STATE OF CALIFORNIA

BOARD OF EQUALIZATION

BUSINESS TAXES APPEALS REVIEW SECTION

In the Matter of the Claim for Refund Under the Sales and Use Tax Law of:	)	DECISION AND RECOMMENDATION
REDACTED TEXT Corporation	)	No. REDACTED TEXT-001
Claimant	)	

The Appeals conference in the above-referenced matter was held by Paul O. Smith, Staff Counsel on September 23, 1993, in Sacramento, California.

Appearing for Claimant:	REDACTED TEXT Controller
	REDACTED TEXT, CPA
Appearing for the Sales and Use Tax Department:	Michael P. Kitchen Tax Auditor

Subject of Claim

Claimant seeks a refund of tax for the period July 1, 1987 through March 31, 1991, measured by:

Items Subject to Claim	Amount
B. Section 6009.1 credit on tax-paid purchases of raw materials used in the clinical testing of drugs.	$111,525
C. Cost of raw materials consumed in the clinical testing of medicines in California.	$ 32,828
Total	$144,353

Claimant's Contentions

Claimant contends that the raw materials incorporated into [A]tm and [B]tm should be classified as nontaxable "medicines" pursuant to Revenue and Taxation Code Section 6369, and Sales and Use Tax Regulation 1591. Claimant also contends that it used [A]tm and [B]tm in the exempt manner prescribed in this section and regulation, and Sales and Use Tax Annotation 425.0050. Claimant, citing Sales and Use Tax Annotations 440.1860, and 440.1880, also contends that its raw material purchases are exempt because of incorporation into a finished product. Claimant contends, in the alternative, that it is entitled to an additional Revenue and Taxation Code Section 6009.1 deduction for raw materials used outside this state.

Summary

Claimant REDACTED TEXT Corporation is a leading biotechnology company developing therapeutic products using monoclonal antibody and recombinant DNA technologies. During the period in issue, claimant entered into Clinical Research Agreements (agreements) to conduct controlled studies to investigate the safety and efficacy of [A]tm and [B]tm in the treatment of patients with suspected Gram Negative Sepsis and various immune related disorders.[1] In June 1987, claimant entered into an agreement for the transfer of the exclusive worldwide rights to [A]tm in exchange for funding clinical testing and development activities by claimant. For this right claimant received an initial fee of $2.0 million in 1987, and research development fees in 1988, 1989, and 1990. There was no mention of any revenue being generated by [B]tm. (REDACTED TEXT Corporation Annual Report, 1990, p. 20-21.)

The Federal Drug Administration (FDA) has not approved either drug for marketing. While the FDA continued its review, the products were made available to patients in clinical studies under claimant's "compassionate use program". The studies were conducted by an "Institution" and a "Principal Investigator".[2] Under the agreement claimant made payments to the Institution and Principal Investigator that varied depending on whether a patient received one complete infusion of the drug, some study drug but less than one complete infusion of study drug, or no drug at all. Some studies were conducted outside this state.

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[1] The 1990 annual Report provided by claimant only makes reference to [B] Plus(tm). For purposes of this Decision and Recommendation I am assuming that [B](tm) and [B] Plus(tm) are one and the same.

[2] The agreement defined a "Principal Investigator" as one who directs the clinical study in accordance with the protocol. Claimant has submitted agreements effective August 9, 1990, with REDACTED TEXT, as the Institution, and REDACTED TEXT, M.D., as Principal Investigator; and effective February 1, 1989, with REDACTED TEXT, Inc., as the Institution, and REDACTED TEXT, M.D., as Principal Investigator. The agreements also provide that the study group would be placed in a protocol entitled "Double Blind Randomized Placebo Controlled Group Comparative Study of the Safety and Efficacy of [A](tm) in Patients with Suspected Gram Negative Sepsis."

The Sales and Use Tax Department (Department) examined claimant's returns for the period in issue, and determined that the raw materials used to produce the above drugs were subject to use tax because they were not purchased for resale, and failed to qualify as a "medicine". Most of the suppliers of the raw materials were located outside the state, and most collected the use tax on their sales. The Department gave claimant credit for the cost of raw materials processed in this state and subsequently sent outside the state for use in claimant's clinical testing program. On October 14, 1992, the Department completed a reaudit.

Analysis and Conclusions

Revenue and Taxation Code section 6369 provides in relevant part that there are exempted from the sale and use tax, the gross receipts from the sale, and the storage, use, or other consumption, in this state of medicines (1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines; (2) furnished by a licensed physician and surgeon for his or her own patient; (3) furnished by a health care facility for treatment of any person; (4) sold to a licensed physician and surgeon; or (5) sold to this state. Section 6369, subdivision (b) provides in relevant part that "medicines" means and includes any substance or preparation intended for use by application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease that is commonly recognized as a substance or preparation intended for that use. (See also Sales and Use Tax Reg., § 1591, Subd. (b)(1).)

Claimant argues that the raw materials incorporated into [A]^{tm} and [B]^{tm} should be classified as "medicines", and are therefore nontaxable.

The facts establish that [A]^{tm} is used in the mitigation, treatment, or cure of gram-negative sepsis, a serious complication of certain bacterial infections, and the drug [B]^{tm} selectively eliminates T lymphocytes involved in immune system disorders. The facts also show that these drugs qualify as experimental drugs, and are furnished by a licensed physician paid under contract by claimant, to his or her patient engaged in the studies. Thus, the drugs are within the definition of medicines and used in an exempt manner, as provided by section 6369 and regulation 1591. (Cf. Sales and Use Tax Annon. 425.0050; Purdue Frederick Co. v. State Bd. of Equalization (1990) 218 Cal.App.3d 1021.) However, the analysis does not end here because the Department assessed the use tax on the "consumption" of the raw materials used to produce these drugs, not on the "use" of the drugs themselves.

It is well settled that exemptions from tax are strictly construed against the taxpayer who has the burden of proving that the statutory requirements have been satisfied. (See Standard Oil Company of California v. State Bd. of Equalization (1974) 39 Cal.App.3d 765; H. J. Heinz Co. v. State Bd. of Equalization (1962) 209 Cal.App.2d 1, 4.) Any doubt must be resolved against the right to an exemption. Estate of Simpson (1954) 43 Cal.2d 594, 602; J. C. Penny Insurance Company v. State Bd. of Equalization (1979) 94 Cal.App.3d 685, 693.) Petitioner's argument that its purchases of raw materials incorporated into [A]^{tm} and [B]^{tm} are exempt from tax is not supported by the clear and unambiguous language of section 6369.

Section 6369, upon which petitioner relies, when enacted in 1961, exempted medicines dispensed on prescription by a registered pharmacist. This statute has undergone numerous amendments since its enactment. One such amendment extended the exemption to cover medicines furnished by persons other than a pharmacist, another amendment exempted medicines furnished by dentist, and expanded the definition of medicines to include items such as sutures and bone screws, and another amendment substituted the term "health facility" for "hospital".[3] As I have stated above, the gross receipts from the sale, and the storage, use, or other consumption, in this state of medicines such as [A]^{tm} and [B]^{tm} are exempt from tax. However, in no instance did any of the many amendments to the statute extend its provisions to items and materials consumed in the manufacture of [A]^{tm} and [B]^{tm}. Nor has claimant directed me to any other authority that provides such exemption. (See e.g. Rev. & Tax. Code, §§ 6369.4, subd. (a), and 6369.5.) Further, the raw materials in question are not "medicines" within the meaning prescribed by section 6369, subdivision (b), nor commonly recognized as a substance or preparation intended for use as a medicine. (See also Sales and Use Tax Reg., § 1591, subd. (b)(1).) Therefore, I must conclude that the Department properly denied classification of the materials as exempt medicines.

Claimant also argues that its raw material purchases are exempt because of their incorporation into a finished product.

Claimant relies on Sales and Use Tax Regulation 1525, subdivision (b), and Sales and Use Tax Annotations 440.1860 and 440.1880, which provide for the exemption of raw materials incorporated into the manufacture of articles to be sold. Claimant's reliance on this authority is misplaced because in each instance the materials must be incorporated into a product that is ultimately sold. As set forth above, both [A]^{tm} and [B]^{tm} were used in human clinical trials under petitioner's compassionate use program, and the FDA had not approved either drug for marketing. I further understand that claimant did not sell either drug during the period in issue. Therefore, it must be concluded that since neither [A]^{tm} or [B]^{tm} were sold, the authority relied on by claimant is inapplicable.

Claimant contends in the alternative that it is entitled to an additional section 6009.1 deduction for raw materials used outside this state.

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[3] Added by Stats. 1961, chap. 866, p.2273, § 1. Amended by Stats. 1962, chap. 7, p.12, §1; Stats. 1963, chap. 716, p.1723, § 1; Stats. 1970, chap. 1511, p. 2999, § 1, operative July 1, 1971; Stats. 1972, chap. 877, p. 1549, § 1, eff. Aug. 14, 1972, operative Oct. 1, 1972; Stats. 1977, chap. 1245, p. 4220, § 1, eff. Oct. 1, 1977, operative Oct. 1, 1977; Stats. 1978, chap. 229, p. 485, § 1, eff. June 13, 1978; Stats. 1982, chap. 1530, p. 5954, § 1, eff. Sept. 30, 1982, operative Jan. 1, 1983; Stats. 1982, chap. 1589, p. 6281, § 12.3.

Sections 6009.1 provides in relevant part that "storage" and "use" do not include the retaining or exercising any right or power over tangible personal property that is subsequently transported outside the state for use solely outside the state, or for manufacture into other tangible personal property to be transported outside the state and used solely outside the state. Section 7054 authorizes the Department to conduct investigations to verify the accuracy of sales and use tax returns. Further, there is the presumption that the Department's determinations as to the amount of tax owed is correct (Marchica v. State Bd. of Equalization (1951) 107 Cal.App.2d 501, 510), and the burden of overcoming this presumption is on the taxpayer. (Paine v. State Bd. of Equalization (1982) 137 Cal.App.3d 438, 445; Riley B's, Inc. v. State Bd. of Equalization (1976) 61 Cal.App.3d 610.)

Here, claimant argues that it is entitled to an additional section 6009.1 deduction for tax-paid purchases of $111,525. I disagree. In the conduct of its audit the Department made two findings of fact regarding consumable materials used in the production of [A]tm and [B]tm. The first was that claimant consumed ex-tax materials of $32,828, and received credit for tax-paid materials of $579,033. (See Audit Sch. 2, Jan. 14, 1992.) The second was that claimant had tax-paid material purchases of $690,558, of which $111,525 was consumed within the state.[4] (See Audit Sch. 2B, Jan. 14, 1992.) Since the Department determined that the $111,525 had been consumed within this state, and claimant has not established otherwise, this amount is not within the exclusion provided by section 6009.1.

Recommendation

Allow the claim according to the Department's reaudit report of October 14, 1992, and deny the claim in all other respects.

Paul O. Smith, Staff Counsel Date

[4] The difference is the $579,033 that claimant received credit for against its ex-tax purchases. Also Schedule R2B in the reaudit workpapers shows tax-paid purchases of $680,956 and materials consumed in California of $109,974 (net difference of $570,982 for tax-paid materials as compared to $579,033 in the original audit).