JURISDICTION: **OKLAHOMA TAX COMMISSION**
CITE: **97-05-08-015 / PRECEDENTIAL**
ID: **P-94-039**
DATE: **MAY 8, 1997**
DISPOSITION: **SUSTAINED**
TAX TYPE: **SALES, MANUFACTURERS EXEMPTION**
APPEAL: **NO APPEAL TAKEN**

ORDER

This comes on before the Oklahoma Tax Commission pursuant to regular assignment on the Agenda. The Commission, having reviewed the facts and authorities presented and being fully advised in the premises, finds and orders that the Application for Oral Argument Before the Tax Commission En Banc is hereby denied. The Findings, Conclusions and Recommendations of the Administrative Law Judge, filed herein on the 29th day of October, 1996, attached hereto and hereby incorporated by reference as though fully set out herein, are hereby adopted as the Order of the Commission.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

The above styled and numbered cause comes on for consideration pursuant to assignment regularly made by the Oklahoma Tax Commission to ALJ, Administrative Law Judge. The protest was submitted for decision without a hearing pursuant to Rule 710:1 -5-38 of the *Oklahoma Administrative Code.* Protestant is represented by ATTORNEY 1, attorney, and ATTORNEY 2, attorney, FIRM. The Audit Division is represented by OTC ATTORNEY, Deputy General Counsel, General Counsel's Office. The parties filed a *Joint Stipulation of Facts* and briefs in support of their respective positions.

FINDINGS OF FACT

The parties stipulate to the following:

1. COMPANY is a company incorporated under the laws of the State of STATE A, with a mailing address of STATE B ADDRESS.

2. COMPANY requested a determination of taxability in January, 1992, and on or about November 2, 1992, COMPANY applied to the Oklahoma Tax Commission for a Manufacturer's Limited Exemption Certificate for purposes of exemption from Oklahoma sales and use tax. (Exhibit A).

3. In April 1993, a Division auditor conducted and on-site visit to COMPANY'S CITY, Oklahoma location and prepared an auditor's worksheet. (Exhibit B).

4. By letter dated April 20, 1993, COMPANY provided "a written description of our manufacturing process, relative to our CITY, Oklahoma location". (Exhibit C).

5. The auditor submitted a memorandum dated June 9, 1993. (Exhibit D).

6. By letter dated June 9,1993, COMPANY submitted a "brief description of the manufacturing process of COMPANY. (COMPANY), as it relates to the manufacturing exemption for Oklahoma sales and use taxes". (Exhibit E).

7. By letter dated November 24, 1993, the Division denied COMPANY'S Application, stating that COMPANY did not qualify as a manufacturer under 68 O.S. § 1359 (1981). (Exhibit F).

8. Pursuant to 68 O.S. § 207, on or about December 21,1993, COMPANY requested a hearing by the Tax Commission and said hearing was set for October 10, 1995, at 9:30 a.m. in front of the Administrative Law Judge, Oklahoma Tax Commission. (Exhibit G).

9. COMPANY operates two plasmapheresis centers in Oklahoma, one located at LOCATION 1 ADDRESS, and the other located at LOCATION 2 ADDRESS (the "centers"). The LOCATION 1 center began business on July 10,1992. The LOCATION 2 center began business in November, 1973.

10. The COMPANY centers have variously prepared three products:

a. Normal Source Plasma prepared through use of the Fenwal Autopheresis-C automated plasmapheresis collection system from donors who have not been immunized.

b. Antibody Source Plasma prepared through use of the Fenwal Autopheresis-C automated plasmapheresis collection system from donors who have been immunized.

c. Serum and red blood cells. These products were prepared only in the LOCATION 2 center and are no longer being prepared.

11. Currently, the COMPANY centers prepare two biological products: (1) Normal Source Plasma and (2) Antibody Source Plasma (collectively known as "Source Plasma").

12. In the past, a small percentage (less than 5%) of blood collected at the LOCATION 2 center was used to prepare serum and red blood cells. The preparation of serum and red blood cells at the LOCATION 2 center has, as of approximately September 1, 1995, been completely discontinued. Currently, both centers prepare only Normal Source Plasma and Antibody Source Plasma.

13. Plasmapheresis is defined in Lesson 1, page 1, Section 1.0 of COMPANY'S Employee Training Manual as follows:

> "Plasmapheresis is a procedure by which whole blood is collected and separated into plasma and cellular components. The plasma is removed via

> centrifugation and filtration and the remaining cellular components are returned to the donor."

14. Exhibit H is a true copy of the COMPANY Employee Training Manual, which is a reference manual used by COMPANY employees in training and in the field operations described herein.

15. Exhibit I is a true copy of the Autopheresis-C operating Manual which contains a description and diagrams of the plasmapheresis system used by the COMPANY centers and accurately describes and diagrams plasmapheresis and the equipment which is used by COMPANY in plasmapheresis.

16. All products prepared at the COMPANY centers are suitable only for further manufacturing; no resulting products are suitable for injection or transfusion at the time they are sold by COMPANY to COMPANY'S customers.

17. COMPANY'S Employee Training Manual states:

> The plasma we collect may be used for further manufacture into Injectable Products, meaning that the end products are medications that may be administered to patients by injection; or it may be used for further manufacture into Non-lnjectable Products, meaning the end products may not be used as injectable medications. Plasma classified for Non-lnjectable use is used in laboratory research, and make laboratory reagents and controls.
>
> Sometimes plasma is used for direct transfusion into a patient without undergoing any further manufacturing. COMPANY does not collect plasma for this use.

Employee Training Manual, Lesson No. 1, Page 1, section 4.0. (Exhibit H).

18. Exhibit J are true copies of the COMPANY Master Label for Source Plasma, which states, "Caution: for manufacturing use only," and excerpts from Title 21 of the Code of Federal Regulations which define "Source Plasma" as "source material for further manufacturing use".

19. Exhibit K is COMPANY'S licensing from the U.S. Food and Drug Administration/Department of Health and Human Services and related correspondence from the files of COMPANY.

20. COMPANY'S centers hold Establishment Licenses and Product Licenses from the U.S. Food and Drug Administration/Department of Health and Human Services for the "manufacture of biological products"; the establishment licenses specifically authorize "the manufacturer [COMPANY] to maintain an establishment for the propagation or manufacture and preparation for sale, barter, or exchange in the District of Columbia, or for sending, carrying, or bringing for sale, barter or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession,

any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives, for which the manufacturer holds an unsuspended and unrevoked product license issued by the Secretary of Health and Human Services pursuant to said Act and regulations." COMPANY'S product licenses authorize COMPANY centers to "propagate or manufacture and prepare for sale Source Plasma." (Exhibit K).

BRIEF DESCRIPTION OF PREPARATION OF SOURCE PLASMA

21. Plasmapheresis of Normal Source Plasma would be briefly described as follows: As outlined in detail below in paragraph 23, whole blood is collected from a donor and mixed with anticoagulant. It is then centrifuged through a filtration device to separate the red blood cells from the plasma. The plasma portion (clear, straw colored portion of the whole blood) is then dispensed into a plastic collection container (bag or bottle). The red cells are concurrently reinfused into the donor. The plasma is then labeled and frozen at -20 °C or colder.

22. Preparation via plasmapheresis of Antibody Source Plasma would be briefly described as follows: The plasma donors are either tested to identify pre-existing antibodies, or immunized to create the production of a specific antibody needed as a characteristic of the Source Plasma to be manufactured. Individuals with pre-existing antibodies are those who have acquired antibodies either through previous immunizations, blood transfusions, or pregnancy. COMPANY actively collects Source Plasma with the following antibodies: Tetanus, Rabies, Hepatitis B, Red Blood Cells (e.g. Anti-D), CMV, VZV, HIV.

Antibody Source Plasma contains higher than normal levels of antibodies and is prepared as described below in Paragraph 23. COMPANY monitors the titer level and specialized plasma process according to COMPANY customer specifications, furnishing the Antibody Source Plasma necessary for them to prepare their products used for immunization purposes.

DETAILED DESCRIPTION OF PREPARATION OF SOURCE PLASMA

The following is a description of plasmapheresis preparation and a description of the handling of the material and resulting plasma.

23.1 The prospective donor of raw material (blood) enters the reception area at the LOCATION 1 or LOCATION 2 center, is briefly screened, executes paperwork, is weighed and given a brief physical.

23.2 The donor's vital signs are taken (weight, blood pressure, pulse, temperature) and blood screening is done as appropriate (to determine hematocrit and total plasma protein). The donor's blood is grouped, not typed.

23.3 The intended venipuncture site on the donor's arm is prepped with an iodophor solution to cleanse the area.

23.4 The fistula (needle) is inserted into a vein and a specific volume of whole blood (deep red-colored material) is collected directly from the donor via a sterile fistula and tubing set. This disposable tubing set (called a Plasmacell-C Disposable Set) is installed on an automated plasmapheresis instrument which performs the transformation process, and is called an Autopheresis-C. The Plasmacell-C Disposable Set includes the tubing, a rotating membrane filtration device, and a reinfusion reservoir. Refer to Exhibit I, Fenwal's Autopheresis-C instrument manual, at page 14. Note that the picture does not show a fistula attached, the fistula would be attached at the connector shown in the lower left part of the diagram.

23.5 The Autopheresis-C automated plasmapheresis instrument pumps anticoagulant solution at a controlled rate into the whole'blood as it enters the Plasmaceli-C Disposable Set tubing from the donor's vein. Referring to Exhibit I, the Fenwal Autopheresis-C manual, page 14, the anticoagulant is added at the point of entry to the Plasmacell-C Disposable Set, just to the right of "H1" on the diagram. The anticoagulant solution then binds and removes active ionic calcium, to prevent initiation of the natural occurrence of clotting and fibrin formation.

23.6 The anticoagulated whole blood then flows into the Plasmacell-C Disposable Set. Here the liquid component of the whole blood (plasma, a clear, straw colored fluid) is separated by centrifugal force via a filtration device from the cellular components of the blood (red blood cells, platelets, leukocytes).

23.7 The plasma component is pumped into a collection bag/bottle, labeled with a product label that identifies the product, the source donor and the center.

23.8 The remaining cells (very dark red in color) are pumped from the Plasmacell-C Disposable Set into a reservoir container. When the reservoir is full, the cells are reinfused into the donor.

23.9 The disposable set consists of the rotating membrane filtration device, a reinfusion reservoir and a tubing set which provides transport for the blood and solutions within a closed, sterile system.

23.10 The plasma now contained in the labeled, final collection bag/bottle is then disconnected from the tubing set and the instrument

23.11 The collection bags/bottles are taken to a collection desk.

23.12 Representative samples are collected from the final collection bag/bottle and sent to a designated COMPANY testing laboratory for further testing, including viral marker (anti-HIV, anti-HCV, and H-BsAg) testing, testing of titers levels (which checks for antibodies) and HIV status.

23.13 Appropriate information is entered into a computer to identify the donor and the sample.

23.14 Additional preparation may include adding a stabilizing solution, adding additional anticoagulant, adding other solutions depending on the end usage, and/or mixing the plasma with that of other donors (called pooling).

23.15 If the plasma is mixed with plasma from other donors, stabilizing solution is added to the pooled plasma in order the stabilize the clotting factor proteins contained in the plasma, insuring that the chemistry of labile proteins behaves biologically in a similar fashion to invivo conditions.

23.16 The collection bag/bottle is then hermetically sealed and frozen in a solid state in a storage freezer at temperature of -20°C or colder.

23.17 Once appropriate test results on the sample are received from the COMPANY testing laboratory, the collection bag/bottle of Source Plasma is shipped on to a customer by truck or plane in a frozen state. The Source Plasma shipped by COMPANY is intended for further processing or fractionation. See Exhibit J, the Master Label used on shipped Source Plasma, which states, "for manufacturing use only".

24. A true copy of a typical customer list for COMPANY'S LOCATION 1 and LOCATION 2 center is contained in Exhibit L. The *Supplement to Joint Stipulations of Fact* added a true copy of the COMPANY LOCATION 2 Center Customer List to Exhibit L.

25. A true copy of sample result reports from the CITY, STATE B, laboratory testing of Source Plasma samples is contained in Exhibit M.

THE PREPARATION OF SERUM AND RED BLOOD CELLS

26. In the past, COMPANY prepared a very small amount of serum and red blood cells.

27. The preparation of serum and red blood cells is no longer done at either center.

The preparation of serum and red blood cells is generally described as follows:

28.1 The intended venipuncture site on the donor arm is prepped with an iodophor solution to cleanse the area.

28.2 The needle is inserted into a vein and a specific volume of whole blood (deep-red colored raw material) is collected directly from the donor via a sterile needle and tubing set, leading directly to a sterile plastic collection bag.

28.3 The filled collection bag containing the whole blood is then placed in a centrifuge machine within a refrigerated environment and the cellular blood components (red blood cells, platelets, leukocytes) are separated via centrifugal separation from the liquid component (serum) within a refrigerated environment.

28.4 The serum component (a clear, straw-colored fluid) is then extracted from the primary collection bag/bottle into a secondary plastic bag. The separated serum component is further processed via a proprietary process to prevent the natural proteolytic degradation of serum proteins which would otherwise occur. This stabilized protein serum component is then extracted into a separate container (bag or bottle) and labeled with a product label that identifies the product, the source donor and the center.

28.5 The serum component containing the stabilized proteins then becomes a product (human serum), and is labeled.

28.6 The final serum container is then hermetically sealed and stored wither under refrigeration at 2-8°C or may be frozen at -20°C or colder. Several individual donor serums may also be pooled into a larger final container in accordance with inherent donor characteristics that are similar.

28.7 An anticoagulant is added to the remaining cellular components. The anticoagulant solution halts the natural process that occurs whenever a blood component is removed from the body.

28.8 The cellular component of the blood is labeled with a product label that identifies the product, the source donor and the center.

28.9 The final red cell container is then hermetically sealed and stored under refrigeration at 1-6°C.

SUPPLIES USED BY COMPANY IN PLASMAPHERESIS

29. Exhibit N is a true list of the supplies and equipment used by COMPANY in preparing Source Plasma at the LOCATION 2 and LOCATION 1 centers.

30. Exhibit O is a true list of the supplies that were previously used by COMPANY in preparing serum and red blood cells.

31. Each time a blood donor undergoes plasmapheresis, a new fistula, Plasmacell-C Disposable Set and anticoagulant bag are utilized. At the end of the plasmapheresis procedure on each donor, the fistula, Plasmacell-C Disposable Set and anticoagulant bag are disposed of as biohazardous waste, i.e. incinerated per federal, state and local regulations.

32. Both COMPANY'S LOCATION 1 and LOCATION 2 center are generally recognized as preparers of Source Plasma through plasmapheresis in the following ways:

a. The donors of whole blood (raw material) generally are aware that this process is not routine blood donation or collection; they understand that a significant portion of their own blood is being returned to them during plasmapheresis; i.e. that COMPANY is only permanently removing plasma from their bodies. Copies of COMPANY prepared literature, literature distributed by COMPANY and COMPANY advertisements are included in Exhibit P.

b. The donors of the whole blood are aware that whole blood donation can only be done once every eight weeks and they are aware that plasmapheresis which removes only the plasma from their blood can be done twice a week.

c. COMPANY'S competitors are aware that COMPANY is not a whole blood collection center, but rather a highly specialized operation that prepares specialty products from whole blood; they are aware that COMPANY'S centers, through plasmapheresis, prepare Source Plasma from whole blood and that Source and Antibody Plasma have different names, purposes and physical properties than whole blood.

d. The blood and biological products industry, in general, is aware and fully informed of the difference between whole blood collection and biological products resulting from whole blood through plasmapheresis; the industry is aware that COMPANY'S centers prepare plasma from whole blood through plasmapheresis and that Source Plasma and Antibody Source Plasma have different names, purposes and physical properties than whole blood. (See Exhibit K)

e. Physicians, medical personnel, hospitals and medical facilities are aware and fully informed as to the difference between whole blood collection and biological products resulting from plasmapheresis; they are aware that COMPANY'S facilities prepare Source Plasma from whole blood and that Source Plasma and Antibody Source Plasma have different names, purposes and physical properties than whole blood.

f. COMPANY'S customers, who actually order and purchase normal and Antibody Source Plasma from COMPANY, are aware that COMPANY'S centers, through plasmapheresis, prepare plasma from blood and that

Source Plasma and Antibody Source Plasma products have different names, purposes and physical properties than whole blood.

g. Michigan, Ohio, Pennsylvania, Tennessee, Texas and Idaho have recognized COMPANY'S operations as manufacturing. Kansas has granted exemption on some of COMPANY'S supplies, as an "ingredient or component part". Exhibit S-1 through S-6 and S-8 are documents confirming the facts contained in this paragraph.

33. Exhibit Q is a true copy of the American Blood Resources Association Journal.

34. COMPANY'S activities as described in the Stipulation require medical skill and sophisticated machinery in order to properly separate and prepare the blood components and prevent clotting and spoilage during the process.

35. COMPANY requires that all personnel participate in a corporate training certification program, a program specifically designed to give employees knowledge and skills required for the COMPANY processing of biological products.

36. COMPANY has Standard Operating Procedures that are used at all COMPANY centers throughout the country. (Exhibit R).

37. Both the LOCATION 1 and LOCATION 2 COMPANY centers have a physician on site or on call at all times when plasmapheresis is being conducted.

38. The purposes for which Source Plasma is used differs greatly from any uses of whole blood.

39. Plasma separation does not occur naturally, and cannot be done without the equipment and operations described above.

40. No whole blood collected from a donor is retained by COMPANY as whole blood. All whole blood provided by donors is prepared into Source Plasma as outlined in this Stipulation. No collected blood is utilized as a whole blood product.

41. The use of "manufacture", "process" or "prepare" in this Stipulation is not meant to imply or concede that the supplies, machinery or equipment at the COMPANY centers located in LOCATION 2 and LOCATION 1 or the centers themselves qualify for the exemption found at Section 1359 or 1404 of Title 68, Oklahoma Statutes.

42. All Exhibits referred to herein and attached hereto are incorporated in this Stipulation and made a part hereof, subject to the right of either party to object to the admissions of such attachments in evidence on the grounds of materiality and relevancy; provided, however, that either party may introduce other and further evidence.

ISSUES

The pivotal issue presented in this protest is whether Protestant is engaged in the process of manufacturing, compounding, processing, assembling, or preparing for sale a finished article. If so, the second issue is whether Protestant is primarily engaged in manufacturing or processing operations and generally recognized as such.

Additional issues presented for decision include—whether property purchased by Protestant is used or consumed in the process of manufacturing, compounding, processing, assembling, or preparing for sale a finished article; and, whether the property purchased by Protestant is consumed in the process of manufacturing, compounding, processing, assembling, or preparing products for resale. These last two issues require a determination of the point in Protestant's operations where the manufacturing process commences and ends.

A discussion of these issues is limited to their relevance to Protestant's present business operations. The parties address the preparation of serum and red blood cells in the stipulation of facts. Protestant no longer prepares serum and red blood cells. Since this protest presents for consideration only the correctness of the denial of Protestant's application for a Manufacturer's Limited Exemption Certificate, and does not present for consideration a proposed sales tax assessment or claim for refund of taxes paid, Protestant's past business operations are not relevant and will not be addressed.

CONTENTIONS

Protestant contends that the COMPANY Centers are engaged in the process of manufacturing Source Plasma from raw material by bestowing labor upon the raw material and giving it new forms, qualities, properties, or combinations. The processes employed by COMPANY Centers in manufacturing their products are basically ones of separation via centrifugal force, injection of anticoagulants or stabilizers, testing, and possible further separation. The elements added to the whole or separated blood also change the natural properties of the blood. Source Plasma, according to Protestant, is a different material from the raw material, whole blood, with new uses. Source Plasma is mainly utilized as a raw material by Protestant's customers in further manufacturing procedures.

Protestant also contends that the COMPANY Centers are manufacturing plants because they are engaged primarily in manufacturing and are generally recognized as such. Protestant relies on its classification by the FDA and the Department of Health and Human Services as a manufacturer of biological products, and its qualification in several states as a manufacturer, as authority for this contention.

Finally, Protestant contends that the actual manufacturing process begins at venipuncture and continues until the Source Plasma is placed in the freezer. Protestant contends that all of its equipment and supplies used in the production of Source Plasma are exempt as property consumed in the production process or directly used in and incorporated into the process.

The Division contends that the Section 1359 exemption does not apply to COMPANY'S operations because there must be a "sale" of a manufactured product for the exemption to be applicable. The Division contends that plasmapheresis is a service, and that the exemption does not apply to services.

The Division next contends that plasmapheresis is not "generally recognized" as manufacturing, which is required for the Section 1359 exemption to apply. As in its first contention, the Division argues that Protestant is primarily engaged in providing a service, i.e. taking of donor history, donor health screening, medical record keeping, donor health teaching, and public relations and customer service. The centers look like medical clinics or blood banks, according to the Division, and therefore, fail to be "generally recognized" as manufacturers.

APPLICABLE LAW

This protest is governed by the Oklahoma Sales Tax Code, 68 O.S. § 1352 et seq. The specific statutory provisions, relied upon herein for a determination of this matter are 68 O.S. §§ 1352(I) and (M), 1354, and 1359(1) and (3). The pertinent portion of these statutes read as follows:

> § 1352. Definitions
>
> Definitions. As used in this article:
>
> * * *
>
> (I) "Manufacturing" means and includes every operation commencing with the first production stage of any article of tangible personal property and ending with the completion of tangible personal property having the physical properties which it has when transferred by the manufacturer to another.
>
> * * *
>
> (M) "Sale" means the transfer of either title or possession of tangible personal property for a valuable consideration regardless of the manner, method, instrumentality, or device by which the transfer is accomplished in this state, or other transactions as provided by this subsection,....
>
> § 1354. Tax levy-Rate-Sales subject to tax
>
> Tax levy-Rate-Sales subject to tax.
>
> 1. There is hereby levied upon all sales, not otherwise exempted in the Oklahoma Sales Tax Code, Section 1350 et seq. of this title, an excise tax of four and one-half percent (4.5%) of the gross receipts or gross proceeds of each sale of the following:

(A) Tangible personal property, except newspapers and periodicals;

* * *

§ 1359. Exemptions-Manufacturers

Exemptions - Manufacturers.

There are hereby specifically exempted from the tax levied by this article:

1. Goods, wares, merchandise, and property purchased for the purpose of being used or consumed in the process of manufacturing, compounding, processing, assembling, or preparing for sale a finished article and such goods, wares, merchandise, or property become integral parts of the manufactured, compounded, processed, assembled, or prepared products or are consumed in the process of manufacturing, compounding, processing, assembling, or preparing products for resale. The term manufacturing plants shall mean those establishments primarily engaged in manufacturing or processing operations, and generally recognized as such;

* * *

3. Sale of machinery and equipment purchased and used by persons establishing new manufacturing plants in Oklahoma, and machinery and equipment purchased or equipment built on site and used by persons in the operation of manufacturing plants already established in Oklahoma. This exemption shall not apply unless such machinery and equipment is incorporated into, and is directly used in, the process of manufacturing property for sale or resale. The term manufacturing plants shall mean those establishments primarily engaged in manufacturing or processing operations, and generally recognized as such;

* * *

The rules, which are relevant to disposition of this protest, are *Oklahoma Administrative Code* 710:65-13-150(a) and (b) and 710:65-13-150(d)(1)(G). These rules read as follows:

710:65-13-150. Manufacturing exemption; taxable and exempt transactions

(a) "Manufacture" defined. The Century Dictionary defines "manufacture" as *"the production of articles for use from raw or prepared materials by giving these materials new forms, qualities, properties or combinations, whether by hand labor or machine. Whenever labor is bestowed upon an article which results in its assuming a new form, possessing new qualities or new combinations, the process of manufacturing has taken place."*

(b) Three divisions of manufacturing. For the purpose of this Part, the business of manufacturing, converting, processing, compounding, assembling, preparing, or producing shall be divided into three parts as follows:

(1) Administration - all administrative work such as general office operations, accounting, purchasing, collection, sales promotion, clerical work in production such as preparation of work records, production records and time records, and machinery or equipment or supplies used in the transporting of raw materials to the industrial plant.

(2) Production - all operations performed in the producing or processing room, shop or plant, including the production line starting with the entry into the production stream in the industrial plant and continuing through the last step of production where the product is finished or completed.

(3) Distribution - all operations subsequent to production such as handling, storing, selling, displaying, loading and transporting the manufactured products.

* * *

(d) Property used in production.

(1) When used in this subsection, "consumed directly" means destroyed, used up, or worn out to the degree or extent that such property cannot be repaired, reconditioned, or rendered fit for further manufacturing use. "Consumed directly" does not mean or include mere obsolescence. The following may be purchased exempt from taxation:

* * *

(G) Equipment and supplies used in testing and/or quality control, if all items produced are subjected to testing and/or quality control.

I.

WHETHER PROTESTANT IS ENGAGED IN THE PROCESS OF MANUFACTURING OR PROCESSING

Sales tax is imposed on the sale of tangible personal property unless otherwise exempted. 68 O.S. § 1354. The exemptions from sales tax, which apply to manufacturers and their operations, are found at 68 O.S. § 1359.

The most critical question presented in this protest is whether the business operation engaged in by Protestant is "manufacturing, compounding, processing, or assembling" a product for sale. See 68 O.S. § 1359(1). While "manufacturing" is defined by statute, 68 O.S. § 1352(I), in terms of its point of commencement and completion, a definition is also found in *Oklahoma Administrative Code* 710:65-13-150. "Manufacture" is defined as, "the production of articles for

use from raw or prepared materials by giving these materials new forms, qualities, properties or combinations, whether by hand labor or machine. Whenever labor is bestowed upon an article which results in this assuming a new form, possessing new qualities or new combinations, the process of manufacturing has taken place." *Id.*

The Oklahoma Supreme Court has had numerous occasions to address the application of Section 1359. See *Schulte Oil Co. v. Oklahoma Tax Commission,* 882 P.2d 65 (Okl. 1994); *McDonald's Corporation v. Oklahoma Tax Commission,* 563 P.2d 635 (Okl. 1977); *Curry Materials Company v. Oklahoma Tax Commission,* 319 P.2d 292 (Okl. 1957); *Tulsa Machinery Co. v. Oklahoma Tax Commission,* 208 Okl. 138, 253 P.2d 1067 (1953); *Cain's Coffee Co. v. City of Muskogee,* 171 Okl. 635, 44 P.2d 50 (1935). The most recent of the manufacturing exemption decisions is the most instructive on the application of Section 1359. In *Schulte Oil Co. v. Oklahoma Tax Commission,* supra, the court made clear that the exemption is not to be narrowly construed. *Schulte* involved the remanufacture of used oil field pipe. The Court concluded that the remanufacturing process involved in converting the unusable pipe to usable pipe qualified for the manufacturing exemption. *Id.* at 72. The Court reasoned that, "While it is true that after the remanufacturing process is accomplished the end product is still used oil field pipe, the remanufactured article is nonetheless new and different from the form of the material used in making it." *Id.*

Several appellate decisions were cited by the Court in its reasoning. *Cain's Coffee Co. v. City of Muskogee,* supra, *Tulsa Machinery Co. v. Tax Commission,* supra, and *McKee Products v. State exrel. Tax Commission,* supra, were cited for the salient point that in each of those cases a product was changed into one that became marketable or more usable. In all three cases, the Court determined that manufacturing was involved. In *Cain's,* raw materials—green and unprepared teas, spices, coffee, and other imports—were treated and milled, but the end product was still tea, spices, and coffee. In *Tulsa Machinery* and in *McKee Products,* rocks were the end product after large pieces were crushed into smaller ones. The Court instructed that limiting manufacturing solely to a process which raw material is transformed into some new and different form would create a restriction not mandated by statute or decisional law. *Schulte* at 72.

In a decision where the Oklahoma Supreme Court held that the manufacturing exemption did not apply, the company involved was in the business of extracting sand, gravel, and other assorted materials from earth, and selling them to contractors and others for use in construction. *Curry Materials Co. v. Oklahoma Tax Commission,* 319 P.2d 292 (Okl. 1957). The Supreme Court distinguished this case from *Tulsa Manufacturing,* stating that "there is no crushing and fracturing which takes part . . . Nor is there claimed to be any blending . . . with other, additional materials." *Id.* at 294. The separation of construction materials by screening did not, according to the Court, constitute manufacturing. *Id.* at 295.

The sales tax exemption in Section 1359 includes not only manufacturing, but also operations described as "compounding, processing, assembling, or preparing" for sale a finished article. Many years ago, the Oklahoma Supreme Court defined the term "process", as that word was used in the resale exemption contained in the Consumers and Users Tax Act of 1937, 68 O.S. § 1249-1249w. The Court defined "process" as follows:

> . . . To subject to some special process or treatment . . . Specif, (a) To heat, as fruit with steam under pressure so as to cook or sterilize; (b) To subject (esp. raw material) to a process of manufacture, development, preparation for the market, etc; to convert into marketable form, as livestock by slaughtering, grain by milling, cotton by spinning, milk by pasteurizing, fruits and vegetables by sorting and repacking; . . . ."

Colbert Mill & Feed Co. v. Oklahoma Tax Commission, 188 Okl. 366, 368,109 P.2d 504(1941).

The word "process" was held to be synonymous with the expression "preparation for the market", which was further held to have the same meaning as "preparation for sale". *Id.* While the sales tax exemption statute for "processing" has been revised and recodified over the years, the context in which the word "process" was used in 1937 and the context in which it is used in Section 1359 today is virtually the same. There remains an exemption from sales tax for goods used in processing an article for sale. The definition employed by the Court in *Colbert Mill & Feed Co.* is relevant and applicable in construing the Section 1359 exemption for goods used in processing an article for sale.

Having discussed the relevant case law, the Court's rationale in those cases must be applied to the case at hand. Protestant's business operations are described at length in the stipulation of facts. The most concise explanation of its operations is found in stipulation of fact No. 13, which is a quote from the training manual, and it states: "Plasmapheresis is a procedure by which whole blood is collected and separated into plasma and cellular components. The plasma is removed via centrifugation and filtration and the remaining cellular components are returned to the donor." A more explicit description of the procedure from the time the donor enters the facility to the time the Source Plasma is shipped for further processing is contained in stipulation of fact No. 23. The bottom line is that whole blood, which is composed of plasma and red blood cells, is separated into the component parts for the purpose of marketing the plasma. The question then, is whether, under the instruction of the Oklahoma Supreme Court in its manufacturing decisions, the process by which the whole blood is separated into its component parts is either "manufacturing, compounding, processing, assembling, or preparing" a product for sale.

At first blush, this case seems to fall squarely under the *Curry Materials* rule. The separation of construction materials by screening did not constitute manufacturing in *Curry Materials.* In *Curry Materials* the company was engaged in extracting gravel and sand from the earth by washing and screening to get rid of the unwanted material. Unlike sand, which is found in a natural state, plasma does not exist aside from the whole blood of which it is a part. This is an important distinction. The removal of plasma from whole blood is the separation of cellular components from the liquid surrounding them, but neither exists by itself in its natural state. Thus, the separation of construction materials is not analogous to the removal of plasma from whole blood. The holding in *Curry Materials* does not govern disposition of this protest.

None of the other court decisions are really on point either. To dispose of this question, the Court's most recent decision is the most instructive for analyzing the present case. The

Court set out criteria in *Schulte Oil Co.* which are important in determining whether a taxpayer is engaged in manufacturing. These criteria are: (1) the manufactured product is new and different from the form of the material used in making it; (2) the manufactured product was changed into one that became marketable or more usable; and (3) it is hot necessary that raw material be transformed into some new and different form for manufacturing to have occurred. *Schulte* at 72. When Protestant's operations are viewed within *Schulte Oil Co.'s* criteria, it appears that plasmapheresis qualifies as manufacturing.

In the case at hand, the raw material, whole blood, is collected by Protestant and is transformed into a new form by the addition of anticoagulant and the application of machines used in plasmapheresis. The process involved operates to convert whole blood to plasma, which, for Protestant's purposes, is a more usable or marketable form. As a matter of fact, Protestant's business purpose is to convert whole blood to plasma so that it is-in marketable form. For Protestant's purposes, whole blood is not marketable, only plasma is. Protestant can only achieve its purpose by employing a process whereby the whole blood is converted to its component parts. Under the *Schulte Oil Co.* decision, this qualifies as manufacturing.

Further, applying the definition of the word "process" to Protestant's operations, as that word has been defined in *Colbert Mill & Feed*, the plasmapheresis clearly subjects the blood to some special process or treatment, which results in a marketable form. Therefore, whether it is viewed as manufacturing or it is viewed as processing, plasmapheresis meets that portion of the Section 1359 exemption requiring the taxpayer to be engaged in manufacturing or processing.

II.

WHETHER THERE IS A SALE OF SOURCE PLASMA BY PROTESTANT

The manufacturing exemption from sales tax is available only to those qualified business operations which prepare a product for "sale". Accordingly, the second issue raised by the Division is whether Protestant provides a service, to which the manufacturing exemption would not apply, or whether Protestant prepares a product for sale.

"Sale" is defined for sales tax purposes in 68 O.S. § 1352(M) as, "the transfer of either title or possession of tangible personal property for a valuable consideration . . . ." According to the evidence presented in the stipulation of facts, Protestant pays individuals for their plasma. Upon completion of the processing of the whole blood for conversion into its component parts, the plasma is sold as Source Plasma to Protestant's customers for "further manufacturing". The facts indicate that a sale takes place; therefore, that portion of the exemption requiring that a product be prepared for sale is satisfied.

In title 63 of the Oklahoma Statutes, which is titled "Public Health and Safety", there is contained a statute addressing blood products. This statute provides as follows:

> The procurement, processing, distribution or use of whole blood, plasma, blood products, blood derivatives and other human tissues such as corneas,

> bones or organs for the purpose of injecting, transfusing or transplanting any of them into the human body, for compensation or otherwise, shall be deemed a transaction for the purposes of this act. No such transaction shall give rise to any implied warranty of the fitness, quality, suitability of purpose, safety, acceptability to the body of the patient or of any other characteristic or circumstance incident to the transaction involved bearing upon the propriety of the transaction, as applied to the recipient, on the part of the person or persons rendering such service, in the absence of negligence. Provided, that the provisions of this act shall in no way be deemed to affect the operations of the Oklahoma State Penitentiary.

63 O.S. § 2151. The Division cites to this statute for its proposition that Protestant is providing a service and is not involved in a sale of a product. Reliance on Section 2151 for this proposition is misplaced. Section 2151, which is not a tax statute, does not govern the classification of Protestant's transfer of Source Plasma to its consumers. Section 2151 addresses the injection, transfusion, and transplantation of blood, organs, and other biologics into the human body. The statute precludes any implied warranty associated with the transfusion or transplantation of the blood or organs. This statute has no application to the protest at hand.

III.

WHETHER THE PROTESTANT'S OPERATIONS ARE GENERALLY RECOGNIZED AS MANUFACTURING

Section 1359 requires not only that the goods, wares, merchandise, and property be purchased for the purpose of being used or consumed in the process of manufacturing or processing to qualify for the exemption, but also, that the machinery and equipment purchased must be used in the operation of manufacturing plants in order for those purchases to be exempt from sales tax. Manufacturing plants are defined in Section 1359 as "those establishments primarily engaged in manufacturing or processing operations, and generally recognized as such."

In *McDonald's Corp. v. Oklahoma Tax Commission*, 563 P.2d 635, 638 (Okl. 1977), the Supreme Court held that the "preparation of food for immediate retail sale is not manufacturing or processing, . . . in that such preparation or cooking of food is not generally recognized as manufacturing or processing." The Court reasoned that the primary effort, the success of the business venture, and the essence of operations was the selling or merchandising of products. *Id.* at 639.

Following the guidance of *McDonald's Corp.*, the question that must be answered is, what is the essence of Protestant's business operations? Protestant's primary effort is the manufacture or processing of blood plasma for sale to its consumers, who use it in further manufacturing. It is not engaged in a whole blood collection service, with which most people are

familiar.[1] As urged by Protestant, a determination of whether a manufacturer or processor is "generally recognized as such" should be based on recognition by relevant persons and entities. Familiarity of all of today's technological advancements by the average man on the street is not realistic. Moreover, the average man might believe Protestant's operations are charitable in nature, much like blood banks are operated.

Protestant's operation is classified by the FDA and the Department of Health and Human Services as a manufacturer of biologic products. Plasmapheresis is also referred to as manufacturing in the Code of Federal Regulations. See 21 C.F.R. § 640:71. Additionally, documentation has also been provided in the record of six states which classify Protestant's centers as manufacturers for the purpose of those state's manufacturer's tax exemption. Further, the evidence entered through stipulation indicates that the persons who sell their plasma to Protestant understand that Protestant's operations are not a medical service for the collection of whole blood.

In light of the evidence in the record, the conclusion can be reached that Protestant is "generally recognized" as a manufacturer or processor of blood plasma by those persons and entities related to and familiar with Protestant's operations. Accordingly, the Section 1359 requirement for "manufacturing plants" is met.

IV.

WHETHER THE MANUFACTURING OR PROCESSING OF SOURCE PLASMA BEGINS AT VENIPUNCTURE AND CONTINUES TO THE POINT THAT SOURCE PLASMA IS PLACED IN THE FREEZER

Not all property or equipment purchased by a manufacturer or processor is exempt from sales tax. Section 1359 requires that the property purchased be used or consumed in the manufacturing process, or become integral parts of the manufactured or processed product, or be consumed in the process of preparing products for resale. 68 O.S. § 1359(1). For the machinery or equipment purchased by a manufacturer or processor to be exempt from sales tax, the machinery or equipment must be incorporated into, and directly used in, the manufacturing process. 68 O.S. § 1359(3).

Manufacturing is defined in Section 1352(I) of title 68 to mean and include "every operation commencing with the first production stage of any article of tangible personal property and ending with the completion of tangible personal property having the physical properties which it has when transferred by the manufacturer to another." To implement this definition and the statutory requirements, the Tax Commission has adopted rules dividing the manufacturing process into three parts, administration, production, and distribution. See *Oklahoma Administrative Code* 710:65-13-150(b). There is no sales tax exemption for equipment and

[1] Although the individuals who sell their plasma are referred to as "donors", that name connotes giving of a gift. These individuals are not donors in the strict sense of the word, but to the contrary, are marketers of a commodity. That commodity has value in the marketplace to businesses like Protestant's.

supplies used in the administration and distribution stages of the manufacturing process. However, property consumed directly in the production stage, and machinery and equipment directly used and incorporated into this stage of production, are exempt from sales tax.

In order to determine which of Protestant's purchases of property, equipment, and machinery are exempt from sales tax, the beginning and end of the production stage must be first be identified. Protestant argues that production activities begin the moment the needle is inserted into the supplier's arm and continues until the Source Plasma is placed into the freezer.

The Plasmacell-C Disposable Set is described in stipulations 23.4 through 23.9. This equipment is connected to the Autopheresis machine and contains the needle and the tubing used to transport blood to the machine, the separation and filtration device, and the return reservoir used to collect red blood cells for return to the donor. Although the tubing and reservoir equipment might be viewed as collection equipment and classified as administrative activity, the separation device is the equipment that actually separates plasma from whole blood, thereby making the tubing and reservoir equipment necessary parts of the plasmapheresis process. The Plasmacell-C Disposable Set in its entirety is part of the production equipment and is directly used in and incorporated into the process. Accordingly, the processing of blood plasma begins with the extraction of whole blood from the donor. The needle, which is apart of the Plasmacell-C Disposable set, is directly used in that process and is exempt from sales tax. The production phase is complete when the plasma is collected in the collection bag and hermetically sealed.

Supplies and equipment used in testing and quality control are directly used in the manufacturing process if all items produced are subjected to testing and/or quality control. *Oklahoma Administrative Code* 710:65-13-150(d)(1)(G). In Protestant's operations, every unit of plasma is tested. The post-plasmapheresis Source Plasma testing is analogous to the inspection phase or the quality testing phase of any manufacturing. Therefore, the equipment and supplies used in performing such tests are exempt from taxation.

The distribution stage of the manufacturing process includes the storing of the manufactured product. See *Oklahoma Administrative Code* 710:65-13-150(b)(3). The freezer in which the collected plasma is placed is not included as manufacturing equipment, as it is used after the production stage is completed, and consequently, it is not exempt from taxation.

DISPOSITION

It is the ORDER of the OKLAHOMA TAX COMMISSION, that the application of COMPANY for a Manufacturer's Limited Exemption Certificate be approved.

OKLAHOMA TAX COMMISSION