

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 ON THE AGENDA

DATE: TUESDAY, NOVEMBER 23, 2010
1:30 P.M.

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

BRS FILE NO.: 88857

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF AMENDMENTS TO IP REGULATIONS TO IMPLEMENT SB 1064. ITEM 3 EXHIBIT A	4
4. PUBLIC COMMENT.	NONE

BARRISTERS' REPORTING SERVICE

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TUESDAY, NOVEMBER 23, 2002

1:30 P.M.

CHAIRMAN PENHOET: WE'RE FIVE MINUTES INTO A 30-MINUTE MEETING, SO I THINK WE NEED TO GO. WILL YOU CALL THE ROLL, PLEASE.

MS. KING: JACOB LEVIN FOR SUSAN BRYANT. MICHAEL GOLDBERG.

MR. GOLDBERG: HERE.

MS. KING: TED LOVE. ED PENHOET.

CHAIRMAN PENHOET: HERE.

MS. KING: PHIL PIZZO. FRANCISCO PRIETO.

DR. PRIETO: HERE.

MS. KING: JOHN REED. DUANE ROTH.

MR. ROTH: HERE.

MS. KING: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. KING: OSWALD STEWARD.

CHAIRMAN PENHOET: OKAY. SOUNDS LIKE WE DON'T HAVE A QUORUM, BUT WE'LL PROCEED ANYWAY BECAUSE WE DON'T HAVE TO HAVE ONE FOR THIS PURPOSE.

SO JAMES HAS SENT TO US A NICE SUMMARY OF AN ANALYSIS OF THE WAY THAT SB 1064 INTERACTS WITH OUR PREVIOUSLY DETERMINED IP REGS AND IN TWO AREAS, REVENUE SHARING AND ACCESS. IN ONE CASE OF REVENUE

BARRISTERS' REPORTING SERVICE

1 SHARING, WE HAVE THE DISCRETION TO MAKE A CHANGE IF
2 WE WISH TO MAKE IT AT THIS TIME. IT'S NOT
3 NECESSARY. WITH RESPECT TO ACCESS, THERE ARE A
4 COUPLE OF FEATURES OF THIS WHICH DRAWS A NECESSARY
5 CHANGE ON OUR PART IF WE WANT TO MAKE OUR
6 REGULATIONS CONSISTENT WITH SB 1064.

7 I THINK THE MOST EFFICIENT WAY FOR US TO
8 GET THROUGH THIS IS TO ASK JAMES TO SUMMARIZE
9 QUICKLY FOR US THOSE CHANGES. JAMES, THANK YOU VERY
10 MUCH FOR YOUR WHITE PAPER ON THE SUBJECT. AND IF
11 YOU WOULDN'T MIND JUST WALKING US THROUGH THE
12 CRITICAL ISSUES.

13 MR. HARRISON: SURE. MAYBE I'LL JUST GIVE
14 A BRIEF OVERVIEW AND THEN TURN IT OVER TO ELONA
15 BAUM, WHO PROVIDED A MEMO REGARDING THE SPECIFIC
16 CHANGES.

17 AS DR. PENHOET SAID, THERE ARE TWO AREAS
18 IN WHICH SB 1064 MADE MODIFICATIONS TO CIRM'S IP
19 RULES. AND THEY ARE IN THE AREA OF REVENUE SHARING
20 AS WELL AS IN THE ACCESS PROVISION. AND IN GENERAL,
21 WHAT SB 1064 DID WAS TO CODIFY CIRM'S EXISTING
22 REVENUE SHARING REGULATIONS WITH ONE SLIGHT
23 MODIFICATION THAT ELONA WILL DISCUSS. BUT THEY DO
24 PERMIT THE IP TASK FORCE TO MAKE RECOMMENDATIONS AND
25 THE BOARD TO MAKE CHANGES TO THE REVENUE SHARING

BARRISTERS' REPORTING SERVICE

1 FORMULAS THAT ARE SET FORTH IN SB 1064 IF THE BOARD
2 DETERMINES THAT IT'S NECESSARY TO DO SO IN ORDER TO
3 MAINTAIN THE BALANCE THAT UNDERLINES THE POLICY
4 BETWEEN ENSURING THAT RESEARCH IS UNIMPEDED AND THAT
5 THE STATE HAS AN OPPORTUNITY FOR RETURN ON ITS
6 INVESTMENT.

7 IN THE SECOND AREA, ACCESS, SB 1064 ALSO
8 LARGELY CODIFIES CIRM'S EXISTING REGULATIONS WITH
9 RESPECT TO ACCESS PLANS, BUT IT DOES MAKE SOME
10 CHANGES, ONE OF WHICH ELONA WILL DESCRIBE, AND
11 OTHERS OF WHICH WILL REQUIRE FURTHER DISCUSSION AND
12 DEVELOPMENT BY STAFF. AND THOSE ARE THAT, NO. 1,
13 CIRM'S EXISTING REGULATIONS REQUIRE ACCESS PLANS TO
14 COVER UNINSURED CALIFORNIANS; WHEREAS, SB 1064 USES
15 THE TERM "CALIFORNIANS WHO HAVE NO OTHER MEANS TO
16 PURCHASE THE DRUG." AND THAT CAME OUT, IN PART, AS
17 A RESULT OF THE UNCERTAINTY IN THE HEALTHCARE
18 LANDSCAPE WITH HEALTHCARE REFORM NOW BEING
19 IMPLEMENTED. AND THAT'S SOMETHING THAT STAFF WILL
20 DEVELOP PROPOSALS ON AND COME BACK TO THE IP TASK
21 FORCE WITH SEVERAL SUGGESTIONS FOR YOUR
22 CONSIDERATION.

23 AND THEN THE SECOND PIECE, WHICH WE WILL
24 DISCUSS AT A LATER DATE, RELATES TO A PROCEDURE
25 WHEREBY THE BOARD CAN WAIVE THE ACCESS REQUIREMENT

BARRISTERS' REPORTING SERVICE

1 UNDER CERTAIN CIRCUMSTANCES. AND WE WILL NEED TO
2 ESTABLISH A REGULATORY PROCESS IN ORDER FOR THAT TO
3 OCCUR.

4 SO WITH THAT AS A BROAD OVERVIEW, I WILL
5 TURN IT OVER TO ELONA BAUM TO DISCUSS THE SPECIFICS.

6 CHAIRMAN PENHOET: ELONA, LET ME APOLOGIZE
7 FOR ASCRIBING THIS DOCUMENT TO JAMES. IT'S A LOVELY
8 DOCUMENT, BUT JAMES DIDN'T WRITE IT. YOU DID, SO
9 THANK YOU VERY MUCH.

10 MS. BAUM: MAYBE THERE'S CONFUSION, BUT AT
11 ANY RATE, THERE'S, I THINK, TWO DOCUMENTS. ONE THAT
12 WAS POSTED AS PART OF THE AGENDA.

13 MS. KING: THAT'S ACTUALLY YOUR DOCUMENT.
14 THE ONE THAT WAS POSTED IS YOURS.

15 JUST BEFORE ELONA GETS STARTED, I JUST
16 WANT TO CHECK. I KNOW SOMEONE JOINED WHILE JAMES
17 WAS TALKING. WHO JOINED THE CALL?

18 DR. LEVIN: JACOB LEVIN FROM UCI. SO
19 SORRY I'M LATE.

20 MS. KING: EXCELLENT. THANK YOU. NO
21 WORRIES. WE HAD JUST REALLY GOTTEN STARTED, SO I'M
22 GOING TO TURN IT BACK OVER TO ELONA.

23 MS. BAUM: JUST TO CLARIFY, WE'RE ONLY
24 ADDRESSING TWO PROPOSED AMENDMENTS TODAY. THERE
25 WILL BE TWO OTHERS THAT WE WILL SEEK TO BRING BEFORE

BARRISTERS' REPORTING SERVICE

1 THE TASK FORCE, I THINK WE DECIDED, SOMETIME IN
2 FEBRUARY. THEY REQUIRE MUCH MORE DELIBERATION ON
3 THE PART OF STAFF TO DETERMINE WHAT AN APPROPRIATE
4 SET OF RECOMMENDATIONS AND SOME BACKGROUND
5 MATERIALS. AND, THEREFORE, WE'RE NOT PREPARED TO DO
6 THAT TODAY.

7 BUT TODAY WHAT WE HAVE BEFORE YOU IS
8 FAIRLY STRAIGHTFORWARD. AS JAMES HAD INDICATED, THE
9 FIRST PROPOSED AMENDMENT THAT WE HAVE FOR YOUR
10 CONSIDERATION RELATES TO THE TIMING OF WHEN A
11 PROPOSED ACCESS PLAN IS PRESENTED TO THE ICOC FOR
12 APPROVAL. UNDER OUR REGULATIONS THE TIMING IS 90
13 CALENDAR DAYS PRIOR TO THE TIME THE DRUG IS
14 COMMERCIALIZED IN CALIFORNIA. THE STATUTE ENACTED
15 BY SB 1064 PROVIDES A DIFFERENT TIMELINE, WHICH IS
16 WHY WE NEED TO MAKE IT CONSISTENT, THAT TIMELINE
17 BEING WITHIN TEN DAYS FOLLOWING FINAL APPROVAL OF
18 THE DRUG BY THE FEDERAL FDA UNLESS THE GRANTEE,
19 COLLABORATOR, OR EXCLUSIVE LICENSEE SEEKS AN
20 EXTENSION. AND THEN WE PROVIDE FURTHER PROPOSED
21 AMENDMENT AS SET FORTH IN SB 65 TO DO THAT
22 EXTENSION, SAYING THAT THE EXTENSION OF THE
23 SUBMISSION OF THE ACCESS PLAN MUST BE SUBMITTED NO
24 LATER THAN 30 DAYS FOLLOWING FINAL APPROVAL.

25 SO THIS PROPOSED AMENDMENT IS SIMPLY TO

BARRISTERS' REPORTING SERVICE

1 MAKE OUR REGULATIONS CONSISTENT AND ALIGNED WITH
2 SB 1064. I THINK THAT'S PRETTY STRAIGHTFORWARD; BUT
3 IF ANYONE HAS ANY QUESTIONS, I'M HAPPY TO ANSWER
4 THEM.

5 THAT BEING SAID, I DON'T HEAR ANY
6 QUESTIONS, I THINK WE SHOULD TURN TO THE OTHER
7 PROVISIONS FOR CONSIDERATION, AND THIS ONE --

8 CHAIRMAN PENHOET: I WAS JUST CONFUSED.
9 THEY'RE SUPPOSED TO SUBMIT IT WITHIN TEN DAYS UNLESS
10 THEY WANT TO SEEK AN --

11 MS. BAUM: EXTENSION.

12 CHAIRMAN PENHOET: -- EXTENSION. BUT THEN
13 THEY HAVE TO DO IT WITHIN 30 DAYS, SO THE EXTENSION
14 WOULD JUST BE FROM 10 TO 30 DAYS?

15 MS. BAUM: THAT'S WHAT THE LANGUAGE IN THE
16 STATUTE STATED.

17 CHAIRMAN PENHOET: BUT THEY HAVE TO LET US
18 KNOW BY TEN DAYS WHAT THEIR INTENTION IS, EITHER TO
19 FILE IT OR TO ASK FOR AN EXTENSION?

20 MS. BAUM: RIGHT.

21 CHAIRMAN PENHOET: AS IT'S WRITTEN, IT
22 SAYS IF THEY SEEK AN EXTENSION, THE PLAN MUST BE
23 SUBMITTED NO LATER THAN 30 DAYS, BUT IT DOESN'T SAY
24 WHEN THEY HAVE TO -- THEY HAVE TO ASK FOR THE
25 EXEMPTION WITHIN THE TEN DAYS.

BARRISTERS' REPORTING SERVICE

1 MS. BAUM: RIGHT. YES. IT STATED THAT.
2 I DIDN'T READ IT VERBATIM, BUT IT'S STATED WITHIN
3 THE PROPOSED.

4 CHAIRMAN PENHOET: OKAY.

5 MR. ROTH: THAT HAS TO DEAL WITH NOBODY
6 KNOWS WHEN YOU GET APPROVAL.

7 CHAIRMAN PENHOET: I UNDERSTAND.

8 MR. ROTH: THAT'S WHY YOU CAN'T KNOW 90
9 DAYS IN ADVANCE; BUT WITHIN TEN DAYS OF THEIR
10 APPROVAL, THEY'VE GOT TO TELL US EITHER WHAT THEY'RE
11 GOING TO DO OR WITHIN 30 DAYS IF THEY EXTEND IT.

12 CHAIRMAN PENHOET: THEY HAVE TO APPLY FOR
13 THE EXTENSION WITHIN THE TEN-DAY PERIOD.

14 MR. ROTH: THAT'S CORRECT. AND THEN THE
15 EXTENSION IS 30 DAYS, WHICH I THINK IS SHORT.

16 MS. BAUM: THAT'S IN THE STATUTE.

17 DR. PRIETO: THAT'S IN SB 1064?

18 MS. KING: JUST TO CLARIFY, IS EVERYBODY
19 LOOKING AT -- THERE'S A MEMO AT THE FRONT OF THE
20 DOCUMENT, AND THEN BEHIND THAT THERE'S THE ACTUAL
21 TEXT OF WHAT ELONA IS GOING THROUGH. AND IT SHOWS
22 TRACK CHANGES. IF YOU READ THE LANGUAGE ON EXACTLY
23 WHAT YOU WERE JUST TALKING ABOUT, WHERE YOU SEE THE
24 TRACK CHANGES, IT ACTUALLY NOT ONLY SAYS THAT THEY
25 HAVE TO ASK FOR THE EXTENSION WITHIN TEN BUSINESS

BARRISTERS' REPORTING SERVICE

1 DAYS, BUT ALSO THAT IT HAS TO BE APPROVED, WHICH IN
2 THE MEMO PORTION OF IT I DON'T THINK IT SAYS THAT.
3 JUST WANT TO MAKE SURE EVERYONE IS ON PAGE 4 OF A
4 TOTAL OF SEVEN PAGES.

5 MS. BAUM: OKAY.

6 DR. STEWARD: I JUST JOINED YOU.

7 MS. KING: THANK YOU, DR. STEWARD.

8 MS. BAUM: ARE WE READY TO MOVE ON? THE
9 SECOND CHANGE RELATES TO REVENUE SHARING IN SECTION
10 10608. AND IT RELATES TO SUBSECTION (B)(3), WHICH
11 SHOULD BE THE LAST PAGE OF THE MEMO, I BELIEVE.
12 THAT CHANGE ESSENTIALLY IS TO ALIGN OUR REGULATION
13 WITH THE STATUTE WHICH PROVIDES THAT THE 1-PERCENT
14 ROYALTY RATE WHICH APPLIED IN INSTANCES OF WHAT WE
15 HAVE IN THE PAST DEFINED AS A BLOCKBUSTER DRUG, IT
16 WOULD CHANGE OUR REGULATIONS JUST AS THE STATUTE
17 DOES SO AS TO APPLY THE 1-PERCENT ROYALTY IN
18 INSTANCES WHERE THERE ARE ONLY PATENTED INVENTIONS
19 OR TECHNOLOGY.

20 IN OUR REGULATIONS CURRENTLY, IT APPLIES
21 REGARDLESS OF WHETHER OR NOT THERE IS A PATENT OR
22 NOT. SO THAT WAS A CHANGE THAT WAS DONE TO ALIGN
23 OURSELVES WITH THE STATUTE. AS JAMES STATED, THIS
24 IS NOT REQUIRED OF THE ICOC. I BELIEVE THAT THE
25 STATUTE LIMITED THE ROYALTY TO PATENTED INVENTIONS

BARRISTERS' REPORTING SERVICE

1 IN ORDER SO THAT WE CAN ASSURE THAT WE RIDE THE
2 BALANCE OF THE INTEREST IN ENSURING REVENUES TO THE
3 STATE WHILE AT THE SAME TIME MAKING SURE THAT WE
4 ATTRACT THE CRITICAL INVESTMENT THAT IS NEEDED IN
5 ORDER TO ENSURE THAT OUR DRUGS THAT ARE UNDER
6 DEVELOPMENT OBTAIN THE FINANCING THEY NEED IN ORDER
7 TO BECOME COMMERCIALIZED.

8 SO WHAT WE'RE TRYING TO DO IS MIRROR THE
9 LANGUAGE THAT IS IN THE STATUTE.

10 CHAIRMAN PENHOET: ON THIS ONE WE DON'T
11 HAVE TO UNLESS WE WANT TO.

12 MS. BAUM: EXACTLY.

13 CHAIRMAN PENHOET: WE HAVE MORE
14 FLEXIBILITY IN OURS THAN IN THIS ONE. OURS SAYS
15 PATENTED OR UNPATENTED IF IT RESULTED FROM AN
16 INVENTION.

17 MS. BAUM: OURS IS BROADER.

18 CHAIRMAN PENHOET: OURS IS BROADER, SO WE
19 COULD NARROW IT IF WE WANTED TO, BUT WE DON'T HAVE
20 TO.

21 DR. PRIETO: WHAT WOULD BE THE ADVANTAGE?
22 JUST A QUESTION, ELONA, IF YOU CAN ANSWER THIS.
23 WHAT WOULD BE THE ADVANTAGE OF NARROWING IT IF WE'RE
24 NOT REQUIRED TO BY THE STATUTE?

25 MS. BAUM: IT'S TO ENSURE THAT OUR FUNDED

BARRISTERS' REPORTING SERVICE

1 PROJECTS REMAIN AS COMPETITIVE AS REASONABLE TO
2 ATTRACT ADDITIONAL FOLLOW-ON FINANCING. WE ARE ONLY
3 GOING TO FUND THROUGH PHASE II. I'VE HEARD ALREADY
4 FROM VARIOUS INDUSTRY REPRESENTATIVES THAT THEY'RE
5 VERY CONCERNED ABOUT THE 1-PERCENT ROYALTY TO BEGIN
6 WITH. THIS IS A WAY TO ENSURE THAT IT ONLY APPLIES
7 TO PATENTED INVENTIONS.

8 SO THE CONCERN VOICED BY SOME INDUSTRY
9 REPRESENTATIVES IS THAT IF I GET A \$5 MILLION GRANT
10 AND I END UP HAVING A VERY MINUSCULE UNPATENTED
11 INVENTION, ALL OF A SUDDEN -- AND INVEST HUNDREDS OF
12 MILLIONS OF DOLLARS IN DEVELOPING A DRUG, THE 1
13 PERCENT SEEMS TO BE ONEROUS IN THEIR EYES.

14 DR. PRIETO: IT'S NOT 1 PERCENT OF THE
15 INVENTION. IT'S 1 PERCENT OF THE COST. IT'S 1
16 PERCENT OF THE RETURN; ISN'T THAT CORRECT?

17 MS. BAUM: IT'S OF THE PRODUCT.

18 CHAIRMAN PENHOET: IT'S 1 PERCENT OF THE
19 SALES OF THE PRODUCT ABOVE --

20 DR. PRIETO: OF THE PRODUCT. SO THERE ARE
21 NEGLIGIBLE SALES, THEN THERE'S NEGLIGIBLE ROYALTIES.

22 CHAIRMAN PENHOET: IT ONLY COMES INTO
23 ACCOUNT -- THIS IS THE BLOCKBUSTER PROVISION.

24 DR. PRIETO: I'M NOT SURE I UNDERSTAND
25 THAT CONCERN IF IT DOESN'T KICK IN UNLESS YOU HAVE A

BARRISTERS' REPORTING SERVICE

1 PRODUCT WITH SUBSTANTIAL SALES.

2 MS. BAUM: SOME OF THE CONCERNED VOICE
3 WAS, AND THEY ACKNOWLEDGE IT COULD BE A BLOCKBUSTER,
4 BUT THE BLOCKBUSTER WOULD BE, IN THEIR EYES, DUE TO
5 MOST OF THEIR INVESTMENT, NOT CIRM'S INVESTMENT. SO
6 IT SEEMED UNBALANCED IN LIGHT OF THE FACT THAT CIRM
7 WOULD ALREADY BE RECOVERING 9 X TO BEGIN WITH.

8 DR. LEVIN: THIS IS A GREAT CHANGE BECAUSE
9 THIS BRINGS CLARITY TO SOMETHING THAT A LOT OF THE
10 PEOPLE WERE NOT CLEAR ON BEFORE IN THAT WHETHER OR
11 NOT THE 1 PERCENT IS ENOUGH TO DISSUADE POTENTIAL
12 INVESTORS OR COMPANIES TO PUT INTO GROWING A NEW
13 PRODUCT. IT'S CERTAINLY TO SAY THAT IT'S ONLY
14 PATENTABLE INVENTIONS REDUCES THE CHANCE THAT THERE
15 WILL BE SIGNIFICANT LITIGATION LATER ON TRYING TO
16 DETERMINE WHOSE IP IT IS OR WHETHER CIRM HAD SOME
17 OWNERSHIP. AND THAT IN AND OF ITSELF WOULD BE
18 CONSOLING TO A COMPANY, THAT THEY KNOW CLEARLY WHAT
19 INVENTION CIRM HAS A STAKE AND WHAT WE DON'T BECAUSE
20 THERE IS A PATENT OUT THERE THAT WILL STATE WHO IS
21 THE OWNER.

22 MS. BAUM: THAT'S A GOOD POINT TOO.

23 CHAIRMAN PENHOET: I THINK IT'S
24 CLARIFYING. AND IT'S GOING TO BE VERY HARD TO GO
25 BACK AND TRACK UNPATENTED INVENTIONS THAT HAPPENED

BARRISTERS' REPORTING SERVICE

1 YEARS AND YEARS BEFORE. WE MAY NOT EVER GET TO 1
2 PERCENT ON ANYTHING THAT'S NOT PATENTED ANYWAY.

3 MR. ROTH: ED, I JUST WANT TO RAISE A
4 CONCERN HERE EVEN BEYOND -- I'M IN COMPLETE
5 AGREEMENT THAT CLARITY IS IMPORTANT HERE, BUT I'M
6 EVEN CONCERNED THAT SOMEBODY HAS A MINOR PATENT, ONE
7 FOR WHICH THEY CLEARLY AREN'T RELYING ON TO KEEP
8 COMPETITION OUT, THAT THAT'S GOING TO BECOME AN
9 ISSUE AS WELL DOWN THE ROAD. I THINK WE MAY HAVE TO
10 DEAL WITH THAT. I WOULD HAVE LIKED THE TERM A
11 PRIMARY PATENT OR -- I DON'T KNOW THE RIGHT LEGAL
12 TERM FOR IT. BUT, AS YOU KNOW, THERE ARE MULTIPLE,
13 MULTIPLE PATENTS ON A GIVEN PRODUCT, MANY OF WHICH
14 ARE PRETTY MINOR. BUT THERE WILL BE A FUNDAMENTAL
15 PATENT SOMEWHERE THERE. AND IF WE DIDN'T FUND THAT
16 AND THAT EITHER EXISTED PREVIOUSLY OR CAME LATER,
17 THEN I THINK WE MAY HAVE TO DEAL WITH DEFINING THAT
18 IT HAS TO BE A PATENT THEY'RE RELYING ON AND NOT ONE
19 THEY HAPPENED TO FILE FOR AND GOT, BUT HAS NO
20 MATERIAL MEANING.

21 CHAIRMAN PENHOET: WELL, IN ONE SENSE I
22 AGREE WITH YOU, DUANE, BUT THEN IT OPENS UP A WHOLE
23 AREA OF INTERPRETATION.

24 MR. ROTH: I REALIZE THAT, BUT I'M JUST
25 SAYING FOR NOW LET'S GO WITH WHAT WE HAVE, BUT

BARRISTERS' REPORTING SERVICE

1 RECOGNIZE THAT I THINK WE'RE GOING TO HEAR AND THE
2 QUESTIONS WILL BE ASKED DOES THAT MEAN THIS MINOR
3 PATENT WE TOOK OUT WOULD CAUSE US TO KICK IN THE 1
4 PERCENT? WHILE 1 PERCENT DOESN'T SOUND LIKE A LOT,
5 IF YOU LOOK AT IT IN TERMS OF THE PROFITABILITY,
6 IT'S CONSIDERABLE. IT'S A LARGER PERCENT OF THE
7 PROFIT THAN OF SALES.

8 CHAIRMAN PENHOET: TRUE ENOUGH.

9 MR. ROTH: ANYWAY, JUST A HEADS UP.

10 CHAIRMAN PENHOET: BUT YOU'RE SUPPORTING
11 JACOB'S PROPOSAL TO GO WITH 1064 AND DROP THE
12 NONPATENTED?

13 MR. ROTH: THE NONPATENTED WE SHOULD
14 DEFINITELY DROP. THERE MUST BE A PATENT. WE SAID
15 THAT FROM DAY ONE IN THE CONVERSATIONS. IN FACT, IT
16 HAPPENED AT CONNECT, AND JEFF MAY REMEMBER THIS.
17 THAT'S WHERE WE CAME UP WITH THIS LANGUAGE. AND IT
18 WAS SOMEBODY IN THE AUDIENCE WHO POINTED OUT THAT
19 YOU MUST HAVE A PATENTED INVENTION TO GET THAT 1
20 PERCENT. WE SAID, YES, THAT'S CORRECT. AND SOMEHOW
21 WE DIDN'T QUITE GET THAT TRANSLATED CORRECTLY. IT
22 SAID PATENTED OR UNPATENTED. CLEARLY THAT WAS THE
23 DISCUSSION.

24 MR. SHEEHY: I REMEMBER THAT, DUANE. I
25 THINK YOUR RECOLLECTION IS ACCURATE.

BARRISTERS' REPORTING SERVICE

1 MR. ROTH: THE REASON I REMEMBER IS THE
2 GUY WHO MADE IT IS THE ONE THAT DIED OF A SUDDEN
3 HEART ATTACK, AND I REMEMBER THAT SO CLEARLY THAT
4 WAS HIS ONLY POINT IN THAT MEETING.

5 CHAIRMAN PENHOET: I THINK, DUANE, YOU'RE
6 THE ONE THAT CAME UP WITH THAT NICE FLOWCHART ON HOW
7 THIS WOULD ALL WORK, AND IT CONTAINED PATENTED
8 INVENTION. AND THAT'S SORT OF WHAT WE RELIED ON AS
9 THE SORT OF DESCRIPTOR, VISUAL DESCRIPTOR OF WHAT WE
10 WANTED TO DO.

11 SO, FRANCISCO, YOU HAD SOME CONCERNS ABOUT
12 THIS. DO YOU STILL HAVE CONCERNS?

13 DR. PRIETO: I GUESS NOT. I'M WILLING TO
14 GO WITH THIS. I THINK IT SEEMS LIKE A REASONABLE
15 CHANGE.

16 CHAIRMAN PENHOET: ANYBODY ELSE DISAGREE?
17 OKAY.

18 SO THEN I THINK WE NOW HAVE A QUORUM, DO
19 WE NOT, MELISSA?

20 MS. KING: THAT IS CORRECT.

21 CHAIRMAN PENHOET: SO WE'D LIKE TO MAKE A
22 RECOMMENDATION THAT WE ACCEPT THE LANGUAGE OF 1064
23 IN PLACE OF OUR LANGUAGE AND MAKE THIS 1-PERCENT
24 ROYALTY SUBJECT TO A PATENT.

25 MR. ROTH: I'LL MAKE THAT MOTION.

BARRISTERS' REPORTING SERVICE

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MR. GOLDBERG: SECOND.

CHAIRMAN PENHOET: ALL RIGHT. ALL IN FAVOR.

MS. KING: SORRY TO HAVE TO DO THIS, BUT WE HAVE TO MAKE A ROLL CALL VOTE SINCE WE'RE ON THE PHONE.

CHAIRMAN PENHOET: GO FOR IT.

MS. KING: JACOB LEVIN.

DR. LEVIN: YES.

MS. KING: MICHAEL GOLDBERG.

MR. GOLDBERG: YES.

MS. KING: ED PENHOET.

CHAIRMAN PENHOET: YES.

MS. KING: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. KING: DUANE ROTH.

MR. ROTH: YES.

MS. KING: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. KING: OSWALD STEWARD.

DR. STEWARD: YES.

MS. KING: FOR THE RECORD, THE MOTION CARRIES. SEVEN YES VOTES, NO NO VOTES, NO ABSTENTIONS.

MS. BAUM: AND THEN NOW WE JUST NEED TO

BARRISTERS' REPORTING SERVICE

1 ADDRESS THE OTHER AMENDMENT, PROPOSED AMENDMENT.

2 CHAIRMAN PENHOET: THIS IS THE ACCESS
3 PLAN.

4 MS. BAUM: DOES SOMEONE WANT TO MAKE A
5 MOTION TO APPROVE THE PROPOSED AMENDMENT TO 10607?

6 CHAIRMAN PENHOET: THAT AMENDMENT IS OF
7 THE THREE THINGS WE'RE DISCUSSING UNDER ACCESS, THE
8 ONE WE'RE GOING TO MOVE ON TODAY IS THE TIMING OF
9 THE PROPOSAL SUBSEQUENT TO FDA APPROVAL, RIGHT?

10 DR. PRIETO: WHAT PAGE IS THAT ON ON THE
11 DOCUMENT?

12 MS. BAUM: IT'S, I BELIEVE, ON PAGE 1 AND
13 2.

14 MR. ROTH: WHILE YOU'RE LOOKING FOR THAT,
15 I'LL MAKE A MOTION THAT WE APPROVE THE 1064 LANGUAGE
16 FOR ACCESS.

17 CHAIRMAN PENHOET: THE REDLINE VERSION IS
18 UNDER EXHIBIT A, NOT IN THE OVERVIEW DOCUMENT THAT
19 ELONA GAVE YOU.

20 MS. KING: THERE'S ONE WHOLE DOCUMENT.
21 THERE ARE ESSENTIALLY TWO DOCUMENTS. ONE IS A MEMO
22 THAT ELONA PREPARED, AND THEN THE SECOND PART OF IT
23 IS THE ACTUAL LANGUAGE THAT IS BEING EDITED HERE
24 FROM THE ORIGINAL REGULATORY LANGUAGE, I BELIEVE.
25 AND SO IT WAS SENT TO YOU AS ONE DOCUMENT. SO FOR

BARRISTERS' REPORTING SERVICE

1 WHAT WE'RE TALKING ABOUT NOW, IT'S ACTUALLY ON PAGE
2 4 OF A SEVEN-PAGE DOCUMENT, BUT IT IS THE FIRST PAGE
3 OF THE REDLINED VERSION, WHICH IS --

4 DR. PRIETO: OKAY.

5 MS. BAUM: THAT BEING THE CASE --

6 DR. PRIETO: EXHIBIT A.

7 MS. BAUM: EXHIBIT A, BUT THE REDLINING IS
8 INCORRECT ON THAT EXHIBIT A UNFORTUNATELY.

9 CHAIRMAN PENHOET: IF I COULD, THE MAJOR
10 DIFFERENCE IS OUR CURRENT LANGUAGE SAYS THAT THEY
11 HAVE TO SUBMIT AN ACCESS PLAN NO FEWER THAN 90 DAYS
12 PRIOR TO THE TIME THE DRUG IS COMMERCIALIZED IN
13 CALIFORNIA. THE NEW LANGUAGE SAYS WITHIN TEN
14 BUSINESS DAYS FOLLOWING THE FINAL APPROVAL OF THE
15 DRUG BY FDA, THEY HAVE TO SUBMIT A PROPOSAL FOR
16 ACCESS OR APPLY FOR AN EXTENSION SO THEY CAN GET
17 ANOTHER 20 DAYS TO 30 DAYS.

18 MS. KING: JUST FOR ANY MEMBERS OF THE
19 PUBLIC THAT HAVE JOINED US, IT SOUNDS LIKE THE
20 LANGUAGE THAT WAS JUST READ WAS JUST RECEIVED TODAY,
21 AND SO WE WILL POST IT THIS AFTERNOON. I WASN'T
22 AWARE OF IT, SO I APOLOGIZE THAT MOST OF YOU ON THE
23 PHONE DON'T HAVE IT. WE'LL E-MAIL IT TO YOU
24 FOLLOWING THE MEETING, AND ALSO WE'LL GET IT POSTED.

25 CHAIRMAN PENHOET: IT'S DESCRIBED IN THE

BARRISTERS' REPORTING SERVICE

1 DOCUMENT THAT ELONA SENT US. CLEARLY DESCRIBED
2 THERE.

3 MS. BAUM: IT'S CLEARLY DESCRIBED THERE.

4 DR. PRIETO: OKAY.

5 CHAIRMAN PENHOET: THAT'S THE PROPOSAL.
6 DUANE HAS MADE A MOTION THAT WE APPROVE THAT CHANGE.

7 DR. PRIETO: SECOND.

8 CHAIRMAN PENHOET: OKAY. CALL THE ROLL
9 THEN, MELISSA.

10 MR. HARRISON: DR. PENHOET, DO YOU WANT TO
11 JUST SEE IF THERE'S ANY PUBLIC COMMENT?

12 CHAIRMAN PENHOET: OH, NO. EXCUSE ME. OF
13 COURSE. DO WE HAVE ANY PUBLIC COMMENT?

14 MS. KING: WE DO HAVE ONE HERE IN SAN
15 FRANCISCO.

16 MR. REED: THIS IS DON REED. I'M VERY
17 ANXIOUS THAT THIS GO FORWARD. WE DON'T WANT ANY
18 MORE LEGISLATIVE LAWS THAT HAVE UNPREDICTABLE AND
19 NEGATIVE EFFECT. I JUST WANT TO MAKE SURE. I THINK
20 THAT WE ARE NOT TALKING ABOUT THE PART ON PAGE 2
21 WHICH SAYS SB 1064, FIRST CALIFORNIANS WHO HAVE NO
22 OTHER MEANS TO PURCHASE THE DRUG BECAUSE THAT
23 SENTENCE, I THINK, WILL COME BACK TO HAUNT US.
24 THAT'S NOT UNDER DISCUSSION AT THIS POINT?

25 CHAIRMAN PENHOET: IT'S NOT UNDER

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1 DISCUSSION AT THIS POINT.

2 MR. REED: THANK YOU.

3 CHAIRMAN PENHOET: THIS IS PURELY THE
4 TIMING OF THE SUBMISSION OF THE PLAN, CHANGING FROM
5 90 DAYS PRIOR TO COMMERCIALIZATION IN CALIFORNIA TO
6 WITHIN TEN DAYS POST FINAL APPROVAL BY THE FDA OR 30
7 DAYS IF SOMEBODY HAS APPLIED FOR AN EXTENSION DURING
8 THE TEN-DAY WINDOW AFTER FDA APPROVAL.

9 MS. BAUM: AND IF GRANTED.

10 CHAIRMAN PENHOET: YES. OF COURSE. OKAY.
11 ANY OTHER PUBLIC COMMENT? THANK YOU, DON. NOW --

12 DR. PRIETO: I HAVE A QUESTION BEFORE
13 WE -- IS THE GRANTING OF THE EXTENSION DEPENDENT ON
14 A DECISION OF THE ICOC, OR IS THAT SOMETHING THAT
15 PRESIDENT OF CIRM AND HIS OR HER STAFF COULD DECIDE?

16 CHAIRMAN PENHOET: I THINK IT WOULD HAVE
17 TO BE STAFF BECAUSE THE LOGISTICS OF GETTING AN ICOC
18 MEETING PULLED TOGETHER WITHIN FIVE DAYS -- FIRST OF
19 ALL, NO ONE CAN PREDICT WHEN YOU'LL GET FINAL
20 APPROVAL. IT COMES LIKE, YOU KNOW, A RAINSTORM,
21 JUST DROPS ON YOU. I THINK IT WOULD HAVE TO BE
22 STAFF.

23 DR. PRIETO: OKAY.

24 CHAIRMAN PENHOET: I THINK THE FINAL PLAN
25 HAS TO BE APPROVED BY THE ICOC, BUT THE SUBMISSION

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1 FOR THE APPROVAL, I THINK --

2 MS. KING: FOR THE EXTENSION.

3 CHAIRMAN PENHOET: FOR THE EXTENSION.

4 DR. PRIETO: OKAY.

5 CHAIRMAN PENHOET: APPROVAL FOR THE
6 EXTENSION WOULD HAVE TO BE GIVEN BY STAFF.

7 MS. KING: I THINK ACTUALLY I'D LIKE TO
8 HAVE SCOTT TOCHER MAKE A COMMENT ON THIS SINCE
9 THERE'S CONFUSION. IT'S ALWAYS GOOD TO RESORT TO
10 SCOTT.

11 MR. TOCHER: THE WAY THE REGS CURRENTLY
12 ARE STRUCTURED, THE PLAN IS SUBMITTED TO CIRM, AND
13 CIRM HOLDS A HEARING PRIOR TO THE PLAN.

14 CHAIRMAN PENHOET: WE'RE TALKING ABOUT
15 SUBMISSION OF THE PLAN, NOT APPROVAL OF THE PLAN.
16 THAT'S WHAT THIS IS ABOUT.

17 DR. PRIETO: OKAY.

18 CHAIRMAN PENHOET: RIGHT.

19 MR. TOCHER: THAT'S RIGHT.

20 MS. BAUM: YOU'RE RIGHT. I THINK 30 DAYS
21 IS SHORT, BUT THAT'S WHAT'S IN THE STATUTE.

22 CHAIRMAN PENHOET: SO WE'RE NOT CHANGING
23 THE WAY IN WHICH A SUBMITTED PLAN IS APPROVED.
24 WE'RE JUST CHANGING THE TIMING OF THE SUBMISSION.

25 MR. TOCHER: THAT'S RIGHT.

BARRISTERS' REPORTING SERVICE

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DR. PRIETO: OKAY.

CHAIRMAN PENHOET: OKAY. IT'S BEEN MOVED BY DUANE. WE'VE HAD COMMENTS. ANY OTHER COMMENTS FROM MEMBERS OF THE SUBCOMMITTEE? NOW, MELISSA.

MS. KING: JACOB LEVIN.

DR. LEVIN: YES.

MS. KING: MICHAEL GOLDBERG.

MR. GOLDBERG: YES.

MS. KING: ED PENHOET.

CHAIRMAN PENHOET: YES.

MS. KING: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. KING: DUANE ROTH.

MR. ROTH: YES.

MS. KING: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. KING: OSWALD STEWARD.

DR. STEWARD: YES.

MS. KING: AND THAT MOTION CARRIES FOR THE RECORD.

CHAIRMAN PENHOET: OKAY. AND THEN, ELONA, THERE ARE TWO OTHER ISSUES THAT STAFF WOULD LIKE SOME MORE TIME TO WORK ON. ONE IS THE LANGUAGE AROUND WHO WOULD QUALIFY FOR THE ASSISTANCE, IF YOU WILL, THE LANGUAGE WHICH 1064 CURRENTLY SAYS ANYONE

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1 UNABLE TO PAY VERSUS UNINSURED. AND THEN THE OTHER
2 ONE --

3 MS. BAUM: WELL, THE STATUTE PROVIDES A
4 WAIVER PROCEDURE. AND WE DID NOT DECIDE TO TAKE
5 THAT UP AT THIS TIME. WE'LL HAVE TO RECONVENE IN
6 FEBRUARY AND DISCUSS THOSE ASPECTS.

7 CHAIRMAN PENHOET: SO STAFF WILL COME BACK
8 WITH FURTHER REFINEMENTS OF A RECOMMENDATION FOR US
9 TO CONSIDER ON THOSE TWO ISSUES.

10 MS. BAUM: CORRECT.

11 CHAIRMAN PENHOET: IS THAT CORRECT?

12 MS. BAUM: CORRECT.

13 CHAIRMAN PENHOET: OKAY. ALL RIGHT. DO
14 WE HAVE ANY OTHER BUSINESS BEFORE THIS COMMITTEE
15 TODAY?

16 MS. KING: NOT TODAY. BUT I WILL BE IN
17 TOUCH WITH YOU ABOUT A NEXT MEETING, AND I BELIEVE
18 THE TIMELINE FOR THAT THAT'S BEEN DISCUSSED IS
19 FEBRUARY.

20 MS. BAUM: CORRECT.

21 MS. KING: SO IT WON'T BE UNTIL AFTER THE
22 MARATHON OF MEETINGS THAT WE HAVE IN THE COUPLE
23 WEEKS AND THEN THE HOLIDAYS THAT I ACTUALLY COME TO
24 YOU ABOUT THE NEXT IP TASK FORCE MEETING. AREN'T
25 YOU HAPPY ABOUT THAT?

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1 MR. GOLDBERG: I'M NOT HAPPY ABOUT THAT
2 FOR ONE REASON. THAT WOULD MAKE THIS DR. PENHOET'S
3 LAST MEETING AS CHAIR OF THIS SUBCOMMITTEE.

4 MS. KING: THAT IS AN EXCELLENT POINT, MR.
5 GOLDBERG.

6 MR. GOLDBERG: DR. PENHOET, YOUR SERVICE
7 HAS BEEN EXTRAORDINARY.

8 CHAIRMAN PENHOET: THANK YOU VERY MUCH.

9 (A CHORUS OF HERE, HERE)

10 (APPLAUSE.)

11 MR. SHEEHY: ABSOLUTELY. I ECHO THAT.

12 CHAIRMAN PENHOET: EASY TO DO A GOOD JOB
13 IF YOU HAVE SUCH GREAT COLLEAGUES, ALL OF STAFF AND
14 REST OF THE PEOPLE ON THIS SUBCOMMITTEE. I THINK IT
15 WAS AN AMAZING GROUP, FRANKLY.

16 MS. KING: AGREED.

17 MS. BAUM: YOU WILL VERY MUCH BE MISSED.

18 CHAIRMAN PENHOET: THANKS TO ALL OF YOU
19 FOR YOUR HELP WITH THIS, FOR SURE. THANK YOU FOR
20 YOUR KIND WORDS.

21 MS. KING: THANK YOU, EVERYBODY. HAPPY
22 THANKSGIVING.

23 (THE MEETING WAS THEN CONCLUDED AT
24 02:02 P.M.)

25

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 HELD ON TUESDAY, NOVEMBER 23, 2010, 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