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Letter Ruling 07-1: Qualification as a Manufacturing Corporation under G.L. c. 63, s. 38(l)

February 16, 2007

You have requested a ruling on behalf of ***** ("the Company"), a Delaware corporation doing business in Massachusetts. In particular, you inquire as to whether the production of working cell banks which are then provided to third party contractors to produce an antibiotic drug for the treatment of bacterial skin and skin structure infections constitutes manufacturing activity for purposes of being deemed a manufacturing corporation as defined in G.L. c. 63, § 38(l).

STATEMENT OF FACTS

The Company is a biopharmaceutical company focusing on the research, development, manufacture and commercialization of products that address unmet medical needs in the acute care environment. The Company's headquarters are in *****, Massachusetts. It has one marketed product, which was approved by the Food and Drug Administration in 2003 for the treatment of complicated bacterial skin and bloodstream infections. The manufacturing process relating to this product involves production of working cell banks, fermentation, purification, fill and finish, and packaging and labeling. The Company produces the working cell banks at its facility in *****, Massachusetts. Third party contract manufacturers located in Italy and the United States perform the subsequent production steps. The Company sells the finished drug product to wholesalers who resell it to hospitals and clinics.

The Company's production of working cell banks entails preparation of a liquid growth medium by mixing various chemicals. The growth medium is placed into a device that sterilizes it using heat and pressure. A frozen vial of the bacteria will then be removed from the Company's master cell bank. The frozen vial is thawed and its contents transferred into the growth medium using a laminar flow cabinet to avoid contamination. The Company next produces a cell culture by placing the bacteria cells and the growth medium into a shaking incubator which mixes and aerates the mixture. Once the cell culture is formed, the Company analyzes the pH, cell mass, microbiological purity and cell morphology of the culture to ensure the quality and conformity of the newly formed bacteria cells.

The Company next prepares the cell culture for a freezing process by adding a glycerol-based preservation agent. The cell culture and preserving agent are mixed together using a magnetic stirrer that ensures homogeneous mixing. The Company dispenses the cell culture/preservation agent mixture into cryo-preservation vials which are sealed to prevent contamination, transferred to specialized foam containers and placed in a freezer. Twenty or more vials of the frozen cell culture/preservation agent mixture are together referred to as the working cell bank. The Company tests the quality and productivity of the working cell bank by fermenting sample cultures. Once the Company has fermented the samples and determined that the culture is suitable for further processing, the working cell banks are transferred to a contract manufacturer for use in the subsequent commercial fermentation steps necessary to prepare the antibiotic drug for market.

The Company projects that approximately 95% of its gross receipts for the 2007 taxable year

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will be from the sale of this antibiotic drug product. All of the antibiotic sold will be produced using the working cell banks created by the Company.

DISCUSSION

General Laws chapter 63, section 38(l)(2)(v) provides that, for taxable years beginning on or after January 1, 2000, a manufacturing corporation shall apportion its taxable net income based upon one hundred percent of its sales factor rather than the percentage that results from the three factor formula set out in section 38(c). Section 38(l)(1) defines a "manufacturing corporation" as "a domestic or foreign corporation that is engaged in manufacturing. In order to be engaged in manufacturing, the corporation must be engaged, in substantial part, in transforming raw or finished physical materials by hand or machinery, and through human skill and knowledge, into a new product possessing a new name, nature and adapted to a new use."

As re-stated and elaborated in the Department of Revenue's Apportionment Regulation, 830 CMR 63.38.1(10)(b):

A corporation...is a section 38 manufacturer for any taxable year if (i) it is engaged in manufacturing during the taxable year and (ii) its manufacturing activity during the taxable year is substantial. A corporation that is so engaged in manufacturing and whose manufacturing activities are substantial is a section 38 manufacture[r] for the taxable year regardless of whether, or to what extent, it conducts its manufacturing activities in Massachusetts.

Engaged in Manufacturing

You cite Mobil Oil Corporation v. Commissioner of Revenue, A.T.B. Docket No. F239392 (March 15, 2000) for the proposition that a process that chemically alters the original substances and transforms them into something different qualifies as manufacturing activity. While the Mobil Oil case dealt with that taxpayer's entitlement to certain exemptions from sales/use tax, the Board did find that the raw ingredients were altered using a multiplicity of processes and had a new use as a marketable and useable product. Thus, the taxpayer's petroleum treatment and recovery operations were found to constitute manufacturing for purposes of the sales/use tax exemptions contained in G.L. c. 64H, § 6(i) and (r).

The Department's Manufacturing Corporations Regulation, 830 CMR 58.2.1(6), provides guidelines for determining whether a corporation may be classified as a manufacturing corporation for purposes of G.L. c. 63, §§ 38C and 42B. These guidelines are also applicable by analogy to corporations seeking manufacturing corporation status for purposes of G.L. c. 63, § 38(l). Among the guidelines as to what constitutes manufacturing are the following:

If the process involves chemical change to property rather than only physical change, it is more likely to be manufacturing. 830 CMR 58.2.1(6)(b)2

* * * *

A process that does not produce a finished product, but constitutes an essential and integral part of a total manufacturing process, may constitute manufacturing. A process that is a practical and necessary step in the production of a finished product for sale is generally an essential and integral part of a total manufacturing process. 830 CMR 58.2.1(6)(b)7

Based upon the foregoing standards, we conclude that that the Company is engaged in manufacturing as contemplated for purposes of G.L. c. 63, § 38(l)(1).

Substantiality

The Department's Apportionment Regulation, 830 CMR 63.38.1(10)(b)2 provides that:

A corporation's manufacturing activity is substantial for any taxable year if the corporation meets any of the following tests:

- a. The corporation derives twenty-five percent or more of its receipts for the taxable year from the sale of manufactured goods that the corporation manufactures;
- b. The corporation pays twenty-five percent or more of its payroll for the taxable year to employees working in manufacturing operations and derives fifteen percent or more of its receipts for the taxable year from the sale of manufactured goods that the corporation manufactures;
- c. The corporation uses twenty-five percent or more of its tangible property in manufacturing during the taxable year and derives fifteen percent or more of its receipts for the taxable year from the sale of manufactured goods that the corporation manufactures;
- d. The corporation uses thirty-five percent or more of its tangible property in manufacturing during the taxable year.

With regard to the substantiality of the Company's manufacturing activities, you have indicated that it is projected that 95% of the Company's gross receipts for the 2007 taxable year will be from the sale of the drug product at issue. Assuming the validity of this percentage and taking into account the discussion in the next two paragraphs, the Company would meet the substantiality requirements set out in G.L. c. 63, § 38(l) and 830 CMR 63.38.1(10)(b)2.

The Apportionment Regulation, at 830 CMR 63.38.1(10)(b)2, further states that a corporation must derive 25% or more of its receipts for the taxable year from the sale of manufactured goods "that the corporation manufactures." Although, as previously indicated, the Company utilizes third-party contract manufacturers to ultimately produce the antibiotic drug, the activities of the Company would constitute a substantial and integral step in the process of manufacturing based upon the standard enunciated in Commissioner of Revenue v. Houghton Mifflin Company, 423 Mass 42 (1996).

In Houghton Mifflin, the taxpayer was engaged in the business of publishing textbooks. It neither printed nor bound the books which it published. Instead, the books were printed and bound by independent contractors. The Court found that Houghton Mifflin's activities, which included researching, writing, editing, the production of page proofs and ultimately a manuscript on diskette, were essential and integral steps in the manufacture of the books. Thus, the Court held that the taxpayer was entitled to classification as a manufacturing corporation under G.L. c. 63, § 38C. In light of the analogous factual circumstances, we reach a similar conclusion in this matter.

CONCLUSION

Based on the facts and the Company's projected sales as you have presented them, the Company would qualify as a manufacturing corporation as defined in G.L. c. 63, § 38(l)(1). Thus, the Company would be entitled to apportion its taxable net income based solely upon its sales factor pursuant to the provisions of G.L. c. 63, § 38(l)(2)(v) for the period at issue.

While you have indicated that the Company also intends to seek foreign manufacturing corporation status pursuant to G.L. c. 63, § 42B, classification as such is a separate question and is not addressed in this letter ruling. Nor should this letter ruling be read as conferring entitlement to the investment tax credit under G.L. c. 63, § 31A, a property tax exemption under G.L. c. 59, § 5(16)(3) or exemption from sales and use tax under G.L. c. 64H, § 6(r) and (s). See Regulation 830 CMR 58.2.1(6) for the requirements for manufacturing corporation classification and determination of the gross receipts fraction relating to manufacturing in Massachusetts. See also Administrative Procedure 303 for information with respect to the application process for such status.

Very truly yours,

/s/Alan LeBovidge

Alan LeBovidge

Commissioner of Revenue

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