OFFICE OF TAX APPEALS

STATE OF CALIFORNIA

In the Matter of the Appeal of: **INTARCIA THERAPEUTICS, INC.**	OTA Case No. 220911369 CDTFA Case ID: 2-304-634

OPINION

Representing the Parties:

For Appellant:	John Huk, Representative William Loew, Representative
For Respondent:	Amanda Jacobs, Attorney Cary Huxsoll, Attorney Jason Parker, Chief of Headquarters Ops.
For Office of Tax Appeals:	Corin Saxton, Attorney

S. BROWN, Administrative Law Judge: Pursuant to Revenue and Taxation Code (R&TC) section 6901, Intarcia Therapeutics, Inc. (appellant) appeals a Decision issued by respondent California Department of Tax and Fee Administration (CDTFA)[1] denying, in part, appellant's claim for refund dated September 25, 2020, for the period January 1, 2014, through December 31, 2019.

Office of Tax Appeals (OTA) Administrative Law Judges Suzanne B. Brown, Michael F. Geary, and Josh Aldrich held an oral hearing for this matter in Sacramento, California, on February 21, 2024. At the conclusion of the hearing, the record was closed and this matter was submitted for an Opinion.

[1] Sales and use taxes were formerly administered by the State Board of Equalization (board). In 2017, functions of the board relevant to this case were transferred to CDTFA. (Gov. Code, § 15570.22.) For ease of reference, when this Opinion refers to events that occurred before July 1, 2017, "CDTFA" shall refer to the board.

ISSUE

Whether appellant is entitled to an additional refund for use tax paid on its purchases of ITCA-650 components.

FACTUAL FINDINGS

1. Appellant, a Delaware corporation, is a biopharmaceutical company with a manufacturing facility in Hayward, California, a headquarters location in Boston, Massachusetts, and a research and development location in Research Triangle Park, North Carolina.
2. Appellant developed and manufactured ITCA-650, a new prescription medicine and drug delivery system for the treatment of type 2 diabetes. ITCA-650 is a subcutaneous drug implant device that releases exenatide, a type 2 diabetes drug. ITCA-650 is designed to be implanted in a patient for up to 12 months.
3. On January 28, 2009, the Food and Drug Administration (FDA) granted ITCA-650 the status of an Investigational New Drug, which allowed appellant to begin human clinical trials. In the clinical trials, an ITCA-650 unit was implanted in each patient for a period of either 3, 6, or 12 months. After performing a series of these clinical trials, appellant filed a New Drug Application with the FDA on November 26, 2016. On September 2, 2021, the FDA published a proposal to deny appellant's New Drug Application. As of September 2023, the FDA has rejected appellant's application a total of three times.
4. During the claim period, appellant paid use tax to out-of-state vendors, RMS and Invibio, for its purchase of ITCA-650 component parts. Approximately 12 percent of the components appellant purchased were incorporated into ITCA-650 units for use in the clinical trials. The remaining components were stored at appellant's Hayward facility pending the outcome of appellant's appeal with the FDA.
5. On September 25, 2020, appellant submitted the aforementioned claim for refund on the basis that its purchase of component parts for resale and its use of component parts in ITCA-650 clinical trials are nontaxable. In a November 5, 2020 audit report letter, CDTFA allowed a portion of the claim for refund, for purchases of $75,112 of components used in ITCA-650 clinical trials under California Code of Regulations,

title 18, (Regulation) section 1591(e)(4); CDTFA found that these items were for an exempt use because during the clinical trials they were implanted for periods of at least six months, which constituted being permanently implanted, and therefore met the definition of medicines pursuant to R&TC section 6369(c)(2). CDTFA denied the remainder of the claim for refund, including for purchases of components that remained in storage in Hayward, components that were used in ITCA-650 clinical trials that involved placebos, or components in ITCA-650 units that were implanted for only three months.

6. Following an appeals conference with CDTFA's Appeals Bureau, CDTFA issued a Decision on May 25, 2022, generally upholding the results of the audit.[2]

7. This timely appeal followed.

DISCUSSION

California imposes use tax on the storage, use, or other consumption in this state of tangible personal property purchased from any retailer for storage, use, or other consumption in this state, unless the use is excluded or otherwise exempt. (R&TC, § 6201.) Every person storing, using, or otherwise consuming tangible personal property in California purchased from a retailer is liable for the use tax, and that liability is not extinguished until the tax has been paid. (R&TC, § 6202(a).) "Storage" includes any keeping or retention in California for any purpose, except sale in the regular course of business or subsequent use solely outside this state, of tangible personal property purchased from a retailer. (R&TC, § 6008.) "Use" includes the exercise of any right or power over tangible personal property incident to the ownership of that property, except for the sale of that property in the regular course of business. (R&TC, § 6009.)

Tax does not apply to sales of tangible personal property to persons who purchase it for the purpose of incorporating it into the manufactured article to be sold, as, for example, any raw material becoming an ingredient or component part of the manufactured article. (Cal. Code Regs., tit. 18, § 1525(b).)

[2] The Decision ordered CDTFA to perform a reaudit to "compute the allowable refund for the tax [appellant] paid for the component parts purchased from RMS and Invibio during the claim period which were incorporated into ITCA-650 units that were implanted during human trials for six, nine, or twelve months and which contained exenatide." The evidence indicates that, in response, CDTFA found that no additional adjustments to the amount of appellant's refund were warranted.

Exemptions from tax are strictly construed against the taxpayer. (*H. J. Heinz Co. v. State Board of Equalization* (1962) 209 Cal.App.2d 1, 4.) R&TC section 6369 provides a general exemption from sales and use taxes for the sale and storage, use, or other consumption in this state of prescription medicines. R&TC section 6369(c)(2) specifies that medicines include articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body. Regulation section 1591 interprets and explains R&TC section 6369. Regulation section 1591(e)(4) provides that section 6369's exemption for medicines includes the sale or use of clinical trial medicines that are substances or preparations the FDA has approved as "investigational new drugs" intended for treatment of, and 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. (Cal. Code Regs., tit. 18, § 1591(e)(4).)

Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute. (Gov. Code, § 11342.2.) Each regulation adopted, to be effective, shall be within the scope of authority conferred and in accordance with standards prescribed by other provisions of law. (Gov. Code, § 11342.1.) The rulemaking power of an administrative agency does not permit the agency to exceed the scope of authority conferred on the agency by the Legislature. (*GMRI, Inc. v. California Dept. of Tax and Fee Administration* (2018) 21 Cal.App.5th 111, 123-124 (*GMRI*).)

A taxpayer who claims a refund bears the burden of establishing its entitlement thereto. (*Honeywell, Inc. v. State Bd. of Equalization* (1982) 128 Cal.App.3d 739, 744-745.) If CDTFA determines that any amount has been erroneously collected, it shall credit the excess amount collected or paid on any amounts then due and payable from the person from whom the excess amount was collected or by whom it was paid, and the balance shall be refunded to the person, or his or her successors. (R&TC, § 6901(a).) Any overpayment of the use tax by a purchaser to a retailer who is required to collect the tax and who gives the purchaser a receipt therefor shall be credited or refunded by the state to the purchaser. (R&TC, § 6901(b).) Where a retailer reimbursed its vendor for tax which the vendor is required to pay to the state, or has paid the use

tax with respect to the property, and has resold the property prior to making any intervening use of the property (other than retention, demonstration, or display while holding it for sale in the regular course of business), the retailer may take a deduction from its gross receipts of the purchase price of the property. (R&TC, § 6012(a)(1); Cal. Code Regs., tit. 18, § 1701(a).)

Appellant argues that a refund should be granted for use tax paid on its purchases of ITCA-650 components from RMS and Invibio during the claim period.[3] With respect to the ITCA-650 components in devices implanted for three months during clinical trials, appellant argues that this use was exempt because the components were clinical trial medicines pursuant to Regulation section 1591(e)(4).

Regarding the ITCA-650 remaining in storage in Hayward, appellant contends that that it has made no taxable use of this property because it has held the property in California solely for the purpose of sale in the regular course of business, and therefore its possession of this property is excluded from tax pursuant to R&TC section 6008.[4] Appellant states that it had intended to sell the manufactured ITCA-650 units as soon as it obtained FDA approval to do so, but it has been unable to obtain FDA approval. Appellant also states that if it does not obtain FDA approval, the ITCA-650 may be destroyed, which appellant states is a nontaxable use consistent with opinions such as Sales and Use Tax Annotations (Annotations) 570.1380 (10/23/64) and 570.1182 (2/18/75).[5] Furthermore, appellant argues that it is entitled to a refund pursuant to Regulation section 1525(b) because appellant is a person that purchased the property for the purpose of incorporating it into the manufactured article to be sold. Moreover, appellant argues

[3] In its briefing prior to the hearing, appellant had argued that it was entitled to a tax-paid purchases resold deduction pursuant to Regulation section 1701(b)(4). At the hearing, appellant clarified that it no longer contends that a tax-paid purchases resold deduction applies under the current facts. Appellant states that it is not a retailer and thus cannot incur a tax liability that a tax-paid purchases resold deduction can be applied to.

[4] CDTFA's Appeals Bureau Decision states that CDTFA "agrees that it has no knowledge of any use by [appellant] of the retained ITCA-650 components." In contrast, at the oral hearing before OTA, CDTFA argued that because appellant is not a retailer and cannot sell the property, appellant cannot be holding the property for the purpose of sale in the regular course of business; thus, CDTFA contends that, pursuant to the definition of "storage" under R&TC section 6008, appellant's storage of the property constitutes taxable use.

[5] Annotations are not binding authority and do not have the force or effect of law. (Cal. Code Regs., tit. 18, § 5700(a)(1); *Appeal of Martinez Steel Corporation*, 2020-OTA-074P.) However, OTA may give some consideration to annotations and will independently determine the appropriate weight to afford an annotation. (*Yamaha Corp. of America v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 15 (*Yamaha*); *Appeal of Martinez Steel Corporation*, *supra*.) The weight given to an annotation in a particular case will depend upon "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." (*Yamaha*, *supra*, 19 Cal.4th at pp.14- 15, quoting *Skidmore v. Swift & Co.* (1944) 323 U.S. 134, 140.)

that a refund of tax is required in this instance because R&TC section 6901 states that any overpayment of use tax by a purchaser to a retailer shall be credited or refunded by the state to the purchaser, and appellant asserts that it will not incur a tax liability that a tax-paid purchases resold deduction can be applied to. In addition, appellant asserts that a refund is warranted here because CDTFA previously issued refunds to appellant for similar transactions.

With respect to ITCA-650 components used in clinical trials, the issue concerns whether devices implanted for only three months meet the exemption's definition of "clinical trial medicines."[6] Regulation section 1591 interprets and explains R&TC section 6369. An administrative agency may not adopt a regulation that exceeds the scope of the enabling statute. (Gov. Code, § 11342.1; *GMRI*, *supra*, 21 Cal.App.5th at pp. 123-124.) Accordingly, Regulation section 1591(e)(4)'s application of the exemption to "investigational new drugs" approved by the FDA is limited to those substances and preparations that qualify as "medicines" under R&TC section 6369(c)(2). R&TC section 6369(c)(2) requires that items such as ITCA-650 be "permanently implanted in the human body" in order to qualify as medicines. CDTFA's interpretation of R&TC section 6369(c)(2) states that "permanently implanted" means items implanted in the human body for at least six months (see, e.g., Annotations 425.0163 (10/6/93), 425.0521 (2/24/95)); OTA finds that this longstanding position is well-established and entitled to weight. Consequently, the devices implanted for only three months do not qualify as clinical trial medicines, and therefore do not meet the requirements of the exemption.

Thus, this analysis turns to the ITCA-650 components that remain in storage in Hayward. Regulation section 1525(b) provides that tax does not apply when the property is purchased for the purpose of incorporating it into the manufactured article to be sold. Thus, if appellant made nontaxable use of the units, without any intervening taxable use, then a refund would be warranted for the tax paid. Given the facts of this case, evidence proving appellant's nontaxable use would show that the property is no longer in appellant's possession and, thus, not subject to further use by appellant. However, appellant has not proven such facts. The evidence does not establish what happened to the remaining ITCA-650 units; they were last known to be in

[6] Although it did not explain the reasons therefor, appellant confirmed at the hearing that it does not believe that ITCA-650 qualifies as a programmable drug infusion device pursuant to Regulation section 1591(b)(6) and R&TC section 6369(c)(6), thereby effectively removing that issue from consideration in this appeal.

appellant's possession and the evidence does not establish that appellant disposed of them.[7] Thus, under the current facts, appellant's incorporation of the property into the ITCA-650 units does not establish that an overpayment of use tax occurred.

As for appellant's assertions that it may destroy the property, OTA finds that the possible prospective destruction of the property in the future does not currently establish a basis for granting a refund of use tax at this time. In addition, whether CDTFA previously issued refunds for similar transactions is not relevant to this analysis, nor is CDTFA's previous treatment of transactions that are not the subject of this appeal. Therefore, OTA finds that these contentions do not establish any basis for granting the claim for refund.

While appellant asserts that its storage of the property in California has been solely for resale in the regular course of business, the parties also agree that appellant has never had the ability to sell the property as a medicine in the United States due to the lack of FDA approval. Given these facts, it is unclear from the evidence whether, following the FDA's repeated rejections of appellant's application, appellant's storage has become a taxable use of the property. In order for OTA to grant a refund, appellant must prove by a preponderance of the evidence that it has not made a taxable use of the property. Instead, here the evidence shows either that: (1) appellant continues to hold the property for resale, which does not establish an overpayment of use tax; or (2) appellant has stored the property for purposes other than holding it for resale in the regular course of business, which would be a taxable use. Thus, under either analysis, appellant has not met its burden of proof, and accordingly has not established that an overpayment of use tax occurred.

[7] At the hearing, appellant stated that all of its assets, including the ITCA-650 units, have been moved into a trust for assignment of benefit of creditors, and that, as a result, appellant currently does not have possession of, nor any ability to sell, the ITCA-650. The administrative record in this appeal does not contain any evidence regarding the assignment of benefit of creditors; thus, OTA does not consider whether such transfer of the property would constitute a taxable use.

HOLDING

Appellant is not entitled to additional refunds for use tax paid on its purchases of ITCA-650 components.

DISPOSITION

CDTFA's action is sustained.

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Suzanne B. Brown
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Suzanne B. Brown
Administrative Law Judge

We concur:

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Josh Aldrich
Administrative Law Judge

DocuSigned by:
Michael F. Geary
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Michael F. Geary
Administrative Law Judge

Date Issued: 5/14/2024