

STATE OF CALIFORNIA
BOARD OF EQUALIZATION

425.0743

BUSINESS TAXES APPEALS REVIEW SECTION

In the Matter of the Petition)
for Redetermination Under the) DECISION AND RECOMMENDATION
Sales and Use Tax Law of:)
)
I--- CORPORATION) No. SC -- XX XXXXXX-010
)
Petitioner)

The Appeals conference in the above-referenced matter was held by Senior Staff Counsel Stephen A. Ryan on January 7, 1994 in Sacramento, California.

Appearing for Petitioner: Mr. D--- F---
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Appearing for the Sales and Use Tax Department: Mr. Rick Zellmer
Senior Tax Auditor

Mr. Jack Warner
District Principal Auditor

Protested Item

The protested tax liability for the period January 1, 1989 through December 31, 1991 is measured by:

<u>Item</u>	<u>State, Local and County</u>
A. Revenue and Taxation Code section 6204 debt on receipts from nonexempt retail sales of Prosorba Treatment Columns--disallowed medicine deductions	\$300,450

Petitioner's Contentions

1. The receipts are exempt since each Prosorba Treatment Column is exempt pursuant to either Revenue and Taxation Code sections 6369 or 6369.1.
2. In the alternative, most sales were for resale.

Summary

Petitioner is a Washington entity which, in addition to its primary medical research and development work, manufactures and sells the Prosorba Treatment Column ("Prosorba"). It had solicitors who operated in California. This was the first audit.

Petitioner claimed deductions for the \$300,450 in question as having been derived from sales of exempt medicines, but the auditor disallowed the deductions. Petitioner sold Prosorba with delivery made from its Washington location via common carrier to hospitals, medical clinics, and blood banks located in California. On these transactions, petitioner did not collect tax or tax reimbursement. On some other sales of Prosorba which petitioner also claimed as exempt, the Out-Of-State District allowed the deductions because those other Prosorba were found to have been used by petitioner's customers for kidney dialysis type of hemodialysis on patients without functioning kidneys, and thus were exempt pursuant to Revenue and Taxation Code section 6369.1. The District's reason for denying any exemption for the sale of the Prosorba in question was that such product was used in non-kidney dialysis type of hemodialysis for patients with functioning kidneys, which led the District to conclude that this Prosorba had not been applied internally or externally to a human body, and were devices pursuant to Revenue and Taxation Code section 6369(b)(2). The District agrees that Prosorba was used and can only be used under a physician's order or prescription.

Each Prosorba consists of 200 milligrams of Protein A attached to special silica granules which are sold in a cylindrical non-returnable plastic container about the size of a soup can. There are two small openings at each end of the container to which sterile tubes are attached.

Prosorba is used in a process called immunoadsorption which removes specific molecules from the blood of human beings. The patients primarily include people with functioning kidneys who have a blood disorder called idiopathic thrombocytopenic purpura ("ITP"). These patients are in need of having immunoglobulin G circulating immune complexes removed from their blood. Immunoglobulin G ("IgG") is an antibody found naturally in the blood. When an antibody such as IgG attacks a foreign matter ("antigen") such as bacteria, infections, fungi, toxins, etc., a chemical reaction occurs between the antigen molecules and the antibody molecules which usually leaves a clump of waste or creates a waste by-product known as a circulating immune complex ("CIC") which then needs to be excreted from the blood. Patients with ITP need IgG CICs removed from the blood.

Prosorba is also used for other patients to remove CICs from the blood. In people whose kidneys do not function, kidney dialysis is needed to cleanse the blood of these and other waste products. Prosorba is sometimes used as part of that kidney dialysis type of hemodialysis. In some patients with functioning kidneys, their blood is in need of a thorough cleansing in order to give their immune system a fresh start as part of a physician's treatment for various diseases. Examples of the latter people include those with other blood disorders, immune disorders, and certain cancers, namely breast, colon, and Kaposi's sarcoma associated with AIDS. Research has

shown that ProSORBA speeds up their normal excretion of the IgG CIC waste products from the blood, and provides their immune system with an opportunity to start functioning properly again to combat disease. It is also believed that IgG CICs in the blood inhibit the patient's immune system from killing tumor cells. Sometimes, ProSORBA is used in an emergency situation, but it is usually used in a planned process of six to twelve treatments.

During the most common use, blood is temporarily circulated outside the human body through a needle placed in a vein in one arm, and is directed through a tube to a apheresis machine which separates blood cells from blood plasma. The cells are immediately returned to the body through another tube with a needle placed into a vein in the other arm. The plasma flows from the machine through another tube into ProSORBA, and then out another tube back into the blood cell tube leading into the other arm. In a less-common use, several pints of blood are removed from the patient for approximately 30 minutes and put through a similar process before the plasma is returned to the body. Each ProSORBA is discarded after the use. Small amounts of protein A leach out of ProSORBA and eventually go into the body in each process, but this is not a purpose for the use of ProSORBA.

Petitioner pointed out that this immunoadsorption procedure is not a plasmapheresis process. In plasmapheresis, the patient's blood cells are separated from the plasma with only the cells sent back into the body along with a replacement plasma from another source. In this immunoadsorption process with ProSORBA, the patient's own cells and plasma are returned into the body. Only the IgG CICs have been removed from the blood.

Petitioner charges approximately \$3,400 for each ProSORBA. Mr. F--- represented that the container has only a nominal value with almost all value being attributed to the protein A and special silica. In its laboratory, petitioner isolates protein A and attaches it to the silica granules which are then enclosed inside the container.

In a letter dated May 19, 1992 to a hospital customer of petitioner, the Board's Legal Division opined on general and misplaced facts that petitioner's sales of ProSORBA are subject to tax. The Board's attorney identified Revenue and Taxation Code section 6369 and Sales and Use Tax Regulation 1591 as providing that "items used to diagnose a condition or to apply medicine or treatment to the patient are not considered to be medicines". It was concluded that ProSORBA "is a device the purpose of which is to administer treatment to a patient", and is not a medicine. The critical evidence cited in the analysis is that a "powder" "remains in the device acting to separate blood cells from plasma, much like a filter, and then re-introduce them to the patient". In a memorandum dated June 22, 1992 from that same Board attorney to the field auditor in this case, it was opined that petitioner's sales of ProSORBA for hemodialysis use are exempt pursuant to Regulation 1591(j). That attorney referred to the primary use of ProSORBA as plasmapheresis.

We also note that for some other sales of ProSORBA, petitioner reported and paid tax because some customers had paid it tax, although it believed an exempt medicine was sold. Petitioner has offered to return these funds to the customers if the Board decides sales of ProSORBA are exempt.

Analysis and Conclusions

Revenue and Taxation Code section 6369.1 exempts from sales and use taxes those hemodialysis products which are both supplied to a patient on order of a licensed physician pursuant to Business and Professions Code sections 4050.7 or 4227, and which constitute a medicine pursuant to Revenue and Taxation Code section 6369.

Pursuant to section 6369, "medicines" mean any substance or preparation intended for use by external or internal application to the human body in the diagnosis, care, mitigation, treatment or prevention of a disease, and which is commonly recognized as such, but not articles in the nature of instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic or physical equipment or articles (§ 6369(b)). However, any appliance and related supplies necessary as the result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste, is also included as a "medicine" and is deemed to be dispensed on a prescription (6369(g)). The Board has interpreted section 6369.1 together with 6369(g) to mean that appliances and related supplies for hemodialysis products are exempt pursuant to section 6369.1. Regulation 1591(j) identifies appliances and related supplies to include kidney dialysis machines plus the pumps, tubing, blood sets and other passageway sets used in conjunction with such machines. This is interpreted by the Department as examples of appliances and supplies, rather than as a restricted list.

The District concluded that when ProSORBA is used for the kidney dialysis type of hemodialysis, ProSORBA is a hemodialysis product which is exempt under section 6369.1. Conversely, the District has found that when ProSORBA is used for hemodialysis which does not involve kidney dialysis, petitioner is not exempt under section 6369.1.

This result cannot stand. ProSORBA is a hemodialysis product used in hemodialysis. Hemodialysis means the removal of certain elements from the blood while the blood is being circulated outside the body. Hemodialysis is not limited to kidney dialysis. In hemodialysis, ProSORBA removes certain elements from the blood, such as items normally excreted in urine. ProSORBA is used in hemodialysis as part of the two types of described surgical procedures by which artificial openings are made in the human body for the elimination of natural waste in the form of IgG CIC waste by-products.

It is our conclusion that petitioner's sales are exempt pursuant to section 6369.1. This hemodialysis product is an appliance or related supply for the elimination of natural waste in the procedure identified in 6369(g) and of the type provided for in Regulation 1591(j). This result fits with the District's conclusion that ProSORBA is exempt when sold for use for the kidney dialysis type of hemodialysis. In the non-kidney dialysis type of hemodialysis, ProSORBA is used to specifically target IgG CIC natural waste products for those patients who cannot excrete such CICs or who need such excretion speeded up.

Our conclusion is consistent with the general statement made by the Board's Legal Division on June 22, 1992 that petitioner's sales for hemodialysis use are exempt. We do not follow the May 19, 1992 Legal Division letter which concludes that sales of ProSORBA are not exempt. Initially, that attorney did not have knowledge of the relevant facts about the makeup of ProSORBA or of its actual use. It was then thought ProSORBA was a powder used to actually separate blood cells from plasma. But ProSORBA is exempt pursuant to section 6369.1 as hereinabove described.

Recommendation

Grant the petition. In order to prevent a separate deficiency for excess tax reimbursement, petitioner should file a claim for refund/credit and follow through on its offer to return tax reimbursement which it collected from its customers on the other sales not in question in this petition process.

Stephen A. Ryan, Senior Staff Counsel

Date