BEFORE THE OFFICE OF TAX APPEALS

STATE OF CALIFORNIA

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

TRANSCRIPT OF PROCEEDINGS

Sacramento, California

Wednesday, February 21, 2024

Reported by:

CHRISTINA RODRIGUEZ
Hearing Reporter

Job No.:
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TRANSCRIPT OF PROCEEDINGS, taken at 400 R Street, Sacramento, California, commencing at 1:00 p.m. and concluding at 3:04 p.m. on Wednesday, February 21, 2024, reported by Christina L. Rodriguez, Hearing Reporter.

APPEARANCES:

Administrative Law Judge:	JUDGE BROWN JUDGE GEARY JUDGE ALDRICH
For the Appellant:	WILLIAM LOEW JOHN HUK
For the Respondent:	AMANDA JACOBS CARY HUXSOLL JASON PARKER

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)

PRESENTATION

REBUTTAL

Sacramento, California; Wednesday, February 21, 2024

1:00 p.m.

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

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

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

MS. JACOBS: Amanda Jacobs, Attorney for CDTFA.

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

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

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

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

MS. BROWN: Thank you everyone.

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

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

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

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

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

MS. BROWN: My understanding that we clarified

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

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

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

I'll read from it. It says:

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

I guess I'll start with Appellant.

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

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

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

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

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

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

MR. LOEW: Correct.

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

MR. LOEW: The the same arguments.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Although all of the issues that we are going

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

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

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

MR. LOEW: Same amount. Same issue.

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

MR. LOEW: Correct.

JUDGE BROWN: Okay. But it is still the

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

MR. LOEW: Correct.

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

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

JUDGE BROWN: Alright. I think we have clarified.

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

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

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

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

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

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

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

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

MS. JACOBS: No objection. Thank you.

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

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

MR. LOEW: No objections.

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

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

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

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

And then after CDTFA completed it's

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

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

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

I will say appellant has 45 minutes.

PRESENTATION

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

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

As you mentioned, Intarcia was developing an

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

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

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

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

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

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

(Reporter Interruption)

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

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

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

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

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

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

They were ultimately to be for resale.

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

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

MR. LOEW: Sure. Thank you.

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

Section 6008, in part, says:

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

storage.

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

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

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

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

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

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

Regulation 1525 -- California Sales of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

manufactured article."

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

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

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

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

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

Regulations 1684 (h), Refunds of Excess Tax

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

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

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

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

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

Whereas a manufacturer, particularly of a

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

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

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

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

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

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

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

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

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

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

I'm done.

MR. LOEW: We've concluded.

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

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

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

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

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

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

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

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

MR. HUK: Yes. So the vice president of

taxation, I remember talking with him --

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

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

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

MR. HUK: That's correct.

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

MR. HUK: That's correct.

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

MR. HUK: That's correct.

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

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

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

MR. HUK: Yes, that's correct.

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

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

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

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

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

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

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

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

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

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

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

JUDGE GEARY: $51,219.

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

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

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

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

MR. HUK: Sure.

JUDGE GEARY: Did Intarcia expect approval sometime in 2016?

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

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

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

JUDGE GEARY: There were additional clinical trials in 2019?

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

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

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

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

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

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

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

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

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

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

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

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

JUDGE GEARY: So --

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

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

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

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

things look like a little fuse for your car.

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

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

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

(Quoting)

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

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

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

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

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

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

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

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

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

JUDGE GEARY: Okay.

MR. HUK: Except for clinical trials.

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

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

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

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

(Break)

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

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

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

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

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

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

(Read back)

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

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

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

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

MR. HUK: That's correct.

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

Thank you, Judge Brown.

JUDGE BROWN: Thank you.

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

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

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

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

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

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

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

secretary of the state.

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

JUDGE ALDRICH: Okay. Thank you.

Back to Judge Brown.

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

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

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

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

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

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

MR. LOEW: That's correct.

MR. HUK: Correct.

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

MR. HUK: We are not.

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

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

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

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

in patients for three months.

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

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

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

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

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

Whether you're arguing that those are --

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

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

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

MR. HUK: Okay.

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

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

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

trials' perspective.

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

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

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

PRESENTATION

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

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

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

ITCA-650 consists of a osmotic pump that is placed succedaneously and continuously release a dose of the FDA approved type 2 diabetes drug, Exenatide. Appellant filed a new drug application, or NDA, seeking approval to market and sell ITCA-650.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b)(2).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

tax resulting from appellant's circumstances.

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

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

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

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

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

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

JUDGE BROWN: Sorry go ahead.

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

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

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

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

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

But you can't have something in resale

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

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

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

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

MS. JACOBS: Section 6008 says:

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

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

MR. HUXSOLL: Can you repeat that.

JUDGE BROWN: I'm just saying is it necessary

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

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

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

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

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

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

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

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

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

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

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

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

MR. HUK: There was a possibility because of

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

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

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

JUDGE BROWN: So the shipment never --

MR. HUK: They never did that.

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

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

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

JUDGE ALDRICH: I do not.

JUDGE BROWN: Okay.

Judge Geary?

JUDGE GEARY: Yes, I do. Thank you.

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

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

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

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

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

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

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

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

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

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

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

If a manufacturer of a new drug not yet

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

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

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

MS. JACOBS: We've been presented with no evidence that Intarcia disposed of it's assets.

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

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

Is that Intarcia has basically sold its assets.

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

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

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

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

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

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

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

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

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

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

Thank you, Judge Brown.

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

JUDGE GEARY: Thank you, Mr. Loew.

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

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

REBUTTAL

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

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

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

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

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

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

MR. LOEW: No further comments.

JUDGE BROWN: You've completed your rebuttal then?

MR. LOEW: We're completed.

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

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

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

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

JUDGE BROWN: Thank you.

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

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

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

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

The hearing is now adjourned.

(Proceedings adjourned at 3:04 p.m.)

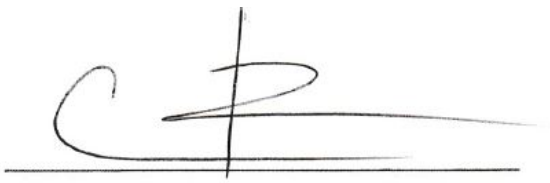
HEARING REPORTER'S CERTIFICATE

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

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

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

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



Hearing Reporter

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