

BEFORE THE OFFICE OF TAX APPEALS

STATE OF CALIFORNIA

In the Matter of the Appeal of:)
)
INTARCIA THERAPEUTICS, INC.) OTA NO. 220911369
)
Appellant.)
)

CERTIFIED COPY

TRANSCRIPT OF PROCEEDINGS

Sacramento, California

Wednesday, February 21, 2024

Reported by:

CHRISTINA RODRIGUEZ
Hearing Reporter

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14 TRANSCRIPT OF PROCEEDINGS, taken at
15 400 R Street, Sacramento, California,
16 commencing at 1:00 p.m. and concluding
17 at 3:04 p.m. on Wednesday, February 21, 2024,
18 reported by Christina L. Rodriguez,
19 Hearing Reporter.
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1 APPEARANCES:

2
3 Administrative Law Judge: JUDGE BROWN
4 JUDGE GEARY
5 JUDGE ALDRICH

6 For the Appellant: WILLIAM LOEW
7 JOHN HUK

8 For the Respondent: AMANDA JACOBS
9 CARY HUXSOLL
10 JASON PARKER
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I N D E X

E X H I B I T S

(Appellant's Exhibits 1-123 were received at page 14)

(CDTFA's Exhibits A-H were received at page 14)

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By Ms. Jacobs

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By Mr. Loew

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1 Sacramento, California; Wednesday, February 21, 2024

2 1:00 p.m.

3
4 JUDGE BROWN: We are on the record for the
5 appeal of Intarcia Therapeutics Inc. OTA case number
6 220911369. Today is Wednesday, February 21, 2024. It
7 is approximately 1:02 p.m. We are holding this hearing
8 in Sacramento, California.

9 I am Suzanne Brown, and I am the lead ALJ for
10 this case. My co-panelist today are Judge -- Judges
11 Josh Aldrich and Michael Geary. Although I am the lead
12 ALJ for purposes of conducting the hearing, all three
13 ALJ's are coequal decision makers in this process and
14 are free to ask questions at anytime.

15 I will start by asking each of the
16 participants to please state their name for the record.
17 I'll begin with CDTFA

18 MS. JACOBS: Amanda Jacobs, Attorney for
19 CDTFA.

20 MR. HUXSOLL: Cary Huxsoll for the
21 Department's Legal Division.

22 MR. PARKER: Jason Parker, Chief of
23 Headquarter's Operation Bureau of CDTFA.

24 MR. LOEW: William Loew, Representative Myles
25 Consulting Group.

1 MR. HUK: John Huk, Representative Myles
2 Consulting Group.

3 MS. BROWN: Thank you everyone.

4 The first thing I want to do is briefly
5 confirm the issue that we are hearing today. We had two
6 prehearing conferences in this matter.

7 One was on October 9th, and the second one or
8 more recent one was on January 24th, 2024. And I issued
9 prehearing Minutes and Orders after both prehearing
10 conferences so I'm just confirming the issues and other
11 things we talked about at those prehearing conferences.

12 As we discussed at both prehearing
13 conferences, the issue is Appellant's claim for refund
14 that is dated September 25th, 2020. And the issue is
15 whether Appellant is entitled to an additional refund
16 for used-tax paid on it's purchases of ITCA-650
17 components.

18 And I'll just confirm with the parties that
19 that is correct and that is their understanding.
20 Appellant?

21 MR. LOEW: Judge Brown, there was also a
22 earlier claim for refund I believe on July 13th, 2020.
23 That also should -- is a part of the record and is under
24 consideration today as well.

25 MS. BROWN: My understanding that we clarified

1 in both prehearing conferences, that, I thought, was
2 only the September 25th, 2020 claim for refund that is
3 at issue. Can everybody pull up their Minutes and
4 Orders.

5 For example, I'm looking at the Minutes and
6 Orders; the most recent one from January 2024. Under
7 the Section, it says "issue." It's at the bottom of
8 page one.

9 It says -- if I should give everyone a moment
10 to find the document, I can.

11 I'll read from it. It says:

12 "At issue is Appellant's claim for refund
13 dated September 25th, 2020."

14 I guess I'll start with Appellant.

15 Is that not correct? What we clarified at the
16 prehearing conference.

17 MR. LOEW: Partially correct. The claim for
18 -- again, a earlier claim for refund that was part of
19 the audit record that was addressed in the audit report
20 and the appeal's conference that -- it was also part of
21 the appeal's conference report, but it's dated July
22 13th, 2020.

23 JUDGE BROWN: And you're saying that's an
24 issue in this case as well.

25 MR. LOEW: I believe -- it's the contentions

1 under that claim for refund are going to be brought up
2 today.

3 JUDGE BROWN: Are you saying simply that there
4 were arguments that were raised for that claim for
5 refund and you're going to raise the same arguments?

6 MR. LOEW: Correct.

7 JUDGE BROWN: Or are you saying that there are
8 -- is a tax amount that was part of that claim for
9 refund that you are -- is currently in dispute in this
10 case.

11 MR. LOEW: The the same arguments.

12 JUDGE BROWN: Okay. Were the arguments that
13 you're talking about for the July claim for refund not
14 raised regarding the September 2020 claim for refund?

15 MR. LOEW: As you will see in the September
16 reclaim for refund it was a more narrow issue that was
17 raised. But the July 2020 claim for refund is a broader
18 claim for refund and it covers all areas of used-tax.

19 JUDGE BROWN: Again, but you're saying all the
20 money that is at issue in the -- concerning the units
21 are all covered only by the September 2020 claim for
22 refund. We're not concerned with the July 2020? I
23 think you said July 2020 claim for refund.

24 MR. LOEW: No, we are concerned with July '20.
25 July 13th, 2020.

1 JUDGE BROWN: But in the appeal's decision,
2 hold on. The appeal's decision says:

3 "The following discussion pertains only to
4 claimant's September 2020 claim for refund."

5 So the appeal's decision said it did not
6 include the July claim for refund. In fact, it says:

7 "During the appeal's conference, claimant
8 confirmed that it no longer seeks a refund."

9 And then it describes some items which were
10 the subject of claimants July 13th, 2020 claim for
11 refund. So when you said that, you thought that the
12 July 2020 claim for refund was part of the appeal's
13 decision; is that still correct?

14 MR. LOEW: We did believe it was still part of
15 the appeal.

16 JUDGE BROWN: Alright. Well -- and I'm going
17 to let CDTFA respond. I'm going to ask for CDTFA's
18 response in just a minute, but I just want to clarify my
19 questions first.

20 If the July 2020 claim for refund is also part
21 of this appeal, then when I held the two prehearing
22 conferences and issue the minutes and orders that said
23 that we clarified during the prehearing conferences
24 that it was only the September 2020 claim for refund
25 that was at issue.

1 Is there a reason Appellant didn't speak up at
2 that time and say, "No. That's wrong. That's
3 incorrect"?

4 MR. LOEW: I think as we go through the
5 arguments today, it will become clearer as we -- that
6 all of the issues have been raised. They were all
7 raised in the appeal's conference. We're not going to
8 be -- we just want to make sure that everyone is aware
9 of the claim for refund that was filed in July of 2020.

10 JUDGE BROWN: When you say "aware," do you
11 mean as part of the background facts? Or as part of the
12 remedy that you are asking me to grant -- asking the
13 panel --

14 MR. LOEW: This claim may be both, but that
15 will be your decision. But it may be both.

16 JUDGE BROWN: Is there a reason why this
17 wasn't clarified during either of the two prehearing
18 conferences or after I issued the prehearing conference
19 minutes and orders that clarified -- that confirmed what
20 we talked about at the prehearing conferences.

21 MR. LOEW: Judge Brown, you may recall in our
22 last pre -- most recent prehearing conference. We
23 raised -- since the appeal's decision came down, we
24 looked at this issue from a bit of a different angle.

25 Although all of the issues that we are going

1 to be raising today in terms of regulation, statute, are
2 all -- were all raised with the appeal's officer. So we
3 had talked about this a bit in our preconference. I
4 think the CD -- you would ask the CDTFA how you'd like
5 to resolve that and come to the hearing and discuss it.

6 JUDGE BROWN: I do recall, and I was going to
7 recount that. And it's in the most recent minutes and
8 orders that -- we discussed that appellant was raising a
9 new legal theory related to the September 2020 claim for
10 refund, and we discussed whether we'd have prehearing
11 briefing on that. And the CDTFA had some concerns about
12 the timing.

13 So I agree, I hear the arguments -- or the
14 panel will hear the arguments for that legal theory now;
15 and I understand that. I just want to make sure that
16 you aren't raising a new claim for refund about a
17 different amount of money or a different units. Units
18 meaning the ITCA-650 units components.

19 MR. LOEW: Same amount. Same issue.

20 JUDGE BROWN: Okay. So to the extent, you're
21 raising legal arguments that you may have raised for the
22 July 2020 claim for refund that's part of the new legal
23 theory that you talked about?

24 MR. LOEW: Correct.

25 JUDGE BROWN: Okay. But it is still the

1 September 2020 claim for refund that is the only one
2 that's in dispute here?

3 MR. LOEW: Correct.

4 JUDGE BROWN: Okay. Then I will turn to CDTFA
5 and say is this -- I guess do you have any response? Is
6 it your understanding that, again, we are -- that the
7 issue as stated earlier about the September 25th, 2020
8 claim for refund is the correct issue -- statement of
9 the issue?

10 MS. JACOBS: That's also our understanding in
11 the department's brief which we filed November 28th,
12 2022. We clarified that in footnote too that we
13 understood that it was only the September 25th, 2020
14 claim for refund that was at issue on this appeal.

15 JUDGE BROWN: Alright. I think we have
16 clarified.

17 Again, it's the September 25th, 2020 claim for
18 refund. There are new and is confirmed in the January
19 2024 prehearing conference minutes and orders appellant
20 is raising a new legal argument -- legal theory and may
21 have been raised regarding a previous claim for refund
22 is now being raised -- is a legal argument regarding
23 this claim for refund at issue.

24 Okay. Then I think I have covered all of that
25 in terms of clarifying what the issue is.

1 Okay. And as I noted in the minutes and
2 orders and we discussed at the prehearing conference, at
3 the end of the hearing today, we, the panel, determined
4 in consultation with the parties whether any
5 post-hearing briefing is necessary to raise -- to
6 address appellant's new argument.

7 If we are done confirming the issue, I'm going
8 to move on to admitting the exhibits into evidence.
9 Both parties timely submitted their proposed exhibits
10 prior to the 15 day deadline.

11 The prehearing conference minutes and orders
12 set out a February 15th deadline for the parties to
13 notify OTA any opposing party -- if they had any
14 objection to either to the opposing party's exhibits
15 being admitted into evidence, and I did not receive any
16 objections.

17 So -- and I -- from what the parties indicated
18 at the prehearing conferences, I was not anticipating
19 any objection. So I will just address each party's
20 exhibits one by -- in turn.

21 First, I'll address Appellant's Exhibits.
22 Appellant timely submitted Exhibits 1-123.

23 Does CDTFA have any objection to these
24 exhibits being admitted into evidence?

25 MS. JACOBS: No objection. Thank you.

1 JUDGE BROWN: Thank you. And then I will
2 address CDTFA's Exhibits A-H.

3 Does appellant have any objection to these
4 exhibits being admitted into evidence?

5 MR. LOEW: No objections.

6 JUDGE BROWN: Thank you. Appellant's Exhibits
7 1-123, and CDTFA's Exhibits A-H are admitted into
8 evidence.

9 And I'll just briefly note that as we
10 discussed at the prehearing conferences, Appellant's
11 Exhibit 37 and 38 are video exhibits. And all have
12 confirmed that all the panel members have watched the
13 video prior to this hearing, and, therefore, we don't
14 need to actually play the videos during the hearing.

15 But the parties are, of course, here to make
16 any arguments about those exhibits or any of the
17 exhibits during their presentations. And then I'm just
18 going to briefly go over the timeline that we anticipate
19 for the hearing today.

20 Appellant estimated it will take 45 minutes
21 for it's opening presentation. And after appellant's
22 opening presentation, there will be -- anticipate there
23 will be questions from the panel. And then we will have
24 CDTFA's presentation. CDTFA estimated 25 minutes.

25 And then after CDTFA completed it's

1 presentation, I anticipate we may have questions from
2 the panel. After that, we will have time for
3 appellant's rebuttal; we estimated five minutes.

4 If, at any point, during the proceeding anyone
5 needs a short break after -- you know, at a natural
6 breaking point, like, after one party has completed its
7 presentation or both parties have; please, just request
8 a break, and we should be able to take one.

9 Does anyone have anything to raise before we
10 begin with appellant's presentation? Have I covered all
11 of the logistical things we need to address at this
12 point? Okay. Given that no one's raised anything, I
13 think that we are ready to begin with appellant's
14 presentation.

15 I will say appellant has 45 minutes.

16
17 PRESENTATION

18 MR. LOEW: Thank you, Judge Brown, and Judge
19 Aldrich, and Judge Geary. Thank you.

20 Intarcia Therapeutics is founded in 1995.
21 They're headquartered -- or were headquartered in
22 Boston, Massachusetts. They had a large research and
23 development facility in North Carolina, and their
24 manufacturing facility was in Hayward, California.

25 As you mentioned, Intarcia was developing an

1 implantable medical device for the treatment of
2 diabetes. It was called the ITCA-650. So, basically,
3 the device was rather having many injections, the
4 patient would be -- the device would provide patients
5 with an extended release of medicine, and it would last
6 up to 12 months.

7 Intarcia have been approved by the FDA to
8 conduct clinical trials. Clinical trials ran between
9 2013 and 2018, approximately, on human beings and over
10 5,000 patients. Had over 500 locations around the world
11 were part of the study -- the testing. An estimated
12 over 12,000 devices were used during those clinical
13 trials.

14 Intarcia was in their final stage of clinical
15 trials, phase three, and was anticipating approval of
16 its drug by the FDA. At that time, there was
17 approximately over a billion dollars of investment in
18 Intarcia. There was a huge capital outlay that have
19 been made, and investors were anticipating a return on
20 their investment.

21 So Intarcia started ramping up their
22 procurement of components of ITCA-650 so that they could
23 be ready to go to market upon FDA approval. It must be
24 emphasized that the company was anticipating that FDA
25 approval, and that it was going to market.

1 We've provided, as you said, 123 exhibits.
2 Most of them are around the business environment that
3 Intarcia was dealing with as they went through the
4 revolution; and were -- ultimately, they ended up
5 towards the end of the clinical trial phases.

6 Company began procuring large quantities of
7 components. Over 4,000 units from primarily four
8 vendors; two were in-state, and two were out-of-state.
9 The two out of state vendors were -- that were the
10 largest out-of-state vendors were known as RMS and
11 Invibio.

12 (Reporter Interruption)

13 MR. LOEW: R-M-S, and Invibio, I-N-V-I-B-I-O.

14 All of the units that we have in our claim for
15 refund were shipped to Hayward, the manufacturing
16 facility; and accounted for as raw materials in their
17 books and records.

18 At issue in this case, is that Intarcia paid
19 used-tax on approximately \$10 million dollars of
20 component purchases from out-of-state vendors. This is
21 Exhibit 84. We've listed three vendors. Two that I
22 just mentioned, and one varying significant vendor
23 that's also listed in that exhibit.

24 All of these components were purchased for two
25 reasons and two reasons only: For use of clinical

1 trials or as raw material components that were
2 ultimately to be resource.

3 Intarcia did not issue a resale's certificate
4 as it did not have approval to sell the ITCA-650 and did
5 not have a seller's permit in California. It's our
6 position that Intarcia is entitled to a refund of the
7 tax on the ITCA-650 devices used in clinical trials; as
8 well as a refund for the tax on components purchased of
9 manufacturer, assemble, and fabricate the ITCA-650.

10 They were ultimately to be for resale.

11 I'll pause right there and just ask if anybody
12 has questions about the facts.

13 JUDGE BROWN: You can proceed with your whole
14 presentation. Occasionally, we might interrupt you if
15 we are confused, but usually we hold our questions until
16 the end of the presentation so that we don't interrupt
17 you.

18 MR. LOEW: Sure. Thank you.

19 I'd like to start with California Revenue and
20 Taxation Code 6008; I'll just refer to it as "Section"
21 from here on out.

22 Section 6008, in part, says:

23 "Storage including any keeping retention in
24 the state for any purpose except in regular course of
25 business." Again, Section 6008 is the definition of

1 storage.

2 Section 6009 nine is the definition of use.
3 And it states:

4 "Use includes the exercise of right or power
5 over tangible personal property, incident to the
6 ownership of that property." It goes on to say, "except
7 that it does not include the sale of that property in
8 the regular course of business."

9 The only use made of the ITCA-650 was in
10 clinical trials and that was in an exempt use pursuant
11 to Regulation 1591 (e)(4).

12 Section 6201 is the Imposition of used-tax.
13 The definition for the Imposition of used-tax requires
14 storage, use, or other consumption of tangible property
15 in California.

16 Intarcia meets the exception noted in the
17 definition of storage under Section 6008 for the
18 components of the ITCA-650 in California.

19 Again, its only other use of the ITCA-650 were
20 for exempt clinical trials. Intarcia's possession of
21 tangible personal property in California is for the
22 purpose of sale in the regular course of business.
23 There's should be, and therefore no used-tax should be
24 imposed or due by Intarcia.

25 Regulation 1525 -- California Sales of

1 used-tax, Regulation 1525 (b), states the following:

2 "Tax does not apply to the sales of tangible
3 personal property to persons." I want to highlight the
4 word "persons" and emphasize that.

5 "Persons who purchase it for the purpose of
6 incorporating it into the manufactured article to be
7 sold as, for example, any raw materials becoming an
8 ingredient or a component of a manufactured article."

9 Section 6005 is the definition of a person. A
10 person includes any individual, firm, partnership, joint
11 venture -- it goes on; corporation, this other type of
12 entities that goes on within the definition.

13 Please note that the specific entities listed
14 in the definition of a person do not include the
15 following: The definition of a seller or a retailer.
16 They do not include those terms; seller or retailer.

17 Section 6014 is the definition of a seller.
18 It says:

19 "The seller includes every person engaged in
20 the business of selling tangible personal property. Of
21 a kind that gross receipts from the retail sale of which
22 are required to be in the measure of sales tax."

23 A person is not necessarily a seller. To be a
24 seller, a person must be engaged in the business of
25 selling tangible personal property.

1 The definition of a retailer is Section 6015.
2 And it states:

3 "Every seller who makes any retail sell or
4 sales of tangible personal property and every person
5 engaged in the business of making retail sales of an
6 auction of tangible personal property owned by a person
7 or others."

8 Intarcia has never sold any tangible personal
9 property. So they are neither a seller, nor a retailer.
10 The CDTFA auditor in the audit never found -- never
11 found evidence of Intarcia making any sale of tangible
12 personal property. During the audit -- and, again,
13 Intarcia was prohibited from selling the ITCA-650 until
14 it received FDA approval.

15 So Intarcia is nothing more than a person by
16 definition. As defined by Section 6005 and within the
17 context of California sales and used-tax Laws and
18 Regulations.

19 Again, I must reiterate that Section -- or
20 that Regulation 1525 states:

21 "Tax does not apply to the sales of tangible
22 personal property to persons who purchase it for any
23 purpose of incorporating it into the manufactured
24 article to be sold; or as, for example, any raw
25 materials becoming an ingredient or a component of the

1 manufactured article."

2 Intarcia is that person. Again, the
3 regulation does not require the person purchasing the
4 items to be manufactured to be a seller or a retailer.

5 Therefore, Intarcia's purchase of it's raw
6 materials and components are not taxable. I do want to
7 note that this regulation was raised in the earlier
8 appeal's conference. And all parties that were present
9 were aware of the manufacturing facilities in Hayward
10 and that Intarcia was not a retailer.

11 Section 6901 is entitled Credits and Refunds,
12 and it states that if the department determines that any
13 amount, penalty, or interest has been paid more than
14 once or have erroneously or illegally collected, the
15 department shall set forth that fact in the records of
16 the department and shall certify the amount collected;
17 and excess of the amount legally due and the person from
18 whom it was collected or by whom paid.

19 It goes on to say under Section -- Subsection
20 (1), any amount of tax interest appellant was not
21 required to be paid.

22 Intarcia erroneously paid used-tax to it's
23 vendors as outlined in Exhibit 84 and is entitled to a
24 refund of the tax pay.

25 Regulations 1684 (h), Refunds of Excess Tax

1 Collections states, in part, Section 6901 of the Revenue
2 Tax requires any overpayment of used-tax be credited or
3 refunded only to the purchaser who made the overpayment.
4 Therefore, the refund of the tax should be paid directly
5 to Intarcia.

6 Also like to note that Regulation 1701,
7 Tax-Paid Purchases Resold, was raised in the claim for
8 refund, as well as in our appeal's conference. The
9 first sentence of the Regulations states that Tax-Paid
10 Purchases Resold provides for a deduction for sales tax
11 paid by a retailer; Intarcia is not a retailer.

12 Therefore, Regulation 1701 is not relevant in
13 this case. We refer back to the Regulation 1525.

14 MR. HUK: Just to add to the Regulation 1525,
15 in the distinction between person verses retailer verses
16 seller, the Regulation very easily could have included
17 the word "retailer" instead of "person"; or the word
18 "seller" instead of "person."

19 But it specifically stated "person." And we
20 want to emphasize that particularly because
21 manufacturers are not the same as a Hallmark store
22 where, you know, you buy inventory, you put it on the
23 shelf, and you're ready to go. You're in business.
24 You're selling.

25 Whereas a manufacturer, particularly of a

1 medical device of the complexity of the ITCA-650, which
2 had an osmotic pump, it had an ears-worth in micrograms
3 of the medicine Exenatide. It's a extremely complex
4 device.

5 And part of that process -- the FDA approval
6 was to actually go through the manufacturing line, go
7 through the assembly to make sure that it met all the
8 FDA qualifications just to manufacture it. So they had
9 issues with sterileness of the manufacturing line.

10 And so it's one thing to make very simple
11 widgets, but even then the applicable Regulation would
12 be 1525 for somebody that is first manufacturing to have
13 a product that is viable to sell and then sell. Whereas
14 this, as Bill stated right in the beginning, they
15 started in 1995. They licensed a delivery system from
16 another company, and then they had, you know, all of the
17 animal phases that they had to go through.

18 Phase 1, phase 2, phase 3 -- as they
19 accomplish each one of those and it proves not to be
20 dangerous to the human beings, et cetera; they moved to
21 the next phase and their manufacturing all this. And as
22 you saw when you watched the videos, they thought they
23 were very close to starting to sell. So they ramped up.

24 And you can see it in our exhibits that
25 there's, for example, Exenatide. There was about, what,

1 \$2 million dollars worth of Exenatide purchased
2 initially in the clinical trial phase over the course of
3 the audit period who was \$12 million dollars. They
4 bought \$12 million dollars worth of Exenatide in, what,
5 like, last year.

6 So they were getting ready. And so this
7 manufacturing process -- I do not think that the State
8 of California and Legislators just casually chose the
9 word that defines who the exemption is applicable to.

10 And it was clearly a person because they
11 recognized that manufacturing is much different than
12 somebody that already has a product that is ready to go;
13 and they're at the ear of the seller or the retailer
14 level.

15 So I think that needs to be emphasized. It's
16 not a cas -- it's not a mistake that the word "person"
17 is in Regulation 1525. And there's no question, the
18 auditor recognized it, as Bill stated, that they were a
19 manufacturer.

20 Research and development was done in North
21 Carolina in a place called RTP, which stands for
22 Research Triangle Park. And there's lots of companies.
23 Wikipedia is actually one of our exhibits. That's what
24 they do there. Assembly was done. Manufacturing was
25 done in Hayward, California.

1 I'm done.

2 MR. LOEW: We've concluded.

3 JUDGE BROWN: Thank you very much. And, as I
4 said, now I think we're going to have questions from the
5 panel. And I'll let my co-panelist go first.

6 Judge Geary, do you want to ask any questions
7 at this time?

8 JUDGE GEARY: I do. It just went a lot
9 quicker than I've -- it went a lot faster than expected.

10 JUDGE BROWN: You can take a minute if you'd
11 like.

12 JUDGE GEARY: I'll direct my questions to you,
13 Mr. Loew. If Mr. Huk wants to answer, that's fine.

14 Is there anything in the evidence that you
15 submitted that tells us why specifically Intarcia
16 decided or did pay used-tax in connection with these
17 purchases.

18 MR. LOEW: As I said, they did not have a
19 seller's permit.

20 JUDGE GEARY: I remember what you said in your
21 argument. I'm trying to find out if any of that is set
22 forth. For example, letters between Intarcia and the
23 vendors. Anything where there's a discussion of why
24 Intarcia was being asked to pay used-tax.

25 MR. HUK: Yes. So the vice president of

1 taxation, I remember talking with him --

2 JUDGE GEARY: Let me interrupt you for a
3 second, Mr. Huk. You're not testifying today, you're
4 just arguing. That's why I want you to direct me to the
5 evidence that, if there is any, that talks about the
6 decision to pay used-tax for these purchases. Is there
7 anything in there?

8 MR. LOEW: We'll have to get back to you on
9 that, Mr. Geary.

10 JUDGE GEARY: If you can before the hearing is
11 over, point me to something that might be some
12 assistance to me. You were making comments -- Mr. Huk,
13 and I believe Mr. Loew made comments -- about Intarcia
14 being a manufacturer. Manufacturers sometimes use
15 materials that they purchase; correct? And in fact --

16 MR. HUK: That's correct.

17 JUDGE GEARY: -- Intarcia used materials that
18 it purchased. Some.

19 MR. HUK: That's correct.

20 JUDGE GEARY: Some of those used might have
21 been taxable, some of them may have not been. That's
22 not concern, but everything that it purchased was not
23 purchase for resell?

24 MR. HUK: That's correct.

25 JUDGE GEARY: Okay. I had a question -- I

1 think you may have answered it -- why Intarcia was
2 making substantial purchases when there should have been
3 inventory left over from prior years. Purchases.

4 And is your answer to that type of inquiry
5 that they were ramping up and trying to accumulate
6 components for what they believe was the inevitable need
7 to manufacture the product so that investors can see
8 return on their investment.

9 MR. HUK: Yes, that's correct.

10 And part of the video, the CEO Kurt Graves,
11 said that \$1 billion dollars had been invested and they
12 had just consummated a deal where they would share --
13 you know, the investor would share in the revenue from
14 2018 to 2031 and I think one half percent of the
15 revenue.

16 So there was lots of interest in starting to
17 recover the billion dollars that have been invested in
18 the company by many investors, including Bill Gates.

19 JUDGE GEARY: There were no purchases in 2017
20 or 2018; correct? I think one of the charts in your
21 brief had purchases -- and I don't think it went back to
22 2013, but it had purchase in 2015, 2016. And I think it
23 showed no purchases or components in 2017 or 2018; am I
24 incorrect about that?

25 MR. HUK: I think that's incorrect. I would

1 have to go back and check, but they were ramping up.
2 Specifically I had an E-mail from RMS that said that
3 they were ramping up, so they were producing more of the
4 body of this device.

5 So RMS was the manufacturer in Minnesota that
6 made certain components, and then they purchased --
7 Intarcia purchased from Invibio who is in Pennsylvania.
8 I'll call it the "coding" that we get heated and then
9 RMS will put on the outside of the item.

10 And the RMS person specifically said that
11 there was more purchases occurring and there was
12 definitely, as we already stated, of Exenatide which
13 would have a shelf life. And so they started buying --
14 they bought, like, \$10 million dollars worth of
15 Exenatide in that -- 2017.

16 MR. GEARY: And -- but I think as you brief
17 it, it's called an executive summary or something like
18 that. Part of it is a -- has a chart that appears to
19 list purchases made -- excuse me, purchases used in
20 clinical trials in 2014, '15, '16, '17, '18, and '19.
21 So there were no purchases that were used in -- and
22 maybe that's what it indicates. It's indicating perhaps
23 that there were no clinical trials in 2017 and 2018; is
24 that correct?

25 MR. HUK: Yeah. And so -- which, actually, I

1 feel supports our position is that that they thought
2 that they were at the point where they could do less
3 clinical trials because the approval was imminent.

4 And so there was -- there was only -- there
5 was less than a thousand clinical trials in, like, 2018
6 or 2019. And there was a big drop off so when you look
7 at that chart, I think you're seeing the one that the
8 total of the bottom is \$51,000.

9 JUDGE GEARY: \$51,219.

10 MR. HUK: Yeah. So there's a lot of clinical
11 trials early on 2013, '14, '15; and then as phase 3 is
12 looking good, he's on Mad Money. You know, expecting
13 that in a year and a half or two years they'll be going
14 to market. And then that's the ramp up.

15 JUDGE GEARY: So I believe Intarcia submitted
16 their application in 2016 for FDA approval.

17 MR. HUK: Well the process is called an
18 investigational new drug and so there's actually phases
19 that they go through, and I mentioned them briefly --

20 JUDGE GEARY: Let me just interrupt you for a
21 second.

22 MR. HUK: Sure.

23 JUDGE GEARY: Did Intarcia expect approval
24 sometime in 2016?

25 MR. HUK: Yeah, they did. I think they --

1 when you listen to Kurt Graves the CEO on Mad Money, Jim
2 Cramer is -- you know, he's upbeat. Real optimistic, et
3 cetera. He has to be careful, Kurt Graves does, from
4 his position as a CEO.

5 He can't mislead people that he got approval
6 but the inspection, and he said it in his -- in the
7 video; that he expected to be going to market in a year
8 in a half to two I believe.

9 JUDGE GEARY: There were additional clinical
10 trials in 2019?

11 MR. HUK: There was just a handful because
12 they were running into problems. You know, there was
13 this what they call AKI, Acute Kidney Injury. It was
14 starting to crop up in patients that were using the
15 Exenatide. And I think that was one of the things that
16 hung him up.

17 JUDGE GEARY: Mr. Loew, when he was speaking
18 about Intarcia and I may have imagined this, but I
19 thought he was speaking in the past tense.

20 Is Intarcia still in the business of
21 attempting to get these -- this product approved for
22 retail use or medical use in the population?

23 MR. HUK: Yeah. So they went through -- and
24 this is beyond the audit period -- but they went through
25 many what they call CRLs, which is an FDA letter that

1 comes back and says you got an issue or that issue.

2 And I don't have the expert on that process.
3 But they had, you know, people over at the head
4 engineering, head of manufacturing, the CEO, et cetera,
5 going before the FDA, going to hearings to try to
6 convince them that they should be approved. That they
7 could tackle the problems that they were encountering.

8 And at each stage, at each one of these -- I
9 think there was one back in September of 2023. They
10 were still trying to get it to, you know, to get the
11 attention of FDA. So I don't know all the ins-and-outs
12 of this, but I believe that a trustee came in to sell
13 off all of the assets.

14 There was an assignment of benefit of
15 creditors. I don't know exactly when that happened.
16 All of this happened after the audit period and -- but,
17 Kurt Graves still believes in it. And so there is a
18 company that I think is called High Zero Two or IO2 and
19 he's the CEO of that. And their still pursuing it but
20 it's a completely separate legal entity.

21 JUDGE GEARY: Are you saying Intarcia sought
22 bankruptcy protection, and that the assets were sold?

23 MR. HUK: They didn't go for bankruptcy. I
24 think they went for this assignment for benefit of
25 creditors.

1 JUDGE GEARY: And does the evidence that
2 appellants submitted in this case show that it's assets
3 were sold?

4 MR. HUK: We have -- that's a completely
5 separate legal entity. The ABC.

6 JUDGE GEARY: So --

7 MR. HUK: And I don't know how that -- I don't
8 know how that transpired, but what I do know is that
9 they paid tax of components, raw materials that they
10 were -- they intended to -- that they purchased for
11 manufacturing.

12 And to the extent that the product failed, I
13 think the product is with CSBio, who were the vendor of
14 Exenatide and we got a refund for the Exenatide. That
15 was a sale's tax transaction. And we also got a refund
16 from Basel, that was a sale's tax.

17 So Intarcia got the tax routed back through
18 the vendors, but as far as what happened to the product,
19 the product is completely useless.

20 It is not in the possession of the ABC is our
21 understanding, but I do know that there is an annotation
22 that says that. And I know that annotations aren't the
23 same as law, but that says that if you have a product
24 that for business purposes, you can not mark it and it's
25 destroyed; or it's not being held for resale. And these

1 things look like a little fuse for your car.

2 They had no other purpose that that is not a
3 taxable event. So where they were with the product
4 after it couldn't be sold -- the FDA said it can't be
5 sold -- there was no other reason for it. And I can
6 give you the annotation number for that if you --

7 JUDGE GEARY: Is it in your papers? I know you
8 cited numerous --

9 MR. HUK: It was in the brief to Ryan Kaye,
10 the appeal's conference holder. Yeah, it was Annotation
11 570 -- wait a second here. Yeah, 5701380, Destruction
12 of Property Purchased For Resale.

13 (Quoting)

14 "The deliberate destruction of goods purchased
15 for resale is not taxable use when the goods are not
16 suitable for their intended purpose, and the purchaser
17 has sound business reasons for destroying the goods
18 rather than marketing them."

19 And it was a short backup letter to that and
20 that backup letter essentially says the same thing.

21 JUDGE GEARY: So if I understand you
22 correctly, there is -- there is zero likelihood that
23 Intarcia will ever market the ITCA-650 because it
24 essentially has dissolved and sold it's assets to other
25 companies.

1 MR. HUK: I would say that that is true for
2 the legal entity Intarcia. Kurt Graves might say
3 something different because he's -- my understanding
4 from reading articles from Google is that that there is
5 an entity that he is the CEO of, but it's not Intarcia
6 Therapeutics, Inc.

7 JUDGE GEARY: Is that why -- is one of the
8 reasons why the appellant's position is that the -- the
9 treatment of devices -- programmable drug infusion
10 treatment devices -- that's why appellant thinks that
11 the statute and regulation that deals with that type of
12 device has no relevance to this proceeding.

13 Do you recall in the decision that was
14 prepared by the Appeals Bureau in a footnote, it states
15 that during the appeal's conference, the author asked
16 claimant whether it believed the ITCA-650 qualified as a
17 medicine under Revenue and Taxation Code, Section 6369,
18 Subdivision (c)(6); and Regulation 1591, Subdivision
19 (b)(6), as a programmable drug infusion device.

20 And claimant replied, "We do not see that the
21 drug infusion section of California Regulation 1591 has
22 any relevance to the claim in hand."

23 First of all, is that a correct attribution?
24 Did the claimant essentially make that statement at the
25 appeal's conference?

1 MR. HUK: I don't dispute that, no. But I
2 would also say that when you read 1591, prescription
3 medicine has to be approved by the FDA. And their
4 medicine was not approved by the FDA.

5 JUDGE GEARY: Okay.

6 MR. HUK: Except for clinical trials.

7 JUDGE GEARY: You -- the appellant refers in
8 it's brief to -- it's believed that if a product becomes
9 obsolescent, it's not subject to tax, and it's similar
10 to the arguments -- one of the arguments you're making
11 here; that the ITCA-650 is for all intensive purposes.
12 At least from Intarcia's point of view. Obsolescent, it
13 cannot be made.

14 MR. HUK: Yeah. One, they would be breaking
15 the law if they attempted to market it and for business
16 purposes --

17 JUDGE BROWN: I'm sorry, I need to interrupt.
18 Can I ask you to please hold your thought. I just
19 gotten a message that we need to pause the hearing
20 because they're having an issue with the live stream.

21 Write down what you were saying. We'll get
22 back to it. We're going to pause the hearing for just a
23 moment, and I'm going to wait for confirmation that we
24 can restart.

25 (Break)

1 JUDGE BROWN: We're resuming the hearing.
2 Apologies for the break due to the glitch with the live
3 streaming. I was informed that the live streaming was
4 cut off during the questioning and discussion that Judge
5 Geary had with appellant's representatives. So the live
6 stream may have missed a minute or two.

7 I'm not -- we don't know exactly when it cut
8 off, but it was in that minute that we got the message.
9 So I will just note for anyone watching on the live
10 streaming if there was some period at some omission, it
11 will be covered by the transcript -- the hearing
12 transcript.

13 Oh, and did I note, we are back on the record.
14 We are back on the record, and the period -- any
15 omission in the live streaming is covered by the
16 transcript.

17 Judge Geary was asking questions, and I will
18 revisit exactly where we were.

19 JUDGE GEARY: Judge Brown, I think we'll let
20 our stenographer -- if you don't mind --

21 Judge BROWN: That's true. Can the
22 stenographer pick up what the last question that we had
23 before the break.

24 (Read back)

25 JUDGE GEARY: I'm sure Mr. Huk recalls -- I

1 think we were talking about obsolescence and whether
2 that was --

3 JUDGE BROWN: And I'll just note we are back
4 on the record.

5 JUDGE GEARY: -- and whether that was one of
6 the points you were trying to make in the argument of
7 you and Mr. Loew. In essence because you can't make the
8 product and sell it. It's essentially the components
9 that you have are obsolete.

10 MR. HUK: That's correct.

11 JUDGE GEARY: Okay. Mr. Huk, those are the
12 only questions that I have; Mr. Loew, the only
13 questions that I have right now. I may come back to you
14 later after CDTFA gives it's argument.

15 Thank you, Judge Brown.

16 JUDGE BROWN: Thank you.

17 And I will turn to Judge Aldrich and ask if he
18 has any questions for appellant's representatives at
19 this time.

20 JUDGE ALDRICH: Good afternoon. I do have a
21 couple of quick questions. During the -- you're
22 argument, you mentioned that the Exenatide has a shelf
23 life. So after the Exenatide is incorporated with the
24 other components, how the shelf life are we talking
25 about.

1 MR. HUK: So my understanding, again, not an
2 expert on Exenatide, is that for one -- and CEO Kurt
3 Graves said to Jim Cramer in Mad Money -- that one of
4 the the big hurdles that they got over was that the
5 medicine could stay in the body at body temperature and
6 not deteriorate.

7 And so in clinical trials, they had
8 iterations that were for three months. Some were six
9 months test, some were nine months, some were 12 months
10 test.

11 And from the video on Mad Money, I'm not sure
12 if it was the Exhibit 37 or Exhibit 38, he talked about
13 the goal was to beat Merck and their product which was
14 taken orally and that it would -- the big advantage,
15 especially over injections, is that it would only have
16 to be done once a year.

17 So that was the goal, was for the Exenatide to
18 last in the body. And I don't know how much shelf life
19 it has as it's awaiting to go to a distributor or to a
20 doctor, hospital, et cetera. I don't know what that
21 shelf life was, but I think that it's telling that they
22 ramped up and started buying \$10 million dollars worth
23 of Exenatide in 2017. Yeah.

24 JUDGE ALDRICH: Okay. And is Intarcia still
25 in existence as far as being registered with the

1 secretary of the state.

2 MR. HUK: I don't know the answer to that
3 question. All that I know is that -- I'm a CPA, not an
4 attorney -- so I believe it's a trustee that not through
5 bankruptcy, but through the assignment of benefit of
6 creditors was it control of the selling off of assets,
7 et cetera.

8 JUDGE ALDRICH: Okay. Thank you.

9 Back to Judge Brown.

10 JUDGE BROWN: Thank you. I think I may have
11 some couple questions now and then maybe more later. So
12 is the ITCA -- are the ITCA-650 components still being
13 held in inventory in California?

14 MR. HUK: My understanding is that they're at
15 CSBio, which is Menlo Park, California, and they were
16 the seller -- they were the vendor of Exenatide. I do
17 not know why it's there, but that's where they're at.

18 So they're still in California. There was a
19 hope that they would go to North Carolina or Boston, but
20 that didn't happen because then we will be making a
21 different argument.

22 JUDGE BROWN: And then I just want to confirm
23 that in appellant's argument here today, appellant is
24 arguing that the tax-paid purchase resold deduction
25 under Regulation 1701 does not apply because in

1 appellant's initial brief to OTA back in 2022, my
2 reading of it was that appellant was arguing that the
3 tax-paid purchases resold deduction did apply.

4 So I just want to confirm you're no longer
5 making the argument that you're entitled to the tax-paid
6 purchases resold deduction under Regulation 1701;
7 correct?

8 MR. LOEW: That's correct.

9 MR. HUK: Correct.

10 JUDGE BROWN: Okay. And then I also want to
11 confirm whether you're making any argument about
12 placebos.

13 MR. HUK: We are not.

14 JUDGE BROWN: Okay. Because, yeah, I noticed
15 your brief didn't mention the placebos. Your argument
16 here today doesn't mention the placebos. So all of that
17 stuff about placebos in the appeal's decision, that is
18 off; that's not something that's before us here today.

19 MR. HUK: I think the last couple sentences of
20 1591 (e)(4) took care of that for us.

21 JUDGE BROWN: Okay. Thank you. I'm just
22 clarifying because I don't want to spend time focusing
23 on things that are not before us here.

24 I also wanted to ask about the question of the
25 medical exemption for the ITCA-650 that were implanted

1 in patients for three months.

2 My understanding is that in terms of what is
3 still at issue, what -- you know, because of what the
4 appeal's decision ruled about the units that were
5 implanted for six months or more that those are not
6 before us here.

7 But units that were implanted in patients for
8 less than six months -- meaning for the three month
9 clinical trials, those are still part of the units that
10 are in the tax that's in dispute here today; correct.

11 MR. HUK: That's correct. You know, really, I
12 just kind -- I find -- it's probably not a strong
13 argument, but I just find it to be very arbitrary.

14 Especially given the purpose of this medicine
15 is to not give it to somebody for 12 months and so, you
16 know, to sneak up on it, sort to speak, to give a three
17 month dose, see how the patient does; and then a six
18 months. It's all clinical trials.

19 JUDGE BROWN: My question in terms of what I
20 have to -- of what the panel has to decide concerns
21 whether we are looking at -- whether you're arguing that
22 the ITCA-650 that were implanted in patients for three
23 months meets the medical exception under Regulation 1591
24 and Revenue and Taxation Code, Section 6369.

25 Whether you're arguing that those are --

1 whether you're continuing to make the argument that
2 those are exempt.

3 MR. HUK: That would be the case. Yes.

4 JUDGE BROWN: Okay. And your original brief
5 that was filed in 2022, you argued that appellant will
6 show that the intent was that the ITCA-650 be implanted
7 for 12 months. And you cited the Annotation 4250163,
8 which is regarding -- which has that rule about six
9 months --

10 MR. HUK: Okay.

11 JUDGE BROWN: -- that it's permanently in plan
12 -- to consider permanently implanted under the
13 regulation if it's implanted for at least six months. I
14 wanted to ask what your -- make sure I understand what
15 your argument is regarding the units that were implanted
16 through the clinical trials for less than six months for
17 the three-month trials.

18 MR. LOEW: Correct me if I'm wrong, but the
19 clinical trials exemption that were cited today I don't
20 believe deals with the implantation issue, which is a
21 prescription medicine exemption.

22 If something is planted in the body for
23 greater than six months, then it's sold under the
24 prescription. Then it's deemed to be an exempt
25 medicine. Today we're looking from purely a clinical

1 trials' perspective.

2 MR. HUK: Of 12 months, I mean, that was --
3 but as far as the viability, they -- again not being an
4 expert on the FDA approval process -- but the safety and
5 the health of the patients was the most important thing
6 and this was clinical trials at this point. It's not a
7 prescription medicine at that point.

8 JUDGE BROWN: I think those are all the
9 questions I have for appellant at this time. I may
10 revisit, but now I'm going to turn to CDTFA and let
11 CDTFA make it's presentation.

12 I'll say CDTFA if you're ready, you can go
13 ahead. If you need a moment, that's fine.

14
15
16 PRESENTATION

17 MS. JACOBS: Thank you. I think we're ready.

18 Good afternoon. Again, my name is it Amanda
19 Jacobs. I'm an attorney for CDTFA's legal division.

20 Appellant is a biopharmaceutical company that
21 develops drug therapies and operates a manufacturing
22 facility in Hayward, California. Appellant developed
23 and manufactured ITCA-650, a prescription medicine and
24 drug delivery system intended for the treatment of type
25 2 diabetes.

1 ITCA-650 consists of a osmotic pump that is
2 placed succedaneously and continuously release a dose of
3 the FDA approved type 2 diabetes drug, Exenatide.

4 Appellant filed a new drug application, or NDA, seeking
5 approval to market and sell ITCA-650.

6 However to date, appellant has not received
7 approval of its NDA and is prohibited from selling
8 ITCA-650 in the United States. Appellant filed a claim
9 for refund for the period of January 1st, 2014, through
10 December 31st, 2019, pertaining to appellant's tax-paid
11 purchases of component parts for the manufacture of
12 ITCA-650.

13 During the claim period and relevant to the
14 appeal at issue, appellant paid used-tax on components
15 parts of the manufacture ITCA-650, which were shipped
16 from out-of-state suppliers to appellant in California
17 and incorporated into finish ITCA-650 units in it's
18 Hayward manufacturing facility.

19 It's suppliers, RMS and Invibio, each held a
20 certificate of registration of used-tax and provided
21 appellant with receipts for its payment of used-tax on
22 the components; Appellant's Exhibit 77 and 85.
23 Appellant furnished some of it's manufactured ITCA-650
24 units to licensed physicians without charge for the use
25 of human clinical trials.

1 Certain clinical trial units of ITCA-650
2 contained the active ingredient Exenatide while others
3 contained a placebo; Exhibits F, page 2 and G, page 5.

4 The trial units were implanted and studied
5 participants bodies for periods of three, six, nine, or
6 12 months; Exhibits D and E, page 3.

7 It is our understanding that appellant has
8 retained the remaining component parts not used in human
9 clinical trials in California. It is department's
10 further understanding that the matter is still open with
11 the FDA.

12 The sole issue in this appeal is whether
13 appellant is entitled to a refund for used-tax paid in
14 connection with it's purchase of component parts for the
15 manufacture of certain ITCA-650 units during the claim
16 period.

17 It is our understanding that the issue is
18 limited to the purchase of component parts either used
19 in human clinical trials in which the ITCA-650 unit was
20 implanted for less than six months, or those not used in
21 clinical trials but retained in California.

22 It is now our understanding that the
23 components used in human clinical trials in which the
24 unit was loaded with a placebo are not at issue since
25 Regulation 1591 (e)(4) specifically states the placebos

1 are not included in the exemption for use in clinical
2 trial medicines.

3 As you know, California imposes used-tax on
4 the sale's price of tangible personal property, TPP,
5 purchase from any retailer for storage, use, or any
6 consumption in this state unless excluded or otherwise
7 exempt; Sections 6201 and 6401.

8 The used-tax is imposed on the person who
9 stores, use, or otherwise consumes the TPP; Section
10 6202. It is presumed that TPP sold by any person for
11 delivery in California is sold for storage, use, or
12 other consumption in this state until the contrary is
13 established.

14 The burden of proving the contrary is on the
15 person who makes the sale unless he takes from the
16 purchaser a certificate to the effect that the property
17 is purchased for resale; Section 6241.

18 It is presumed that TPP shipped or brought to
19 California, by the purchaser, was purchased from a
20 retailer for storage use or other consumption in this
21 state; Section 6246.

22 Storage includes any keeping or retention in
23 California for any purpose except sale and the regular
24 course of business or subsequent use solely outside this
25 state; Section 6008.

1 Use includes the exercise of any right or
2 power over TPP, incident the ownership of that property
3 except sale in the regular course of business; Section
4 6009.

5 Section 6369, which is interpreted and
6 implemented by Regulation 1591, exempts from tax the
7 storage, use, or other consumption of medicine as
8 defined if they are dispensed or otherwise provided to
9 the patient under specified circumstances; Section 6369
10 (a) and Regulation 1591 (d).

11 The term "medicines" is defined to include any
12 substance or preparation intended for use by external or
13 internal application to the human body and the diagnoses
14 cure mitigation treatment or prevention of disease;
15 Section 6369 (b).

16 It also includes what specified exceptions any
17 product fully implanted or injected in the human body or
18 any drug or any biologic when such are approved by the
19 the U.S. FDA to diagnose, cure, mitigate, treat, or
20 prevent disease, illness, or medical condition;
21 Regulation 1591 (a)(9)(a).

22 The term "medicines" does not include articles
23 that are in the nature of instruments, apparatuses,
24 contrivances, appliances, devices, or other mechanical
25 or physical equipment; or article and component parts in

1 accessories thereof; Section 6369 (b)(2), and Regulation
2 1591 (c)(2).

3 However medicines do include permanently
4 implanted articles other than dentures permanently
5 planted in the human body to assist the functioning of
6 any natural organ, artery, vein, or limb and which
7 remain or dissolve in the body; Section 6369 (c)(2), and
8 Regulation 1591 (a)(9)(b) and (b)(2).

9 Statutes granting a tax exemption are strictly
10 construed to avoid enlarging or extending the concession
11 beyond the plain meaning of the language used in
12 granting it; see Associated Beverage Company v. Board of
13 Equalization (1990) 224 Cal.App.3d, pin sight 211.

14 Appellant bares the burden of showing it
15 clearly comes within the terms of the exemption by a
16 preponderance of the evidence; see Regulation 35003
17 Subdivision (a), and Paine v. State Board of
18 Equalization (1982) 137.Cal.App3d 438, pin sight 443.

19 With all of that in mind, appellant's use of
20 ITCA-650 units for human clinical trials was a taxable
21 use where the units were implanted for less than six
22 months.

23 We first note that ITCA-650 does not meet the
24 definition of medicine for purposes of the exemption as
25 it is not a substance or preparation as described by

1 Regulation 1591 (a)(9)(b), or a product approved by the
2 FDA as required by 1591 (a)(9)(a).

3 Regulation 1591 (e)(4) provides that tax does
4 not apply to the storage, use, or consumption of, quote:

5 "Clinical trial medicines during the United
6 States food and drug administrations drug development
7 and approval process." End quote.

8 Clinical trial medicines are defined as
9 substances of preparations approved as investigational
10 new drugs by the FDA and intended for treatment of an
11 application to the human body which are furnished by a
12 pharmaceutical developer, manufacturer, or distributor
13 to a licensed physician and subsequently dispensed,
14 furnished, or administered pursuant to the order of the
15 licensed physician.

16 Subdivision (e)(4) does not create a new
17 classification or category of medicines. Rather it
18 allows an exemption for medicines as otherwise defined
19 by Section 6369, and Regulation 1591, that are in the
20 clinical trial stage and have not yet received approval
21 from the FDA.

22 In this case, the department determined that
23 ITCA-650 implanted and studied participants' bodies for
24 periods of six, nine, or 12 months, met the definition
25 of a permanently implanted article under Regulation 1591

1 (b)(2).

2 However, the department's longstanding over 40
3 year interpretation of permanently implanted has made
4 implanted with the intent to remain in the body for at
5 least six months. See Annotations 425.0887, 425.0163,
6 and 425.0521 as examples of that interpretation.

7 As some of the ITCA's -- of the units of
8 ITCA-650 were implanted for less than six months -- in
9 this case, three months -- those units and their
10 component parts do not meet the definition of
11 permanently implanted articles pursuant to Regulation
12 1591 (b)(2), or clinical trial medicines pursuant to
13 Subdivision (e)(4).

14 As such, appellant's use of the ITCA-650 units
15 in those human clinical trials was a taxable use.

16 Finally, we will discuss appellant's remaining
17 ITCA-650 components.

18 Appellants purchase of the components were
19 presumed to be subject to tax. It's suppliers were
20 registered with the department and required to collect
21 used-tax on such purchases because appellant did not
22 provide a resale certificate at the time of purchase;
23 Section 6241.

24 And appellant no longer possesses a valid
25 sellers permit and is still legally prohibited from

1 selling ITCA-650 in the United States because it has not
2 obtained FDA approval. Until April 1st, 2019, well
3 after the component purchases were made between 2014 and
4 2017; Exhibit 56.

5 And appellant no longer possesses a valid
6 seller's permit and is still legally prohibited from
7 selling ITCA-650 in the United States because it has not
8 obtained FDA approval. And, in fact, it's seller's
9 permit was closed in July of 2019 with an effective
10 closeout of April 1st, the day that it had been issued.

11 While appellant -- sorry, appellant has argued
12 that the reason for purchasing TPP issue was for
13 incorporation into products and intended to resale.

14 The fact of the matter is the remaining TPP at
15 issue cannot have been held for sale in the regular
16 course of business because, as established, appellant
17 was not legally permitted to sell it. Appellant
18 continues to stores these products in California.

19 Appellant asserts that these purchases were
20 nontaxable purchases for resale because appellant
21 retained the TPP for purposes of resale once it obtained
22 FDA approval. But appellant -- so appellant is
23 requesting a refund of the used-tax it paid to vendors
24 on it's initial purchases.

25 However, Section 6012, Subdivision (a)(1),

1 implemented by Regulation 1701, specifically
2 contemplates that a retailer may pay its vendor tax or
3 tax reimbursement when purchasing TPP and then reselling
4 the property; Regulation 1701 (b)(4).

5 The remedy, as you know, is the tax-paid
6 purchases resold deduction in cases where a retailer
7 sells the property without making any use other than
8 retention, demonstration, or display while holding a
9 property for sale in the regular course of business, the
10 retailer may take a deduction for the tax it paid when
11 the purchase property was resold; 1701, Subdivision (a).

12 However, the deduction must be taken on the
13 retailer's return in which the sale of the TPP is
14 included; Subdivision (a), again. Thus the tax paid
15 purchases resold deduction is only available when the
16 TPP is resold and has been established, appellant has
17 not and could not resale the TPP at issue.

18 Appellant is now arguing that it is not a
19 retailer, and that the tax paid purchases resold
20 deduction does not apply. Appellant is also arguing
21 that the components at issue were purchased for resale
22 and should have been as tax. It cannot be both.

23 As it stands, appellant continues to store the
24 TPP at issue which it is not permitted to sell in
25 California. The law makes no provision for a refund of

1 tax resulting from appellant's circumstances.

2 In sum, appellant has not established that it
3 is entitled to a further refund for used-tax paid in
4 connection with its purchase of component parts for the
5 manufacture of certain ITCA-650 units during the claim
6 period.

7 For these reasons, we request that the appeal
8 be denied. Thank you.

9 Judge BROWN: Thank you. I think I will start
10 off with a few questions and then I'll turn to my
11 co-panelists next.

12 I want to pick up on essentially the last
13 point that you made, Ms. Jacobs, that there's no
14 provision for a refund of tax resulting from these
15 circumstances. So if the -- if a taxpayer continues to
16 hold items that it purchased and paid-used tax for in
17 inventory, there's just never a provision that for a
18 refund. Like, it doesn't exist in the law.

19 Is that essentially your argument? And I can
20 rephrase that if there's a better way.

21 MR. HUXSOLL: Well that there's no provision
22 under these circumstances for issuing appellant refund.

23 JUDGE BROWN: Sorry go ahead.

24 MR. HUXSOLL: Appellant -- when the vendors
25 sold the property in question to appellant, those were

1 presumed to be subject to tax, and appellant did not
2 issue a resale's certificate at the time which
3 manufacturers often do when they purchase stuff for the
4 attention of reselling it.

5 But when that wasn't done and now appellant
6 holds and continues to hold these products in California
7 without the ability to sell them, there's no basis for
8 refunding the tax.

9 JUDGE BROWN: Well the Appeal's Bureau
10 decision says that the department agrees that it has no
11 knowledge of any use by appellant of the retained
12 ITCA-650 components; is that correct? Does the
13 department agree that there's no evidence that there's
14 been a taxable use of the components other than -- I'm
15 sorry, I guess I should say other than -- I'm talking
16 about the ones that are still being retained. Not the
17 units that were used in clinical trials for less than
18 six months.

19 MR. HUXSOLL: Those do continue to be stored
20 in California. Like, with -- they say for resale, but
21 there's -- storage is a used absent holding it for
22 purposes of resale, and here they say they're not a
23 retailer. So the tax-paid purchases resold deduction
24 doesn't apply.

25 But you can't have something in resale

1 inventory without being a retailer so it's -- in the
2 event that appellant were able to sell these, perhaps
3 the avenue would be a tax-paid purchases resold
4 deduction, but appellant continues to not be a retailer
5 in this case.

6 JUDGE BROWN: So are you arguing that because
7 appellant can't resell the ITCA-650 that it's there for
8 a taxable use because they're not holding it for resale?

9 MR. HUXSOLL: They were never authorized to
10 sell the ITCA-650.

11 JUDGE BROWN: But if their purpose is to
12 resell it, does it matter whether they are currently
13 authorized for purposes analyze the taxable use.

14 MS. JACOBS: Section 6008 says:

15 "Storage includes any keeping or retention in
16 California for any purpose except sale in the regular
17 course of business or subsequent use solely outside the
18 state."

19 JUDGE BROWN: What if appellant -- just
20 hypothetically -- what if appellant were holding it for
21 resale outside of the United States where FDA approval
22 is not required? I know nobody have an answer -- I'm
23 just trying to frame how this fits in with that.

24 MR. HUXSOLL: Can you repeat that.

25 JUDGE BROWN: I'm just saying is it necessary

1 that they have -- that they'd be storing it for resale
2 within the United States in order to -- are you arguing
3 that they have to be authorized to resell it within the
4 United States in order to be holding it for resale.

5 MS. JACOBS: I wouldn't say that we're arguing
6 that, we're saying that Section 6008 says storage
7 includes keeping it in California for any purpose except
8 sale and the regular course of business or use solely
9 outside the state.

10 We don't have any facts that this was being
11 held for sale in the regular course of business or that
12 it was subsequently being used outside the state.

13 JUDGE BROWN: Then my next question is,
14 hypothetically, if the taxpayer shipped the ITCA to an
15 out of state facility under -- would that entitle
16 taxpayer to a refund under Revenue Taxation Code,
17 Section 6009.1, the Storage and Use Exclusion.

18 MS. JACOBS: We don't have any facts that
19 speak to that being an issue in this case.

20 JUDGE BROWN: Well, actually, that does remind
21 me of something I wanted to ask both parties. I did see
22 that in the report of discussions of audit findings
23 dated September 16th, 2021, I found it in CDTFA's
24 Exhibit C. Although I don't have a page number, and I
25 know Exhibit C has over a thousand pages.

1 MS. JACOBS: The audit report letter? Or
2 because that's a separate Exhibit E.

3 JUDGE BROWN: No. I was looking at -- it was
4 a report of discussion of audit findings that raised
5 6009.1. And, actually, this might be a better question
6 for appellant.

7 MR. HUXSOLL: Our understanding, based on what
8 you read earlier from the decision in this case, was
9 6009.1 argument is no longer being pursued based on the
10 fact that we looked at the three different claims for
11 refund. And so, I mean, we haven't briefed that issue
12 in anticipation in this case.

13 JUDGE BROWN: That is something I want to --
14 had meant to clarify. In fact, I'm going to ask
15 appellant this first, and I'll come back to CDTFA.

16 There was a -- in one of the reported
17 discussion of audit findings, appellant had raised this
18 argument about Revenue and Taxation Code 6009.1, which
19 is the Storage in Use Exclusion.

20 And appellant stated to the auditor that the
21 components were permanently shipped out of California.
22 But I don't know if that applies to components that were
23 under a different claim for refund that are not at issue
24 here.

25 MR. HUK: There was a possibility because of

1 the research Triangle Park location that when the
2 approval didn't look like it was going to be happening
3 as soon as it was and they were starting to lay off
4 personnel and they were essentially just, you know,
5 stopping everything.

6 And so there was a possibility that they would
7 move it to research Triangle Park. Because they have
8 facilities there that would protect the devices and the
9 medicine, et cetera, in the way that it would need to be
10 protected because, you know, there just wasn't going to
11 be personnel at the Hayward location.

12 So we put that claim in in the anticipation
13 that they were going to do that.

14 JUDGE BROWN: So the shipment never --

15 MR. HUK: They never did that.

16 JUDGE BROWN: -- it never occurred. Okay.
17 That clarifies my question then. I think I don't have
18 to pursue that further.

19 I think that's -- I'm going to stop my
20 questioning for now, and I'm going to turn to my
21 co-panelists and ask if they have any questions for
22 CDTFA.

23 I'll say Judge Aldrich, do you have any
24 questions?

25 JUDGE ALDRICH: I do not.

1 JUDGE BROWN: Okay.

2 Judge Geary?

3 JUDGE GEARY: Yes, I do. Thank you.

4 For respondent first, the discussion regarding
5 implantation of six months or more. I think,
6 Ms. Jacobs, you referred to Annotations that support the
7 department's position. That even when the focus is on
8 trials being conducted as part of the FDA approval
9 process that because there's no separate definition of
10 medicines, that the standard definition applies. And
11 that implantation of less than six months is not a
12 exempt or nontaxable use; right?

13 MS. JACOBS: Yeah. For the clinical trial
14 medicines to be considered to be -- to fall within that
15 definition of clinical trial medicines being exempt must
16 first be a medicine. In this case, the medicine being a
17 permanently implanted article. In order to be
18 considered a permanently implanted article, it needs to
19 be in the body for six months or more.

20 JUDGE GEARY: And do -- are you aware of any
21 annotation that specifically discusses clinical trials
22 where one of the focuses is the effect of implantation
23 of a device for specific periods of time less than six
24 months.

25 MS. JACOBS: I'm not aware, but I do -- but I

1 do know that not every -- so this is a device, meaning
2 it's not a medicine. And there are different ways the
3 devices can be considered medicines and permanently
4 implanted devices is one of them.

5 So there may be other products -- other
6 medicines in clinical trial stages for less than six
7 months but they meet a different definition of medicine.
8 If that makes sense.

9 JUDGE GEARY: What's the department's position
10 about whether or not this device is a infusion device
11 that's discussed in.

12 MR. HUXSOLL: Following appellant's statement
13 that it was not that type of device, the department did
14 not pursue it further.

15 JUDGE GEARY: Okay. So I would assume,
16 Mr. Huxsoll, that you have no particular respondents
17 other than that. You're not prepared to respond at this
18 time.

19 MR. HUXSOLL: I'm not prepared to respond at
20 this time based on what our understanding was with the
21 conversation at the appeal's conference.

22 JUDGE GEARY: Okay. Let me try out
23 hypothetical -- I don't know why my microphone seems to
24 be going in and out. But I'm hoping it's working.

25 If a manufacturer of a new drug not yet

1 approved by the FDA purchases materials that are used to
2 create the drug and because the drug is not yet approved
3 as a medicine, that manufacturer pays used-tax in
4 connection with its purchase of the materials used in
5 manufacturing the drugs. And if the FDA does not
6 approve the drug and that manufacturer is left with
7 components on which it paid used-tax but has no
8 opportunity to recover the used-tax paid through a
9 tax-paid purchases resold deduction, is there any remedy
10 available to that taxpayer to get the money back on
11 materials that it has no opportunity to use,

12 MR. HUXSOLL: Well first, actually, I'd like
13 to state that we know that the FDA -- or the FDA issue
14 here is still open and the materials still continue to
15 be here. So we don't think it would be appropriate in
16 this particular case. But also there's no mechanism
17 we're aware of for issuing a refund in this case.

18 JUDGE GEARY: You mentioned, Mr. Huxsoll, that
19 the FDA process is still open. Was CDTFA aware that
20 apparently Intarcia has disposed of its assets,

21 MS. JACOBS: We've been presented with no
22 evidence that Intarcia disposed of its assets.

23 JUDGE GEARY: Okay. Lets suppose -- well let
24 me ask Mr. Huk again.

25 Mr. Huk, is that what you represented to us?

1 Is that Intarcia has basically sold its assets.

2 MR. HUK: Intarcia has not sold their assets.
3 They -- and, again, all that I know is that they
4 essentially were dissolved, and that there was rather
5 than pursue bankruptcy, they used an assignment for
6 benefit of creditors.

7 And my understanding is that the assets, you
8 know, that we're talking about, the raw materials, are
9 being held at CSBio. I don't know what, but all the
10 assets were moved into the trust. And my understanding
11 is that Intarcia is dissolved and that the last decision
12 that was made on the viability of ITCA-650 by the FDA
13 was 19-0 rejection.

14 MR. LOEW: And that was in 2023 that decision.

15 MR. HUK: So they have no ability. They don't
16 have no possession of the assets. They have no ability
17 to sell them, to do anything with them. And they have
18 no functionality, these are very specific devices that
19 have no purpose beyond that.

20 JUDGE GEARY: Are any of these facts shown by
21 the evidence that Intarcia submitted for our
22 consideration? By any of these facts, obviously, we're
23 referring to this dissolution Intarcia no longer being
24 in possession of any of these components. Those facts.

25 MR. HUK: The only thing that I can think of

1 is that we have an Ernst and Young audit report that I
2 think shows just how dire the situation was. At this
3 moment right now, I wouldn't be able to point my finger
4 to that. But we could -- we could get that. And if
5 there are other -- if you want other information
6 regarding the assignment for benefit of creditors --

7 JUDGE BROWN: Let me just interject, are you
8 referring to Exhibit 122?

9 MR. HUK: Probably. Yes. Yes, that's
10 correct.

11 JUDGE GEARY: Okay. Thank you. Those are
12 only the questions that I have.

13 Thank you, Judge Brown.

14 MR. LOEW: Judge Geary, to finish the answer
15 to your question, Exhibit 61 is an article related to
16 the -- it's the 2023 article that it was referring to.
17 Mr. Huk mentioned that was a 19-0 vote by the FDA.

18 JUDGE GEARY: Thank you, Mr. Loew.

19 JUDGE BROWN: I think if there's nothing
20 further from co-panelists, I think we can proceed to
21 hearing appellant's rebuttal. If -- I think we are
22 ready to hear appellant's rebuttal because we have
23 completed our questioning at this time.

24 If appellant needs a minute that's fine.
25 Whenever appellant is ready, you can go ahead.

1 REBUTTAL

2 MR. LOEW: To repeat my earlier statements,
3 Regulation 1525, Property Used in Manufacturing, we
4 believe is the avenue that the CDTFA has to grant and
5 process refunds under the scenario that we're dealing
6 with today.

7 Specifically, 1525 (b), which states, again,
8 tax does not apply to sales of tangible personal
9 property. To persons -- again, not retailers, not
10 sellers, but to persons. We purchased the property for
11 the purpose of incorporating it into the manufactured
12 article to be sold. To be sold.

13 As, for example, any raw material becoming an
14 ingredient or a component part of manufactured article;
15 Regulation 1525 (b). This was, again, raised in our
16 appeal's conference. It was cited. The appeal's
17 conference officer did not opine of this area of the
18 regulation.

19 MR. HUK: Judge Geary, in response to the
20 question regarding the going concern. Ernst and Young
21 independent report dated September 26th. This is
22 Exhibit 122, states:

23 "As discussed in note one, to the consolidated
24 financial statements, the company has recurring losses
25 from operations and has stated that substantial doubt

1 exist about the company's ability to continue as a going
2 concern."

3 MR. LOEW: No further comments.

4 JUDGE BROWN: You've completed your rebuttal
5 then?

6 MR. LOEW: We're completed.

7 JUDGE BROWN: Okay. Thank you. I'm going to
8 pause for just a second and consult with my co-panelist.

9 I guess I will have one further question to
10 CDTFA. I don't think that in CDTFA's presentation you
11 addressed Regulation 1525. I just want to say do you
12 want to briefly address appellant's argument on that.

13 MR. HUXSOLL: Just that Regulation 1525
14 contemplates a difference between a manufactured
15 consuming certain property and incorporating it into
16 property to be sold.

17 In other words, it's making a sale of said
18 property, and 1525 is based on Sales-Tax General
19 Bulletin 50-24 from July 10th, 1950. Which, again, it
20 contemplates that what's happening here is the
21 manufacturers are purchasing these items for resale.

22 JUDGE BROWN: Thank you.

23 With that, I think I can then say that we
24 heard all the arguments, admitted the evidence, and I
25 think we are ready to complete this hearing. And I note

1 that there will be a recess before -- after we complete
2 this hearing.

3 There will be a recess before we start the
4 next hearing for today. And I believe that hearing is
5 virtual. If I've heard everything from the parties,
6 then I can say that this concludes the hearing.

7 Thank you all very much for participating.
8 The record is now closed. And the case is submitted
9 today. The judges will meet and decide the case based
10 on the evidence, arguments, and applicable law. And we
11 will mail both parties our written decision no later
12 than 100 days from the date that the record closes
13 today.

14 The hearing is now adjourned.

15 (Proceedings adjourned at 3:04 p.m.)
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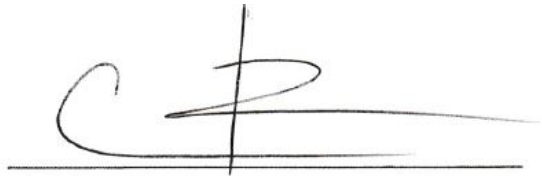
1 HEARING REPORTER'S CERTIFICATE

2
3 I, Christina L. Rodriguez, Hearing Reporter in
4 and for the State of California, do hereby certify:

5 That the foregoing transcript of proceedings
6 was taken before me at the time and place set forth,
7 that the testimony and proceedings were reported
8 stenographically by me and later transcribed by
9 computer-aided transcription under my direction and
10 supervision, that the foregoing is a true record of the
11 testimony and proceedings taken at that time.

12 I further certify that I am in no way
13 interested in the outcome of said action.

14 I have hereunto subscribed my name this 6th
15 day of March, 2024.

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20 Hearing Reporter
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