMIND

10 EVERYBODY THAT RIGHT NOW UNDER BAYH-DOLE WITH A

11 FEDERAL GRANT THE INSTITUTIONS HAVE THE SAME ISSUE.

12 AND THEY WILL HAVE TO DECIDE HOW THEY WANT THAT

13 LICENSE TO READ. THEY WOULD RECEIVE MONEY. IN OUR

14 CASE IT WOULD BE THE SAME THING EXCEPT THAT WE GET

15 25 PERCENT OF ANY REVENUE THEY START TO RECEIVE. SO

16 THEY'RE NOT A HUNDRED PERCENT AVOIDANCE, BUT THEY'RE

17 75 PERCENT AVOIDANCE UNDER THIS AGREEMENT.

18 SO I DON'T -- I THINK WE'RE BRUSHING

19 AROUND SOMETHING THAT'S NOT A REAL ISSUE. REMEMBER,

20 THERE'S GOT TO BE MATERIAL -- THERE'S GOT TO BE

21 REVENUE COMING IN. AND THE QUESTION IS DO YOU WANT

22 TO KEEP A HUNDRED PERCENT OF IT UNTIL YOU COVER YOUR

23 COSTS AFTER THE 500,000 DEDUCTIBLE, OR CAN YOU KEEP

24 75 PERCENT OF IT UNTIL YOU COVER YOUR COSTS?

25 CHAIRMAN PENHOET: YEAH, I MEAN, I DON'T

BARRISTERS' REPORTING SERVICE

1 THINK ANYBODY WOULD SPEND MONEY FOOLISHLY ON PATENT
2 PROSECUTION SIMPLY BECAUSE WE WERE SUBSIDIZING 25
3 PERCENT OF THEIR COST.

4 MR. ROTH: THAT'S RIGHT. THEY WOULD MAKE
5 THIS DECISION INDEPENDENT OF THAT BECAUSE UNTIL
6 MONEY STARTS COMING INTO THE INSTITUTE, WE'RE NOT
7 ENTITLED TO ANYTHING ANYWAY. AND THEN THE FIRST
8 500,000 COMES IN, WE GET ZERO. AND THEN WE START
9 GETTING 25 PERCENT. SO I DON'T THINK IT'S THAT
10 MATERIAL.

11 CHAIRMAN PENHOET: YOU WOULD ARGUE TO MAKE
12 THE PATENT PROSECUTION AN EXPENSE RECOGNIZED IN THE
13 DEFINITION OF NET REVENUE FOR BOTH COMPANIES AND
14 NOT-FOR-PROFITS.

15 MR. ROTH: YEAH. AND I'D GIVE THEM EACH
16 THE \$500,000 BREAK UP FRONT WHETHER THEY USE IT OR
17 NOT. BUT I WANTED TO REMIND EVERYBODY THAT UNTIL
18 MONEY STARTS FLOWING INTO THE INSTITUTION, IT'S ONLY
19 A QUESTION OF WHEN YOU HAVE TO START GIVING US 25
20 PERCENT OF THE MONEY. IF NO MONEY IS FLOWING IN AND
21 YOU'RE GOING SPENDING MONEY DEFENDING, YOU'RE IN THE
22 SAME BOAT YOU'RE IN WITH BAYH-DOLE. YOU BELIEVE
23 ENOUGH IN IT THAT YOU'RE GOING TO PROSECUTE IT. YOU
24 DO A LICENSING AGREEMENT, YOU CAN HAVE THE LICENSOR
25 POTENTIALLY COVER THE COST OF PATENT LITIGATION.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN PENHOET: AND OFTENTIMES THAT IS
2 THE CASE.

3 MR. ROTH: THAT'S OFTEN THE CASE, YES.

4 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM
5 TASK FORCE MEMBERS? NANCY HAS A POINT.

6 MS. KOCH: DUANE, CAN YOU JUST ASK YOU A
7 QUESTION. IN THE CASE OF PROPORTIONAL CONTRIBUTION,
8 WOULD YOU MAKE THAT A PROPORTIONAL OBLIGATION? IN
9 OTHER WORDS, IF WE AND NIH EACH CONTRIBUTED 50
10 PERCENT, WOULD YOU HAVE CIRM PAY A HUNDRED PERCENT
11 OF THE -- OR ALLOW A HUNDRED PERCENT DEDUCTION OF
12 THE COST?

13 MR. ROTH: SAY THAT AGAIN. I'M NOT SURE I
14 FOLLOW THAT. PROPORTIONALITY, THE WAY IT APPLIES
15 NOW?

16 MS. STREITZ: WE HAVE TO SHARE REVENUE
17 WITH THE FEDERAL GOVERNMENT, SO IT'S AN APPLES AND
18 ORANGES ARGUMENT.

19 CHAIRMAN PENHOET: BUT IF IT WAS ANY OTHER
20 ENTITY, IT DOESN'T WORK FOR THE FEDERAL GOVERNMENT.
21 BUT IF IT WAS ANY OTHER ENTITY AND WE ONLY -- AND
22 THE OTHER ENTITY IS GAINING REMUNERATION SOMEHOW FOR
23 THEIR SHARE OF THE INVENTION.

24 MS. KOCH: THEN I WOULD THINK THAT THE
25 PROPORTIONAL -- WE SHOULD IN PROPORTION ABSORB COSTS

BARRISTERS' REPORTING SERVICE

1 RELATING TO PROSECUTION.

2 CHAIRMAN PENHOET: THAT SEEMS FAIR. IF WE
3 GET IT INTO WORKABLE LANGUAGE IS ANOTHER QUESTION,
4 BUT IT'S PROBABLY WORTH THINKING ABOUT. WE
5 SHOULDN'T BEAR ALL THE COST IF WE'RE ONLY GETTING A
6 FRACTION.

7 MR. ROTH: AND THIS DEALS WITH THAT OTHER
8 SECTION, I TAKE IT, THAT YOU'RE TALKING ABOUT, THAT
9 YOU COULD DEDUCT CERTAIN THINGS?

10 CHAIRMAN PENHOET: YES.

11 MR. ROTH: OKAY.

12 CHAIRMAN PENHOET: THAT'S WHAT WE'RE
13 TALKING ABOUT.

14 MR. ROTH: ALL RIGHT.

15 CHAIRMAN PENHOET: ON A DIFFERENT ISSUE OR
16 THIS ISSUE?

17 MS. STREITZ: IT'S ROUGHLY RELATED.

18 CHAIRMAN PENHOET: WELL, LET'S GO AROUND.
19 ANY OTHER TASK FORCE MEMBERS WITH A COMMENT ON THIS
20 MATTER? OKAY. GO AHEAD, WENDY.

21 MS. STREITZ: THE SECOND ISSUE I WANTED TO
22 RAISE, AND I RECOGNIZE THE INTENT OF CAPTURING, YOU
23 KNOW, ANY TIME WE'RE RECEIVING REVENUE FROM
24 SOMETHING THAT CAME OUT OF CIRM-FUNDED SEARCH, THAT
25 SHOULD BE SUBJECT TO ALL THIS. AND I DON'T DISAGREE

BARRISTERS' REPORTING SERVICE

1 WITH THAT, BUT I THINK THERE MAY BE AN UNINTENDED
2 CONSEQUENCE.

3 SOMETHING THAT WAS INTRODUCED HERE, THIS
4 CONCEPT OF TECHNOLOGY, WHICH IS DATA, MATERIALS,
5 RESULTS, KNOW-HOW, WHATEVER, AND THAT GOES
6 THROUGHOUT THE LANGUAGE, AND I HAVEN'T HAD TIME TO
7 REALLY CAREFULLY ANALYZE THE IMPACT THAT, BUT I'D
8 JUST CALL UP SOME OF THE KEY THINGS. AND I JUST
9 WANT TO POINT OUT AT ACADEMIC INSTITUTIONS, WE
10 LICENSE PATENTED INVENTIONS EXCLUSIVELY. WE DON'T
11 LICENSE ANYTHING -- THIS OTHER STUFF EXCLUSIVELY.

12 AND THE REASON WE DO THAT IS BECAUSE WITH
13 A PATENTED INVENTION, YOU CAN PRESERVE EXCLUSIVE
14 COMMERCIAL RIGHTS FOR SOMEBODY AND YOU CAN TELL THE
15 WHOLE WORLD ABOUT IT. SO WE RETAIN OUR ABILITY TO
16 FREELY AND OPENLY DISSEMINATE. THE REASON WE DON'T
17 EXCLUSIVELY LICENSE DATA, RESULTS, KNOW-HOW, THAT
18 KIND OF THING IS BECAUSE THE ONLY WAY TO PRESERVE
19 EXCLUSIVITY FOR SOMEBODY IS TO WITHHOLD
20 DISSEMINATION. AND THAT'S IN COMPLETE VIOLATION OF
21 OUR MISSION. SO WE DON'T DO THAT.

22 HAVING SAID THAT, SOME OF THE IMPLICATIONS
23 OF INTRODUCING THIS CONCEPT OF TECHNOLOGY, AND BY
24 THE WAY I NOTE ALSO IN THE DEFINITION OF INVENTION
25 THE CONCEPT OF PATENTABLE OR NOT HAS BEEN

BARRISTERS' REPORTING SERVICE

1 INTRODUCTION. AND THAT CAUSES SOME OF THESE SAME
2 CONCERNS.

3 ONE IS WE HAVE TO HAVE WRITTEN AGREEMENTS,
4 REQUIRE PROMPT DISCLOSURE, AND WE DO THAT HAVE FOR
5 POTENTIALLY PATENTABLE INVENTIONS, BUT WE DON'T HAVE
6 THAT FOR DATA, RESULTS, OR MATERIALS. AND I'M NOT
7 SURE WE CAN AS A PRACTICAL MATTER MAKE THAT HAPPEN.

8 THE ANNUAL REPORTING FOR 15 YEARS FOR
9 PATENTABLE INVENTIONS IS FINE. WE DO THAT KIND OF
10 THING FOR THE FEDERAL GOVERNMENT. THIS IS A LITTLE
11 MORE EXTENSIVE. I DON'T KNOW HOW WE WOULD DO AN
12 ANNUAL REPORTING FOR KNOW-HOW, FOR DATA, FOR THAT
13 KIND OF THING. THAT'S NOT SOMETHING THAT AS
14 ADMINISTRATORS IS ACCEPTABLE TO US. AND IT'S NOT
15 SOMETHING WE'RE COMMERCIALIZING ANYWAY.

16 THERE'S SOMETHING IN HERE THAT SAYS IF
17 WE'RE NOT DEVELOPING THE TECHNOLOGY, WE HAVE TO
18 NEGOTIATE NONEXCLUSIVE LICENSES FOR THIRD-PARTY
19 DEVELOPMENT. WE DON'T WANT TO BE NEGOTIATING
20 LICENSES FOR -- WE DON'T EVEN OWN THE KNOW-HOW OF
21 OUR FACULTY, BUT WE DON'T WANT TO BE NEGOTIATING
22 LICENSES TO OUR DATA, MATERIALS, RESULTS, THAT SORT
23 OF THING. WE'D RATHER JUST SAY THAT WE WON'T
24 ASSERT -- YOU KNOW, WE WON'T PREVENT ANYBODY FROM
25 USING IT, BUT WE DON'T WANT TO BE IN THE BUSINESS OF

BARRISTERS' REPORTING SERVICE

1 EXECUTING LICENSES FOR THAT SORT OF STUFF.

2 AND THEN THE THIRD ONE, IN THE MARCH-IN
3 LANGUAGE, THERE'S -- CIRM HAS THE ABILITY TO MARCH
4 IN AND GRANT EXCLUSIVE LICENSES TO TECHNOLOGY ON
5 PATENTABLE INVENTIONS AND THOSE THINGS, AND THAT
6 CONCERNS ME VERY MUCH FOR THE REASONS I JUST SAID.
7 TYING UP THOSE THINGS EXCLUSIVELY WOULD BE A
8 PROBLEM.

9 CHAIRMAN PENHOET: LET'S SEE. THE EFFORT
10 HERE WAS TO COVER EVERYTHING THAT GETS FUNDED WITH
11 OUR MONEY; BUT AS A PRACTICAL MATTER, IN YOUR CASE,
12 UNIVERSITIES DON'T LIKE TO SAY ANYTHING EXCEPT
13 PATENTS. IT'S MAYBE NOT RELEVANT TO YOU. AND I
14 DON'T THINK WE CAN KEEP TRACK OF ALL YOUR KNOW-HOW
15 ANYWAY. THAT WOULD BE IMPOSSIBLE. BUT THERE MIGHT
16 BE A CIRCUMSTANCE, I GUESS, IN THE CASE OF A COMPANY
17 IF THERE'S A -- TO GO BACK TO THE EXAMPLE OF
18 SOMEBODY BUYING, A, STEM CELLS, INC. FOR THEIR WHOLE
19 BATTEN'S DISEASE PROGRAM, SOME MONEY WOULD RESULT
20 FOR KNOW-HOW AND FOR A LIST OF PATENTS THAT THEY
21 HAVE ASSOCIATED WITH IT. IF THE KNOW-HOW WAS
22 ACHIEVED WITH OUR FUNDING EXCLUSIVELY, THEN I GUESS
23 WE'D LIKE TO GET A PIECE OF THE ACTION. MAYBE IT'S
24 IMPRACTICAL. I DON'T KNOW.

25 MR. ROTH: BUT DOESN'T THE WORD "REVENUES"

BARRISTERS' REPORTING SERVICE

1 QUALIFY EVERYTHING?

2 CHAIRMAN PENHOET: IT DOES.

3 MR. ROTH: I MEAN TO ME --

4 CHAIRMAN PENHOET: IF THEY GOT

5 REVENUES -- WHATEVER THEY GET REVENUES FOR BY

6 DEFINITION WOULD BE PLUGGED INTO OUR THING, AND WE

7 DON'T CARE -- WE'RE AGNOSTIC ABOUT WHETHER IT'S FOR

8 PATENTS OR FOR KNOW-HOW OR --

9 MR. ROTH: TRADE SECRETS OR ANYTHING ELSE.

10 CHAIRMAN PENHOET: -- MEDIA THAT THEY

11 DEVELOP WITH OUR FUNDING.

12 MR. ROTH: I THINK WHAT WE'RE SAYING IS IF

13 YOU GET PAID, WE GET 25 PERCENT OF THAT.

14 CHAIRMAN PENHOET: THAT MIGHT WORK. MR.

15 STRATTON, YOU WANT TO MAKE A POINT?

16 MR. TOCHER: COULD I JUST INTERRUPT FOR A

17 SECOND JUST TO CLARIFY WENDY'S POINT ON HER LAST

18 POINT ABOUT MARCH-IN. IF I UNDERSTOOD YOU

19 CORRECTLY, YOU MENTIONED THAT IT'S YOUR

20 UNDERSTANDING THAT CIRM WOULD BE REQUIRING FORCING

21 AN EXCLUSIVE LICENSE?

22 CHAIRMAN PENHOET: THAT WE COULD GRANT

23 ONE.

24 MR. TOCHER: YEAH. BECAUSE THE LANGUAGE

25 IS ACTUALLY BROADER, AND I WANT TO MAKE SURE THAT

BARRISTERS' REPORTING SERVICE

1 WE'RE ON THE SAME PAGE ON THAT. THAT CIRM COULD
2 BE -- COULD FORCE ANY TYPE OF LICENSE.

3 MS. STREITZ: A NONEXCLUSIVE WE'RE LESS
4 CONCERNED ABOUT BECAUSE WE CAN STILL -- THAT MEANS
5 WE CAN STILL DISSEMINATE. IF WE HAVE AN EXCLUSIVE,
6 THAT WOULD BE A SHOW STOPPER.

7 MR. TOCHER: I SEE BECAUSE IT WOULD REMOVE
8 YOUR RIGHT TO --

9 MS. STREITZ: AND ONLY IN REGARD TO
10 UNPATENTED -- THE CONCERN WOULD BE A REQUIREMENT FOR
11 AN EXCLUSIVE LICENSE TO A MATTER THAT'S NOT PATENTED
12 BECAUSE THEN WE WOULD BE REQUIRED TO WITHHOLD
13 DISSEMINATION.

14 MS. KOCH: SO THE CURRENT DRAFT GIVES HER
15 THE OPTION TO EXERCISE -- TO EXCLUSIVE,
16 NONEXCLUSIVE, OR PARTIALLY EXCLUSIVE. AND THIS IS
17 IN THE MARCH-IN SECTION, SO YOU HAVE TO CONTEMPLATE
18 A SITUATION WHERE THE UNIVERSITY HAS DEVELOPED
19 TECHNOLOGY THAT COULD BE BROUGHT TO PRACTICAL
20 APPLICATION IN SOME WAY, AND THE UNIVERSITY IS
21 FAILING TO PURSUE IT. THAT'S THE CONTEXT OF THE
22 MARCH-IN RIGHTS, RIGHT?

23 MS. STREITZ: THEN ONE OF THE DIFFERENCES
24 IN THE CURRENT REGS WE'RE JUST TALKING ABOUT
25 PATENTABLE INVENTIONS.

BARRISTERS' REPORTING SERVICE

1 MS. KOCH: THAT' S RIGHT.

2 MS. STREITZ: THE NEW CONCEPT HERE IS
3 UNPATENTABLE MATTER.

4 MS. KOCH: BROADER. THE PENDING PATENT
5 APPLICATION OF SOMETHING THAT MIGHT BE
6 PATENTABLE --

7 MS. STREITZ: YOU CAN SAY PATENTABLE OR
8 POTENTIALLY PATENTABLE IS FINE. BUT IF IT' S STUFF
9 THAT' S NOT PATENTABLE AND GAVE OUT KNOW-HOW,
10 MATERIALS, SOMETHING THAT MAYBE WE' D CHOOSE --
11 WELL, --

12 MS. KOCH: BUT CERTAINLY IN THE COMMERCIAL
13 SECTOR, YOU CAN GET A LOT OF TECHNOLOGY AND
14 KNOW-HOW.

15 MS. STREITZ: THAT' S RIGHT. THAT' S
16 PROPRIETARY AND WE' RE NOT.

17 MS. KOCH: AND THAT' S THE DIFFERENCE.

18 CHAIRMAN PENHOET: WELL, SO THERE ARE A
19 WHOLE SET OF RAMIFICATIONS ABOUT THE DIFFERENCE
20 BETWEEN THE COMMERCIAL SECTOR AND THEIR SECTOR. FOR
21 THE MARCH-IN RIGHTS, IT DOESN' T HAVE ANYTHING TO DO
22 WITH REVENUE. IT' S TECHNOLOGY ROTTING A WAY ON A
23 SHELF SOMEPLACE THAT WE' RE WORRIED ABOUT.

24 MR. SHEEHY: WHY WOULD WE MARCH IN?

25 CHAIRMAN PENHOET: WE' D ONLY MARCH IN

BARRISTERS' REPORTING SERVICE

1 BECAUSE WE DON'T WANT IT TO ROT.

2 MR. SHEEHY: BUT IF THEY'RE --

3 MS. KOCH: THEY'RE MAKING IT AVAILABLE TO
4 OTHER PEOPLE --

5 (SIMULTANEOUS DISCUSSION.)

6 CHAIRMAN PENHOET: IF THEY'RE MAKING IT
7 BROADLY AVAILABLE, THEY'VE DONE WORK WE WOULD
8 OTHERWISE DO. SO THERE'S NOTHING TO MARCH IN. SO
9 IT'S ONLY LIMITED TO PATENTED OR POTENTIALLY
10 PATENTED OR --

11 MS. KOCH: IN THAT CASE I THINK THE
12 THRESHOLD HASN'T BEEN MET IS THAT THEY ARE
13 EXPLOITING IT AND MAKING IT AVAILABLE TO OTHERS.

14 MS. STREITZ: IT'S A LEGAL DOCUMENT AND WE
15 HAVE TO LOOK AT IT IN KIND OF A POLAR EXAMPLE, WE
16 HOPE THEY DON'T OCCUR. BUT WE DON'T -- I MEAN WE
17 CREATE A LOT OF DATA IN THE COURSE OF A RESEARCH
18 PROJECT AND WE DON'T PUBLISH AT ALL. WE DON'T MAKE
19 IT ALL AVAILABLE, AND MOST PEOPLE DON'T WANT IT. I
20 KNOW THAT'S NOT THE KIND OF THING SOMEONE WOULD BE
21 COMING FOR, BUT JUST THE FACT THAT -- (INAUDIBLE)
22 HIGH NONPATENTABLE MATTER EXCLUSIVELY. FORTUNATELY
23 THEY ALMOST NEVER ASK.

24 MR. SHEEHY: THE EXCLUSIVITY HAS TO DO
25 BECAUSE THERE'S SOME VALUE THERE. THAT'S WHY YOU

BARRISTERS' REPORTING SERVICE

1 WOULD LICENSE EXCLUSIVELY BECAUSE THERE'S VALUE. I
2 MEAN I CAN THINK OF A STUDY THAT, IN FACT,
3 (INAUDIBLE) A COUPLE WEEKS AGO AND NEVER GOT
4 PUBLISHED OUT OF UCSF RELATED TO PAUPERS AND THEIR
5 IMPACT ON HIV INFECTION. YOU COULD NEVER GET THE
6 RESEARCHER TO PUBLISH THAT DATA.

7 NOW, HE WOULDN'T WANT AN EXCLUSIVE
8 LICENSE, BUT HE HAD A VERY LEGITIMATE DEMAND THAT
9 THIS FUNDED RESEARCH REACH OUT TO THE PUBLIC AND
10 HAVE A PUBLIC HEALTH CONTEXT. SO, YOU KNOW, YOU
11 TALKED ABOUT DATA THAT MAY BE ROTTING ON THE SHELF,
12 BUT IF THERE'S SOMEBODY WHO HAS AN INTEREST IN
13 HAVING IT GET OUT INTO THE PUBLIC RECOMMEND, WE PAID
14 FOR IT, WE SHOULD BE ABLE TO GO AND DEMAND THAT YOU
15 MAKE THAT AVAILABLE.

16 NOW, I DON'T THINK ANYBODY IS GOING TO
17 LICENSE DATA LIKE THAT UNLESS -- EXCLUSIVELY UNLESS
18 THERE'S SOME VALUE TO BE ACHIEVED. AND IF THERE'S
19 VALUE TO BE ACHIEVED BY EXCLUSIVELY LICENSING IT,
20 THEN YOU GUYS ARE KIND OF REMISS IN NOT LICENSING
21 IT.

22 MS. STREITZ: NO. BECAUSE THE ONLY WAY
23 YOU CAN EXCLUSIVELY LICENSE DATA IS TO WITHHOLD IT
24 FROM EVERYBODY ELSE BECAUSE THERE'S NO OTHER MEANS
25 OF PROTECTION. WE CAN'T DO THAT.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: WHAT IF WE COME AND DEMAND
2 THAT YOU EXCLUSIVELY LICENSE IT IF YOU WERE MAKING
3 IT READILY AVAILABLE TO EVERYBODY? OUR GOAL, IN
4 FACT, OUR BIAS IN ALL THESE POLICIES ALL ALONG,
5 GOING BACK TO OUR VERY FIRST MEETING, WAS AGAINST
6 EXCLUSIVE LICENSES AND TOWARDS THE WIDEST
7 DISSEMINATION OF RESEARCH FINDINGS AND THE MOST
8 UNENCUMBERED, BUT WE RECOGNIZE THAT WE LIVE IN A
9 WORLD WHERE PEOPLE LICENSE. CIRM'S MISSION FROM THE
10 VERY BEGINNING IN IP WAS NOT TO PURSUE EXCLUSIVE
11 LICENSING. SO --

12 MS. STREITZ: OUR MISSIONS ARE ACTUALLY
13 VERY SIMILAR. WHAT I MIGHT SUGGEST, JUST TO ADDRESS
14 A SITUATION LIKE YOU DESCRIBE, I DON'T THINK YOU
15 WOULD WANT EXCLUSIVE -- TO TIE THAT PARTICULAR
16 REPORT, THAT PUBLICATION UP EXCLUSIVELY WITH ONE
17 PARTY. YOU'D WANT BROAD NONEXCLUSIVE ACCESS. BUT
18 MAYBE THE EXCLUSIVE ELEMENT OF THIS PERTAINS TO
19 PATENTABLE INVENTIONS, AT LEAST IN THE ACADEMIC
20 WORLD; AND WHEN WE'RE TALKING DATA AND KNOW-HOW,
21 WHATNOT, THAT'S ABOUT MAKING IT BROADLY AVAILABLE.
22 THAT'S NOT ABOUT --

23 MS. KOCH: I UNDERSTAND YOUR POINT. THE
24 PROPOSED LANGUAGE IS NOT MANDATORY. IT'S CIRM MAY.
25 SO THERE IS DISCRETION WITHIN THE AGENCY THAT'S

BARRISTERS' REPORTING SERVICE

1 EMBODIED HERE. WHAT SHE'S TALKING ABOUT IS HOW WE
2 (INAUDIBLE) THAT DISCRETION IN THE CONTEXT OF AN
3 ACADEMIC INSTITUTION. THIS POLICY DOES NOT GRANT
4 EXCLUSIVE LICENSES.

5 CHAIRMAN PENHOET: WELL, WE WILL ONLY BE
6 APPRISED OF THAT TECHNOLOGY WHICH IS DESCRIBED IN
7 PROGRESS REPORTS SUBMITTED TO US BECAUSE WE ARE
8 NEVER GOING TO HAVE AN AUDITING FUNCTION HERE. OF
9 COURSE, GO AROUND TO PEOPLE'S LABS AND DIG AROUND IN
10 THERE IN TERMS OF WHAT YOU'VE GOT HERE. SO OUR ONLY
11 WINDOW ON THIS IS GOING TO BE WHAT'S DESCRIBED IN
12 OUR PROGRESS REPORTS; ISN'T THAT RIGHT, DR. OLSON?

13 DR. OLSON: THAT IS CORRECT INsofar AS THE
14 GRANTEE REPORTS ON WHATEVER PROGRESS THEY'VE MADE IN
15 THE CONTEXT OF THE PROJECT, THAT IS HOW WE WOULD
16 KNOW, PLUS WHATEVER FORMAL DISCUSSIONS WE HAVE WITH
17 THE INVESTIGATOR.

18 CHAIRMAN PENHOET: BUT ALSO IN OUR
19 AGREEMENT, ALL OF OUR GRANTEES HAVE AN AFFIRMATIVE
20 OBLIGATION, BACK TO THE CONVERSATION WE WERE HAVING
21 EARLIER, TO PROVIDE THEIR REAGENTS, TO PUBLISH THEIR
22 FINDINGS. ALL OF THOSE THINGS ARE EMBODIED
23 SOMEWHERE ELSE IN OUR DOCUMENT. SO I THINK THAT
24 OBLIGATION TO GET IT OUT IS PART OF SOME OTHER
25 SECTIONS IN OUR DOCUMENT. IS THAT NOT TRUE?

BARRISTERS' REPORTING SERVICE

1 MS. KONSKI: HI. THIS IS ANTOINETTE. I
2 JUST WANT TO MAKE ANOTHER POINT HERE AND DIRECT
3 EVERYONE'S ATTENTION TO THE DEFINITION OF EXCLUSIVE
4 LICENSE. THAT'S A VERY NARROW DEFINITION, AND WITH
5 THE NOT FOR-PROFIT SECTOR, I'M CURIOUS IF THEIR
6 DEFINITION OF EXCLUSIVE LICENSE IS THAT NARROW.

7 CHAIRMAN PENHOET: JUST AS A GENERAL
8 COMMENT, THEY SINK OR SWIM ON VALIDITY OF PATENTS.
9 NOBODY EVER BUYS ANYTHING FROM THE UNIVERSITY UNLESS
10 IT'S PATENTED TECHNOLOGY, AT LEAST AS FAR AS I KNOW.

11 MS. KONSKI: SOME INDIVIDUALS WHEN THEY
12 CONSIDER EXCLUSIVE, THEY MEAN EXCLUSIVE AS TO ANY
13 USE, ANY GEOGRAPHY. YOU CAN HAVE TWO LICENSEES IN
14 DIFFERENT FIELDS OF USE, AND THEY'LL BE CONSIDERED
15 EXCLUSIVE; BUT IN THE REAL WORLD THEY'RE REALLY
16 NONEXCLUSIVE. IT MIGHT BE EXCLUSIVE AS TO A CERTAIN
17 USE.

18 CHAIRMAN PENHOET: SO YOU WOULD LIKE A
19 LITTLE MORE ROBUST DEFINITION OF EXCLUSIVE LICENSEE.

20 MS. KONSKI: NO. I THINK IT'S FINE. I'M
21 JUST TRYING TO MAKE THE POINT THAT YOU NEED TO LOOK
22 AT WHAT THE DIFFERENCE IS BETWEEN AN EXCLUSIVE AND A
23 NONEXCLUSIVE LICENSE AND WHAT IS EXCLUSIVE AND WHAT
24 ISN'T EXCLUSIVE.

25 CHAIRMAN PENHOET: OKAY.

BARRISTERS' REPORTING SERVICE

1 MR. TOCHER: TO ANSWER YOUR QUESTION, ED,
2 I THINK THAT THE REGULATIONS PLACE AN AFFIRMATIVE
3 DUTY WITH REGARD TO MATERIALS THAT ARE PUBLISHED
4 THEMSELVES, BIOMEDICAL MATERIALS, AND THERE'S
5 CERTAINLY THAT. AND EARLY ON, AS YOU KNOW, THERE
6 WAS AN ENDORSEMENT BY THE -- AN EARLY ENDORSEMENT BY
7 THE IP TASK FORCE FOR A CONCEPT OF A RESEARCH USE
8 EXEMPTION THAT WOULD BE USED AS A TOOL TO COMPEL.
9 BUT THE ICOC, ON THE TASK FORCE RECOMMENDATION,
10 LATER PULLED THAT ELEMENT OUT OF THE POLICY AND
11 WE'RE TAKING SORT OF A WAIT AND SEE ON THAT.

12 SO THE AFFIRMATIVE OBLIGATION THAT REMAINS
13 RIGHT NOW IS TRIGGERED ON PUBLISHING IN A SCIENTIFIC
14 JOURNAL REGARDING BIOMEDICAL MATERIALS, BUT THERE'S
15 NOT AN AFFIRMATIVE DUTY TO PUBLISH IN THE
16 REGULATIONS THEMSELVES.

17 DR. PRIETO: SCOTT, SO THERE'S NO
18 AFFIRMATIVE REQUIREMENT THAT MATERIAL OR DATA BE
19 MADE AVAILABLE?

20 MR. TOCHER: WELL, THAT'S DIFFERENT WHEN
21 YOU SAY BE MADE AVAILABLE. I MEAN, I WOULD COME
22 BACK TO WHERE WE STARTED, WHICH IS THE MARCH-IN. I
23 MEAN THERE'S -- YOU CAN SEE A CIRCUMSTANCE WHERE
24 CIRM WOULD ASK OUR GRANTEE TO MAKE THIS AVAILABLE
25 UNDER THE CIRCUMSTANCES, THE LIMITED CIRCUMSTANCES

BARRISTERS' REPORTING SERVICE

1 THAT ARE DESCRIBED IN THE MARCH-IN IN REGULATION.
2 BUT YOU'RE RIGHT, JUST GENERICALLY THERE IS NOTHING
3 OUT BETTER THAN WHAT I'VE DESCRIBED.

4 CHAIRMAN PENHOET: ALL RIGHT. SO I THINK
5 WE UNDERSTAND THAT UNIVERSITY KNOW-HOW IS RARELY, IF
6 EVER, PAID FOR BY ANYONE. AND THAT ALMOST ALL OF
7 THEIR LICENSING REVENUE IS STRICTLY WITHIN THE SCOPE
8 OF THEIR PATENT; IS THAT RIGHT, WENDY? OKAY. SO AS
9 A PRACTICAL MATTER, THEY'RE NEVER GOING TO GET ANY
10 PAYMENT FOR ANYTHING BUT THAT, BUT FOR PATENTS. YOU
11 EXPECT A CONCERN ABOUT THE INTERMEDIATE ROUND WHICH
12 IS PATENT APPLICATIONS. IF THERE ARE CONTINUATIONS
13 IN PART OR OTHER FORMS OF PATENTS, THAT PROBABLY
14 SHOULD BE INCLUDED IN THE BUNDLE OF WHATEVER THEY
15 LICENSE.

16 SO IF YOU WANTED TO NARROW IT TO THAT, YOU
17 WOULD EXCLUDE KNOW-HOW AND THE REST OF FROM THIS
18 DISCUSSION, BUT YOU WOULD SWEEP IN PATENTS OR PATENT
19 APPLICATIONS.

20 MR. ROTH: ED, AS LONG AS YOU HAVE THE
21 WORD "REVENUE," I THINK -- IF YOU GO BACK TO SLIDE
22 14, I DON'T KNOW WHICH ONE YOU'RE ON BECAUSE I SORT
23 OF GOT LOST HERE, THE POLICY INTENT WAS TO REACH ALL
24 PATENT REVENUES. IT REALLY SHOULD SAY REACH ALL
25 REVENUES.

BARRISTERS' REPORTING SERVICE

1 MS. STREITZ: CAN I MAKE A COMMENT ON
2 THAT? I THINK -- I DON'T THINK WE'RE IN
3 DISAGREEMENT. IF WE'RE RECEIVING REVENUE FROM ANY
4 MEANS, AND IT WON'T BE KNOW-HOW LIKE YOU SAID, IT
5 COULD BE AVAILMENT OF A TANGIBLE MATERIAL THOUGH IN
6 ADDITION TO. I DON'T THINK WE'RE OBJECTING TO THE
7 CIRM PROVISIONS REGARDLESS OF THE REVENUE. MY
8 CONCERN IS WITH OTHER IMPLICATIONS WITHIN THE
9 PROPOSED REGS OF NOW INCORPORATING THE CONCEPT OF
10 INVENTIONS WHETHER PATENTABLE OR NOT AND TECHNOLOGY
11 THAT INCLUDES KNOW-HOW, DATA, AND STUFF. I THINK
12 THERE WERE OTHER IMPLICATIONS THAT HAVE NOTHING TO
13 DO WITH REVENUE.

14 MS. KOCH: SO, ED, CERTAINLY THE WAY THAT
15 YOU FRAMED IT UP, WE COULD NARROW IT THAT WAY IF YOU
16 WANT TO. I WANT TO GO BACK TO --

17 CHAIRMAN PENHOET: WHAT ARE YOU TRYING TO
18 ACHIEVE BY BROADENING THIS TO INCLUDE THESE OTHER
19 ELEMENTS?

20 MS. KOCH: WHAT WE WERE TRYING TO ACHIEVE
21 IS THE FACT THAT SOMETIMES TECHNOLOGY AND KNOW-HOW,
22 WHICH ARE NOT PATENTED OR MAYBE NOT EVEN PATENTABLE,
23 COULD HAVE GREAT VALUE.

24 CHAIRMAN PENHOET: OKAY. MONETARY VALUE,
25 IS THAT THE VALUE WE'RE TALKING ABOUT HERE?

BARRISTERS' REPORTING SERVICE

1 MS. KOCH: IT MIGHT NOT BE MONETARY VALUE
2 IN THE SHORT RUN. IT MIGHT BE SOMETHING THAT
3 ENABLES THE FIELD TO MOVE FORWARD, FOR INSTANCE.
4 AND IN THAT CIRCUMSTANCE, IF THE CIRM-FUNDED
5 INVENTOR WERE FAILING TO BRING IT FORWARD AND MAKE
6 IT AVAILABLE, CIRM WOULD LIKE TO HAVE THE RIGHT TO
7 SAY WILL YOU PLEASE BRING IT FORWARD AND MAKE IT
8 AVAILABLE? AND IF THEY FAIL TO DO SO AFTER A
9 REASONABLE PERIOD OF TIME AND A CURE PERIOD, THEN
10 CIRM WOULD LIKE TO HAVE CERTAIN MARCH-IN RIGHTS.

11 NOW, WENDY IS SAYING SHE TENDS TO MAKE
12 KNOW-HOW AND TECHNOLOGY THAT'S NOT PATENTABLE
13 AVAILABLE ANYHOW. SO TO ME IT'S VERY REMOTE, WENDY,
14 THAT WE WOULD COME TO THE UC AND SAY DO SOMETHING
15 DIFFERENT BECAUSE YOU'RE ALREADY PUTTING IT OUT
16 THERE. AND I THINK THAT'S JEFF'S CIRCUMSTANCE. SO
17 THE MARCH-IN RIGHTS IN MY MIND IN THAT CIRCUMSTANCE
18 ARE KIND OF IRRELEVANT. IT'S UNLIKELY THAT CIRM
19 WOULD COME TO YOU AND SAY DO SOMETHING OTHER THAN
20 WHAT YOU'RE ALREADY DOING.

21 BUT CERTAINLY IN THE COMMERCIAL SECTOR
22 WHERE TRADE SECRETS AND KNOW-HOW ARE NOT REGULARLY
23 PUBLISHED, BUT CAN HAVE VALUE AND COULD MOVE THE
24 FIELD FORWARD, IF SOMEONE IS FAILING TO BRING THEM
25 FORWARD TO PRACTICAL APPLICATION, I THINK WE SHOULD

BARRISTERS' REPORTING SERVICE

1 HAVE THE RIGHT TO PURSUE THAT WITH THEM.

2 CHAIRMAN PENHOET: WELL, BUT THAT'S IN
3 CONFLICT WITH -- WE HAVE TAKEN SPECIAL PAINS TO
4 ENSURE THAT WE ARE NOT FORCING ANY OF OUR GRANTEES
5 TO DIVULGE CONFIDENTIAL INFORMATION. SO AT WHAT
6 POINT, WHO DECIDES WHETHER THE INFORMATION IS NO
7 LONGER CONFIDENTIAL AND, THEREFORE, WE SHOULD BE
8 ABLE TO EXTRACT IT OUT OF YOU AND DO SOMETHING WITH
9 IT VERSUS -- BECAUSE IT GOES BACK TO DUANE'S POINT.
10 IF IT BECOMES VALUABLE AND IT'S SUBJECT TO A
11 LICENSE, THEN IT WILL FALL INTO THE REVENUE
12 CATEGORY. I THINK, YOU KNOW, WE'RE IN AN AREA WHERE
13 I UNDERSTAND THE ARGUMENT THAT CAN BE MADE FOR
14 MAKING SURE ALL THIS TECHNOLOGY SOMEHOW GETS USED,
15 BUT IT'S IN CONFLICT WITH SOME OTHER PRINCIPLES THAT
16 WE'VE BEEN DEVELOPING HERE.

17 MS. KOCH: I GUESS AT THE MARGIN IT COULD
18 BE, BUT YOU CAN IMAGINE A CIRCUMSTANCE IN THE
19 COMMERCIAL SECTOR WHERE SOMEONE WOULD INVENT TWO
20 INVENTIONS WHICH COULD POSSIBLY BE IN CONFLICT WITH
21 ONE ANOTHER, AND THEY CAN DECIDE TO BRING ONE
22 FORWARD AND NOT THE OTHER. SO I HAVE TWO THINGS
23 THAT MIGHT WORK, AND I'M GOING TO BRING ONE FORWARD,
24 I'M GOING TO CAPITALIZE ON THAT, AND I'M GOING TO
25 HOLD THE OTHER ONE BACK BECAUSE I DON'T WANT TO HAVE

BARRISTERS' REPORTING SERVICE

1 COMPETITION. IS THAT IN OUR BEST INTEREST?

2 CHAIRMAN PENHOET: AND IT'S PATENTED OR
3 NOT PATENTED?

4 MS. KOCH: THINK OF IT AS KNOW-HOW. THINK
5 OF IT AS TECHNOLOGY AND IT'S NOT PATENTED BECAUSE I
6 DON'T WANT IT OUT THERE.

7 MR. ROTH: HOW WOULD WE KNOW ABOUT IT?

8 CHAIRMAN PENHOET: HOW WOULD WE KNOW?

9 MS. KOCH: IT WOULD BE ON YOUR ANNUAL
10 REPORT TO DR. OLSON. I'M JUST SAYING WHAT THE
11 MARCH-IN RIGHTS SAY IS IN THAT CIRCUMSTANCE THAT
12 CIRM COULD GO TO OUR GRANTEE AND SAY WHAT'S THE
13 SITUATION HERE? WHAT IS THE THINKING? WHAT IS THE
14 PRACTICAL APPLICATION HERE? ARE THE BEST INTERESTS
15 OF THE PEOPLE OF CALIFORNIA BEING SERVED? AND IF WE
16 SAY -- GO THROUGH THAT ANALYSIS WITH OUR GRANTEE AND
17 DECIDE, NO, YOU KNOW, THIS TECHNOLOGY SHOULD BE
18 BROUGHT FORWARD, WE COULD SAY TO THE GRANTEE PLEASE
19 BRING IT FORWARD IN WHATEVER WAY YOU DEEM MOST
20 APPROPRIATE. AND IF THE GRANTEE SAYS, NO, WE'LL NOT
21 DO IT.

22 MR. ROTH: NANCY.

23 MS. KOCH: IT'S NOT IN MY BEST COMMERCIAL
24 INTEREST AND THIS MIGHT BE QUITE UNLIKELY. I THINK
25 CIRM NEEDS TO HAVE A PARACHUTE.

BARRISTERS' REPORTING SERVICE

1 MR. ROTH: JUST I FEEL IF THEY'RE THAT
2 DEVIOUS IN TRYING TO HIDE THIS INFORMATION, IT'S NOT
3 GOING TO SHOW UP IN AN ANNUAL REPORT EITHER.

4 MS. KOCH: NOT THE ANNUAL REPORT.

5 MR. ROTH: ANYTHING. IT'S NOT GOING TO
6 SHOW UP. I MEAN IF THEY'VE GOT TWO INVENTIONS AND
7 YOU THINK THEY'RE GOING TO SUPPRESS ONE AND PUT THE
8 OTHER ONE FORWARD, I DON'T THINK YOU'RE EVER GOING
9 TO HEAR ABOUT THE SUPPRESSION.

10 ANYWAY, LET'S GIVE THIS SOME THOUGHT
11 BECAUSE I'M UNABLE TO FOLLOW THIS LAST CONVERSATION
12 ON MARCH-IN RIGHTS. BUT LET'S GIVE IT SOME IT
13 THOUGHT AND MAKE SURE WE DON'T GET UNINTENDED
14 CONSEQUENCES HERE.

15 MR. SHEEHY: ISN'T THE REAL ISSUE THE
16 BROADENING OF THE DEFINITION THAT'S DRIVING THIS?
17 IT'S NOT THE MARCH-IN RIGHTS. I REALLY DON'T THINK
18 THERE IS AN ISSUE ON MARCH-IN RIGHTS BECAUSE I
19 THINK, AS YOU'VE NOTED, IF THE COMPANY WANTS TO
20 SHELF SOMETHING, IT WILL NEVER SEE THE LIGHT OF DAY
21 WHETHER WE WANT TO MARCH IN OR NOT. AND I THINK
22 THIS PROBLEM THAT'S BEEN IDENTIFIED BY THE
23 UNIVERSITIES IS NOT A LEGITIMATE PROBLEM BECAUSE WE
24 SHARE THE SAME INTEREST IN GETTING THIS WIDELY
25 DISSEMINATED, AND WE WOULD NOT SUBSTITUTE THE DESIRE

BARRISTERS' REPORTING SERVICE

1 TO SOMEHOW GET INCOME OUT OF THIS BY GIVING AN
2 EXCLUSIVE LICENSE FOR OUR ALREADY WELL-DECLARED
3 INTEREST, WHICH WE SET IN THE VERY BEGINNING TO
4 ACHIEVE THE WIDEST DISSEMINATION. WE STATED AT THE
5 VERY BEGINNING TWO YEARS AGO THAT OUR GOAL, OUR BIAS
6 WAS TOWARD NONEXCLUSIVE LICENSES FOR EVERYTHING AND
7 FOR A RESEARCH USE EXEMPTION.

8 SO, YOU KNOW, IT WOULD BE CONTRARY TO US
9 TO GO AND SAY YOU HAVE KNOWLEDGE THAT YOU'RE NOT
10 PATENTING, BUT YOU'RE MAKING WIDELY AVAILABLE THAT
11 WE'RE GOING TO TAKE AND NOW MAKE YOU PATENT SO WE
12 CAN GET MONEY. THAT'S NOT -- THAT'S NOT REASONABLE
13 TO GO BACK AND CHANGE THIS BROAD DEFINITION THAT I
14 THINK IT WAS THE BROAD TO MATCH LANGUAGE IN
15 BAYH-DOLE.

16 MS. STREITZ: BAYH-DOLE IS ONLY TO
17 PATENTABLE INVENTIONS. SO THIS GOES WELL BEYOND
18 BAYH-DOLE. I THINK IT WAS BROUGHT IN TO CAPTURE
19 TRADE SECRETS AND SUCH.

20 MS. KOCH: COMPANIES MIGHT CHOOSE NOT
21 PURSUE PATENT APPLICATIONS -- PROTECTION. AND THERE
22 IS SOME LITERATURE SUGGESTING THAT THAT IS SOMETHING
23 THAT ENTITIES WILL DO MORE OF AS WE MOVE FORWARD.

24 CHAIRMAN PENHOET: WELL, MAYBE. PATENTS
25 HAVE BEEN THE BEDROCK OF BIOTECH SINCE IT WAS

BARRISTERS' REPORTING SERVICE

1 INVENTED.

2 MS. KOCH: ABSOLUTELY.

3 MR. ROTH: MY SUGGESTION IS LET'S GIVE IT
4 SOME MORE THOUGHT. AND IF WE HAVE TO SEPARATE
5 THESE, MAYBE IN THIS SCENARIO WE HAVE TO. NANCY,
6 YOUR CONCERNS ARE MOSTLY ON THE CORPORATE SIDE.

7 MS. KOCH: YES.

8 DR. LOVE: DUANE, I HAVE A QUESTION ABOUT
9 THIS. I HOPE THAT MY CONCERN IS NOT REALISTIC
10 BECAUSE I DON'T WANT TO ADD TO A COMPLEX SITUATION.
11 BUT ONE OF THE THINGS THAT DOES HAPPEN OBVIOUSLY
12 VERY COMMONLY IN INDUSTRY IS THAT THERE ARE SEVERAL
13 INDICATIONS THAT COULD BE PURSUED WITH A PRODUCT.
14 AND SOMETIMES INDICATIONS SIMPLY GO UNPURSUED
15 BECAUSE, NOT ONLY DO THEY NOT HAVE VALUE, BUT THEY
16 WOULD ACTUALLY PULL DOWN THE VALUE THAT YOU COULD
17 GENERATE IN THE INDICATION THAT YOU DO WANT TO
18 PURSUE.

19 AND I JUST CITE AS AN EXAMPLE THE CURRENT
20 GENENTECH SITUATION WITH AVASTIN IN CANCER AND
21 LUCENTIS IN AGE-RELATED MACULAR DEGENERATION. TO BE
22 LONG-WINDED, YOU KNOW, WOULD THE FAILURE TO PURSUE A
23 POTENTIAL INDICATION IN AN AREA OPEN UP ANY OF THESE
24 ISSUES?

25 CHAIRMAN PENHOET: WELL, IT THEORETICALLY

BARRISTERS' REPORTING SERVICE

1 CERTAINLY COULD; BUT, YOU KNOW, I THINK IF IT'S VERY
2 VALUABLE, THE PROBABILITY THAT ITS USE WOULD NOT BE
3 PATENTED AT SOME POINT IN TIME IS PROBABLY SMALL.
4 SO IF THEY PATENT IT, THEN IT'S IN THE LITERATURE
5 AND WE WOULD KNOW ABOUT IT, AND IT WOULD FALL UNDER
6 OUR PATENT ISSUE. I DO THINK COMPANIES WOULD BE
7 VERY NERVOUS ABOUT US COMING IN AND ESSENTIALLY
8 DICTATING THEIR COMMERCIAL STRATEGIES.

9 MR. ROTH: I THINK IT'S POSSIBLE, TED,
10 THAT THAT COULD HAPPEN AND SOMETIMES DOES. BUT,
11 AGAIN, I THINK IF YOU TRY TO WRITE LANGUAGE FOR
12 THAT, YOU'RE GOING TO MAKE SURE, I THINK, MOST
13 PEOPLE WOULDN'T WANT TO TOUCH THE CIRM MONEY OR THE
14 PATENTED INVENTIONS FROM INSTITUTIONS THAT HAVE
15 THAT.

16 DR. LOVE: THAT'S EXACTLY MY -- I WANT TO
17 MAKE SURE WE DON'T PUT OURSELVES IN THAT KIND OF
18 CONCERN.

19 CHAIRMAN PENHOET: YOU KNOW, LOOKING BACK,
20 I THINK THE AREA THAT WE GOT -- ONE OF THE GREATEST
21 AREAS OF CONCERN WAS THE MARCH-IN RIGHTS. SO TO
22 MAKE THEM EVEN BROADER I THINK WILL CERTAINLY MAKE
23 PEOPLE NERVOUS. WE GOT ONE NERVOUS PARTICIPANT HERE
24 IN SAN FRANCISCO. MR. STRATTON, DO YOU WANT TO
25 COMMENT ON THIS ISSUE?

BARRISTERS' REPORTING SERVICE

1 MR. STRATTON: SO IT SOUNDS LIKE THE GROUP
2 IS INCLINED TO GO BACK AND THINK ABOUT THIS A BIT,
3 AND THAT'S APPRECIATED. I DO WORRY THAT THE
4 PROPOSED CHANGES ALONG THE LINES THAT HAVE BEEN
5 DISCUSSED RECENTLY WILL HAVE QUITE A CHILLING
6 EFFECT, PARTICULARLY FOR TRANSLATIONAL COMPANIES
7 SUCH AS OURS. TO KEEP IN MIND THAT WE ALREADY HAVE
8 A STABLE OF PATENTS THAT PROTECT OUR PRODUCTS. AND
9 I KEEP GOING BACK TO THE HYPOTHETICAL THAT YOU
10 ROLLED OUT OF MERCK ACQUIRING US AND TRYING TO TAKE
11 SOME OF THE VALUE FOR THAT.

12 IF MERCK ACQUIRES US, IT'S ACQUIRING US, I
13 ASSURE YOU, BECAUSE OF THE ISSUED PATENTS BECAUSE
14 THE ISSUED PATENTS ALLOW THEM TO EXCLUDE
15 COMPETITORS, AND IT'S THAT MONOPOLY, IF YOU WILL,
16 THAT LEGALIZED MONOPOLY, THAT HAS REAL VALUE FOR THE
17 COMPANY.

18 IT IS POSSIBLE, IT IS POSSIBLE THAT TRADE
19 SECRETS OR KNOW-HOW WILL BE DEVELOPED THAT HAVE
20 ABSOLUTELY NO VALUE WHATSOEVER, BUT IT'S STILL
21 KNOW-HOW. AND AS DRAFTED, I WORRY THAT EVEN A
22 FAILED CIRM-FUNDED PROJECT, BECAUSE MONEY WENT INTO
23 THE COMPANY TO DEVELOP ESSENTIALLY WORTHLESS
24 KNOW-HOW, WILL GET ROLLED UP IN AND WE'LL FIND
25 OURSELVES HAVING TO PAY THE 25 PERCENT ON THE

BARRISTERS' REPORTING SERVICE

1 ACQUISITION OF COMPANIES.

2 SO DO PLEASE THINK ABOUT WHERE THE VALUE
3 IS FOR THE COMMERCIAL ENTITY. IT'S AN ISSUED
4 PATENT. I COULD EXPLORE AND UNDERSTAND AN INTEREST
5 IN TRYING TO CAPTURE VALUE FROM PATENT APPLICATIONS.
6 NINE TIMES OUT OF TEN COMMERCIAL COMPANIES DON'T
7 LICENSE PATENT APPLICATIONS BECAUSE THEY REALIZE THE
8 PATENT PROSECUTION PROCESS IS SO ARBITRARY, AND
9 THERE MAY NOT BE ANY VALUE IN IT AT THE END OF THE
10 DAY. CERTAINLY NOT MUCH IN THE WAY OF UP-FRONT
11 PAYMENTS.

12 BUT IN ANY CASE, THESE ARE VERY BROAD
13 DEFINITIONS. I'LL NEED TO GO BACK AND LOOK AT THEM,
14 BUT THEY ALMOST FEEL LIKE AN INTEREST IN RECEIVING A
15 PIECE OF THE REVENUE IF CIRM PUTS MONEY IN AND
16 NOTHING OF VALUE COMES FROM IT. AND THAT NEVER
17 SEEMED LIKE THE DEAL. THE EARLIER REGULATIONS WERE
18 VERY CLEAN AND EFFICIENT THAT WAY. EITHER THE CIRM
19 GENERATES A PATENTED INVENTION OR IT GENERATES DATA
20 THAT'S USEFUL; AND IT IF IT GENERATES DATA THAT'S
21 USEFUL, THAT'S FINE BECAUSE DATA ACTUALLY HAS SOME
22 PRECLUSIVE EFFECT BECAUSE YOU CAN SUBMIT IT TO
23 REGULATORY AUTHORITIES AND GET YOUR INDICATIONS, AND
24 OBVIOUSLY THE PATENT GIVES YOU SOME VALUE.

25 SO PLEASE DO RECONSIDER THIS. I THINK THE

BARRISTERS' REPORTING SERVICE

1 CHILLING EFFECT WILL BE QUITE SEVERE.

2 CHAIRMAN PENHOET: OKAY. WHERE ARE WE?

3 MR. ROTH: MR. CHAIR, I'VE GOT TO LEAVE
4 SOON. I WONDER IF I CAN BRING UP ONE ISSUE THAT I'D
5 LIKE TO GET ON THE TABLE.

6 CHAIRMAN PENHOET: SURE. PLEASE.

7 MR. ROTH: SO IN THE PAYBACK BY THE
8 COMPANIES, THE THREE TIMES PAYBACK ONCE THEY
9 COMMERCIALIZE.

10 CHAIRMAN PENHOET: YES.

11 MR. ROTH: WE HAVE A RANGE OF ROYALTY IN
12 THERE, AND I THINK IT'S 2 TO 5 PERCENT, IF I
13 REMEMBER RIGHT. YOU KNOW, IN THINKING THROUGH THAT,
14 I THINK THAT WAS A MISTAKE. I THINK WE SHOULD HAVE
15 SET IT AT A FIXED PAYBACK NUMBER BECAUSE I DON'T
16 KNOW WHO'S GOING TO, ONE, NEGOTIATE WITH THE
17 COMPANY; AND, TWO, I DON'T KNOW WHAT THE BASIS FOR
18 THE TWO AND THE FIVE WOULD BE. WHEN WE ORIGINALLY
19 TALKED ABOUT IT, WE USED SOME RATIONALE, AND I THINK
20 IT WAS MINE, SO I TAKE FULL RESPONSIBILITY, BUT IT
21 WAS SOMETHING LIKE MAYBE ON TOOLS, YOU'D PAY 2
22 PERCENT RATE VERSUS A THERAPEUTIC THAT YOU'D PAY A
23 HIGHER RATE.

24 BUT IN THINKING ABOUT THAT, IT REALLY
25 MAKES NO SENSE BECAUSE THE SALES ARE LOWER AND, YOU

BARRISTERS' REPORTING SERVICE

1 KNOW, THERE ARE VERY UNIQUE DIFFERENCES THERE, BUT
2 THEY REALLY WOULDN' T MATTER MATERIALLY IN THE RATE
3 OF THE PAYBACK.

4 SO I WOULD LIKE TO CLEAN THIS UP SINCE
5 WE' RE DOING IT AND SIMPLY FIX THAT AMOUNT AND NOT
6 LEAVE IT TO CIRM STAFF TO HAVE TO NEGOTIATE WITH
7 EVERY SINGLE COMPANY OUT THERE.

8 CHAIRMAN PENHOET: YOU HAVE A SUGGESTION?

9 MR. ROTH: THREE.

10 CHAIRMAN PENHOET: SHEEHY IS NODDING HIS
11 HEAD IN AGREEMENT.

12 MR. SHEEHY: YEAH, BECAUSE THE NUMBER --
13 YOU KNOW, I FEEL LIKE THAT IN ALL LIKELIHOOD IF THEY
14 START GENERATING REVENUE, THEY' LL GENERATE THE
15 PAYBACK. AND IT' S JUST THE SPEED AT WHICH THEY PAY
16 US BACK --

17 MR. ROTH: EXACTLY.

18 MR. SHEEHY: -- THAT YOU' RE TALKING ABOUT.
19 SO WHETHER IT' S TWO, THREE, FOUR, OR FIVE, IF YOU
20 LIKE THREE, I LIKE THREE.

21 MR. ROTH: I THINK THREE IS FAIR. YOU
22 KNOW IN TERMS OF A ROYALTY 5 PERCENT, 5 PERCENT
23 ROYALTY, AND THEY MAY HAVE SOME OTHER ROYALTIES THAT
24 THEY' VE GOT TO PAY ON THIS AS WELL. YOU GET THIS
25 STACKING SITUATION, BUT THREE I THINK PEOPLE WOULD

BARRISTERS' REPORTING SERVICE

1 LIVE WITH.

2 CHAIRMAN PENHOET: OKAY. WE'LL TAKE THAT.
3 WHAT DO OTHER PEOPLE IN THE COMMITTEE THINK ABOUT
4 THAT?

5 DR. PRIETO: I THINK THAT'S FINE.

6 DR. LOVE: I AGREE.

7 CHAIRMAN PENHOET: ANY PUBLIC COMMENT
8 HERE? WE DO HAVE A PUBLIC COMMENT.

9 MR. VALENCIA: SIMPLY, MR. CHAIRMAN, JOHN
10 VALENCIA FOR INVITROGEN, SOON TO BE LIFE
11 TECHNOLOGIES, THAT IS A POINT THAT GOES BACK TO SOME
12 OF OUR EARLIEST COMMENTS. AND WE WOULD ENDORSE THE
13 SIMPLIFICATION OF THAT PROPORTIONALITY STANDARD.

14 CHAIRMAN PENHOET: THANK YOU. IN THE
15 CONTEXT OF OTHER THINGS WE'VE DISCUSSED TODAY, WE
16 SEEM TO HAVE UNIVERSAL AGREEMENT ON THIS ONE. SO
17 WE'LL GO FORWARD WITH THIS AS A CHANGE. THANK YOU,
18 DUANE.

19 MR. ROTH: YEAH.

20 CHAIRMAN PENHOET: I GUESS WE'RE ON WHAT'S
21 CALLED ISSUE 4, SCOPE OF REVENUE SHARING, TIGHTENING
22 THE SCOPE OF LICENSING REVENUES. NANCY, DO YOU WANT
23 TO GUIDE US THROUGH THIS ONE? SHOULD LICENSES APPLY
24 TO TRANSFERS OF THE SAME RIGHTS AS BAYH-DOLE?

25 MS. KOCH: SO, ED, IN THE EXISTING

BARRISTERS' REPORTING SERVICE

1 REGULATIONS, IT TALKS ABOUT LICENSES TO USE OR
2 DEVELOP. AND THE TERM OF ART BOTH IN THE PATENT
3 COMMUNITY AND I BELIEVE IN BAYH-DOLE, CORRECT ME IF
4 I'M WRONG, IS MAKE, USE, OR SELL. AND THIS IS AN
5 EFFORT TO JUST CONFORM OUR REGULATIONS WITH THE
6 BAYH-DOLE REGULATIONS WHEN IT COMES TO DEFINING
7 LICENSES AND WHAT THEY DO.

8 SIMILARLY, IN TERMS OF WHAT IS AN
9 INVENTION, OUR REGULATIONS ARE INCONSISTENT WITH
10 BAYH-DOLE. BAYH-DOLE TALKS ABOUT SOMETHING WHICH IS
11 CONCEIVED AND/OR REDUCED TO PRACTICE DURING THE
12 COURSE OF THE WORK THAT'S BEING FUNDED. AND OUR
13 REGULATIONS ARE NOT CONSISTENT. SO WE'RE SUGGESTING
14 THAT WE MOVE INTO CONFORMANCE WITH BAYH-DOLE ON BOTH
15 OF THESE FRONTS.

16 CHAIRMAN PENHOET: SO TWO SUGGESTIONS.
17 MAKE, USE, OR SELL.

18 MS. KOCH: AND/OR REDUCE TO PRACTICE.

19 CHAIRMAN PENHOET: AND THEN MAKE OUR
20 DEFINITION OF PATENT CONCEIVED OR REDUCED TO
21 PRACTICE BE CONSISTENT WITH BAYH-DOLE. ANY COMMENT
22 ON THOSE SUGGESTIONS?

23 MR. ROTH: I WOULD SUPPORT THOSE BOTH.

24 CHAIRMAN PENHOET: ANY OTHER COMMENTS?

25 DR. LOVE: I AGREE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM
2 THE COMMITTEE MEMBERS? WENDY STREITZ.

3 MS. STREITZ: THE CONCEIVED OR
4 IMPLEMENTATION IS ACTUALLY ONE OF OUR BIGGEST
5 CONCERNS WITH THE NEW -- WITH THE PROPOSED
6 REGULATIONS. THE FEDERAL GOVERNMENT IS ACTUALLY THE
7 ONLY ENTITY THAT WE OBLIGATE INVENTIONS CONCEIVED OR
8 REDUCED TO PRACTICE WITH THEIR FUNDING, AND THAT'S
9 BECAUSE WE DON'T HAVE A CHOICE. I WOULD POINT OUT
10 THAT THE EXISTING REGS, CIRM REGS, ON THIS POINT ARE
11 ENTIRELY COMPATIBLE WITH BAYH-DOLE. I DON'T KNOW
12 THAT THEY HAVE TO MIRROR BAYH-DOLE.

13 NOW, HERE'S THE ISSUE FOR US IS WE'RE
14 TRYING TO MANAGE AN ENTIRE WEB OF OBLIGATIONS. THE
15 FEDERAL OBLIGATIONS ARE VERY BENIGN AND WORK WITH
16 MOST OF OUR OTHER FUNDING. SO IF WE HAVE AN
17 INVENTION THAT'S CONCEIVED UNDER A FEDERAL AWARD AND
18 REDUCED TO PRACTICE SOMEWHERE ELSE OR VICE VERSA, WE
19 CAN USUALLY MAKE THAT WORK. WE HAVE AT ANY GIVEN
20 TIME IN THE UC SYSTEM OVER 31,000 ACTIVE AWARDS THAT
21 WE'RE TRYING TO MANAGE. AND IF WE WERE TO START
22 COMMITTING RIGHTS CONCEIVED OR, WE'D HAVE A CROSS
23 COMMITMENT OF OBLIGATIONS THAT WOULD BE UNMANAGEABLE
24 FOR US.

25 SO WHILE OUR INTENTION IS NOT TO GAME

BARRISTERS' REPORTING SERVICE

1 ANYTHING HERE, WE NEED TO BE ABLE TO MANAGE OUR
2 OBLIGATIONS. SO SOME OF THE CIRM OBLIGATIONS ARE
3 GOING TO BE CHALLENGING FOR US. AND IF WE CONCEIVE
4 AN INVENTION UNDER CIRM FUNDING AND REDUCE IT TO
5 PRACTICE UNDER SOMEBODY ELSE'S FUNDING OR VICE
6 VERSA, I MEAN EVEN WORSE IN ONE RESPECT WOULD BE TO
7 CONCEIVE AN INVENTION UNDER INDUSTRY FUNDING AND
8 REDUCE IT TO PRACTICE HERE AND NOT BE ABLE TO -- AND
9 GRANTED INDUSTRY WOULD HAVE BEEN CONCEIVED OR
10 REDUCED TO PRACTICE; BUT IF THEY'RE INTERESTED IN
11 THE INVENTION, WE WOULD WANT TO MOVE AHEAD, BUT THIS
12 CONTAMINATION OF THE CONCEIVED OR IS GOING TO MAKE
13 LIFE VERY DIFFICULT FOR US. AND IT'S DEFINITELY NOT
14 OUR STANDARD.

15 CHAIRMAN PENHOET: I THINK YOU JUST ARGUED
16 FOR OUR POLICY, WENDY. I UNDERSTOOD WHAT YOU SAID.
17 YOU WANT A -- THIS CASE WAS CONCEIVED WITH SOMEBODY
18 ELSE'S MONEY AND REDUCED TO PRACTICE WITH OURS, THAT
19 WE WOULDN'T -- WHO WOULDN'T HAVE ANY RIGHTS TO IT?
20 I'M TRYING TO GO THE OTHER THE WAY AROUND. I MEAN
21 IF IT WAS CONCEIVED WITH OUR FUNDING AND REDUCED TO
22 PRACTICE IN SOMEBODY ELSE'S FUNDING, THEN WE WOULD
23 NOT GET A PART OF IT. IS THAT WHAT -- YOU WANT TO
24 TAKE THE CONCEIVED WORDS OUT OF OUR POLICY.

25 MS. STREITZ: THE "OR" WORD OUT.

BARRISTERS' REPORTING SERVICE

1 MS. KOCH: CONCEIVED AND REDUCED TO
2 PRACTICE WITH OUR MONEY; AND IF IT IS CONCEIVED WITH
3 OUR MONEY, BUT NOT REDUCED TO PRACTICE OR CONCEIVED
4 WITH SOMEONE ELSE'S MONEY AND ONLY REDUCED TO
5 PRACTICE WITH OURS, SHE WANTS IT TO BE OUTSIDE OF
6 OUR OBLIGATIONS. AND WE ARE TRYING TO COVER THE
7 SITUATION WHERE IT'S CONCEIVED WITH OUR MONEY OR
8 REDUCED TO PRACTICE WITH OUR MONEY OR BOTH.

9 MS. STREITZ: LIKE I SAID, THE FACT THAT
10 YOU'RE THE ONLY ENTITY THAT WE DO THE CONCEIVED OR
11 JUST BECAUSE OF THE DIFFICULTY OF MANAGING THE
12 OBLIGATIONS. IN ONE -- I WAS JUST KIND OF THINKING
13 OUT LOUD NOW. ONE POSSIBLE APPROACH WOULD BE THAT
14 IF IT'S CONCEIVED AND REDUCED TO PRACTICE WITH CIRM
15 FUNDING, THAT'S THE EASY SCENARIO. MAYBE IF IT'S AN
16 OR, THERE NEEDS TO BE AN ACKNOWLEDGEMENT THAT THERE
17 MAY BE CONFLICTING OBLIGATIONS. AND CERTAINLY IF
18 THERE ARE PRIOR OBLIGATIONS --

19 MS. KOCH: IF THERE ARE PRIOR OBLIGATIONS
20 WITH REGARD TO REVENUE SHARING, THERE WOULD BE
21 PROPORTIONALITY.

22 MS. STREITZ: IT'S NOT THE REVENUE
23 SHARING.

24 MS. KOCH: SO WHAT IS THE -- THE EFFECT OF
25 MARCH-IN RIGHTS.

BARRISTERS' REPORTING SERVICE

1 MS. STREITZ: THE MARCH-IN, THE ACCESS,
2 THOSE KIND OF THINGS WHICH ARE GOING TO BE AN ISSUE
3 FOR A COMPANY THAT DIDN'T THINK IT WAS TOUCHING CIRM
4 FUNDING.

5 CHAIRMAN PENHOET: SO LET'S SEE THEN, A
6 CASE MIGHT OCCUR, THEN, WHERE IN THE COURSE OF
7 CARRYING OUT A PROJECT WITH OUR FUNDING, AN INVENTOR
8 COULD CONCEIVE A PROJECT -- COULD CONCEIVE AN
9 INVENTION AND THEN SAY -- WELL, THIS PROBABLY DOES
10 HAPPEN ALL THE TIME. I'M GOING TO GO ACROSS THE
11 STREET AND REDUCE THIS TO PRACTICE AND, THEREFORE, I
12 HAVE NO OBLIGATION TO CIRM. SO THAT WOULD CAUSE US
13 A PROBLEM, I THINK.

14 DR. PRIETO: I WOULD THINK SO.

15 MS. STREITZ: I WOULD LIKE TO THINK OUR
16 INVENTIONS ARE NOT THAT DUPLICATIVE.

17 CHAIRMAN PENHOET: BUT IT HAS TO BE THE
18 SAME INVENTOR, RIGHT? I MEAN CONCEPTION AND
19 REDUCTION TO PRACTICE, IF THE INVENTOR'S NOT -- IF
20 IT'S NOT, YOU WON'T GET A PATENT.

21 MS. STREITZ: REDUCED TO PRACTICE BY A
22 NONINVENTOR. I MEAN AND THAT'S ONE OF THE
23 DIFFICULTIES. THE REDUCTION TO PRACTICE --

24 CHAIRMAN PENHOET: WOULD THIS BE CAUGHT TO
25 DO THIS BY THE INVENTOR.

BARRISTERS' REPORTING SERVICE

1 MS. STREITZ: PAIR OF HANDS.

2 CHAIRMAN PENHOET: WELL, THEN IT WOULD BE
3 AN INVENTOR. PAIR OF HANDS IS NOT AN INVENTOR BY
4 DEFINITION.

5 MS. STREITZ: NO. NO, BUT THE RIGHTS
6 WOULD BE IMPLICATED.

7 MR. STRATTON: IT DOESN'T WORK WELL THE
8 OTHER WAY AROUND EITHER WHERE YOU HAVE --

9 DR. PRIETO: I CAN'T HEAR.

10 CHAIRMAN PENHOET: I'M SORRY. WE'LL GET
11 THE SPEAKER TO THE FRONT OF THE ROOM.

12 MR. STRATTON: SORRY. IT WAS JUST A SMALL
13 POINT. IT DOESN'T WORK WELL THE OTHER WAY AROUND
14 EITHER WHERE YOU HAVE INDUSTRY SPONSORING RESEARCH
15 WHEN THERE'S CONCEPTION AND THEN CIRM-SPONSORED
16 RESEARCH REDUCTION TO PRACTICE, RIGHT, BECAUSE THEN
17 THE INDUSTRY SPONSOR THAT JUST PUT THE MONEY IN
18 GETS, IF YOU WILL, TAINTED BY THE OBLIGATIONS
19 WITHOUT ANY CONTROL OVER THE -- WHAT YOU'D HAVE
20 TO --

21 MS. STREITZ: BOTH OF YOU VOTED TO PAY FOR
22 IT THEMSELVES.

23 MR. SHEEHY: YOU READ MY MIND.

24 MR. STRATTON: RIGHT. BUT THE PROBLEM IS
25 IT'S A VERY FLUID DYNAMIC RELATIONSHIP BETWEEN

BARRISTERS' REPORTING SERVICE

1 INDUSTRY SPONSORS AND ACADEMIA, RIGHT. AND I DO
2 UNDERSTAND AND APPRECIATE THE INTEREST IN TRYING TO
3 CAP TO BROADEN THAT. BUT PLEASE THINK ABOUT WHAT'S
4 WORKABLE IN REALITY. RIGHT. AND AGAIN, THAT WAS
5 WHAT WAS VERY NICE ABOUT THE REGS BEFORE. PATENT
6 INVENTION, VERY CLEAR. REDUCED TO PRACTICE UNDER
7 THAT RESEARCH AND DATA THAT'S USED FOR A CLINICAL
8 TRIAL. RIGHT. WHEN YOU THROW IN EVERYTHING ELSE,
9 IT BASICALLY MEANS CIRM MONEY IN, YOU DON'T TOUCH
10 IT. RIGHT. BECAUSE THE RISK THAT SOMEHOW IT WILL
11 TAIN THE OVERALL PROCESS WITHOUT US REALLY KNOWING
12 WHAT THE BENEFIT IS MAKES IT VERY CHILLING.

13 NO PREDICTIONS HERE OBVIOUSLY, BUT I
14 APPRECIATE YOUR CONSIDERATION.

15 CHAIRMAN PENHOET: SO LET'S TAKE A
16 NIGHTMARE. ONE OF YOUR GUYS GOES TO UCSF AND DOES
17 AN EXPERIMENT FOR A WEEK AND LEARNS HOW TO -- I
18 DON'T KNOW -- CULTURE A CERTAIN KIND OF CELLS WHILE
19 THEY'RE THERE. IT'S NOT A PATENTED INVENTION; IT'S
20 A PIECE OF KNOW-HOW. GOES BACK TO YOUR COMPANY AND
21 USES THIS KNOW-HOW TO DO SOMETHING. THAT'S THE KIND
22 OF THING YOU'RE AFRAID WOULD HAPPEN AND, THEREFORE,
23 CONTAMINATE YOUR WHOLE COMPANY BECAUSE A GUY SPENT A
24 FEW DAYS AT UCSF.

25 MR. STRATTON: ONE AMONG MANY PONDERABLE,

BARRISTERS' REPORTING SERVICE

1 POSSIBLE. THEY'RE RESULTS, I ACKNOWLEDGE. BUT
2 THAT'S WHY CERTAINTY IS WHAT WE CRAVE.

3 CHAIRMAN PENHOET: I THINK MAYBE DUANE HAS
4 THE ANSWER, WHICH IS IF IT'S INSIDE REVENUES, IT
5 COUNTS. AND IF IT'S NOT INSIDE, MAYBE WE'RE TRYING
6 TO GO TOO FAR WITH TRYING TO SWEEP IN KNOW-HOW AND
7 TRADE SECRETS AND ALL THE REST OF THE STUFF BECAUSE
8 IT DOES EXACERBATE THIS COLLABORATION PROBLEM, I
9 THINK. THAT'S WHAT PEOPLE HAVE BEEN REALLY WORRIED
10 ABOUT.

11 MS. KOCH: IT MIGHT BE TWO SEPARATE
12 ISSUES, ED, THOUGH. TECHNOLOGY ON THE ONE HAND
13 BEING ONE ISSUE AND CONCEIVED AND REDUCED TO
14 PRACTICE, WHICH IS THE CLASSIC DEFINITION OF THE
15 INVENTION OF A PATENTABLE INVENTION. SO THIS IS A
16 SEPARATE ISSUE THAN WHAT WE JUST GOT DONE WRESTLING,
17 AND I THINK WE SHOULD THINK OF THEM SEPARATELY.

18 MR. SHEEHY: I TEND TO AGREE WITH YOUR
19 POINT FOR THE DEFINITION, THE OTHER ONE. BUT ON THE
20 INVENTION I TEND TO AGREE WITH YOU. FOR THE
21 DEFINITION, TECHNOLOGY, CIRM-FUNDED TECHNOLOGY AND
22 CIRM FUNDING, THAT IS SORT OF A NEW DEFINITION. I
23 DO THINK THOSE MAY BE PROBLEMATIC. IF THIS IS THE
24 CLASSIC DEFINITION, IT'S WITHIN BAYH-DOLE.

25 I DON'T -- IT'S NOT CLEAR -- I MEAN THE

BARRISTERS' REPORTING SERVICE

1 SEPARATION, I JUST DON'T -- YOU REALLY THINK THAT IF
2 WE PAY SOMEBODY TO COME UP WITH THE IDEA AND THEY
3 TAKE IT SOMEWHERE ELSE TO GET IT DEVELOPED, WE HAVE
4 NO CALL ON IT? AND, YOU KNOW, JUST THE ONEROUSNESS
5 THAT KEEPS BEING ASCRIBE TO REALLY OUR COVENANTS,
6 RIGHT, OUR MARCH-IN WHICH ARE NOT -- YOU KNOW,
7 THEY'RE JUST NOT THE BOOGIE MAN EVERYBODY KEEPS
8 SAYING THAT THEY ARE.

9 AND THE REAL QUESTION, AS DUANE HAS NOTED,
10 IS THE REVENUE, AND NOBODY IS HERE SCREAMING ABOUT
11 HAVING TO GIVE US REVENUE. THEY'RE SCREAMING ABOUT
12 ALL THESE -- THE BOOGIE MAN. AND THE BOOGIE MAN
13 ISN'T A BOOGIE MAN. I JUST DON'T BELIEVE THE IDEA
14 THAT YOU HAVE TO GIVE A PROFITABLE PREFERENTIAL
15 PRICE TO CALIFORNIA BUYERS OF GOODS OF THESE
16 PRODUCTS, AND THAT YOU HAVE TO COME UP WITH SOME
17 NOTION OF SOME SORT OF ACCESS PLAN FOR SOME SUBSET
18 OF CALIFORNIA'S UNINSURED IN THE SCENARIO WHERE WE
19 DON'T HAVE SOME FORM OF HEALTH INSURANCE FIVE TO TEN
20 YEARS FROM NOW WHEN THESE PRODUCTS ARE ACTUALLY
21 GOING TO BE SELLING. I MEAN IT'S JUST NOT
22 FRIGHTENING ME. IT'S NOT TERRIFYING ME.

23 AND THE MARCH-IN RIGHTS ARE SO CLOSE TO
24 WHAT'S IN BAYH-DOLE, WHICH HAVE NEVER BEEN FULLY
25 ENFORCED AND IN ALL LIKELIHOOD WON'T BE STRONGLY

BARRISTERS' REPORTING SERVICE

1 ENFORCED IN CALIFORNIA. AND, AGAIN, THESE ARE LIKE
2 STRAWMEN, AND THOSE ARE NOT THE PARTS OF THIS POLICY
3 THAT SHOULD BE SO TERRIFYING. AND, YOU KNOW,
4 COMPANIES ARE APPLYING FOR OUR GRANTS RIGHT NOW
5 UNDER OUR EXISTING POLICY. AND WE HAVE THOSE IN
6 THERE AND THEY'RE NOT SCARING THEM, SO AND YOU GUYS
7 HAVE DECIDED NOT TO, AND YOU MAY DECIDE NEVER TO,
8 WHICH, YOU KNOW, IS FINE -- I MEAN THAT'S HOW IT
9 GOES.

10 MR. ROTH: ED, I'M GOING TO HAVE TO FALL
11 OFF. SORRY, GUYS.

12 CHAIRMAN PENHOET: WELL, I THINK WE'VE
13 COVERED A LOT OF GROUND. AND, DUANE, AS USUAL,
14 YOU'VE BEEN A GOOD CONTRIBUTOR TO THIS MEETING.
15 THANK YOU.

16 MR. ROTH: THANK YOU ALL.

17 MS. STREITZ: CAN I COMMENT ON THAT? SO
18 MAYBE -- SO WE ACTUALLY AS A SYSTEM HAVE TALKED
19 ABOUT THE CONCEIVED OR REDUCED TO PRACTICE ISSUE
20 EXTENSIVELY IN THE LAST YEAR BECAUSE COMPANIES --

21 CHAIRMAN PENHOET: IRRESPECTIVE OF OUR --

22 MS. STREITZ: IRRESPECTIVE OF CIRM BECAUSE
23 WE'RE STARTING TO SEE PEOPLE ASK US FOR IT MORE, AND
24 WE'RE VERY CONCERNED ABOUT IT. AND THE ISSUE IS
25 REALLY ONE OF THE ADMINISTRATIVE BURDEN OF THE

BARRISTERS' REPORTING SERVICE

1 PATENT APPLICATIONS. WHEN WE ENTER INTO AN
2 AGREEMENT WITH ANOTHER ENTITY, WE FULLY INTEND TO
3 MEET OUR OBLIGATIONS. WHEN WE HAVE A LINGERING
4 FORWARD REACHING OBLIGATION, THAT'S A REALLY HARD
5 THING TO DO. SO NOW WE HAVE A RESEARCHER WHO'S
6 CONCEIVED OF AN INVENTION UNDER CIRM FUNDING. WE
7 HAVE TO LIMIT THEIR FUNDING SOURCES FOREVER UNTIL
8 THAT INVENTION IS REDUCED TO PRACTICE OR UNTIL THEY
9 GO OFF ON A COMPLETELY DIFFERENT LINE OF RESEARCH.

10 SO THERE WILL BE INDUSTRY FUNDING. THERE
11 WILL BE COMPANIES WHOSE TERMS OF FUNDING CONFLICT
12 WITH CIRM'S, AND WE HAVE TO WATCH FOR THAT AND
13 MANAGE THAT INVENTOR FOREVER AND RESTRICT THEIR
14 FUTURE FUNDING SOURCES. AND THAT'S ACTUALLY OUR
15 BIGGEST CONCERN, ESPECIALLY WHEN IT'S A YOUNG
16 RESEARCHER, A GRAD STUDENT, A POST-DOC, MAYBE A NEW
17 FACULTY MEMBER.

18 SO JUST SOMETHING TO THINK ABOUT. JUST
19 THE NEVER ENDING NATURE OF THAT REDUCTION TO
20 PRACTICE.

21 CHAIRMAN PENHOET: THE OTHER LANGUAGE --
22 THIS LANGUAGE SAYS THAT IT NEEDS TO BE A THIRD
23 PARTY. WE WOULD BENEFIT IF IT'S CONCEIVED IN OUR
24 SHOP AND REDUCED TO PRACTICE IN THEIR SHOP.

25 MS. STREITZ: RIGHT.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN PENHOET: THE OTHER WAY -- SO
2 THERE'S A TRANSFER OF VALUE. IN THAT CASE BOTH
3 PARTIES WOULD BE PRESUME -- THE PRESUMPTION HERE
4 WHEN IT COMES TO REVENUE SHARING, THE OTHER PARTY
5 WOULD HAVE CONTRIBUTED SOME MONEY TO THE REDUCTION
6 TO PRACTICE IF IT'S NOT US. RIGHT. SO THEN THEY
7 ONLY HAVE TO PAY PROPORTIONAL PARTS.

8 MS. STREITZ: REVENUE SHARING ISN'T THE
9 ISSUE BECAUSE THAT'S OUR OBLIGATION IRRESPECTIVE OF
10 OUR OTHER -- YOU KNOW, IF WE HAVE -- IF A COMPANY
11 WERE TO FUND US AND NOT CARE THAT THERE WAS CIRM
12 FUNDING INVOLVED.

13 THE REPORTER: SOMETHING IS RUBBING
14 AGAINST THE MICS HERE.

15 MS. STREITZ: THAT'S NOT THE ISSUE. THE
16 ISSUE IS THAT SOME OF THE OBLIGATIONS WILL CONFLICT
17 WITH SOME SOURCES OF FUNDING. AND IN ORDER TO AVOID
18 ENTERING INTO A CONFLICTING OBLIGATION, WE'RE GOING
19 TO HAVE TO MANAGE THAT -- ALL THOSE RESEARCH
20 PARTICIPANTS' FUTURE FUNDING FOR AN INDEFINITE
21 AMOUNT OF TIME.

22 CHAIRMAN PENHOET: SO WHAT YOU'RE TELLING
23 US IS YOU'RE GOING TO, NO. 1, LOBBY TO CHANGE
24 BAYH-DOLE SO THAT IT ONLY TALKS ABOUT REDUCTION TO
25 PRACTICE AND, NO. 2, REQUEST OF ALL YOUR OTHER

BARRISTERS' REPORTING SERVICE

1 COLLABORATORS THAT THEY ONLY GET RIGHTS IF IT'S
2 REDUCED TO PRACTICE. YOU'RE GOING TO GET RID OF
3 CONCEIVE THE INVENTION ALTOGETHER?

4 MS. STREITZ: YOU MEAN --

5 CHAIRMAN PENHOET: YOU'RE ALWAYS GOING TO
6 HAVE A BIAS IN SOMEBODY'S FAVOR OR OTHER.

7 MS. STREITZ: RIGHT. SO THERE WERE TWO
8 QUESTIONS THERE. ONE, IS, NO, WE'RE NOT GOING TO
9 LOBBY TO CHANGE BAYH-DOLE BECAUSE THAT WOULD BE
10 IMPRACTICAL. BUT, AS I SAID EARLIER, THOSE
11 OBLIGATIONS ARE RELATIVELY BENIGN. WE ACTUALLY DO
12 IN OUR OTHER FUNDING -- I MEAN AS LONG AS WE'RE
13 KEEPING EVERYBODY ELSE CONFINED TO CONCEIVED AND
14 REDUCED TO PRACTICE, WE'RE NOT GOING TO HAVE AN
15 ISSUE. WHERE WE CAN, WE DO SAY SUBJECT TO OUR LEGAL
16 ABILITY TO DO ANYTHING ELSE WE SAID WE'RE GOING TO
17 DO IN THE AGREEMENT OR SUBJECT TO FEDERAL
18 OBLIGATIONS IF THEY KICK IN. SO THAT WAS THE ONE.

19 YOUR OTHER ONE WAS?

20 CHAIRMAN PENHOET: IF I MADE A SPONSORED,
21 I AS A THIRD PARTY TO A SPONSORED RESEARCH AGREEMENT
22 TO YOU TODAY, WHAT DOES YOUR TYPICAL AGREEMENT SAY
23 ABOUT REDUCED TO PRACTICE OR CONCEIVED AND/OR
24 REDUCED TO PRACTICE UNDER MY FUNDING?

25 MS. STREITZ: YOU HAVE RIGHTS TO

BARRISTERS' REPORTING SERVICE

1 INVENTIONS THAT WE CONCEIVE AND REDUCE TO PRACTICE
2 UNDER YOUR FUNDING.

3 CHAIRMAN PENHOET: SO YOU'RE SAYING CIRM
4 OUGHT TO BE DIFFERENT THAN THE REST OF YOUR
5 GRANTEES?

6 MS. STREITZ: NO, ACTUALLY.

7 MS. KOCH: BAYH-DOLE IS DIFFERENT, AND SHE
8 DOESN'T WANT CIRM TO BE DIFFERENT.

9 CHAIRMAN PENHOET: NO. SHE SAID --

10 MS. STREITZ: BAYH-DOLE IS CONCEIVED OR.
11 EVERYBODY ELSE IS CONCEIVED AND.

12 CHAIRMAN PENHOET: CONCEIVED AND.
13 EVERYBODY. SO THIS IS -- YOU'RE MAKING A
14 REPRESENTATION TO US THAT MOST OF YOUR AGREEMENTS
15 TODAY SAY CONCEIVED AND REDUCED TO PRACTICE.

16 MS. STREITZ: THAT'S HOW WE TRY TO MANAGE
17 OUR OBLIGATIONS.

18 CHAIRMAN PENHOET: I SEE.

19 MS. KOCH: WENDY, CAN I JUST ASK A
20 QUESTION BECAUSE I UNDERSTAND THE LOGISTICS, BUT I'M
21 HAVING A HARD TIME UNDERSTANDING WHY THIS IS A
22 FOREVER PROBLEM AND ESPECIALLY TROUBLESOME IN THE
23 CASE OF THE YOUNG SCIENTISTS WHEN UNDER THE PATENT
24 LAWS, ONCE YOU CONCEIVE, YOU HAVE AN OBLIGATION TO
25 REDUCE TO PRACTICE WITH DUE HASTE. I MEAN YOU HAVE

BARRISTERS' REPORTING SERVICE

1 TO REASONABLY PURSUE. AND SO THE NOTION THAT
2 SOMEONE WOULD CONCEIVE AND THEN SIT ON A VALUABLE
3 INVENTION AND NOT REDUCE TO PRACTICE FOR THE
4 INDEFINITE FUTURE WOULD CONTAMINATE THEIR ABILITY TO
5 GET FUNDING, AND THAT SEEMS UNLIKELY TO ME.

6 MS. STREITZ: UNDER BAYH-DOLE WE HAVE TO
7 MOVE FORWARD WITH, YOU KNOW, NOT HASTE, BUT
8 PROMPTLY, WHATEVER. UNDER PATENT LAW, THE PATENT
9 LAW DOESN'T CARE WHEN WE REDUCE TO PRACTICE IF WE
10 EVER REDUCE TO PRACTICE. YOU CAN'T GET A PATENT
11 UNTIL IT HAS BEEN REDUCED TO PRACTICE.

12 MS. KOCH: YOU CAN'T GET A PATENT UNTIL
13 IT'S REDUCED TO PRACTICE --

14 CHAIRMAN PENHOET: I THINK YOU HAVE TO --

15 MS. KOCH: AND YOU HAVE TO CONCEIVE AND
16 REDUCE TO PRACTICE IN ORDER TO GET YOUR PRIORITY.

17 MS. STREITZ: THAT'S RIGHT.

18 MR. STRATTON: THERE'S NO TIME LIMIT.

19 MS. KOCH: THERE'S NO TIME LIMIT, BUT IN
20 TERMS OF GETTING A PATENT THAT'S ENFORCEABLE AND
21 MEANINGFUL WITH A GOOD PRIORITY DATE, THERE'S EVERY
22 INTENT WRITTEN INTO THE PATENT LAWS TO PROCEED WITH
23 DUE HASTE TO REDUCE TO PRACTICE THINGS THAT YOU
24 CONCEIVE OF. SO THE CONCEPT THAT THAT IS A FOREVER
25 PROBLEM FOR YOU TO MANAGE IN THE CASE OF A YOUNG

BARRISTERS' REPORTING SERVICE

1 SCIENTIST, THAT'S NOT MAKING A LOT OF SENSE TO ME.

2 MS. STREITZ: WE'RE A RESEARCH
3 INSTITUTION, AND OUR GOAL IS NOT FIRST AND FOREMOST
4 TO OBTAIN PATENTABLE INVENTIONS AND DO SOMETHING
5 WITH THEM. OUR GOAL FIRST AND FOREMOST IS TO HELP
6 OUR RESEARCHERS CONDUCT THE RESEARCH.

7 CHAIRMAN PENHOET: SO DO YOU HAVE AN
8 AFFIRMATIVE REQUIREMENT OF YOUR FACULTY THAT THEY
9 DISCLOSE TO YOU CONCEPTION?

10 MS. STREITZ: WE DO. DO WE THINK THEY
11 FOLLOW IT ALL THE TIME?

12 CHAIRMAN PENHOET: NO. I KNOW THEY DON'T.

13 MS. STREITZ: YES, WE DO.

14 CHAIRMAN PENHOET: AND THEY'RE SUPPOSED
15 TO.

16 MS. STREITZ: IT'S REQUIRED UNDER
17 BAYH-DOLE. SO EVEN WITH FEDERAL FUNDING, THERE'S
18 SUPPOSED TO DISCLOSE IT.

19 DR. PRIETO: I HAVE A QUESTION. IF WE PUT
20 IN THAT SORT OF LANGUAGE, THOUGH, DON'T WE GIVE
21 PEOPLE AN INCENTIVE TO REDUCE TO PRACTICE ELSEWHERE
22 TO AVOID THAT OBLIGATION TO US?

23 MS. KOCH: UNDER THE REGULATIONS AS THEY
24 EXIST, BECAUSE CONCEPTION AND REDUCTION TO PRACTICE
25 ARE BOTH REQUIRED, THERE IS, IF SOMEONE WERE TO BE

BARRISTERS' REPORTING SERVICE

1 NEFARIOUS AND INCENTED TO DO ONLY ONE ON OUR WATCH,
2 AND WHAT THIS PROPOSED REGULATION WOULD DO WOULD BE
3 TO ELIMINATE THAT INCENTIVE. IT WOULD -- EITHER ONE
4 WOULD BE ENOUGH TO FOLD IN OUR OBLIGATIONS.

5 CHAIRMAN PENHOET: IT'S VERY HARD TO PROVE
6 WHEN THE CONCEPTION OCCURRED, BUT THEY WOULD HAVE TO
7 ATTEST IN THEIR PATENT FILINGS ABOUT WHEN THE
8 CONCEIVED THE INVENTION. SO THERE WOULD BE A DATE,
9 SOMEBODY SOMEPLACE WOULD PEG A DATE. BUT, YOU KNOW,
10 I THINK YOU MAKE SOME POINTS WORTH CONSIDERING.
11 THANK YOU.

12 OKAY. WHERE ARE WE? RELATIONSHIP TO
13 GRANTEE, WHAT KIND OF AFFILIATION? WELL, THIS IS
14 BACK TO OUR DIAGRAM. WE'RE TRYING TO DEFINE HERE
15 WHO'S A PARTY TO OUR AGREEMENT WITH THE INSTITUTION.
16 AND IT'S BASICALLY A CONCEPT OF AN AFFILIATE HERE.
17 PARTNERSHIP DOES NOT MEAN A COLLABORATION IN THE
18 SECOND SENSE OF THE WORD WE'RE USING COLLABORATION.
19 IT'S A FORMAL LEGAL PARTNERSHIP THAT WE'RE REFERRING
20 TO. SO IT'S JUST TRYING TO MAKE SURE WE UNDERSTAND
21 WHAT GRANTEE MEANS, WHAT THE SCOPE OF A GRANTEE IS
22 IN TERMS OF THEIR VARIOUS PARTIES WILL BE UNDER THE
23 TENT.

24 ANY COMMENTS ABOUT THAT? I KNOW WE HAVE
25 TO BE CAREFUL WITH THIS LANGUAGE NOT TO

BARRISTERS' REPORTING SERVICE

1 INADVERTENTLY SWEEP IN PEOPLE WHO SHOULDN' T BE
2 THERE, BUT OKAY.

3 AND THEN REVENUE SHARING, WELL, WE'VE BEEN
4 TALKING ABOUT THIS FOR ALMOST THE WHOLE MEETING.
5 SHOULD IT REACH ONLY CIRM-FUNDED PATENTED
6 INVENTIONS? THE REVENUE STATEMENT DOES ADDRESS THIS
7 ISSUE.

8 MS. KOCH: THE ASPECT THAT WE HAVEN' T
9 DISCUSSED SO FAR, ED, IS THAT THE PROPOSAL IS TO
10 EXPAND OUR NET, OUR TENT, TO INCLUDE REVENUES THAT
11 ARE DERIVED FROM FOREIGN PATENTS AND FOREIGN
12 LICENSING ACTIVITIES. I THINK INADVERTENTLY, BY
13 USING THE UNITED STATES CODE TO DEFINE WHAT' S A
14 PATENT, YOU'VE INADVERTENTLY EXCLUDED ALL THE
15 FOREIGN PATENTS AND SUCH THAT OBVIOUSLY GENERATE
16 POTENTIAL REVENUE.

17 CHAIRMAN PENHOET: I BELIEVE THAT WAS AN
18 OVERSIGHT. I DON' T THINK THERE WAS ANY INTENTION
19 THAT WE JUST GET REVENUES FROM U. S. PATENTS.

20 ANYBODY ELSE HAVE A DIFFERENT VIEW OF
21 THAT? WE'VE AGREED ON A CHANGE. WE'VE AGREED ON
22 MORE THAN ONE.

23 AND THEN FINALLY, WE'RE ON THE LAST SLIDE.
24 MARCH-IN, SHOULD THE EXISTING MARCH-IN PROVISION FOR
25 FAILURE TO ABIDE REQUIREMENTS OF PUBLIC USE BE

BARRISTERS' REPORTING SERVICE

1 ELIMINATED. AND THE ANSWER IS YES. SO YOU WANT TO
2 GIVE US SOME BACKGROUND ON YOUR CONCLUSION THERE?

3 MR. TOCHER: MAYBE I'LL GO FIRST AND,
4 NANCY, JUMP IN AS YOU LIKE. THE EXISTING PROVISION
5 AS WE HAVE TRIED, AS CLOSELY AS POSSIBLE, TRIED TO
6 FOLLOW OR MIRROR BAYH-DOLE'S MARCH-IN PROVISIONS,
7 THIS IS AN ELEMENT OF THE FAILURE TO SATISFY
8 REQUIREMENTS FOR PUBLIC USE DRAWN FROM BAYH-DOLE.

9 IN BAYH-DOLE, HOWEVER, THE MECHANISMS FOR
10 DESCRIBING WHAT A PUBLIC USE ARE ARE DELEGATED TO
11 AGENCIES WITHIN THE FEDERAL GOVERNMENT. AND AS YOU
12 KNOW, WE DON'T HAVE ANYTHING TO GO ON YET. I THINK
13 IN RETROSPECT IT PROBABLY DOESN'T ADD A WHOLE LOT
14 SUBSTANTIVELY TO THE GROUNDS THAT CIRM WOULD
15 ENVISION EXERCISING MARCH-IN FOR. BUT WHAT IT DOES
16 ADD IS PROBABLY A LITTLE UNCERTAINTY OR CONFUSION AS
17 TO WHEN THAT TRIGGER WOULD BE.

18 AND SO THINGS LIKE ALL IN ALL, WHILE WE
19 WERE TAKING A LOOK AT MARCH-IN, YOU KNOW, WE WERE
20 TAKING A LOOK AT ALL OF THE REGULATIONS TO FIND WAYS
21 TO TIGHTEN AND REMOVE AMBIGUITIES TO THE CANDIDATE
22 FOR DOING SO HERE.

23 CHAIRMAN PENHOET: ANY COMMENTS ABOUT
24 THAT?

25 MR. SHEEHY: SO YOU'RE TALKING ABOUT NO.

BARRISTERS' REPORTING SERVICE

1 3, RIGHT?

2 MR. TOCHER: THAT'S RIGHT. SUBDIVISION
3 (B)(3).

4 MR. SHEEHY: AND YOU'D KEEP FOUR, RIGHT?

5 MR. TOCHER: YEAH.

6 MR. SHEEHY: PUBLIC USE, I THINK IT'S
7 FEARFUL AND IT DOESN'T -- I'D BE TERRIFIED BECAUSE
8 IT'S UNDEFINABLE. AND, YOU KNOW, THE FEDERAL
9 LEVEL --

10 CHAIRMAN PENHOET: DEFINED BY THIRD
11 PARTIES, NOT US.

12 MR. SHEEHY: YEAH. AND SO IT SOUNDS GOOD,
13 BUT I DON'T KNOW IF IT HAS ANY -- I COULD UNDERSTAND
14 IF POTENTIAL GRANTEES FELT IT WAS -- MIGHT
15 POTENTIALLY BE AN EXCUSE FOR MISCHIEF.

16 CHAIRMAN PENHOET: OKAY.

17 MR. SHEEHY: PLUS WE HAVE FOUR, WHICH, YOU
18 KNOW, THAT MIGHT BE A LEGITIMATE. THE GOVERNOR GETS
19 UP AND SAYS THERE'S SOMETHING TERRIBLE, A FLU
20 EPIDEMIC, SARS. I DO THINK WE NEED THAT COVERAGE.

21 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM
22 THE COMMITTEE ON THIS ISSUE? ANY COMMENTS FROM THE
23 PUBLIC?

24 MR. VALENCIA: JUST A LONG HEALTH QUESTION
25 NOW THAT THERE'S CONSOLIDATION THAT IS NOT BUILT IN

BARRISTERS' REPORTING SERVICE

1 WITH REGARD TO THE APPEAL, WHAT THE EFFECT OF THE
2 APPEAL IS. I THINK IF IT'S NOT IN THERE, THERE'S
3 NOT A TOLLING EFFECT FROM THE APPEAL. BUT IT'S NOT
4 CLEAR WHETHER IF ONE FILES AN APPEAL FROM THE
5 MARCH-IN NOTICE OF INTENT BY CIRM, WHAT EFFECT THAT
6 HAS. YOU'RE CLAIMING TO NOTIFY THE PRESIDENT OR THE
7 EXECUTIVE OFFICER WITHIN A CERTAIN TIMEFRAME OF A
8 PENDING ICOC HEARING, DOES THAT HAVE AN EFFECT ON
9 THE CIRM INTENT TO MARCH IN OR NOT. IT'S NEVER BEEN
10 RESOLVED. IT WASN'T A FORTHRIGHT ISSUE THE FIRST
11 GO-ROUND, BUT NOW THAT WE'RE CONSOLIDATING AND
12 LOOKING FORWARD, IT'S ONE THAT WARRANTS --

13 CHAIRMAN PENHOET: MORE SPECIFICITY AROUND
14 THE PROCEDURE IS WHAT YOU'RE ASKING FOR. ALL RIGHT.

15 DO WE HAVE ANY OTHER ISSUES? IT'S NOT --
16 I'D LOVE SOMEONE, SCOTT OR NANCY, TO SUMMARIZE WHAT
17 WE'VE ACCOMPLISHED TODAY. MAYBE WE CAN GO THROUGH
18 THESE SO WE KNOW WHAT ISSUES WE HAVE TO WORK ON,
19 WHERE WE REACHED AGREEMENT.

20 MS. KOCH: OTHER THAN GIVING YOU ME A
21 HEADACHE, WHAT HAVE WE ACCOMPLISHED? OKAY. I'LL
22 TAKE A SHOT, AND THEN YOU CAN ALL TAKE SHOTS AT ME.

23 THE REPORTER: JUST PLEASE WATCH THE
24 PAPERS.

25 MS. KOCH: WITH REGARDS TO THE LOAN

BARRISTERS' REPORTING SERVICE

1 PROGRAM, WE RECOGNIZE THAT WE NEED TO INTEGRATE AND
2 DEVELOP SOME IP POLICIES AS THE LOAN PROGRAM IS
3 DEVELOPED. AND WE JUST PUT THAT ON THE SIDE OF
4 SOMETHING ON OUR TICKING LIST.

5 WITH REGARD TO ACCESS PLANS, I THINK WE
6 AGREE --

7 CHAIRMAN PENHOET: WELL, WITH ONE CAVEAT,
8 WHICH IS I BELIEVE WE'VE AGREED THAT THE COVENANTS
9 WILL FOLLOW TO THE LOAN PROGRAM AND THE PAYBACK
10 PROVISIONS WILL NOT; IS THAT RIGHT? OKAY.

11 MS. KOCH: THANK YOU. WITH REGARD TO
12 ACCESS PLANS, ED, I THINK THAT WE WANTED TO ADD
13 SOMETHING WHICH INDICATED SOME AFFIRMATIVE
14 OBLIGATION, IS HOW YOU PUT IT, ON THE STATE NOT TO
15 IMPOSE MORE THAN THE THEN CURRENT INDUSTRY STANDARDS
16 AT THE TIME THAT THE ACCESS PLAN IS SUBMITTED FOR
17 CONSIDERATION AND SOMETHING WHICH SUGGESTED APPROVAL
18 WOULD NOT BE UNREASONABLY WITHHELD. I THINK THOSE
19 ARE THE THINGS THAT WE REACHED CONSENSUS ON.

20 WE TALKED ABOUT THE NEED TO CLARIFY THE
21 USE OF THE TERM "COLLABORATOR" AS YOU DESCRIBED, ED,
22 WHICH SOMETIMES IS USED IN THESE PROPOSALS AS BEING
23 THE PEOPLE WORKING AT THE GRANTEE INSTITUTION AND IS
24 SOMETIMES USED TO MEAN THE PEOPLE AT THE GRANTEE
25 INSTITUTION PLUS THOSE FROM OUTSIDE THE GRANTEE

BARRISTERS' REPORTING SERVICE

1 INSTITUTION. AND WE WILL FIND SOME OTHER WORDS WITH
2 THE HELP OF A FRIEND THAT YOU SEE, IF WENDY IS STILL
3 TALKING TO US AFTER THIS MEETING.

4 AND WE HAVE TO ADD SOMETHING TO CLARIFY
5 THAT WE UNDERSTAND THAT OUR GRANTEES AND THEIR
6 COLLABORATORS MAY WELL DEVELOP SEPARATE CONTRACTUAL
7 ARRANGEMENTS AMONG THEMSELVES, AND OUR UNDERSTANDING
8 IS THAT THOSE ARRANGEMENTS WILL NOT BE INCONSISTENT
9 WITH THE OBLIGATIONS OF OUR GRANTEES UNDER THE CIRM
10 IP REGULATIONS.

11 IN RESPONSE TO SOME QUESTIONS RAISED BY
12 STEM CELLS, INC., I THINK WE ALL AGREED THAT THE
13 MERE SUPPLYING OF MATERIALS TO A CIRM-FUNDED
14 RESEARCHER WOULD NOT DRAG THE MATERIAL SUPPLIER INTO
15 THE TENT. I THINK THAT THAT IS PRETTY CLEAR FROM
16 THE PROPOSED REGS AS THEY CURRENTLY READ, BUT I
17 THINK WE SHOULD GO BACK, HAVE A LOOK AT THAT, AND
18 MAKE SURE THAT THE WAY THAT WE ALL UNDERSTAND IT IS
19 ACTUALLY THE WAY THAT THE REGULATIONS WORK. AND
20 PERHAPS KEN WILL GIVE US SOME HELP IN FINDING ANY
21 AMBIGUITIES THAT ARE THERE.

22 I WROTE TO MYSELF IN PARTICULAR IN
23 RESPONSE TO SOME QUESTIONS THAT DUANE RAISED THAT WE
24 NEED TO MAKE SURE THAT THE REGS ARE CLEAR ABOUT WHAT
25 HAPPENS IN THE CASE OF A SALE OF A BUSINESS WHERE

BARRISTERS' REPORTING SERVICE

1 THE BUSINESS HAS RECEIVED CIRM FUNDING JUST TO MAKE
2 SURE THAT WE FOLLOW THE TECHNOLOGY WHERE IT GOES,
3 AND THE REVENUE STREAM THAT COMES FROM THAT COMES TO
4 US UNDER THE TERMS OF REGULATIONS.

5 WE HAD AN EXTENSIVE DISCUSSION ON THE
6 500,000 DEDUCTION AND THE DEDUCTION -- AND WHETHER
7 THERE SHOULD BE AN ADDITIONAL DEDUCTION FOR THE COST
8 OF PROSECUTING THE PATENTS AND/OR DEFENDING THE
9 PATENT. AND I THINK THE CONCLUSION WAS THAT WE
10 WOULD GIVE ALL GRANTEES, BOTH FOR-PROFIT AND
11 NOT-FOR-PROFIT, THE BENEFIT OF THE \$500,000
12 DEDUCTION AND ALLOW A DEDUCTION OF COSTS RELATING TO
13 PATENT PROSECUTION; IS THAT RIGHT?

14 CHAIRMAN PENHOET: I THINK SO.

15 MS. KOCH: AND WE ALSO SAID THAT THERE
16 WOULD BE PROPORTIONALITY OF THAT COST IF THERE WERE
17 ANOTHER CO-FUNDER FOR WHOM WE WERE GOING TO GRANT
18 PROPORTIONALITY WITH REGARD TO REVENUE SHARING.

19 ON THE ISSUE OF WHETHER WE SHOULD EXPAND
20 TO INCLUDE TECHNOLOGY AND KNOW-HOW, I DON'T THINK
21 THAT WE REACHED CONCLUSION ON THAT. AND THERE WERE
22 SEVERAL POSSIBILITIES CONSIDERED, ONE OF WHICH WAS
23 TO EXCLUDE -- NOT INCLUDE UNIVERSITIES WITHIN THAT.
24 THE OTHER IS NOT TO REACH THAT FAR FOR ANY GRANTEE
25 WHETHER IT'S FOR-PROFIT OR NOT. I THINK YOU WANTED

BARRISTERS' REPORTING SERVICE

1 TO HAVE FURTHER CONSIDERATION OF THAT ISSUE; AND IN
2 PARTICULAR IN THE CONTEXT OF MARCH-IN RIGHTS, NOTING
3 THAT THE UNIVERSITIES DON'T EVER EXCLUSIVELY LICENSE
4 OWN PATENTED TECHNOLOGY. KNOW-HOW AND SUCH HAD TO
5 DO WITH MARCH-IN RIGHTS IN LIGHT OF THAT.

6 CHAIRMAN PENHOET: I THINK THIS ONE ISSUE
7 PROBABLY PERVADES MORE SPACE IN THE DOCUMENT THAN
8 ANY OTHER ISSUE. SO I THINK THIS IS ONE WE HAVE TO
9 FOCUS ON GOING FORWARD TO TRY TO UNDERSTAND THE
10 RAMIFICATIONS OF WHAT IN THIS DOCUMENT IS THE
11 SOMEWHAT BROADER DEFINITION AND SCOPE OF WHERE WE
12 PUT OUR HANDS ON THINGS.

13 MS. KOCH: YOU DID REACH CONCLUSION WITH
14 REGARD TO THE PAYBACK PERCENTAGE ROYALTY IN THE
15 CONTEXT OF REVENUE SHARING, AND WE'RE GOING TO
16 ELIMINATE THE 2 TO 5 PERCENT RANGE AND MAKE IT 3
17 PERCENT, AS DUANE SUGGESTED.

18 AND HAD AN EXTENSIVE DISCUSSION ON WHETHER
19 WE SHOULD CHANGE OUR REGS TO BE TRIGGERED BY
20 ANYTHING THAT'S CONCEIVED AND/OR REDUCED TO
21 PRACTICE, WHICH WOULD BRING US IN LINE WITH
22 BAYH-DOLE, BUT ACCORDING TO THE UC SYSTEM, WOULD
23 MAKE US DIFFERENT THAN MANY OTHER FUNDERS.
24 EXTENSIVE DISCUSSION. I DON'T THINK WE RESOLVED
25 THAT ISSUE TODAY. WE NEED FURTHER CONSIDERATION.

BARRISTERS' REPORTING SERVICE

1 I THINK WE AGREED THAT WE ALWAYS INTENDED
2 TO AND WOULD SWEEP IN REVENUES FROM FOREIGN PATENTS,
3 FOREIGN GENERATED AND THE LIKE. AND WE GOT A
4 SUGGESTION, WHICH I THINK WE AGREED TO ACCEPT, THAT
5 WE SHOULD ADD SOME PROCEDURAL LANGUAGE IN THE
6 CONTEXT OF MARCH-IN RIGHTS ABOUT WHETHER THE FILING
7 OF AN APPEAL TO THE ICOC WOULD TOLL THE EXERCISE OF
8 A MARCH-IN OR NOT AND HOW THAT WOULD WORK.

9 THAT'S WHAT I HAVE ON MY TO-DO LIST.

10 MR. TOCHER: THE ONLY THING, PERHAPS I
11 JUST DIDN'T HEAR IT, WAS IN THE CONTEXT OF OUR
12 DEFINITION OF LICENSE REGARDING THE RIGHT TO MAKE,
13 USE, OR SELL.

14 MS. KOCH: THANK YOU. THANK YOU.

15 CHAIRMAN PENHOET: WHICH I BELIEVE WE'VE
16 AGREED UPON.

17 MR. SHEEHY: I THINK WE'RE ALL FINE. I
18 DON'T THINK ANYBODY OBJECTED.

19 MR. TOCHER: OTHER THAN THAT, YOU'VE GOT
20 EVERYTHING THAT I HAVE.

21 CHAIRMAN PENHOET: MAYBE I'LL ASK WENDY.
22 WENDY, PERHAPS IF YOU COULD WRITE US A LETTER
23 PERHAPS, PERHAPS SOME OF YOUR COLLEAGUES IN THE
24 MAJOR PRIVATES ON THIS ISSUE OF CONCEPTION AND/OR
25 REDUCTION TO PRACTICE IN TERMS OF MAKING SOME

BARRISTERS' REPORTING SERVICE

1 REPRESENTATION TO US ABOUT WHAT YOUR CURRENT
2 PRACTICE IS. IF PEOPLE AT STANFORD AND USC WANT TO
3 JOIN AND YOU, THAT WOULD BE FINE. WE'D BE GLAD TO
4 HEAR FROM THEM.

5 VERY GOOD SUMMARY, NANCY. THANK YOU. I
6 WOULD HAVE ATTEMPTED IT, BUT I KNEW I'D FAIL AFTER
7 THE FIRST ITEM, SO THAT'S WHY I ASKED YOU TO DO IT.
8 YOUNGER AND SMARTER.

9 ANY OTHER COMMENT AT THE END OF THIS
10 MEETING FROM ANYONE? FIRST OF ALL, THANK YOU TO THE
11 VARIOUS MEMBERS OF OUR TASK FORCE, BUT ALSO VERY
12 CONSTRUCTIVE INPUT FROM OUR SMALL AUDIENCE TODAY,
13 BUT NEVERTHELESS GOOD AUDIENCE. THANK YOU FOR
14 COMING FROM SACRAMENTO. AND I THINK WE'LL WRAP THIS
15 MEETING UP EARLY.

16 AND THEN WHAT DO WE HAVE TO LOOK FORWARD
17 TO? WHAT'S THE NEXT STEP? THERE WILL BE SOME
18 REVISIONS OF WHAT -- OF THE GROUND WE HAVE GAINED IN
19 THIS PROCESS.

20 MR. TOCHER: THAT'S RIGHT.

21 CHAIRMAN PENHOET: THEN WE'LL HIGHLIGHT
22 THE AREAS, JUST EXTRACT OUT OF THE DOCUMENT THOSE
23 AREAS WHERE WE STILL NEED FURTHER DISCUSSION
24 PRESUMABLY FOR ANOTHER MEETING OF THIS GROUP; IS
25 THAT RIGHT?

BARRISTERS' REPORTING SERVICE

1 MR. TOCHER: MR. CHAIRMAN, WE CAN BRING IT
2 BACK FOR ANOTHER GO-ROUND ON THESE ISSUES WHICH
3 HAVEN'T BEEN NAILED DOWN. AT SOME POINT, THEN, WE
4 WILL TAKE THAT WITH DRAFT LANGUAGE TO THE OAL TO
5 BEGIN THE FORMAL PROCESS OF GETTING PUBLIC FEEDBACK.

6 CHAIRMAN PENHOET: WHAT'S YOUR TARGET DATE
7 FOR OAL SO WE CAN BACK UP FROM THAT? WHEN WOULD YOU
8 LIKE TO HAVE IT IN PLACE? REMEMBER, OUR GOAL IS TO
9 HAVE THIS FINISHED BY THE TIME WE ACTUALLY MAKE SOME
10 DISEASE TEAM GRANTS. DR. OLSON, THAT WILL BE?

11 DR. OLSON: THE FALL OF NEXT YEAR.

12 CHAIRMAN PENHOET: THE FALL OF NEXT YEAR.
13 OKAY.

14 MR. TOCHER: WE HAVE SOME FLEXIBILITY, OF
15 COURSE. THE DATE THAT I AM WORKING WITH IS AN ICOC
16 ADOPTION AT ITS MARCH 2009 MEETING. IT MAY BE THAT
17 IN THE NEXT SHORT PERIOD, NAILING DOWN WHEN EXACTLY
18 THE FALL MEETING WOULD BE, WHEN THOSE NGA'S GET
19 SIGNED, IT COULD ACTUALLY GIVE US EVEN MORE
20 FLEXIBILITY SUCH AS JUNE -- A MAY MEETING.

21 MS. KING: A MARCH MEETING, AND I DON'T
22 KNOW HAVE IT RIGHT IN FRONT OF ME, END OF APRIL AND
23 THEN JUNE.

24 CHAIRMAN PENHOET: WELL, YOU KNOW, MY OWN
25 VIEW IS THERE'S NOT A LOT MORE HOMEWORK THAT'S COME

BARRISTERS' REPORTING SERVICE

1 OUT OF THIS. I THINK WE'VE GOT SOME DECISIONS TO
2 MAKE. I THINK WE SHOULD ALL THINK CAREFULLY ABOUT
3 THESE ITEMS IN FRONT OF US. AND IF YOU GUYS
4 WOULDN'T MIND SENDING TO THE COMMITTEE, BECAUSE MANY
5 OF OUR -- WE DO NOT HAVE A QUORUM TODAY, FOR ONE
6 THING, SO WE MADE THIS DECISION -- WE MADE SOME
7 DECISIONS WE ACTUALLY WEREN'T IN POWER TO MAKE FOR
8 THE WHOLE COMMITTEE, BUT I THINK WE HAVE A GOOD
9 CROSS SECTION OF THE COMMITTEE HERE.

10 MS. KING: A SENSE OF THE COMMITTEE.

11 CHAIRMAN PENHOET: THANK YOU VERY MUCH FOR
12 YOUR LANGUAGE AROUND THAT ISSUE. WE DID GET A SENSE
13 OF THE COMMITTEE FROM THIS MEETING.

14 MR. TOCHER: ONE THING I WOULD ADD ALSO,
15 ED, IS THAT THERE'S NOTHING THAT PREVENTS THE AGENCY
16 AND, IN FACT, IS ENCOURAGED TO PUT OUT A PUBLIC
17 COMMENT ALTERNATIVES FOR THE PUBLIC FOR THE PURPOSE
18 OF GETTING FEEDBACK. SO IT MAY BE HELPFUL, IN FACT,
19 THAT A BETTER USE OF THE TASK FORCE TIME WOULD BE
20 PUTTING OUT ON SOME OF THESE THORNIER ISSUES
21 ALTERNATIVE LANGUAGE THAT SOLICITS AND INVOKES
22 COMMENTS FROM THE PUBLIC THAT THEN THE TASK FORCE
23 CAN WEIGH AT THE END OF THAT FIRST COMMENT PERIOD.

24 CHAIRMAN PENHOET: AT ITS NEXT MEETING.

25 MR. TOCHER: THAT'S RIGHT.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN PENHOET: THAT'S A GOOD
2 SUGGESTION.

3 MS. KOCH: WERE YOU SAYING, ED, THAT YOU
4 WANTED, IN ADDITION, TO HAVE A MEMO TO ALL THE
5 COMMITTEE MEMBERS SORT OF EXPRESSING THE SUMMARY OF
6 HAPPENED HERE TODAY?

7 CHAIRMAN PENHOET: WE COULD HAVE JUST
8 TAPE-RECORDED WHAT YOU JUST SAID.

9 MS. KING: WE DID ACTUALLY. WE HAVE THE
10 TRANSCRIPT.

11 CHAIRMAN PENHOET: WE HAVE THE TRANSCRIPT.
12 SO IF WE CAN EXCERPT THE TRANSCRIPT AND EDIT THE
13 TRANSCRIPT OF WHAT NANCY JUST SAID, THAT'S -- I
14 FORGOT. THAT WOULD BE GREAT.

15 MS. KING: AND I THINK SENDING THEM THE
16 TIMELINE THAT SCOTT WAS JUST GOING THROUGH, BUT I
17 THINK THAT WOULD BE HELPFUL FOR THEM AS WELL.

18 CHAIRMAN PENHOET: THE POINT I WAS
19 STARTING TO MAKE IS ABOUT LITTLE NEW INFORMATION
20 BEING REQUIRED TO MAKE THESE DECISIONS. WHAT'S
21 REQUIRED TO MAKE THE DECISIONS, I DON'T SEE ANY
22 REASON TO DELAY THIS PROCESS UNDULY. SO I THINK WE
23 SHOULD MOVE FORWARD WITH SOME -- THANK YOU.

24 MR. TOCHER: THANK YOU, ED.

25 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM

BARRISTERS' REPORTING SERVICE

1 THE MEMBERS OF THE COMMITTEE, TASK FORCE? WELL,
2 THANK YOU ALL FOR PARTICIPATING.

3 DR. PRIETO: THANK YOU.

4 MS. KING: THANKS, EVERYBODY.

5 (THE MEETING WAS THEN CONCLUDED AT
6 4:47 P.M.)

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BARRISTERS' REPORTING SERVICE

REPORTER' S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE INTELLECTUAL PROPERTY TASK FORCE OF THE INDEPENDENT CITIZEN' S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING ON NOVEMBER 18, 2008, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.



BETH C. DRAIN, CSR 7152
BARRISTER' S REPORTING SERVICE
1072 BRISTOL STREET
SUITE 100
COSTA MESA, CALIFORNIA
(714) 444-4100