

BEFORE THE
INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE
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 ON THE AGENDA

DATE: JUNE 11, 2012
8:30 A.M.

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

BRS FILE NO.: 92432

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
CALL TO ORDER	3
ROLL CALL	3
CONSIDERATION OF PROPOSED AMENDMENTS TO THE INTELLECTUAL PROPERTY REGULATIONS, INCLUDING BUT NOT LIMITED TO REVENUE SHARING PROVISIONS AND DEFINITIONS.	4
PUBLIC COMMENT	NONE

BARRISTERS' REPORTING SERVICE

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

MONDAY, JUNE 11, 2012; 8:30 A.M.

MR. TOCHER: WE'RE BACK. AND MR. JUELSGAARD IS HERE, AND WE ALSO HAVE ELONA BAUM AND MATT PLUNKETT, JAMES HARRISON, MYSELF, AND A MEMBER OF THE PUBLIC. AND, STEVE, YOU CAN TAKE IT AWAY WHEN YOU'RE READY.

CHAIRMAN JUELSGAARD: THANKS, SCOTT.

MR. TOCHER: SURE.

CHAIRMAN JUELSGAARD: SO FIRST ORDER OF BUSINESS IS TO CALL THIS MEETING OF THE INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE TO ORDER. AND THE SECOND ITEM OF BUSINESS IS THE ROLL CALL OF THOSE PRESENT EITHER HERE OR ON THE LINE.

MR. TOCHER: ALL RIGHT. WE'LL DO THE ROLE. SUE BRYANT.

DR. BRYANT: PRESENT.

MR. TOCHER: MICHAEL GOLDBERG. STEVE JUELSGAARD.

CHAIRMAN JUELSGAARD: HERE.

MR. TOCHER: DUANE ROTH.

MR. ROTH: HERE.

MR. TOCHER: OS STEWARD. J.T.

CHAIRMAN THOMAS: HERE.

MR. TOCHER: ALL RIGHT. WE HAVE A QUORUM.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN JUELSGAARD: WONDERFUL. WELL,
2 THE ITEM OF BUSINESS THAT WE'RE GOING TO ADDRESS ARE
3 SOME REVISIONS TO OR PROPOSED REVISIONS TO SOME OF
4 THE REGULATIONS THAT WE HAVE GOVERNING THE
5 INTELLECTUAL PROPERTY AREA WITH RESPECT TO REVENUE
6 SHARING BOTH FOR NON-PROFIT INSTITUTIONS AS WELL AS
7 FOR-PROFIT ENTITIES.

8 AND SO I'M GOING TO TURN THE CALL OVER AT
9 THIS POINT TO ELONA TO JUST DESCRIBE, GENERALLY
10 SPEAKING, WHAT THESE PROPOSED REVISIONS PROVIDE FOR.

11 MS. BAUM: OKAY. THANK YOU, STEVE, FOR
12 THE OPPORTUNITY AND FOR MEMBERS OF THE SUBCOMMITTEE
13 FOR ALLOWING ME TO PROVIDE SOME BACKGROUND AND SOME
14 DETAIL ON WHAT THESE PROPOSED AMENDMENTS ARE. YOU
15 SHOULD HAVE ALREADY RECEIVED COPIES OF THE MEMO AND
16 THE ACTUAL MARKUP SEVEN TO TEN DAYS AGO.

17 SO JUST BY WAY OF BACKGROUND, LET ME
18 REMIND US ALL OF WHAT THE PROPOSITION REQUIRED IN
19 TERMS OF REGULATIONS AND IN PARTICULAR OUR REVENUE
20 SHARING REGULATIONS. AS YOU ALL REMEMBER, WE WERE
21 REQUIRED TO STRIKE A BALANCE THAT ENSURED THAT
22 CIRM'S REVENUE SHARING REGULATIONS, WHILE ALLOWING
23 CALIFORNIA TO BENEFIT FROM INVESTMENTS MADE IN THE
24 RESEARCH, WOULD NOT BE AT THE LEVEL WHERE IT WOULD
25 UNREASONABLY HINDER RESEARCH.

BARRISTERS' REPORTING SERVICE

1 AND IN 2010 SENATOR ALQUIST INTRODUCED SB
2 1064, WHICH CODIFIED THE REGULATIONS THAT WE HAVE
3 BEFORE US TODAY IN WHICH WE STRUCK A BALANCE. BUT
4 THOSE STATUTES SAID THAT IF THE ICOC DETERMINED THAT
5 IT NEEDED TO REBALANCE IN ORDER TO MEET THOSE
6 OBJECTIVES; I.E., ENSURING THAT CALIFORNIANS COULD
7 SHARE IN THE REVENUES, BUT AT THE SAME TIME ENSURING
8 THAT RESEARCH WAS NOT UNREASONABLY HINDERED, IT WAS
9 ABLE TO DO SO.

10 SO AGAINST THAT BACKDROP, I JUST WANT TO
11 GO THROUGH THE FIVE SUBSTANTIVE CHANGES. I'M NOT
12 GOING WORD BY WORD; BUT FROM A GLOBAL PERSPECTIVE,
13 THERE'S FIVE ESSENTIAL CHANGES THAT WE'RE MAKING.
14 AND I'LL JUST SUMMARIZE THEM BELOW.

15 SO THE FIRST ONE IS GEARED TO SECTION
16 100608 A. THAT'S OUR LICENSING REVENUE PROVISION.
17 AND WHAT WE'RE SEEKING TO DO IS SIMPLY SIMPLIFY IT,
18 SIMPLIFY THE PROPORTIONALITY ASPECT OF IT. FOR
19 INSTANCE, THE EXISTING REGULATIONS PROVIDE FOR 25
20 PERCENT OF THE REVENUES, LICENSING REVENUES, THAT A
21 GRANTEE EARNS TO BE SHARED WITH CALIFORNIA, BUT THAT
22 IS SUBJECT TO A REDUCTION BASED ON CALIFORNIANS'
23 CONTRIBUTION TO THE TOTAL COST OF THE PROJECT AS A
24 WHOLE, AND IT REQUIRES A LOT OF DETAILED
25 RECORDKEEPING.

BARRISTERS' REPORTING SERVICE

1 WHAT WE PROPOSE IS SOMETHING TO SIMPLIFY
2 IT.

3 MR. ROTH: ELONA, CAN I INTERRUPT ONE
4 SECOND? I THINK YOU JUST SAID SOMETHING THAT WASN'T
5 QUITE RIGHT. YOU SAID AS A WHOLE. IT'S DURING THE
6 PERIOD.

7 MS. BAUM: DURING THE PROJECT PERIOD, YES.
8 IT'S ALWAYS DURING THE PROJECT PERIOD. THANK YOU IF
9 I DIDN'T MAKE THAT CLEAR.

10 SO WHAT WE'RE PROPOSING TO DO TODAY IS TO
11 SIMPLIFY IT BY JUST CREATING TWO TIERS. IN OTHER
12 WORDS, IF CALIFORNIA FUNDED 50 PERCENT OR MORE OF
13 THE PROJECT, THEN THE ROYALTY SHARING RATE WOULD BE
14 25 PERCENT. IF CALIFORNIA OR CIRM, IN OTHER WORDS,
15 FUNDED LESS THAN 50 PERCENT OF THE PROJECT THAT
16 GENERATED THE IP, THEN IT WOULD BE AT A RATE OF 15
17 PERCENT. SO THAT'S JUST THE FIRST PROPOSED
18 SUBSTANTIVE CHANGE.

19 THE SECOND ONE THAT I WANT TO BRIEFLY
20 DESCRIBE IS TO MAKE US IN LINE WITH THE RECENTLY
21 APPROVED LAST LOAN ADMINISTRATION POLICY REGULATIONS
22 THAT WERE APPROVED BY THE BOARD. AND THAT IS TO
23 CHANGE THE DEFINITION OF LICENSING REVENUE WITH
24 RESPECT TO FOR-PROFIT GRANTEES ONLY SUCH THAT IT
25 WOULD NOT INCLUDE PRECOMMERCIAL REVENUE. AND THIS

BARRISTERS' REPORTING SERVICE

1 WAS DISCUSSED IN THE CONTEXT OF THE BOARD LAST
2 MONTH, AND WE'RE ALIGNING THESE REGULATIONS
3 ACCORDINGLY.

4 THE THIRD CHANGE IS A CHANGE TO 100608 B,
5 AND THAT IS GEARED TOWARDS EXPANDING ITS REACH. SO
6 RIGHT NOW THE CURRENT REGULATION AND STATUTE APPLIES
7 TO GRANTEES AND COLLABORATORS. WE'RE PROPOSING THAT
8 WITH RESPECT TO FOR-PROFIT ENTITIES AND GRANTS TO
9 FOR-PROFITS THAT IT NOW EXPAND TO REACH LICENSEES AS
10 WELL.

11 THE FOURTH CHANGE, JUST THE FOURTH AND ONE
12 MORE AFTER THAT, IS TO ADD A SUBSECTION UNDER 100608
13 A SUCH THAT IF CIRM OR IN REALITY CALIFORNIA IS
14 RECEIVING REVENUE SHARING AS A RESULT OF THE CHANGE
15 THAT I JUST DESCRIBED, THEN IF ANOTHER ENTITY IS
16 RECEIVING REVENUES, THOSE WOULD NOT BE COUNTED OR
17 OBLIGATED TO BE PAID TO CALIFORNIA BECAUSE WE DIDN'T
18 WANT TO DOUBLE-COUNT THE REVENUE STREAM. SO THIS
19 APPLIES TO THE SAME EXACT REVENUE STREAM WHERE YOU
20 HAVE A LICENSEE AND A COMMERCIALIZING ENTITY PAYING
21 CALIFORNIA. THEN IF ANOTHER ENTITY UPSTREAM THAT
22 WAS INVOLVED IN THE DEVELOPMENT IS ALSO OBTAINING
23 SOME SORT OF REVENUES AS A RESULT OF THE
24 COMMERCIALIZATION OF THAT DRUG PRODUCT OR SERVICE,
25 THEY DO NOT NEED TO SHARE WITH CALIFORNIA AS WELL.

BARRISTERS' REPORTING SERVICE

1 SO WE'RE NOT DOUBLE COUNTING.

2 AND THE FINAL AND IN MY MIND PERHAPS ONE
3 OF THE MOST IMPORTANT ASPECTS OF THESE PROPOSED
4 CHANGES IS A CHANGE IN THE ROYALTY FORMULA SO THAT
5 IT SMOOTHS OUT THE OBLIGATION. I THINK THAT THIS
6 WILL DO A GREAT SERVICE TO ATTRACTING INVESTMENT IN
7 OUR FUNDED PROGRAMS TO DATE AND IN THE FUTURE. AND
8 SO HERE'S WHAT THE PROPOSED NEW ROYALTY FORMULA IS.

9 IT'S 1 PERCENT PER \$1 MILLION IN GRANTS
10 PROVIDED TO A FOR-PROFIT GRANTEE FOR THE LESSER OF
11 TEN YEARS OR NINE TIMES -- DID I SAY 1 PERCENT? --
12 .1 PERCENT, SORRY. SO IT'S ZERO -- THAT'S WHY I
13 ALWAYS STICK THE ZERO IN FRONT OF IT TO REMIND ME.
14 0.1 PERCENT PER MILLION DOLLARS TO A FOR-PROFIT
15 ENTITY FOR THE LESSER OF TEN YEARS OR NINE TIMES THE
16 AWARD. AND ONCE THAT IS SATISFIED, IN THE EVENT
17 THAT THERE IS A PATENTED INVENTION THAT ARISES FROM
18 CIRM'S FUNDING, THERE'S A 1 PERCENT ROYALTY FOR THE
19 LIFE OF THE PATENTED INVENTION, ALSO ASSUMING THAT
20 THERE IS A \$5 MILLION INVESTMENT THAT HAS BEEN MADE.
21 AND THAT 1 PERCENT ROYALTY APPLIES TO ANNUAL
22 REVENUES ABOVE \$500 MILLION. IT'S ALL WRITTEN DOWN
23 IN THE DOCUMENTATION IF YOU'RE NOT FOLLOWING ME
24 PRECISELY.

25 SO THOSE ARE THE FIVE SUBSTANTIVE CHANGES

BARRISTERS' REPORTING SERVICE

1 THAT WE'RE PROPOSING. WE'RE DOING IT BECAUSE WE
2 THINK THAT IT WILL SERVE BOTH THE ABILITY OF CIRM
3 AND CALIFORNIA TO SHARE IN THE REVENUES, BUT AT THE
4 SAME TIME MAKING SURE THAT THE BALANCE IS STRUCK
5 SUCH THAT IT'S NOT UNREASONABLY HINDERING RESEARCH.
6 AND WE'RE ALSO TRYING TO, AS WE SAID, SIMPLIFY THE
7 PROPORTIONALITY ASPECTS OF THESE REVENUE SHARING
8 PROVISIONS AS THEY RELATE TO THE FIRST SECTION I
9 DESCRIBED AND AT THE SAME TIME MAKING SURE THAT IN
10 ALL OTHER RESPECTS WE'RE NOT IMPACTING THE TREATMENT
11 OF NON-PROFIT ENTITIES, WHICH IS WHY A LOT OF WHAT I
12 JUST DESCRIBED ONLY APPLIES IN THE CONTEXT OF GRANTS
13 TO FOR-PROFIT ENTITIES.

14 SO THAT'S THE SUM AND SUBSTANCE OF IT.
15 AND WHAT WE HAD PROPOSED IS, AFTER YOU HAVE THE TIME
16 TO CONFER AND DISCUSS, TWO MOTIONS, ONE DETERMINING,
17 IF YOU BELIEVE THIS TO BE THE CASE, THAT THESE
18 AMENDMENTS ARE APPROPRIATE TO RESTRIKE THE BALANCE
19 AND ENSURE THAT RESEARCH IS NOT UNREASONABLY
20 HINDERED. AND, OF COURSE, THE SECOND MOTION, IF YOU
21 SO DESIRE TO APPROVE -- NOT TO APPROVE, BUT TO
22 RECOMMEND THE APPROVAL OF THE PROPOSED AMENDMENTS TO
23 THE BOARD.

24 CHAIRMAN JUELSGAARD: VERY GOOD. THANK
25 YOU, ELONA. SO LET ME START WITH ANY OF THE

BARRISTERS' REPORTING SERVICE

1 COMMITTEE MEMBERS WHO MIGHT HAVE QUESTIONS ABOUT
2 THESE PROPOSED CHANGES OR THE DESIRE TO MAKE THESE
3 CHANGES. ALL RIGHT. WELL, I HAVE A COUPLE OF
4 QUESTIONS THEN.

5 SO THE FIRST IS THE \$500 MILLION ANNUAL
6 REVENUE THRESHOLD THAT IS PART OF THE PATENT ROYALTY
7 SECTION, WHERE DID THAT NUMBER COME FROM? WHY IS
8 THAT THERE?

9 MR. ROTH: I THINK IT'S 500,000, RIGHT?

10 MS. BAUM: 500 MILLION?

11 CHAIRMAN JUELSGAARD: IT'S 500 MILLION,
12 DUANE.

13 MR. ROTH: WHERE IS THAT?

14 CHAIRMAN JUELSGAARD: IT'S TOWARDS THE END
15 OF THE REVISIONS. AND, IN ESSENCE, IT SAYS THAT THE
16 1 PERCENT ROYALTY BASED ON A PATENT DOESN'T COME
17 INTO PLAY UNTIL THERE'S AT LEAST \$500 MILLION OF
18 ANNUAL REVENUES, ANNUAL COMMERCIAL REVENUES. AND SO
19 I'M ASKING WHERE THAT CAME FROM.

20 MS. BAUM: SO LET ME START AND THEN MAYBE
21 SCOTT HAS A LITTLE MORE HISTORY THAN I DO SINCE HE
22 WAS HERE LONGER THAN I'VE BEEN HERE. BUT THAT WAS
23 PART OF THE BLOCKBUSTER PROVISIONS THAT WERE ENACTED
24 YEARS AGO IN THE FIRST ROUND. AND WHEN WE WERE
25 DRAFTING IT, WE JUST PRESERVED WHAT THAT FORMULA WAS

BARRISTERS' REPORTING SERVICE

1 FROM THE PAST BECAUSE IT WAS DETERMINED THAT WE JUST
2 WANTED TO HAVE A LONGER TERM ROYALTY THAT THE PATENT
3 RELATED WITH RESPECT TO REVENUES ABOVE WHAT IS
4 CONSIDERED OR WAS CONSIDERED BLOCKBUSTER REVENUE.

5 MR. ROTH: I CAN ADD TO THAT. THAT'S
6 CORRECT. IT WAS A NEGOTIATION. THERE WAS A LOT OF
7 INPUT FROM THE PATIENT COMMUNITY, THAT THEY WANTED
8 TO MAKE SURE THAT IF SOMETHING REALLY, REALLY
9 WORKED, THAT THERE WAS AN ADDITIONAL UPSIDE PAYBACK.
10 SO WE PUT IN A 1 PERCENT OVER 500 MILLION PROVIDED
11 THERE'S A PATENT AND THERE WAS A MEANINGFUL
12 INVESTMENT ON CIRM'S PART.

13 CHAIRMAN JUELSGAARD: WELL, ALL RIGHT.
14 FINE. I UNDERSTAND THE HISTORIC NATURE. AS I THINK
15 I'VE SAID BEFORE IN OTHER SETTINGS, THE VALUE OF A
16 PATENT IS ITS EXCLUSIONARY VALUE. IT HAS THE
17 ABILITY TO EXCLUDE OTHERS FROM PRACTICING THE
18 INVENTION THAT'S DESCRIBED WITHIN THE PATENT. AND
19 SO IRRESPECTIVE OF THE AMOUNT OF REVENUE THAT'S
20 GENERATED, IT HAS THAT VALUE AND THEN NOBODY ELSE
21 CAN DO THE SAME THING AS THAT IS WITHIN THE PATENT.
22 AND SO IT'S NOT ENTIRELY CLEAR TO ME WHY THERE
23 SHOULD BE ANY THRESHOLD, YOU KNOW, AT ALL, LET ALONE
24 A \$500 MILLION THRESHOLD. I GUESS THAT'S MY
25 QUESTION.

BARRISTERS' REPORTING SERVICE

1 I UNDERSTAND THE NOTION OF WANTING TO
2 RECEIVE MORE REVENUE IF IT'S A BLOCKBUSTER PRODUCT,
3 AND I WOULD ARGUE, THEN, THAT THERE OUGHT TO BE A 1
4 PERCENT ROYALTY NO MATTER WHAT AND THEN 2 PERCENT
5 ROYALTY IF IT'S ABOVE 500 MILLION IF THAT'S THE
6 THINKING. BUT ANYWAY, SO --

7 MR. ROTH: IT WAS ASSUMED THERE WOULD BE A
8 TENFOLD PAYBACK AT THAT POINT OR NINEFOLD PAYBACK.
9 SO -- IT WAS CAPPED AT NINE TIMES THE AMOUNT WE
10 INVESTED. AND SO THEN ONCE THAT NINE TIMES IS PAID
11 BACK, IF IT WAS TRULY A BLOCKBUSTER AT THAT POINT,
12 WHICH IT WOULD BE, THEN THERE WAS THE 1 PERCENT
13 ROYALTY PROVIDED THERE WAS A PATENT.

14 CHAIRMAN JUELSGAARD: WELL, I DON'T FEEL
15 STRONGLY ABOUT THIS, BUT I JUST -- TO ME IT'S A BIT
16 OUT OF SYNC WITH WHAT, AT LEAST, I'M MORE FAMILIAR
17 WITH BASED ON MY PAST EXPERIENCE MORE ON THE
18 COMMERCIAL SIDE.

19 SO THE OTHER QUESTION THAT I HAVE AND,
20 ELONA, IF YOU COULD JUST TAKE US THROUGH AN EXAMPLE
21 OF THIS ISSUE OF POTENTIAL DOUBLE COUNTING THAT
22 WE'VE EXCEPTED OUT OF THESE REGULATIONS. SO JUST IF
23 YOU COULD PROVIDE AN EXAMPLE OF HOW THAT MIGHT COME
24 INTO PLAY SO THAT THAT -- WE PROVIDE THAT THAT ISN'T
25 A CONCERN.

BARRISTERS' REPORTING SERVICE

1 MS. BAUM: OKAY. SO LET'S JUST THINK OF
2 THIS FOLLOWING SCENARIO. YOU HAVE A NON-PROFIT THAT
3 ENDS UP GETTING A GRANT. THEY CREATE A SPIN-OUT
4 COMPANY, THAT'S COMPANY B, AND THEN ULTIMATELY, AS
5 IN THE TYPICAL CASE, THE SPIN-OUT, THE SMALL
6 BIOTECH, ENDS UP OUT-LICENSING TO A PHARMA OR LARGE
7 BIOPHARMA. SO WHAT COULD HAPPEN IS THAT THE -- AND
8 LET'S JUST SAY THAT THE SMALL BIOPHARMA ALSO GETS A
9 GRANT ALONG THE WAY. WHAT COULD HAPPEN IS THE SMALL
10 BIOPHARMA EVENTUALLY COULD CUT THEIR DEAL WITH THE
11 PHARMA AND THEY'LL GET UP-FRONT PAYMENTS, THEY'LL
12 GET DEVELOPMENT MILESTONES, BUT THEN THEY MIGHT
13 ACTUALLY ALSO GET SOME ROYALTY OFF OF THE PRODUCT
14 SALES.

15 WHAT WE'RE SAYING IS THAT ONCE THE
16 LICENSEE, THAT PHARMA, OWES US A CERTAIN AMOUNT OFF
17 OF THE PRODUCT SALES, THAT THEN IT'S THE SAME
18 REVENUE STREAM WHEN THEY SELL THE DRUG THAT WOULD
19 POTENTIALLY, IF WE DIDN'T HAVE THIS EXCLUSION, APPLY
20 AND WE'D BE COLLECTING FROM THE LICENSEE AND THEN
21 WE'D BE COLLECTING FROM COMPANY B, THE SMALL
22 BIOTECH. AND WE THOUGHT IT WOULD BE ONLY
23 APPROPRIATE TO, AND THAT'S HOW I THINK WHEN WE WERE
24 THINKING OF OUR FORMULA, IS THAT WE SHOULD ONLY SEEK
25 TO REVENUE SHARE FROM THE ULTIMATE SALES STREAM AND

BARRISTERS' REPORTING SERVICE

1 NOT FROM BOTH. BECAUSE TECHNICALLY SPEAKING, WHEN
2 THE COMPANY B RECEIVES THESE ROYALTY PAYMENTS, THAT
3 COULD BE CONSIDERED LICENSING REVENUES UNDER
4 SUBSECTION A. AND WE WANTED TO ENCOURAGE INVESTMENT
5 AND NOT MAKE IT TOO EXPENSIVE FOR THE PHARMA TO
6 INVEST IN THE PROJECT. AND, THEREFORE, WE THOUGHT
7 WE SHOULD EXCLUDE THE MIDSTREAM TO THE MIDDLE
8 PLAYER.

9 CHAIRMAN JUELSGAARD: WELL, SO LET ME
10 UNDERSTAND THIS. LET ME JUST USE A LITTLE MORE
11 SPECIFICS. ASSUME WE HAVE A PRODUCT ON THE
12 MARKETPLACE, ASSUME THERE'S A SMALL BIOPHARMA
13 COMPANY THAT INITIALLY LICENSED THIS FROM A
14 UNIVERSITY, HAS DEVELOPED IT SO SOME EXTENT, NOW
15 LICENSED IT TO A MUCH LARGER COMPANY, THE LARGER
16 COMPANY SELLS THE PRODUCT, THE LARGER COMPANY PAYS
17 THE BIOPHARMA A 10-PERCENT ROYALTY ON PRODUCT SALES,
18 FOR EXAMPLE. AND IN TURN, THE SMALL BIOPHARMA
19 COMPANY PAYS THE UNIVERSITY A STREAM OF MONEY
20 ROYALTY PROBABLY BASED UPON ITS ORIGINAL LICENSE
21 FROM THE UNIVERSITY.

22 NOW, AMONGST THOSE THREE ENTITIES IN YOUR
23 EXAMPLE, UNIVERSITY, SMALL BIOPHARMA, BIG BIO, BIG
24 PHARMA, WHO'S THE PAYOR IN THAT PARTICULAR CASE?
25 WHICH OF THOSE ENTITIES ARE WE LOOKING TO?

BARRISTERS' REPORTING SERVICE

1 MS. BAUM: THE ANSWER IS THAT YOU HAVE TO
2 LOOK AT IT ON A GRANT-BY-GRANT BASIS. SO I DIDN'T
3 COPY DOWN THE WHOLE HYPO, BUT THE GRANTS THAT GO TO
4 THE NON-PROFITS WOULD -- WE WOULD JUST SHARE
5 ANY -- THE 25 PERCENT SUBJECT TO THE REDUCTION OF
6 ROYALTIES THAT GO TO THERE. IF THERE'S A GRANT THAT
7 GOES TO THE BIOPHARMA, AND THERE'S THIS ULTIMATE
8 COMMERCIALIZING ENTITY, THEN THAT'S THIS NEW
9 FORMULA. SO THE GRANT TO THE NON-PROFIT IS NOT
10 TOUCHED IN ANY WAY, AND IT'S THE NEW FORMULAS THAT
11 APPLY TO THESE GRANTS TO THE BIOPHARMAS.

12 CHAIRMAN JUELGAARD: AND SO WOULD
13 THAT -- IN THE SECOND OF THOSE TWO PARTS THAT YOU
14 JUST EXPLAINED AS BETWEEN THE SMALL BIOPHARMA AND
15 THE BIG PHARMA ON COMMERCIAL REVENUES, WHICH OF
16 THOSE TWO ENTITIES WILL ULTIMATELY PAY THE STATE OF
17 CALIFORNIA THE ROYALTIES?

18 MS. BAUM: IT WOULD BE C, THE PHARMA.

19 CHAIRMAN JUELGAARD: THE LARGE PHARMA AND
20 NOT THE SMALL BIOPHARMA. AND WHY THE LARGE PHARMA
21 AS OPPOSED TO THE SMALL BIOPHARMA?

22 MS. BAUM: WELL, ULTIMATELY -- I MEAN,
23 QUITE FRANKLY, THE POINT IS JUST TO HAVE ONE ENTITY
24 PAY.

25 CHAIRMAN JUELGAARD: RIGHT.

BARRISTERS' REPORTING SERVICE

1 MS. BAUM: YOU COULD MAKE THE SMALLER
2 BIOPHARMA MAKE THE PAYMENTS DIRECTLY TO US; BUT IF
3 THEY GO OUT OF BUSINESS, IT'S NOT AS ADVANTAGEOUS AS
4 IF WE HAD A DIRECT OBLIGATION TO THE PHARMA COMPANY,
5 WHICH IS WHY WE EXPAND OUR REGULATIONS TO MEET THE
6 LICENSEES -- TO REACH THE LICENSEES.

7 CHAIRMAN JUELSGAARD: ALL RIGHT. FAIR
8 ENOUGH. AND SO WITHOUT GOING BACK AND LOOKING AT
9 THESE PROPOSED CHANGES AGAIN, IS IT ALWAYS THE CASE
10 THAT IT'S THE ULTIMATE LICENSEE OR SUBLICONSEE, I
11 GUESS, THAT PAYS? OR IS IT RATHER IT CAN VARY FROM
12 CIRCUMSTANCE TO CIRCUMSTANCE AT CIRM'S ELECTION?
13 HOW WOULD THAT WORK?

14 MS. BAUM: WELL, YOU KNOW, I THINK THE WAY
15 WE DRAFTED THE REGULATIONS, IT ACTUALLY SAID THE
16 LICENSEE IS OBLIGATED TO PAY. SO I WOULD THINK THAT
17 A READING OF THAT WOULD REQUIRE IT BE THE PHARMA
18 COMPANY THAT PAYS INTO THE FUND. WE COULD CLARIFY
19 THAT.

20 MR. TOCHER: THE COMMERCIALIZING ENTITY, I
21 THINK, IS THE TERM THAT YOU USED.

22 CHAIRMAN JUELSGAARD: OKAY.

23 DR. PLUNKETT: STEVE, ONE CLARIFICATION TO
24 THAT THOUGH. FOR A NON-PROFIT AWARDEE WOULD
25 CONTINUE TO BE UNCHANGED FROM THE CURRENT

BARRISTERS' REPORTING SERVICE

1 CIRCUMSTANCE.

2 CHAIRMAN JUELSGAARD: RIGHT. NO, I
3 UNDERSTAND THAT. YEAH.

4 MS. BAUM: AND THE NUANCE, WHICH I DON'T
5 WANT TO COMPLICATE IT TOO MUCH, IS THAT IT'S THE
6 COMMERCIALIZING ENTITY OF A DRUG PRODUCT OR SERVICE.
7 SO IF THERE IS THIS METHOD SUCH AS THE PDL
8 SITUATION, THE BIOPHARMA HAS A METHOD THAT IT
9 LICENSES FREELY, THEY OWE US DIRECTLY OR OWE
10 CALIFORNIA DIRECTLY.

11 CHAIRMAN JUELSGAARD: ALL RIGHT. THANK
12 YOU. THAT ANSWERS MY QUESTIONS. THANK YOU.

13 ARE THERE QUESTIONS -- ANY OTHER QUESTIONS
14 FROM COMMITTEE MEMBERS NOW THAT I'VE MONOPOLIZED THE
15 LAST TEN MINUTES? HEARING NONE, ARE THERE ANY
16 QUESTIONS OR COMMENTS FROM THE PUBLIC? WELL,
17 HEARING NONE, THEN, THERE ARE TWO MOTIONS THAT ELONA
18 HAS PROPOSED.

19 ELONA, IF YOU COULD REPEAT MORE
20 SPECIFICALLY THE LANGUAGE OF THE FIRST MOTION THAT
21 YOU RECOMMEND WE CONSIDER AND ADOPT, THAT WOULD BE
22 HELPFUL FOR ME.

23 MS. BAUM: OKAY. SO IT WOULD BE A FINDING
24 THAT A MODIFICATION OR AMENDMENT OF OUR REGULATIONS
25 ARE NEEDED TO ENSURE THAT CALIFORNIA HAS AN

BARRISTERS' REPORTING SERVICE

1 OPPORTUNITY TO ECONOMICALLY BENEFIT FROM CIRM'S
2 INVESTMENTS, BUT AT THE SAME TIME THESE ARE NEEDED
3 IN ORDER TO ENSURE THAT ESSENTIAL RESEARCH IS NOT
4 HINDERED.

5 AND THEN, OF COURSE, THE SECOND MOTION --

6 CHAIRMAN JUELSGAARD: NO. HOLD ON FOR A
7 MOMENT. SO DO WE HAVE A MOTION TO THE EFFECT OF
8 WHAT ELONA JUST PROVIDED US?

9 MR. ROTH: SO, STEVE, YOU'RE LOOKING FOR A
10 MOTION ON THE COMPELLING REASON TO CHANGE?

11 CHAIRMAN JUELSGAARD: YES. ON THE REASON
12 FOR DOING THIS, ABSOLUTELY, YES.

13 MR. ROTH: SO I'LL MAKE THAT MOTION. BUT
14 I WANT TO MAKE SURE WE PUT IN THE RECORD THE BASIS
15 FOR THAT.

16 CHAIRMAN JUELSGAARD: NO. WE WILL. I
17 APPRECIATE THAT, DUANE, AND I THINK WE SHOULD.

18 MR. ROTH: I'LL MAKE THE MOTION.

19 CHAIRMAN THOMAS: I'LL SECOND.

20 CHAIRMAN JUELSGAARD: ALL RIGHT. THEN WHY
21 DON'T YOU GO AHEAD AND SPEAK TO THE RATIONALE. I'LL
22 BE HAPPY TO CHIME IN LATER IF I SEE ADDITIONAL
23 REASONING FROM MY SIDE.

24 MR. ROTH: SO YOU WANT ME TO DO THAT OR
25 YOU WANT --

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN JUELSGAARD: PLEASE, GO AHEAD.

2 MR. ROTH: OKAY. WELL, MY UNDERSTANDING
3 IS THAT THERE IS CONCERN ABOUT THE ABILITY TO DO
4 LICENSE AGREEMENTS BASED ON THE WAY THE CURRENT
5 REGULATIONS ARE PROPOSED, AND IT DEALS PRIMARILY
6 WITH THIS ONE-TIME PAYMENT AFTER THE 250 MILLION AND
7 AFTER THE 500 MILLION IN REVENUES. SO THAT'S MY
8 UNDERSTANDING, THAT IN COMMUNICATION WITH VARIOUS
9 LICENSING PROSPECTS, THEY'VE RAISED THIS AS A
10 CONCERN, AND THEY SAY THAT BUT FOR THAT, THEN THEY
11 COULD GO FORWARD WITH SOME OF THESE LICENSING
12 AGREEMENTS.

13 CHAIRMAN JUELSGAARD: ANYBODY ELSE HAVE
14 ANYTHING TO ADD TO THAT? WELL, JUST SO -- SO LET ME
15 THEN WEIGH IN JUST BRIEFLY. SO FIRST OF ALL, I SEE
16 THESE REGULATIONS AS EXPANDING THE REACH ON THE
17 COMMERCIAL SIDE TO ENCOMPASS ANY ENTITY THAT'S
18 INVOLVED IN DERIVING COMMERCIAL REVENUES, AND AS
19 SUCH CLOSES ANY POTENTIAL LOOPHOLES THAT MIGHT EXIST
20 IN TERMS OF GETTING ROYALTY PAYMENTS BACK TO CIRM
21 FOR HAVING PROVIDED FUNDING WHICH RESULTED IN A
22 SUCCESSFUL COMMERCIAL PRODUCT.

23 THE SECOND, AND THIS SPEAKS TO WHAT YOU
24 JUST SPOKE TO, DUANE, WHICH IS TO ELIMINATE THE
25 ONE-TIME PAYMENT NOTION OF RATHER SIGNIFICANT

BARRISTERS' REPORTING SERVICE

1 PAYMENTS OR WHAT COULD BE RATHER SIGNIFICANT
2 PAYMENTS ON A REVENUE STREAM, TO INSTEAD SMOOTH THAT
3 OUT. I COMPLETELY AGREE BOTH HYPOTHETICALLY WITH
4 THAT AS A CONCERN AS WELL AS DIRECTLY WITH THAT AS A
5 CONCERN AS EXPRESSED BY POTENTIAL LICENSEES.

6 SO IT'S IN MY EXPERIENCE EXTREMELY UNUSUAL
7 TO HAVE THAT SORT OF PAYMENT METHODOLOGY WHERE YOU
8 MAKE A VERY SIGNIFICANT PAYMENT AFTER HAVING
9 ACHIEVED JUST A CERTAIN AMOUNT OF REVENUES. AND I
10 CAN SEE THAT IT WOULD REALLY CONCERN COMPANIES WHO
11 MIGHT WANT TO BE INVOLVED IN THESE TRANSACTIONS TO
12 HAVE THAT KIND OF PAYMENT SYSTEM IMPOSED UPON THEM.
13 AND THAT'S BEEN SECONDED BY WHAT WE'VE HEARD FROM
14 POTENTIAL LICENSEES.

15 SO I DO BELIEVE THESE ARE NECESSARY AND
16 ADVISABLE CHANGES TO OUR REGULATIONS THAT ARE
17 COMPLETELY IN ACCORD WITH THE REQUIREMENTS OF THE
18 ALQUIST LEGISLATION.

19 ANY OTHER COMMENTS? HEARING NONE, LET'S
20 CALL THE ROLL. I GUESS WE'RE VOTING, SCOTT.

21 MR. TOCHER: SURE. OKAY. SUE BRYANT.

22 DR. BRYANT: YES.

23 MR. TOCHER: DUANE ROTH.

24 MR. ROTH: YES.

25 MR. TOCHER: J.T.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: YES.

2 MR. TOCHER: AND STEVE JUELSGAARD.

3 CHAIRMAN JUELSGAARD: YES.

4 MR. TOCHER: THE MOTION CARRIES.

5 CHAIRMAN JUELSGAARD: THANK YOU. SO NOW
6 THE SECOND MOTION, THEN, IS ONE THAT SPEAKS TO THE
7 SPECIFIC CHANGES THAT WE'VE ALL BEEN PROVIDED VIA
8 E-MAIL AND THAT ELONA HAS WALKED US THROUGH. AND SO
9 IS THERE A MOTION WITH RESPECT TO THESE PROPOSED
10 CHANGES TO APPROVE THEM?

11 MS. BAUM: TO RECOMMEND TO THE --

12 CHAIRMAN JUELSGAARD: I'M SORRY. TO
13 RECOMMEND TO THE ICOC THAT THEY APPROVE IT.

14 CHAIRMAN THOMAS: SO MOVED.

15 CHAIRMAN JUELSGAARD: IS THERE A SECOND?

16 MR. ROTH: SECOND.

17 CHAIRMAN JUELSGAARD: ARE THERE ANY
18 COMMENTS FROM ANY OF THE BOARD MEMBERS ABOUT THESE
19 PROPOSED CHANGES? ARE THERE ANY COMMENTS FROM THE
20 PUBLIC ABOUT THESE PROPOSED CHANGES? HEARING NONE,
21 THEN LET'S MOVE TO THE VOTE.

22 MR. TOCHER: SUE BRYANT.

23 DR. BRYANT: YES.

24 MR. TOCHER: DUANE ROTH.

25 MR. ROTH: YES.

BARRISTERS' REPORTING SERVICE

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

MR. TOCHER: J.T.

CHAIRMAN THOMAS: YES.

MR. TOCHER: AND STEVE JUELSGAARD.

CHAIRMAN JUELSGAARD: YES.

MR. TOCHER: MOTION CARRIES.

CHAIRMAN JUELSGAARD: THANK YOU.

MS. BAUM: THANK YOU.

CHAIRMAN JUELSGAARD: WELL, I THINK THAT'S THE PRINCIPAL REASON FOR HAVING THIS MEETING. SO I DON'T BELIEVE THERE ARE ANY OTHER ITEMS ON THE AGENDA CERTAINLY TO TAKE ACTION ON. ARE THERE ANY THINGS THAT ANY OF THE COMMITTEE MEMBERS WOULD LIKE TO BRING UP AT THIS MOMENT? WELL, IF NOT, ARE THERE ANY COMMENTS FROM ANY MEMBERS OF THE PUBLIC AT THIS TIME BEFORE WE ADJOURN THE MEETING? IF NOT, THEN, THE MEETING IS ADJOURNED.

MR. TOCHER: THANK YOU, EVERYBODY.

CHAIRMAN THOMAS: JUST LIKE TO WISH MATT A HAPPY BIRTHDAY BEFORE WE GET OFF HERE.

(THE MEETING WAS THEN ADJOURNED AT 9 A.M.)

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 AND INDUSTRY SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON JUNE 11, 2012, 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
160 S. OLD SPRINGS ROAD
SUITE 270
ANAHEIM, CALIFORNIA
(714) 444-4100