

116 T.C. No. 25

UNITED STATES TAX COURT

MEDCHEM (P.R.), INC., Petitioner v.  
COMMISSIONER OF INTERNAL REVENUE, Respondent

MEDCHEM PRODUCTS, INC., Petitioner v.  
COMMISSIONER OF INTERNAL REVENUE, Respondent

Docket Nos. 4065-98, 4066-98.

Filed May 18, 2001.

P-USA is a corporation that is headquartered and has its manufacturing facility in the United States. Its wholly owned subsidiary is P-PR, which lists as its headquarters, officers, and directors the headquarters, officers, and directors of P-USA. A is a corporation unrelated to Ps that manufactures in Puerto Rico a drug named Avitene. On Dec. 18, 1987, A and certain related entities sold to Ps the equipment, technology, and other assets (except A's manufacturing facility in Puerto Rico) connected to Avitene's manufacturing. As part of the sale, A agreed to continue manufacturing Avitene primarily for P-PR using the facility and labor furnished by A and the raw materials and equipment furnished by P-PR. (A also used P-USA's technology.) In return, P-PR generally agreed to pay A a fee equal to its manufacturing costs plus 10 percent. Throughout most of the relevant period, P-PR had no employees and

reported as its primary source of income receipts from the sale of Avitene. P-PR deducted from those receipts amounts that it paid to P-USA and A for labor that they expended on Avitene's manufacturing process. P-PR claimed on its 1992 Federal income tax return that it was entitled to a \$1,993,264 Puerto Rico and possession tax credit under sec. 936(a), I.R.C. Ps argue that P-PR met the "active conduct of a trade or business within a [U.S.] possession" requirement of sec. 936(a)(2)(B), I.R.C., by virtue of: (1) A's activities in Puerto Rico, (2) the fact that A manufactured Avitene using P-PR's raw materials and equipment, (3) the fact that P-PR continued to own the raw materials from the time that it received them until the time that it sold them in their manufactured form as Avitene, and (4) the fact that P-PR paid P-USA and A for the cost of their labor connected to the Avitene manufacturing process.

Held: P-PR did not actively conduct a trade or business in Puerto Rico as required by sec. 936(a)(2)(B), I.R.C.; i.e., P-PR did not participate regularly, continually, extensively, and actively in the management and operation of a profit-motivated activity in that possession.

David A. Hickerson, for petitioners.

Theodore J. Kletnick, Alan S. Kline, George Curran, Jennifer Allan Kassabian, Marie E. Small, and Melanie A. Garger, for respondent.

#### OPINION

LARO, Judge: These consolidated cases were submitted to the Court without trial. See Rule 122. Respondent determined an \$815,196 deficiency in the Federal income tax of MedChem (P.R.), Inc. (MedChem P.R.), for its taxable year ended August 31, 1992. Respondent determined a \$1,705,019 deficiency in the Federal income tax of MedChem Products, Inc., & Subsidiaries (MedChem

Group) for its taxable year ended August 31, 1992. Following concessions, we must decide whether MedChem P.R. meets the "active conduct of a trade or business within a possession" requirement of section 936(a)(2)(B). We hold it does not.<sup>1</sup> Unless otherwise indicated, section references are to the Internal Revenue Code applicable to the relevant years. Rule references are to the Tax Court Rules of Practice and Procedure. We attach hereto as appendix A a summary of some of the critical events that occurred during: (1) The 20½-month period from December 18, 1987, to August 31, 1989, that preceded the 3-year test period relating to our determination under section 936(a)(2)(B), (2) the 3-year test period from September 1, 1989, to August 31, 1992, and (3) the 20-month period from August 31, 1992, to April 1994 that followed the 3-year test period.<sup>2</sup>

#### Background

The parties have filed with the Court a stipulation of facts and certain related exhibits. We incorporate herein by reference

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<sup>1</sup> Given that holding, we need not and do not decide the parties' other dispute; to wit, whether MedChem P.R. manufactures or produces a product in the possession as required by sec. 954(d)(1)(A).

<sup>2</sup> We take into account petitioners' actions in years subsequent to their 1992 taxable year to evaluate their prospects during their 1992 year. See Levin v. Commissioner, 832 F.2d 403, 406 n.3 (7th Cir. 1987) (Tax Court allowed to rely on subsequent events to determine whether those events were consistent with the Court's judgment of the facts available in the year in issue), affg. 87 T.C. 698 (1986).

the stipulated facts and exhibits. We find the stipulated facts accordingly, and we set forth the relevant facts in this background section.

MedChem Products, Inc. (MedChem U.S.A.), is a Massachusetts corporation whose principal place of business is in Woburn, Massachusetts (Woburn). MedChem U.S.A. succeeded MedChem P.R. following the subject years through a merger of the latter into the former. MedChem P.R. was incorporated in Delaware on December 8, 1987, as MedChem Puerto Rico, Inc., it changed its name on December 22, 1987, to BioChem Products, Inc., it changed its State of incorporation on March 1, 1992, to Massachusetts, and it changed its name on November 25, 1992, to MedChem P.R. MedChem P.R. and its predecessors (each hereinafter referred to as MedChem P.R.) were always wholly owned subsidiaries of MedChem U.S.A.

The original books and records of MedChem P.R. and MedChem U.S.A. are maintained in Woburn on an accrual method of accounting and on the basis of a fiscal year ending on August 31. During each of MedChem P.R.'s taxable years ended on August 31, 1990, 1991, and 1992, all of its reported income was "intangible property income", sec. 936(h)(3), attributable to the sale of Avitene, a pharmaceutical manufactured in Puerto Rico by Alcon Puerto Rico Inc. (Alcon P.R.), an unrelated entity. Avitene is a blood clotting drug that is manufactured from the interior

collagen-rich lining (corium) of cowhides. It is used during surgery to control bleeding. It was primarily manufactured by Alcon P.R. during the relevant years in the forms of 35x70 mm. nonwoven web and 1 gram finished flour.

MedChem U.S.A. leases office, research, and manufacturing facilities in Woburn. It leased 32,000 square feet in 1989, and its 63 full-time employees on August 31, 1991, worked in that space. On August 31, 1992, MedChem U.S.A. leased approximately 50,000 square feet at two facilities in Woburn. MedChem U.S.A.'s 144 full-time employees on August 31, 1992, worked at MedChem U.S.A.'s manufacturing facilities in Woburn and San Antonio, Texas.

The individuals who were connected with the Avitene manufacturing and sales business (Avitene business) were employed by MedChem U.S.A., MedChem P.R., Alcon P.R., or Kelly Services, Inc. (Kelly), a supplier of temporary labor. Each MedChem U.S.A. employee connected with Avitene was paid by MedChem U.S.A. and had his or her office at MedChem U.S.A.'s facility in Woburn. MedChem P.R. had no employees after June 30, 1990. MedChem P.R.'s only employee before July 1, 1990, was Jose Perez, and MedChem P.R. terminated him on June 30, 1990. Nor did any of MedChem P.R.'s officers or directors have an office in Puerto Rico after June 30, 1990. All of MedChem P.R.'s officers and directors, except Mr. Perez, were officers and/or directors of

MedChem U.S.A., and, after June 30, 1990, none of MedChem P.R.'s officers or directors was paid by MedChem P.R.

The individuals connected with the Avitene business are listed below by name, affiliate, office location, position, and period of affiliation in the listed capacity.

<u>Name</u>	<u>Affiliate</u>	<u>Office Location</u>	<u>Position</u>	<u>Period of Affiliation</u>
Acosta, Eugenia	MedChem U.S.A.	Woburn	Manager quality systems	<sup>1</sup>
Alifonso, Ramon	Alcon P.R.	P.R.	Director of manufacturing	1985-93
Brophy, Frank	MedChem U.S.A.	Woburn	Vice president-mkt. & sales	2/28/90-9/26/91
			Vice president-marketing	9/26/91-8/31/92
Carrion, Jimmy	Alcon P.R.	P.R.	Avitene production manager	1992-95
Castro, Raymond	Kelly, Alcon P.R.	P.R.	Planner/buyer	1990-91
Donaldson, Jonathan	MedChem U.S.A.	Woburn	Director	9/1/89-8/31/92
			President/chief oper. off.	9/1/89-8/31/92
			Clerk	9/1/89-8/31/92
	MedChem P.R.	Woburn	President	9/1/89-8/31/92
			Secretary	9/1/89-4/12/91
			Director	9/8/89-8/31/92
Falvey, Paul	MedChem U.S.A.	Woburn	Assistant treasurer	12/1/89-8/31/92
Ferdman, Ariel	MedChem U.S.A.	Woburn	Dir. of core technology	1988-94
Geffken, Daniel	MedChem U.S.A.	Woburn	Treasurer	12/1/89-5/29/91
			Chief financial officer	2/28/90-5/29/91
	MedChem P.R.	Woburn	Treasurer	9/1/89-5/29/91
			Assistant secretary	9/1/89-4/12/91
			Secretary	4/12/91-2/17/92
Hansen, Lee	Alcon P.R.	P.R.	General plant manager	1981-94
Micale, Domenic	MedChem U.S.A.	Woburn	Production supervisor	<sup>1</sup>
Moran, Sean	MedChem U.S.A.	Woburn	Treasurer	5/29/91-8/31/92
	MedChem P.R.	Woburn	Secretary/clerk	2/27/92-8/31/92
			Treasurer	2/27/92-8/31/92
McDonough, John	MedChem U.S.A.	Woburn	Financial employee	<sup>1</sup>
Perez, Jose	MedChem P.R.	P.R.	General manager	2/29/88-6/29/90
			Assistant treasurer	9/1/89-6/29/90
Rivera, Luis	Kelly	P.R.	Planner/buyer	1992
Rodriguez, Maria	Alcon P.R.	P.R.	Avitene prod. supervisor	1990-92
Rudolph, Cathy	MedChem U.S.A.	Woburn	Quality assurance worker	<sup>1</sup>
Santiago, Maria	Alcon P.R.	P.R.	Director quality assur.	1980-94
Severance, Scott	MedChem U.S.A.	Woburn	Vice president, operations	<sup>1</sup>
Shepherd, Ronald	MedChem U.S.A.	Woburn	Dir. materials manager	1990-94
Singer, Steven	MedChem U.S.A.	Woburn	Assistant clerk	9/1/89-8/31/92
	MedChem P.R.	Woburn	Assistant secretary/clerk	9/1/89-8/31/92
Stevens, James	MedChem U.S.A.	Woburn	Dir. qlty. control/assur.	<sup>1</sup>
Sullivan, Bernard	MedChem U.S.A.	Woburn	Vice president-operations	9/1/89-9/26/91
			Sr. vice president-operat.	9/26/91-8/31/92
	MedChem P.R.	Woburn	Director	9/1/89-2/28/92
Swann, David	MedChem U.S.A.	Woburn	Director/chairman	9/1/89-8/31/92
			Chief executive officer	9/1/89-8/31/92
	MedChem P.R.	Woburn	Director/chairman	9/1/89-8/31/92
Tanny, Jay	MedChem U.S.A.	Woburn	Cost accountant	<sup>1</sup>
Velez, Nelson	Alcon P.R.	P.R.	Planner/buyer	1991-92

<sup>1</sup>The individual's affiliation occurred sometime between December 1987 and September 1992.

MedChem U.S.A. initially sold only one product, Amvisc. Amvisc, which is unrelated to Avitene, is a hyaluronic-acid-based

product used to lubricate and separate tissues in ophthalmic surgical procedures. MedChem U.S.A. decided in 1987 to diversify its operations by acquiring the Avitene business from Alcon P.R., which at the time was Avitene's manufacturer and seller. MedChem U.S.A.'s decision was based in part on the fact that it was being sued for patent infringement as to Amvisc. The plaintiffs in that lawsuit had commenced the lawsuit in 1984 and were seeking an injunction and treble damages.

On December 18, 1987, petitioners entered into a series of agreements with Alcon P.R., Alcon Pharmaceuticals, Ltd. (Alcon Pharmaceuticals), and Alcon Laboratories, Inc. (Alcon Labs) (these three Alcon entities are collectively referred to as the Alcon Entities), to purchase the Avitene business for approximately \$31 million. The agreements included three asset purchase agreements, three noncompetition agreements, a guaranty, and a processing agreement. All of the Alcon Entities were related, and none of the Alcon Entities was related to either petitioner.

The assets sold under the asset purchase agreements generally included all Avitene inventories, all tangible assets used to manufacture Avitene, and all Avitene-related intangible assets such as receivables, contract rights, and intellectual property. Under the first agreement, Alcon Labs sold to MedChem U.S.A. receivables valued at \$1,085,000, a non-competition

agreement valued at \$200,000, goodwill valued at \$4,490,000, contract rights valued at \$5,000, and records valued at \$5,000; Alcon Labs sold to MedChem P.R. receivables valued at \$1.3 million and inventory valued at \$2.5 million. Under the second agreement, Alcon P.R. sold to MedChem U.S.A. patents and related know-how valued at \$2.6 million, trademarks valued at \$1.9 million, various Food and Drug Administration (FDA) approvals (including the pre-market approval for Avitene) valued at \$300,000, a non-competition agreement valued at \$200,000, goodwill valued at \$4,910,000, and contract rights valued at \$5,000. Under the third agreement, Alcon P.R. sold to MedChem P.R. inventory valued at \$10.1 million and machinery and equipment valued at \$800,000; the machinery and equipment had been used by Alcon P.R. to manufacture Avitene and was located in Alcon P.R.'s Avitene manufacturing facility in Humacao, Puerto Rico (Humacao). That facility consisted of the Avicon (Avitene) plant, two unrelated plants, warehouse space, and administrative offices.

Each of the asset purchase agreements required that the Alcon Entities manufacture and sell to petitioners 20,000 pounds of corium and provided that the Alcon Entities had to refund to petitioners the entire amount paid for the Avitene business, plus interest, if the corium could not be manufactured by December 31, 1990. At all times during the 3-year period ended August 31,

1992, Avitene was manufactured using the patents, know-how, product specifications (as reflected in the FDA pre-market approvals), and goodwill owned by MedChem U.S.A. MedChem P.R. held the legal title to all of the Avitene manufacturing equipment, the raw materials used to manufacture Avitene, the Avitene work-in-process, and the finished Avitene inventory until sold. When the finished Avitene was shipped from the Alcon P.R. facility, title passed to the purchaser, which in all cases but one was MedChem U.S.A.<sup>3</sup> MedChem P.R. would invoice MedChem U.S.A. (or the other purchaser) for the Avitene sold to it at a price equal to MedChem P.R.'s manufacturing cost plus 10 percent. From September 1, 1989, through August 31, 1992, MedChem U.S.A. distributed, marketed, and sold Avitene from its offices in Woburn. MedChem P.R. played no part in these sales or in the other sales of Avitene to end users. The labels which MedChem P.R. used during its fiscal year ended August 31, 1992,

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<sup>3</sup> The sole exception concerned the sale of Avitene for distribution in Japan through June 6, 1991. In that case, MedChem P.R. sold Avitene to Alcon Pharmaceuticals, which owned the distribution rights to the Japanese market until June 6, 1991; title to that Avitene passed to Alcon Pharmaceuticals when the finished Avitene was shipped from the Alcon P.R. facility. Alcon Pharmaceuticals sold the distribution rights to the Japanese market to MedChem U.S.A. on June 6, 1991, for \$15 million, and MedChem U.S.A. transferred those rights to MedChem P.R. on August 31, 1992. MedChem P.R.'s sales of Avitene for the Japanese market accounted for approximately 20 percent of its total net sales of Avitene.

designated Alcon P.R. as Avitene's manufacturer. The labels read:

Manufactured by: Alcon P.R.  
Humacao, Puerto Rico 00661

For: MedChem P.R.  
Humacao, Puerto Rico 00661

Distributed by: MedChem U.S.A.  
Woburn, Massachusetts 01801

Neither petitioner acquired under the asset purchase agreements Alcon P.R.'s Avitene-manufacturing facility in Humacao or the right to market, distribute, or sell Avitene in Japan.<sup>4</sup> That right to the Japanese market was initially retained by Alcon Pharmaceuticals, which, during the period of retention, purchased Avitene for the Japanese market from MedChem P.R. Alcon P.R. manufactured the Avitene sold to Alcon Pharmaceuticals and treated it the same as all other Avitene for purposes of scheduling, planning and buying, manufacturing, and quality control.

The respective parties to the non-competition agreements were: (1) MedChem U.S.A. and Alcon Labs, (2) MedChem U.S.A. and Alcon Pharmaceuticals, and (3) MedChem U.S.A. and Alcon P.R. Under these agreements, the Alcon Entities generally promised not to manufacture, market, or sell any product having the same or

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<sup>4</sup> Neither petitioner has ever had an Avitene manufacturing facility in Puerto Rico.

substantially the same form, function, or application as Avitene during the 5-year period commencing on December 19, 1987.

MedChem U.S.A. gave the guaranty to each of the Alcon Entities. Under the guaranty, which was in effect throughout the fiscal year ended August 31, 1992, MedChem U.S.A. guaranteed to pay any debt and perform any obligation of MedChem P.R. arising from the asset purchase and related agreements.

The processing agreement dealt primarily with a promise by Alcon P.R. to manufacture Avitene for MedChem P.R. using Alcon P.R.'s facility and labor and MedChem P.R.'s raw materials and equipment. (Alcon P.R. also used MedChem U.S.A.'s technology but not pursuant to the processing agreement.) See appendix B for the relevant provisions of the processing agreement. The processing agreement expired initially on December 31, 1990, but was extended on four separate occasions to June 30, 1991, December 31, 1992, December 31, 1994, and the earlier of March 1, 1995, or the date on which Alcon P.R. completed a set delivery schedule, respectively. From September 1, 1989, through August 31, 1992, Alcon P.R. manufactured Avitene for MedChem P.R. pursuant to the processing agreement, and Alcon P.R. sent its invoices for its manufacturing services directly to MedChem U.S.A. for payment from the account of MedChem P.R. Alcon P.R. manufactured Avitene at its manufacturing facility in Humacao, using its own personnel to manufacture, test, and package Avitene

and to supervise each of these functions. Alcon P.R. was solely responsible for resolving any problem that arose during the period from the time that it received the corium up until the time that the finished Avitene was delivered to a carrier for delivery to MedChem U.S.A. (manufacturing process).

Alcon P.R. generally manufactured Avitene in accordance with a two-phase process and kept its inventory of finished Avitene in its warehouse attached to its manufacturing facility. Avitene's two-phase manufacturing process was as follows:

Phase I

(1) Frozen corium and component materials were ordered from the warehouse attached to the Avitene manufacturing facility and transferred to a preparation room in the facility, where the corium was thawed and machine washed.

(2) The corium was machine cut into approximately 4 square inch pieces, manually inspected for imperfections, and machine cut into smaller pieces of approximately one square inch in size.

(3) The smaller pieces were acidified, washed with alcohol, and tested against product specifications.

(4) The resulting product was refrigerated while the initial steps were repeated for a second lot of corium; the two lots were mixed together and dried in a rotary dryer.

(5) The dried corium was machine milled into a loose, powdery, fibrous substance known as bulk flour. The bulk flour was placed in quarantined cages awaiting further processing into its final form as either finished flour or nonwoven web.

Phase II

(6) As to the manufacturing of nonwoven web, bulk flour was transferred from the quarantined cage to the web forming room, where it was machine processed into rolls of nonwoven web.

(7) The rolls of nonwoven web were transferred to the web cutting room where they were machine cut into the required size, visually inspected against product specifications, and placed in trays for drying and sterilization. Once sterilized, the nonwoven web was transferred to the pouch load and seal room where it was packaged in a sealed pouch. The packaged nonwoven web was sterilized, tested, and transferred to the loading and shipping area.

(8) As to the manufacturing of finished flour, jars were machine washed, loaded into trays and carts, and dried in a walk-in oven.

(9) The jars were moved to the filling process room where they were filled with bulk flour and placed back into an oven for further drying.

(10) The dried jars (with bulk flour inside) were transferred by carts to the capping room where they were capped.

(11) The capped jars (with bulk flour inside) were transferred by conveyor to the canning and sealing room where they were canned, banded, and sealed with tamper-proof material.

(12) The resulting jars (with bulk flour inside) were moved to the sterilization room where they were oven sterilized and transferred to the loading and shipping area.

Petitioners entered into the processing agreement to ensure a reliable supply of Avitene while they proceeded to establish MedChem P.R.'s own Avitene manufacturing facility in Puerto Rico. When the December 18, 1987, agreements were entered into, petitioners intended to have that facility ready to take over the

manufacturing of Avitene at the end of the processing agreement's original 3-year term.

In February 1988, Jonathan Donaldson traveled to Humacao and interviewed Mr. Perez for a position with MedChem P.R.<sup>5</sup> At the time, Mr. Perez was involved in and familiar with all aspects of the Avitene manufacturing process; he was a longtime Alcon P.R. employee with various supervisory responsibilities as to Avitene's manufacturing. Shortly thereafter, while in Woburn, Mr. Donaldson decided to hire Mr. Perez and communicated that decision to Mr. Perez in Puerto Rico. Mr. Perez accepted Mr. Donaldson's offer and worked for MedChem P.R. until June 30, 1990, reporting directly to Bernard Sullivan or to Mr. Sullivan's superior, Mr. Donaldson. Mr. Perez worked from May 1988 through June 30, 1990, primarily out of a one-room office (the only office) that MedChem P.R. maintained in Humacao during that period. The office was equipped with three desks, a computer, a facsimile machine, a photocopier, and file cabinets. The office contained product specifications, standard operating procedures, invoices, and copies of some of the financial statements and records which would be needed in the event of an audit.

MedChem P.R. paid Mr. Perez an annual salary, plus benefits, to manage and coordinate its efforts in Puerto Rico as to the

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<sup>5</sup> This was one of the infrequent occasions on which Mr. Donaldson or any of either petitioner's other officers or directors traveled to Puerto Rico on Avitene business.

manufacturing of Avitene. From March 1988 through approximately June 1988, Mr. Perez spent approximately 75 percent of his time visiting Alcon P.R.'s Avitene manufacturing operation, making sure that the operation was running smoothly and aiding the anticipated transfer of that operation to MedChem P.R. He spent the remainder of his time during that period on MedChem P.R.'s effort to establish its own Avitene manufacturing facility in Puerto Rico. During the remainder of his employment by MedChem P.R., Mr. Perez spent approximately 70 percent of his time working on MedChem P.R.'s proposed facility and the rest of his time on Alcon P.R.'s Avitene manufacturing operation and the daily operation of MedChem P.R.'s Humacao office.

Mr. Perez was the only employee that MedChem P.R. ever had during the relevant years. MedChem P.R. did hire three independent contractors (Carlos Moya, Maria Pastrana, and Wanda Rodriguez) to assist Mr. Perez in the Humacao office. Ms. Pastrana and Mr. Moya worked in the office during 1989, and Wanda Rodriguez worked in the office from October 1989 to June 1990. Mr. Moya was a materials coordinator, and Ms. Pastrana and her successor, Ms. Rodriguez, were administrative secretaries. MedChem P.R. directly paid these three individuals and issued to them Forms 1099-MISC, Miscellaneous Income, reporting these payments as nonemployee compensation.

On June 21, 1989, MedChem P.R. paid \$842,500 to the Puerto Rico Industrial Development Co. for approximately 8.5 acres of land in Juncos, Puerto Rico (Juncos), to be used as the site of MedChem P.R.'s proposed manufacturing facility. Conditions of the sale included that MedChem P.R. would submit plans for construction of an industrial building within 6 months, that construction of the building would begin within 6 months of the plans' approval, that the completed building would be devoted to manufacturing operations for a minimum period of 10 years, that the building would include 30,000 square feet of ground floor space and 13,000 square feet of mezzanine space, and that MedChem P.R. would use its reasonable efforts to employ 50 people at the commencement of the facility's manufacturing operations and 120 people within 18 months thereafter. Petitioners anticipated that the proposed facility would cost at least \$9 million to build, and, through January 31, 1990, MedChem P.R. made \$885,216.56 of capital expenditures relating to the facility's proposed construction. Most of these expenditures concerned the services of Unipro, an engineering and architectural firm retained by MedChem P.R. to work on the proposed facility. Unipro prepared architectural drawings and designs for the facility.

In early 1990, MedChem U.S.A. suffered a devastating financial blow from the Amvisc litigation. On February 2, 1990, the District Court hearing the case issued a preliminary

injunction barring MedChem U.S.A. from using, manufacturing, and selling Amvisc in the United States. Amvisc and Avitene were MedChem U.S.A.'s only products. MedChem U.S.A. faced the possible payment of costly patent infringement damages, multiple damages, and an award of attorney's fees. The Amvisc injunction caused MedChem U.S.A. to default on \$10 million in debt and to lay off a third of its workforce. The Amvisc injunction caused petitioners to postpone indefinitely their plans to construct an Avitene manufacturing facility in Puerto Rico.

Petitioners took several steps regarding Avitene in early 1990, following the Amvisc injunction. First, in connection with suspending their plans to construct the manufacturing facility in Puerto Rico, they notified Unipro to stop its work on that facility. Second, in February 1990, MedChem P.R. wrote off for financial accounting and tax purposes all of the capitalized expenditures (\$881,966) relating to the proposed facility. Third, MedChem P.R. closed its Humacao office and terminated the workers there (Mr. Perez and Wanda Rodriguez). In connection therewith, Mr. Perez transferred to Alcon P.R. all of the records as to suppliers and vendors which had been kept in the Humacao office, and he transferred to MedChem U.S.A.'s Woburn facility all of the other records which had been kept in the office, including records relating to the design and construction of MedChem P.R.'s proposed facility in Puerto Rico. Fourth,

petitioners decided to move during the fall of 1990 the Avitene manufacturing process (including the manufacturing equipment) from Alcon P.R.'s Puerto Rico facility to MedChem U.S.A.'s idled Amvisc facility in Woburn.<sup>6</sup> Such a move would and did require MedChem U.S.A. to make additional leasehold improvements in order to conform the Amvisc facility to Avitene's manufacturing requirements. Fifth, MedChem P.R. attempted to sell the land in Juncos that it had purchased for the site of the proposed facility. Sixth, as of July 1, 1990, MedChem U.S.A. employees wrote all of MedChem P.R.'s checks in Woburn and mailed those checks from Woburn to the payees.

Petitioners moved the equipment used to process corium into bulk flour into MedChem U.S.A.'s Woburn facility in June 1990.<sup>7</sup> Within 7 months, they moved into that facility all or part of the frozen corium and the equipment used to process bulk flour into

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<sup>6</sup> MedChem U.S.A. eventually constructed a bulk Avitene manufacturing facility in Woburn in June 1992 and began producing bulk Avitene there 4 months later. In July 1993, MedChem U.S.A. began constructing an Avitene finished goods manufacturing facility in Woburn; at that time, Alcon P.R. performed that part of the Avitene manufacturing process at its facility in Puerto Rico pursuant to the processing agreement. MedChem U.S.A. substantially completed construction of the latter project in April 1994, at which time MedChem U.S.A. controlled Avitene's entire manufacturing process.

<sup>7</sup> At that time, the manufacturing of work-in-process was completed and the machinery and equipment used in that process disassembled and also readied for moving to Woburn.

nonwoven web.<sup>8</sup> These two groups of equipment constituted all of the manufacturing equipment necessary to perform the work in phase 1 of the manufacturing process; as of the later date, all of the manufacturing equipment related to phase 1 was located in MedChem U.S.A.'s facility in Woburn. By January 1, 1991, petitioners had also transferred certain raw material manufacturing functions into MedChem U.S.A.'s Woburn facility as well.

The equipment used to perform the work in phase 2 of the manufacturing process, i.e., processing bulk flour into finished flour and finishing and packaging the nonwoven web, remained in Alcon P.R.'s manufacturing facility in Humacao until early 1995 at which time it was shipped to the Woburn facility. Alcon P.R. continued in Puerto Rico until early 1995 to manufacture finished Avitene from bulk flour and dry, sterilize, and package nonwoven web under the terms of the processing agreement. Alcon P.R. did so using bulk flour and nonwoven web that had been manufactured in Humacao during a buildup in 1989 and 1990; it did not use any bulk flour or nonwoven web manufactured elsewhere. When petitioners moved the bulk and nonwoven web equipment to MedChem U.S.A.'s facility in 1990, Alcon P.R. planned to use the part of

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<sup>8</sup> On separate occasions, MedChem U.S.A. reported to the Securities and Exchange Commission (SEC) that, as of Nov. 30, 1990, and as of Feb. 28, 1991, respectively, MedChem U.S.A. was in the process of redesigning its Amvisc manufacturing facility in Woburn in order to start manufacturing Avitene there.

the plant where the equipment had been located for non-Avitene products.

Alcon P.R. devoted 30 to 35 of its full-time production line employees to the manufacturing of Avitene before June 1990, and it devoted 12 to 15 of its full-time production line employees afterwards. Alcon P.R. included the compensation paid to these employees in the calculation of the processing fee charged to MedChem P.R. under the processing agreement. Of the 30 to 35 production line employees who worked on Avitene before June 1990, approximately 15 to 20 worked in phase 1 of the manufacturing process, and the remainder worked in phase 2. The number of Alcon P.R. employees producing Avitene decreased in June 1990 after MedChem U.S.A. moved to Woburn the equipment used to convert corium into bulk flour.

All of the production line employees were supervised by a manager employed by Alcon P.R.; namely, Maria Rodriguez from January 1990 to January 1, 1992, and Jimmy Carrion afterwards. These managers reported to Ramon Alifonso, Alcon P.R.'s director of manufacturing, who reported to Lee Hansen, Alcon P.R.'s general manager for its manufacturing facility.

Alcon P.R. had a quality assurance department at its manufacturing facility and employed in that department a director and a staff of approximately 85 to 100. The director, Maria Santiago, reported to Alcon Labs' quality assurance director in

Fort Worth, Texas. Alcon P.R. was responsible for the quality of Avitene, and its employees in its quality assurance department performed each of the required tests as set forth in the product specifications owned by MedChem U.S.A. Alcon P.R. kept in its quality assurance department all master documentation for the manufacturing of Avitene and all related records such as inspection documents, charts, and forms. After Alcon P.R. completed its quality assurance tests and document review, it used its regular carrier to ship the packaged Avitene to MedChem U.S.A. in Woburn, where MedChem U.S.A. stored the Avitene in a warehouse or quarantine cage awaiting distribution to its customers (i.e., the end users). MedChem U.S.A. performed secondary quality tests on the finished Avitene product at its quality assurance department in Woburn. MedChem P.R. did not have a quality assurance department, and it never tested Avitene for quality compliance.

MedChem U.S.A. prepared and filed all applications, reports, and other documents required by the FDA to manufacture Avitene. Alcon P.R. provided MedChem U.S.A. with information relating to the manufacturing process, and MedChem U.S.A. incorporated that information into its FDA filings. MedChem P.R. did not submit any applications, reports, or other documents to the FDA. MedChem U.S.A.'s filings with the FDA for the period August 26, 1991, to October 27, 1993, identified Alcon P.R. as Avitene's

manufacturer. MedChem U.S.A. also reported to the SEC for most of 1989 and each of the relevant years thereafter that Alcon P.R. was Avitene's manufacturer and that Alcon P.R. manufactured Avitene at its Puerto Rico facility for MedChem U.S.A.

MedChem P.R. did not have a facility registered with the FDA to manufacture pharmaceuticals. Alcon P.R.'s manufacturing facility was so registered, and the FDA performed a yearlong inspection of that facility beginning in August 1992. During the inspection, the FDA dealt almost exclusively with employees of Alcon P.R.; contacts with non-Alcon P.R. personnel were minimal and insignificant. The FDA's report on the inspection listed Alcon P.R. as Avitene's manufacturer.

MedChem U.S.A. had a department in Woburn where its employees researched and developed Avitene. During the subject years, for example, MedChem U.S.A. researched and developed a new form of Avitene named Endo-Avitene, which it began shipping in November 1992. Ariel Ferdman generally directed MedChem U.S.A.'s research and development activities out of Woburn, and he was assisted in his work by MedChem U.S.A. employees and/or Alcon P.R. employees. On a few occasions from 1990 through 1992, Dr. Ferdman (occasionally accompanied by other MedChem U.S.A. employees) traveled to Alcon P.R.'s manufacturing facility in Puerto Rico to research and develop Avitene. Dr. Ferdman's research and development work at Alcon P.R.'s manufacturing

facility related primarily to preparing validation studies to obtain approval of an application that MedChem U.S.A. had made to the FDA for Endo-Avitene. Dr. Ferdman also worked at the Alcon P.R. facility from April through August 1990 studying and learning Avitene's manufacturing process so that MedChem U.S.A. could later in that year move that process into, and implement that process in, MedChem U.S.A.'s Woburn facility. MedChem P.R. did not have a research and development function, and it played no part in the development of new Avitene or the development of other products.

Kelly provided temporary labor to Alcon P.R. at its facilities from June 1990 through August 31, 1992, pursuant to their written agreement stating in relevant part that the "Kelly assigned employees, are the employees of Kelly, and none of said persons assigned under this contract shall be regarded as employees of [the buyers of the services]". Neither petitioner was involved with that or any other agreement concerning temporary labor to be provided at the Alcon P.R. facility. As relevant herein, Kelly charged Alcon P.R. \$20.40 per hour for the use of a Kelly employee and included in this rate the cost of Kelly's obligation to pay its employees' workers' compensation, unemployment insurance, and Social Security taxes.

Kelly supplied Alcon P.R. with two of the three people who worked at the Alcon P.R. facility from July 1990 through August

31, 1992, as the Avitene planner/buyer.<sup>9</sup> The planner/buyer generally established periodic schedules under which Alcon P.R. manufactured Avitene for MedChem P.R. in accordance with orders placed by MedChem U.S.A. The planner/buyer also: (1) Attended weekly manufacturing meetings held with Alcon P.R. managers at Alcon P.R.'s facility, (2) monitored the inventories of materials used in the manufacturing process, (3) purchased materials and components (exclusive of corium) through Alcon P.R.'s purchasing system, after receiving the authorization of an Alcon P.R. manager (and sometimes also a MedChem U.S.A. manager), (4) dealt with Alcon P.R. or MedChem U.S.A. personnel to cure problems arising mainly from the materials used in the Avitene manufacturing process, and (5) verified with Alcon P.R. personnel that the required quality assurance tests had been performed and confirmed that the product was ready for shipping.

Raymond Castro was a Kelly employee who worked as planner/buyer from on or about June 30, 1990, through March 1991. Kelly hired him and paid him \$12.02 per hour. Neither petitioner was involved in his hiring or in his placement as planner/buyer. He reported to Ronald Shepherd and/or Luis Diaz, an Alcon P.R. manager, and Mr. Castro's work required that he interact with Alcon P.R. employees and MedChem U.S.A. employees. Alcon P.R. invoiced MedChem P.R. for the amount that it paid Kelly as to Mr.

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<sup>9</sup> Before this time, Mr. Perez was the planner/buyer.

Castro, and MedChem P.R. accounted for its payment of these invoices as an expense for outside services for office support. Mr. Castro's status as a Kelly employee ceased in March 1991, when he was hired by Alcon P.R. as a full-time employee. Mr. Castro continued to work on Avitene matters after he was hired by Alcon P.R., and he continued to interact with other Alcon P.R. employees and with MedChem U.S.A. employees.

Nelson Velez succeeded Mr. Castro as planner/buyer from March 1991 through April 1992. Mr. Velez was a longtime Alcon P.R. employee, and neither petitioner was involved in his selection or placement as planner/buyer. Mr. Diaz, who was Mr. Velez's superior, assigned Mr. Velez to serve concurrently as the planner/buyer of both Avitene and an unrelated Alcon P.R. product. Mr. Velez divided his work equally between the two functions, and Alcon P.R. invoiced MedChem P.R. for 50 percent of his salary. MedChem P.R. accounted for its payment of these invoices as an expense for outside services for office support. Mr. Castro's Avitene-related work required that he interact with Alcon P.R. employees and MedChem U.S.A. employees.

Luis Rivera was a Kelly employee who succeeded Mr. Velez as planner/buyer from April 1992 to August 31, 1992. Kelly hired him and paid him \$12 per hour. Neither petitioner was involved in his hiring or with his placement as planner/buyer. Mr. Rivera reported to Mr. Shepherd and/or various Alcon P.R. managers, and

Mr. Rivera's work required that he interact with Alcon P.R. employees and with MedChem U.S.A. employees. Alcon P.R. invoiced MedChem P.R. for the amount that it paid Kelly for Mr. Rivera's services, and MedChem P.R. accounted for its payment of these invoices as an expense for outside services for office support. Mr. Rivera's status as a Kelly employee ceased on November 1, 1993, when he was retained by MedChem P.R. as an independent consultant.

Mr. Sullivan supervised MedChem U.S.A.'s Amvisc operation through 1993. He was listed as a MedChem P.R. director on its corporate records, but he never performed any duties as a MedChem P.R. director. He performed as a MedChem U.S.A. officer the following ancillary activities relating to Avitene: (1) He prepared and maintained schedules listing MedChem U.S.A.'s requirements for Avitene for specified periods during the year, (2) he forwarded those schedules to Mr. Shepherd to deliver (or sometimes he delivered them himself) to Alcon P.R. and to the planner/buyer, (3) he reviewed the results of the quality assurance tests which were prepared by and received from Alcon P.R., and (4) he monitored the sales of Avitene to customers. He did not attend the weekly manufacturing meetings held with Alcon P.R. managers at Alcon P.R.'s facility.

MedChem P.R. maintained a checking account in Puerto Rico through September 25, 1991. MedChem P.R. used that account to

pay the routine operating expenses (e.g., office rent, supplies) of its Humacao office. On September 5, 1991, MedChem P.R. opened a checking account in California (California account), listing as its address MedChem U.S.A.'s address in Woburn. Alcon P.R. sent its invoices under the processing agreement to MedChem U.S.A.'s Woburn address, and MedChem U.S.A.'s personnel reviewed those invoices, authorized their payment, and paid them out of the California account. Vendors also sent their invoices for raw materials and components, among other things, to MedChem U.S.A.'s Woburn address where, after September 4, 1991, MedChem U.S.A. personnel reviewed and paid those invoices out of the California account. Sean Moran and/or John McDonough signed the checks payable to vendors drawn on the California account. Mr. Moran, who reported to Mr. Donaldson, spent approximately 30 percent of his time on Avitene financial matters.<sup>10</sup>

For its fiscal year ended on August 31, 1992, MedChem P.R. elected under section 936(h)(5) to allocate between itself and MedChem U.S.A. the Avitene-related costs, including the salary expense of MedChem U.S.A. employees. MedChem P.R.'s audited financial statements for that year reported petitioners' calculation of 50 percent of the total Avitene product line cost of sales and selling, general, and administrative expenses.

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<sup>10</sup> Daniel Geffken also reported to Mr. Donaldson. Mr. Geffken spent less than 50 percent of his time on Avitene-related matters.

Those statements indicate that cost of goods sold of \$1,730,804 and selling, general, and administrative expenses (including the salary expense of MedChem U.S.A. employees working on Avitene matters) of \$2,789,224 incurred by MedChem U.S.A. were charged to MedChem P.R. On its Federal income tax return for that year, MedChem P.R. reported: (1) Taxable income of \$5,862,541 and (2) direct labor costs of \$323,000. MedChem P.R. claimed a \$1,993,264 tax credit under section 936(a).

Discussion

The parties dispute whether MedChem P.R. may calculate its 1992 Federal income tax liability by using the Puerto Rico and possession tax credit (possession tax credit) provided under section 936(a). A domestic corporate taxpayer such as MedChem P.R. qualifies for this credit if it meets the following statutory requirements:

SEC. 936. PUERTO RICO AND POSSESSION TAX CREDIT.

(a) Allowance of Credit.--

(1) In general.--Except as otherwise provided in this section, if a domestic corporation elects the application of this section and if the conditions of both subparagraph (A) and subparagraph (B) of paragraph (2) are satisfied, there shall be allowed as a credit against the tax imposed by this chapter an amount equal to the portion of the tax which is attributable to the sum of--

(A) the taxable income, from sources without the United States, from-

(i) the active conduct of a trade or business within a possession of the United States, or

(ii) the sale or exchange of substantially all of the assets used by the taxpayer in the active conduct of such trade or business, and

(B) the qualified possession source investment income.

(2) Conditions which must be satisfied.-  
-The conditions referred to in paragraph (1) are:

(A) 3-year period.--If 80 percent or more of the gross income of such domestic corporation for the 3-year period immediately preceding the close of the taxable year (or for such part of such period immediately preceding the close of such taxable year as may be applicable) was derived from sources within a possession of the United States (determined without regard to section 904(f)); and

(B) Trade or business.--If 75 percent or more of the gross income of such domestic corporation for such period or such part thereof was derived from the active conduct of a trade or business within a possession of the United States.

Respondent determined and contends that none of MedChem P.R.'s taxable income for its fiscal year ended August 31, 1992,

qualifies for the possession tax credit.<sup>11</sup> Respondent argues primarily that MedChem P.R. did not meet the active conduct of a trade or business requirement of section 936(a)(2)(B). Petitioners contend that all of MedChem P.R.'s taxable income qualifies for the possession tax credit. Petitioners argue that MedChem P.R. met the active conduct of a trade or business requirement because, petitioners assert, all of MedChem P.R.'s income was derived from its sales in Puerto Rico of Avitene that it manufactured in Puerto Rico. Petitioners assert that, in addition to that sales income, MedChem P.R. had significant business activities in Puerto Rico. Petitioners assert that MedChem P.R.'s business activities in Puerto Rico included purchasing the raw materials necessary for Avitene, monitoring manufacturing and inventory levels of Avitene, and owning all of the manufacturing equipment, raw materials, work-in-process, and finished goods related to Avitene. Petitioners assert that MedChem P.R. performed its business activities in Puerto Rico through its common law employees consisting of its officers, the Kelly employees, and employees who worked concurrently for MedChem P.R. and either MedChem U.S.A. or Alcon P.R. Petitioners assert that MedChem P.R. also performed significant business

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<sup>11</sup> As an alternative to this determination, respondent determined that MedChem P.R.'s income was taxable to the MedChem Group under sec. 482(a). Because respondent does not pursue this argument on brief, we consider it conceded.

activities in Puerto Rico through Alcon P.R., a contract manufacturer. Petitioners argue that activities performed through a contract manufacturer such as Alcon P.R. are imputed to the other party to the contract, in this case, MedChem P.R.

We agree with respondent that MedChem P.R. does not qualify for the possession tax credit because it failed the active conduct of a trade or business requirement of section 936(a)(2)(B). As we read section 936(a), a domestic corporate taxpayer may elect to determine its Federal income tax liability by using the possession tax credit if it meets two requirements. The credit equals the amount of tax attributable to the sum of the taxpayer's qualified possession-source investment income plus the taxpayer's non-U.S.-source income that it earned from: (1) Its active conduct of a trade or business in a U.S. possession or (2) its sale or exchange of substantially all of the assets used in the active conduct of that trade or business. The two requirements are the 80-percent test of section 936(a)(2)(A) and the 75-percent test of section 936(a)(2)(B). We concern ourselves only with the 75-percent test of section 936(a)(2)(B) because the parties agree that MedChem P.R. has met the 80-percent test. Under the 75-percent test, MedChem P.R. qualified for the possession tax credit if at least 75 percent of its gross income for the 3-year period ended August 31, 1992, was derived

from its active conduct of a trade or business within Puerto Rico.

We are unable to find that such was the case. MedChem P.R. did not actively conduct a trade or business within Puerto Rico throughout the 3-year period. Whether MedChem P.R. actively conducted such a trade or business is a highly fact intensive issue as to which petitioners bear the burden of proof. Cf. Higgins v. Commissioner, 312 U.S. 212, 217 (1941); Deputy v. du Pont, 308 U.S. 488, 496 (1940); Welch v. Helvering, 290 U.S. 111, 115 (1933); Plymouth Sav. Bank v. United States, 187 F.3d 203, 210 (1st Cir. 1999). Because Congress has not explicitly defined the phrase "active conduct of a trade or business" for purposes of section 936(a) (or, for that matter, for any other purpose of the Code), Congress has essentially left it to the Secretary to define that phrase by way of regulations or, in the absence of regulations, to the courts to construe the phrase by way of judicial interpretation. As the Supreme Court observed in construing the phrase "trade or business" for purposes of section 162(a):

The phrase "trade or business" has been in § 162(a) and in that section's predecessors for many years. Indeed, the phrase is common in the Code, for it appears in over 50 sections and 800 subsections and in hundreds of places in proposed and final income tax regulations. The slightly longer phrases, "carrying on a trade or business" and "engaging in a trade or business," themselves are used no less than 60 times in the Code. The concept thus has a well-known and almost constant presence on our tax-law terrain. Despite

this, the Code has never contained a definition of the words "trade or business" for general application, and no regulation has been issued expounding its meaning for all purposes. Neither has a broadly applicable authoritative judicial definition emerged. Our task in this case is to ascertain the meaning of the phrase as it appears in the sections of the Code with which we are here concerned. [Commissioner v. Groetzinger, 480 U.S. 23, 26 (1987); fn. refs. omitted.]

Given the lack of a statutory or regulatory definition of the phrase "active conduct of a trade or business" as used in section 936(a), we believe it appropriate to construe that phrase by reference to the Secretary's definitions of the phrase for other purposes of the Code, bearing in mind Congress' intent in enacting section 936 as reflected in its legislative history.<sup>12</sup> Cf. Martin Ice Cream Co. v. Commissioner, 110 T.C. 189, 216 (1998) (Court interpreted the subject phrase for purposes of section 355 by reference to the definition set forth in the regulations prescribed under section 355). Our research reveals that the phrase "active conduct of a trade or business" appears 22 times in the current version of the Internal Revenue Code<sup>13</sup> and that the Secretary has issued extensive regulations interpreting that phrase in three of those sections. First, for

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<sup>12</sup> Of course, we also bear in mind the Supreme Court's interpretation of the phrase "trade or business" as espoused in Commissioner v. Groetzinger, 480 U.S. 23, 35 (1987); to wit, an activity in which a taxpayer is involved with continuity, regularity, and a profit-motivated primary purpose.

<sup>13</sup> See secs. 30A, 49, 168, 179, 351, 355, 367, 407, 543, 731, 806, 861, 865, 936, 954, 957, 995, 1202, 1298, 1362, 2057, 4001.

purposes of section 179, the Secretary prescribed in section 1.179-2(c)(6), Income Tax Regs., the following relevant rules as to the meaning of the phrase:

(6) Active conduct by the taxpayer of a trade or business--(i) Trade or business. For purposes of this section and § 1.179-4(a), the term "trade or business" has the same meaning as in section 162 and the regulations thereunder. \* \* \*

(ii) Active conduct. For purposes of this section, the determination of whether a trade or business is actively conducted by the taxpayer is to be made from all the facts and circumstances and is to be applied in light of the purpose of the active conduct requirement of section 179(b)(3)(A). In the context of section 179, the purpose of the active conduct requirement is to prevent a passive investor in a trade or business from deducting section 179 expenses against taxable income derived from that trade or business. Consistent with this purpose, a taxpayer generally is considered to actively conduct a trade or business if the taxpayer meaningfully participates in the management or operations of the trade or business. \* \* \*  
\* A mere passive investor in a trade or business does not actively conduct the trade or business.

Second, for purposes of section 355, the Secretary prescribed in section 1.355-3(b)(2), Income Tax Regs., the following relevant rules as to the phrase's meaning:

(2) Active conduct of a trade or business immediately after distribution--(i) In general. For purposes of section 355(b), a corporation shall be treated as engaged in the "active conduct of a trade or business" immediately after the distribution if the assets and activities of the corporation satisfy the requirements and limitations described in paragraph (b)(2)(ii), (iii), and (iv) of this section.

(ii) Trade or business. A corporation shall be treated as engaged in a trade or business immediately after the distribution if a specific group of activities are being carried on by the corporation

for the purpose of earning income or profit, and the activities included in such group include every operation that forms a part of, or a step in, the process of earning income or profit. Such group of activities ordinarily must include the collection of income and the payment of expenses.

(iii) Active conduct. For purposes of section 355(b), the determination whether a trade or business is actively conducted will be made from all of the facts and circumstances. Generally, the corporation is required itself to perform active and substantial management and operational functions. Generally, activities performed by the corporation itself do not include activities performed by persons outside the corporation, including independent contractors. A corporation may satisfy the requirements of this subdivision (iii) through the activities that it performs itself, even though some of its activities are performed by others. \* \* \*

(iv) Limitations. The active conduct of a trade or business does not include-

(A) The holding for investment purposes of stock, securities, land, or other property, or

(B) The ownership and operation (including leasing) of real or personal property used in a trade or business, unless the owner performs significant services with respect to the operation and management of the property.

Third, for purposes of section 367, the Secretary prescribed in section 1.367(a)-2T(b), Temporary Income Tax Regs., 51 Fed. Reg. 17942 (May 16, 1986), the following relevant rules as to the phrase's meaning:

(b) Active conduct of a trade or business outside the United States--(1) In general. Property qualifies for the exception provided by this section if it is transferred to a foreign corporation for use in the active conduct of a trade or business outside of the United States. Therefore, to determine whether

property is subject to the exception provided by this section, four factual determinations must be made:

(i) What is the trade or business of the transferee;

(ii) Do the activities of the transferee constitute the active conduct of that trade or business;

(iii) Is the trade or business conducted outside of the United States; and

(iv) Is the transferred property used or held for use in the trade or business?

Rules concerning these four determinations are provided in paragraph (b)(2), (3), (4), and (5) of this section.

(2) Trade or business. Whether the activities of a foreign corporation constitute a trade or business must be determined under all the facts and circumstances. In general, a trade or business is a specific unified group of activities that constitute (or could constitute) an independent economic enterprise carried on for profit. For example, the activities of a foreign selling subsidiary could constitute a trade or business if they could be independently carried on for profit, even though the subsidiary acts exclusively on behalf of, and has operations fully integrated with, its parent corporation. To constitute a trade or business, a group of activities must ordinarily include every operation which forms a part of, or a step in, a process by which an enterprise may earn income or profit. In this regard, one or more of such activities may be carried on by independent contractors under the direct control of the foreign corporation. (However, see paragraph (b)(3) of this section.) The group of activities must ordinarily include the collection of income and the payment of expenses. If the activities of a foreign corporation do not constitute a trade or business, then the exception provided by this section does not apply, regardless of the level of activities carried on by the corporation. \* \* \*

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(3) Active conduct. Whether a trade or business is actively conducted must be determined under all the facts and circumstances. In general, a corporation actively conducts a trade or business only if the officers and employees of the corporation carry out substantial managerial and operational activities. A corporation may be engaged in the active conduct of a trade or business even though incidental activities of the trade or business are carried out on behalf of the corporation by independent contractors. In determining whether the officers and employees of the corporation carry out substantial managerial and operational activities, however, the activities of independent contractors shall be disregarded. On the other hand, the officers and employees of the corporation are considered to include the officers and employees of related entities who are made available to and supervised on a day-to-day basis by, and whose salaries are paid by (or reimbursed to the lending related entity by), the transferee foreign corporation. \* \* \* The rule of this paragraph (b)(3) is illustrated by the following example.

Example. X, a domestic corporation, and Y, a foreign corporation not related to X, transfer property to Z, a newly formed foreign corporation organized for the purpose of combining the research activities of X and Y. Z contracts all of its operational and research activities to Y for an arm's-length fee. Z's activities do not constitute the active conduct of a trade or business.

(4) Outside of the United States. Whether a foreign corporation conducts a trade or business outside of the United States must be determined under all the facts and circumstances. Generally, the primary managerial and operational activities of the trade or business must be conducted outside the United States and immediately after the transfer the transferred assets must be located outside the United States. Thus, the exception provided by this section would not apply to the transfer of the assets of a domestic business to a foreign corporation if the domestic business continued to operate in the United States after the transfer. In such a case, the primary operational activities of the business would continue to be conducted in the United States. Moreover, the transferred assets would be located in the United

States. However, it is not necessary that every item of property transferred be used outside of the United States. As long as the primary managerial and operational activities of the trade or business are conducted outside of the United States and substantially all of the transferred assets are located outside the United States, incidental items of transferred property located in the United States may be considered to have been transferred for use in the active conduct of a trade or business outside of the United States.

(5) Use in the trade or business. Whether property is used or held for use in a trade or business must be determined under all the facts and circumstances. In general, property is used or held for use in a foreign corporation's trade or business if it is--

(i) Held for the principal purpose of promoting the present conduct of the trade or business;

(ii) Acquired and held in the ordinary course of the trade or business; or

(iii) Otherwise held in a direct relationship to the trade or business. \* \* \*

As to Congress' intent for section 936, the roots of that section are found in section 262 of the Revenue Act of 1921, ch. 136, 42 Stat. 271, which exempted a U.S. corporation from Federal taxes on foreign-source income if it derived at least 80 percent of its income from sources within a U.S. possession and satisfied certain other requirements. The requirements for exemption from tax as a possession corporation were generally carried forward into section 931 of the Internal Revenue Code of 1954. Congress promulgated section 931 and its predecessors to encourage American businesses to invest in U.S. possessions. See G.D.

Searle & Co. v. Commissioner, 88 T.C. 252, 350-351 (1987); see also Coca-Cola Co. & Subs. v. Commissioner, 106 T.C. 1, 21 (1996). American companies operating in the possessions were originally subjected to double taxation in the form of the Federal corporate income tax and the taxes of the possessions. See Tariff Act of 1913, ch. 16, sec. II, 38 Stat. 166; Revenue Act of 1918, ch. 18, 40 Stat. 1057. Congress perceived that this double tax burden placed American businesses at a competitive disadvantage when compared with their British and French counterparts which were not subject to taxation upon the profits they earned abroad unless paid back to the home company. Congress enacted section 931 to remove that competitive disadvantage. See H. Rept. 350, 67th Cong., 1st Sess. 1 (1921), 1939-1 C.B. (Part 2) 168, 174. In its original form, section 931 allowed a corporation to exclude its possession-source income if it met an "80-percent source" test and a "50-percent active trade or business" test. Because of the exclusion, and because dividends received by a domestic corporation from its wholly owned possessions subsidiary were not eligible for the intercorporate dividends received deductions under section 246(a)(2)(B), possessions corporations amassed large amounts of income not repatriated to the United States.

In the Tax Reform Act of 1976, Pub. L. 94-455, sec. 1051, 90 Stat. 1643, Congress revised the prior law in order to provide

for a more efficient system exempting possessions corporations so that the possessions would not lose a significant source of capital. See Coca-Cola Co. & Subs. v. Commissioner, supra at 22. In place of the exemption mechanism contained in section 931, Congress enacted section 936 to permit a U.S. corporation to elect a tax credit to offset the U.S. tax on its possessions income. Thus, the current version of the investment incentive takes the form of a tax credit rather than an exemption.

It is clear from the legislative record that Congress was aware of the highly favorable tax benefits afforded U.S. corporations operating in Puerto Rico. It is equally clear that Congress intended to retain and reaffirm such tax benefits by enacting section 936. The Senate Finance Committee and the House Ways and Means Committee stated the following, in virtually identical reports:

The special exemption provided (under sec. 931) in conjunction with investment incentive programs established by possessions of the United States, especially the Commonwealth of Puerto Rico, have been used as an inducement to U.S. corporate investment in active trades and businesses in Puerto Rico and the possessions. Under these investment programs little or no tax is paid to the possessions for a period as long as 10 to 15 years and no tax is paid to the United States as long as no dividends are paid to the parent corporation.

Because no current U.S. tax is imposed on the earnings if they are not repatriated, the amount of income which accumulates over the years from these business activities can be substantial. The amounts which may be allowed to accumulate are often beyond what can be profitably invested within the possession

where the business is conducted. As a result, corporations generally invest this income in other possessions or in foreign countries either directly or through possessions banks or other financial institutions. In this way possessions corporations not only avoid U.S. tax on their earnings from businesses conducted in a possession, but also avoid U.S. tax on the income obtained from reinvesting their business earnings abroad.

The committee after studying the problem concluded that it is inappropriate to disturb the existing relationship between the possessions investment incentives and the U.S. tax laws because of the important role it is believed they play in keeping investment in the possessions competitive with investment in neighboring countries. The U.S. Government imposes upon the possessions various requirements, such as minimum wage requirements and requirements to use U.S. flagships in transporting goods between the United States and various possessions, which substantially increase the labor, transportation and other costs of establishing business operations in Puerto Rico. Thus, without significant local tax incentives that are not nullified by U.S. taxes, the possessions would find it quite difficult to attract investments by U.S. corporations.

However, investing the business earnings of these possession corporations outside of the possession where the business is being conducted does not contribute significantly to the economy of that possession either by creating new jobs or by providing capital to others to build new plants and equipment. Accordingly, while the committee believes it is appropriate to continue to exempt trade or business income derived in a possession and investment income earned in that possession, your committee does not believe it is appropriate to provide a tax exemption for income from investments outside of the possession.

In addition, the committee recognizes that the provision of present law denying a dividends received deduction to the U.S. parent corporation forces a possessions corporation to invest its income abroad until the possessions corporation is liquidated (usually upon the termination of the local tax exemption) when it can be returned to the United States

tax free. These accumulated business profits are not available for investment within the United States, and the income produced is (under present law) not subject to U.S. tax. The committee believes that while it is appropriate to tax the foreign source investment income from possession business earnings, possessions corporations should at the same time be given the alternative of returning the business income to the United States prior to liquidation without paying U.S. tax. Permitting tax-free repatriation of the accumulated earnings only upon the liquidation of the possessions corporation, while taxing the foreign source investment derived from the accumulated earnings, would lessen to a significant extent the tax incentive of making the initial investment.

To accomplish these two major changes, the committee's amendment revises present law to provide for a more efficient system for exemption of possessions corporations. Under the amendment, these corporations are generally to be taxed on worldwide income in a manner similar to that applicable to any other U.S. corporation, but a full 48 percent foreign tax credit is to be given for the business and qualified investment income from possessions regardless of whether or not any tax is in fact paid to the government of the possession. The effect of this revised treatment will be to exempt from tax the income from business activities and qualified investments in the possessions, to allow a dividends received deduction for dividends from a possessions corporation to its U.S. parent corporation, and to tax currently all other foreign source income of possessions corporations (with allowance for the usual foreign tax credit). The committee believes that this revised treatment will assist the U.S. possessions in obtaining employment-producing investments by U.S. corporations, while at the same time encouraging those corporations to bring back to the United States the earnings from these investments to the extent they cannot be reinvested productively in the possession. [S. Rept. 94-938, at 277-278 (1976), 1976-3 C.B. (Vol. 3) 57, 315-316; fn. refs. omitted.]

See also H. Rept. 94-658, at 254-255 (1975), 1976-3 C.B. (Vol. 2) 945, 946-947.

On the basis of our understanding of the legislative record, we believe that Congress promulgated the "active conduct of a trade or business" requirement of section 936(a) intending to prevent a domestic corporate taxpayer from availing itself of the possessions tax credit unless it established and regularly operated an employment-producing, profit-motivated business activity in a U.S. possession. We also believe that Congress expected the taxpayer to participate meaningfully in the management and operation of that activity and to invest significantly in that activity, the expected result of which would be to strengthen the economy of the possession where the activity was located. In light of Congress' intent for section 936, the Secretary's interpretations of the subject phrase for purposes of other sections of the Code, and the Supreme Court's interpretation of the phrase "trade or business" in section 162(a), we believe that, for purposes of section 936(a), a taxpayer actively conducts a trade or business in a U.S. possession only if it participates regularly, continually, extensively, and actively in the management and operation of its profit-motivated activity in that possession. Cf. Commissioner v. Groetzing, 480 U.S. at 26; Higgins v. Commissioner, 312 U.S. at 217; Stanton v. Commissioner, 399 F.2d 326, 329-330 (5th Cir. 1968), affg. T.C. Memo. 1967-137. We also believe that, for the purpose of this participation requirement, the services

underlying a manufacturing contract may be imputed to a taxpayer only to the extent that the performance of those services is adequately supervised by the taxpayer's own employees.

We ask ourselves in this case whether MedChem P.R. participated regularly, continually, extensively, and actively in the management and operation of Avitene's manufacturing in Puerto Rico throughout the requisite 3-year period. Under the facts at hand, we must answer that question in the negative. Indeed, we are not even able to find that MedChem P.R. had any meaningful business activity in Puerto Rico during that period. MedChem P.R.'s investment in the economy of Puerto Rico during that period was almost nonexistent in the sense that it placed in that possession only one employee and established in that possession only a one-room office. Moreover, MedChem P.R. abandoned the office and terminated the employee on June 30, 1990. Although MedChem P.R.'s decision to have Avitene manufactured in Puerto Rico did result in the use of some of that possession's work force, and thus ostensibly harmonize with Congress' intent for the possessions tax credit to produce employment in that possession, we are unable to find that more than a few if any of the individuals who worked in Puerto Rico on Avitene-related matters were hired as a result of the Avitene contract. All the same, we do not believe that the creation of jobs in Puerto Rico

is the sole criterion that a taxpayer must meet in order to be entitled to the possession tax credit.

Petitioners observe correctly that MedChem P.R. was involved with the Puerto Rico-based manufacturing business of Avitene by virtue of the fact that it supplied the raw materials and equipment necessary to manufacture the drug. Such minimal association with a trade or business, however, does not constitute the active conduct of a trade or business in Puerto Rico for purposes of section 936(a). The mere fact that a taxpayer owns property used in a trade or business is simply not enough to characterize the taxpayer as an active conductor of that trade or business. The taxpayer in such a situation does not meet the requirement as to a regular, continual, extensive, and active participant in the management and operation of the profit-motivated activity. Nor, in fact, does such a taxpayer subject itself to many of the economic risks and benefits of business in general.

Here, MedChem P.R. lacked any operational or directional control over the Avitene business. All of the business activities connected to Avitene were directed and controlled by Alcon P.R., out of its Puerto Rico-based operation, and by MedChem U.S.A., out of its Woburn-based facility. In fact, petitioners' involvement in Puerto Rico during the 3-year period failed even to qualify as a trade or business in Puerto Rico,

given that petitioners' involvement in that possession focused mainly on the Woburn-based efforts of MedChem U.S.A.'s personnel to understand the Avitene manufacturing process and, after June 30, 1990, to move that process from Alcon P.R.'s facility in Puerto Rico to MedChem U.S.A.'s facility in Woburn. Whereas petitioners initially planned to establish a manufacturing facility in Puerto Rico during the relevant years and, to that end, hired Mr. Perez, opened an office in Humacao, and purchased land in Juncos, their plans changed in 1990. In 1990, petitioners scuttled their efforts to establish a facility in Puerto Rico, wrote off the proposed facility's capitalized costs, closed the Humacao office, terminated Mr. Perez, and began moving the Avitene manufacturing process into MedChem U.S.A.'s idled Amvisc facility in Woburn. Petitioners also caused Alcon P.R. to move into that facility all of the equipment in Puerto Rico that had been and was required to be used to perform the work in phase 1 of the Avitene manufacturing process.

Petitioners assert that all of MedChem P.R.'s income was attributable to its sale in Puerto Rico of Avitene that was manufactured in that possession and that MedChem P.R. had a significant business presence in Puerto Rico. We disagree.<sup>14</sup>

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<sup>14</sup> We distinguish Frank v. International Canadian Corp., 308 F.2d 520 (9th Cir. 1962), a case cited by petitioners to support their assertion that MedChem P.R. actively conducted a trade or business by virtue of its sales activity. The relevant holding (continued...)

For purposes of section 936(a), MedChem P.R.'s "business presence" in Puerto Rico was insignificant in that it did not contribute significantly to Puerto Rico's economy either by creating new jobs or by providing capital to others to build new plants and equipment. See S. Rept. 94-938, supra at 277-278, 1976-3 C.B. (Vol. 3) at 315-316; see also H. Rept. 94-658, supra, 1976-3 C.B. (Vol. 2) at 946-947. All of MedChem P.R.'s business activities after June 30, 1990, were based in Woburn, and petitioners' primary connection to Puerto Rico during that time was to further its efforts to move the manufacturing of Avitene to Woburn, where the nonmanufacturing, Avitene-related business and ancillary activities (e.g., financial oversight, sales, and product development) were performed by MedChem U.S.A. employees.

Petitioners rely on the fact that title to the non-Japanese-market Avitene passed from MedChem P.R. to MedChem U.S.A. in Puerto Rico. We do not believe that this fact, standing alone, leads to petitioners' proffered conclusion that MedChem P.R. actively conducted a trade or business in Puerto Rico throughout the 3-year period. Indeed, the facts of this case leads us to a contrary conclusion.<sup>15</sup> Avitene was manufactured in Puerto Rico

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<sup>14</sup>(...continued)  
in Frank concerned whether the taxpayer actively conducted a trade or business and did not concern where that trade or business was located.

<sup>15</sup> Petitioners rely in part on their assertion in brief that  
(continued...)

at the Alcon P.R. facility, and Alcon P.R.'s employees performed every task required in the manufacturing process, including the supervision thereof. Alcon P.R.'s employees performed those jobs without the right or ability of either petitioner to manage, direct, or control any part of the manufacturing process. Alcon P.R. employees also performed Avitene's quality assurance function, including the retention of Avitene's master documentation and manufacturing records.<sup>16</sup> MedChem U.S.A.'s employees distributed, marketed, and sold Avitene from Woburn, and they did so without any interaction or involvement by MedChem P.R. MedChem U.S.A.'s employees worked out of Woburn improving Avitene and developing new forms of Avitene. MedChem U.S.A.'s Woburn-based personnel maintained for petitioners the books and records as to Avitene and received, reviewed, and processed payment on any Avitene-related invoice received by petitioners. MedChem U.S.A.'s personnel provided Alcon P.R. and the planner/buyers with manufacturing schedules prepared in Woburn;

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<sup>15</sup>(...continued)  
the parties have stipulated that "100 percent of MedChem P.R.'s income was derived from its sales in Puerto Rico of Avitene that was manufactured in Puerto Rico". Actually, the stipulation reads that "100 percent of MedChem P.R.'s reported income came from the sale of Avitene that was manufactured in Puerto Rico." The stipulation does not say that MedChem P.R. sold the Avitene in Puerto Rico.

<sup>16</sup> Although MedChem U.S.A. occasionally performed limited quality assurance tests on finished Avitene, MedChem P.R. performed no quality testing at all.

the planner/buyers, who were employed at the Alcon P.R. facility by Kelly or Alcon P.R., made sure that Alcon P.R.'s personnel had the materials necessary to manufacture Avitene. MedChem U.S.A. owned all of the intangible assets used to manufacture Avitene and, throughout the 3-year period, guaranteed to the Alcon Entities that it would pay all debts and perform all obligations of MedChem P.R. arising from the asset purchase and related agreements.

Petitioners list in their brief 23 activities which, they assert, demonstrate that MedChem P.R. actively conducted a trade or business in Puerto Rico during the requisite 3-year period. We disagree with this assertion. Some of the activities listed by petitioners preceded the 3-year period, and very few of the other listed activities occurred continually throughout that period. The isolated activities which did occur during the period do not support petitioners' conclusion that MedChem P.R. continued to conduct actively a trade or business in Puerto Rico. The mere fact that MedChem P.R. owned the necessary raw materials and manufacturing equipment and hired Alcon P.R. to use those materials and equipment to manufacture Avitene in Puerto Rico is not enough under the facts herein to conclude that MedChem P.R. actively conducted a trade or business in Puerto Rico throughout

the 3-year period.<sup>17</sup> While it is true that petitioners continued to use the trade or business of Alcon P.R. to manufacture Avitene after June 30, 1990, while MedChem U.S.A. established an Avitene manufacturing facility in Woburn, the use of Alcon P.R.'s business was not MedChem P.R.'s trade or business. In fact, petitioners have consistently reported in all but one instance that Alcon P.R. was Avitene's manufacturer. That one instance is here where, solely for the purpose of Federal income tax, petitioners invite the Court to hold that MedChem P.R. was in fact Avitene's manufacturer. We decline that invitation.

Petitioners argue that MedChem P.R. had employees who performed Avitene-related services in Puerto Rico during the 3-year period. Petitioners assert that MedChem P.R. paid for the Avitene-related services of these individuals and that the individuals represented the interests of MedChem P.R. while working on Avitene matters. Petitioners assert that MedChem P.R. directed and controlled the Avitene-related work of these individuals and that no non-MedChem P.R. employee or entity had the ability to direct or control that work. Petitioners generally identify these individuals as the MedChem P.R. officers

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<sup>17</sup> Contrary to petitioners' request, we do not find that MedChem P.R. employees purchased those raw materials or monitored the production of Avitene or any of the inventory. As discussed herein, employees of either Alcon P.R. or MedChem U.S.A. generally performed all of the services connected to Avitene during the 3-year period.

and/or directors, the Kelly employees, certain MedChem U.S.A. employees, and a certain Alcon P.R. employee; petitioners assert that individuals in the latter two categories worked concurrently as employees of MedChem P.R. and either MedChem U.S.A. or Alcon P.R. Petitioners specifically identify these individuals as:

(1) Mr. Perez and his staff from September 1, 1989, through June 30, 1990, (2) Messrs. Castro and Rivera from July 1990 through March 1991 and from April through August 1992, (3) Messrs. Castro and Velez from April 1991 through April 1992, (4) MedChem P.R. officers and/or directors Donaldson, Geffken, Moran, Sullivan, and Swann, (5) MedChem U.S.A. employees Acosta, Falvey, Ferdman, Micale, McDonough, Rudolph, Severance, Shepherd, Stevens, and Tanny, and (6) various unnamed engineers.

We do not find that any of the listed individuals were MedChem P.R. employees. The presence of an employer-employee relationship is a factual determination that rests on the principles of common law. See, e.g., Nationwide Mut. Ins. Co. v. Darden, 503 U.S. 318, 322-324 (1992); Matthews v. Commissioner, 92 T.C. 351, 360 (1989), affd. 907 F.2d 1173 (D.C. Cir. 1990); Professional & Executive Leasing, Inc. v. Commissioner, 89 T.C. 225, 232 (1987), affd. 862 F.2d 751 (9th Cir. 1988); Simpson v. Commissioner, 64 T.C. 974, 984-985 (1975); see also sec. 3121(d)(2). Factors commonly considered by courts in determining such a relationship are the: (1) Right to control the details of

the work, (2) furnishing of the tools and the work place, (3) withholding of taxes, workers' compensation, and unemployment insurance funds, (4) right to discharge, and (5) permanency of the relationship. See Professional & Executive Leasing, Inc. v. Commissioner, 862 F.2d at 753 (citing United States v. Silk, 331 U.S. 704, 714-716 (1947); Simpson v. Commissioner, supra at 984-985). Although each factor is important, the test that is usually considered fundamental is set out in the regulations. Section 31.3401(c)-1(b), Employment Tax Regs., which generally sets forth rules as to an employer's obligation to withhold Federal income taxes on the payment of wages, provides:

Generally the relationship of employer and employee exists when the person for whom services are performed has the right to control and direct the individual who performs the services, not only as to the result to be accomplished by the work but also as to the details and means by which that result is accomplished. That is, an employee is subject to the will and control of the employer not only as to what shall be done but how it shall be done. In this connection, it is not necessary that the employer actually direct or control the manner in which the services are performed; it is sufficient if he has the right to do so. \* \* \* In general, if an individual is subject to the control or direction of another merely as to the result to be accomplished by the work and not as to the means and methods for accomplishing the result, he is not an employee.

See also secs. 31.3121(d)-1(c)(1) and 31.3306(i)-1(b), Employment Tax Regs., providing language virtually identical to sec. 31.3401(c)-1(b), Employment Tax Regs., in the case of the Federal Insurance Contributions Act and the Federal Unemployment Tax Act, respectively.

Here, we find nothing in the record to persuade us that MedChem P.R. had the right to direct or control any of the purported MedChem P.R. employees in their performance of Avitene-related services. Although petitioners invite us to find that MedChem P.R. directed and controlled the Avitene-related work of these individuals by virtue of the fact that they interacted with one or more individuals who served concurrently as an officer and/or director of MedChem P.R. and MedChem U.S.A., the record indicates to the contrary. All of the individuals who worked on an Avitene matter were directed and controlled by either Alcon P.R. or MedChem U.S.A. In fact, MedChem P.R. was expressly prohibited by the processing agreement from taking a managerial role in the manufacturing process. Moreover, MedChem P.R. never even directed or controlled any of its officers, except possibly Mr. Perez up until July 1, 1990. We also believe it most telling that MedChem P.R. did not hold any of these individuals out or report them as employees until the commencement of this litigation, that each of these individuals was hired and directly paid by MedChem U.S.A. or Alcon P.R., that MedChem P.R. never paid employment taxes as to these individuals, that MedChem P.R. never provided these individuals with workers' compensation insurance or employee benefits, and that all of these individuals worked at the Alcon P.R. and MedChem U.S.A. facilities.

We conclude and hold that MedChem P.R. does not meet the "active conduct of a trade or business within a possession" requirement of section 936(a)(2)(B). In so holding, we note that petitioners rely erroneously on Suzy's Zoo v. Commissioner, 114 T.C. 1 (2000), for a contrary holding. There, the taxpayer was a corporation that sold greeting cards and other paper products bearing copies of one or more of the taxpayer's cartoon characters. The taxpayer's employees developed the characters, and the taxpayer transferred the characters to printing companies to print the paper products in accordance with the taxpayer's specifications. The printers used their own ink and paperstock, and they held title to and bore the risk of loss of the supplies and printed goods until the goods were sent back to the taxpayer for its acceptance or rejection. The printers could not sell any images of the characters, and they could not sell any of the taxpayer's paper products. The taxpayer argued that, for purposes of section 263A, the printers produced the finished goods, and it resold them. We disagreed. We held that the taxpayer was the producer of the finished goods. We noted that the printing of the characters onto the paper products was ministerial and that the critical step in the manufacturing of the finished good was the drawing of the characters. In contrast with the situation there, where the thrust of the work as to the finished product was performed by the taxpayer, the thrust of the

work here as to the manufacturing of Avitene was performed by Alcon P.R. The Avitene manufacturing process was not ministerial but required specialized skill and expertise, unlike the reproduction process in Suzy's Zoo.

We have rejected all arguments not discussed herein as without merit or irrelevant. To reflect the foregoing,

Decisions will be entered  
under Rule 155.

APPENDIX A

Pre-Sec. 936(a)(2)(B) Test Period (1987 to Aug. 31, 1989)

Dec. 18, 1987           Petitioners buy the Avitene business from Alcon P.R., and Alcon P.R. agrees to (and ultimately does) manufacture Avitene for MedChem P.R. for the 3-year period ended Dec. 31, 1990.

Feb. 29, 1988           MedChem P.R. hires Mr. Perez and establishes a one-room office in Humacao.

June 21, 1989           MedChem P.R. purchases land for the construction of an Avitene manufacturing facility in Puerto Rico.

Sec. 936(a)(2)(B) Test Period (Sept. 1, 1989, to Aug. 31, 1992)

Feb. 2, 1990           District Court issues preliminary injunction as to MedChem U.S.A.'s manufacture and sale of Amvisc. MedChem P.R. writes off capitalized expenses relating to its proposed facility in Puerto Rico. Unipro notified to stop work on that facility.

Feb. 28, 1990           MedChem U.S.A. initiates plans to locate an Avitene manufacturing facility into its idled Amvisc facility in Woburn during the fall of 1990.

June 30, 1990           Petitioners move their bulk flour manufacturing equipment from Humacao to Woburn. Mr. Perez terminated, Humacao office closed, and records shipped to Woburn. Kelly hires Mr. Castro to replace Mr. Perez as Avitene planner/buyer.

July 1, 1990           MedChem U.S.A. personnel in Woburn write all MedChem P.R. checks and mail those checks to the payees. MedChem U.S.A.'s personnel in Woburn approve and pay from MedChem P.R. bank account all invoices delivered to MedChem P.R.

December 1990            Petitioners move their bulk nonwoven web manufacturing equipment from Humacao to Woburn.

March 1991              Mr. Castro becomes Alcon P.R. employee with non-Avitene duties, and Alcon P.R. assigns Mr. Velez to perform Mr. Castro's former duties.

April 1992              Kelly hires Mr. Rivera to replace Mr. Velez as Avitene planner/buyer.

August 1992            FDA audits the Avitene manufacturing process and deals almost exclusively with Alcon P.R. personnel.

Post-Sec. 936(a)(2)(B) Period (Aug. 31, 1992, to Apr. 1994)

October 1992            MedChem U.S.A. starts manufacturing Avitene in Woburn.

July 1993              MedChem U.S.A. begins constructing a new Avitene finished goods manufacturing facility in Woburn.

April 1994              MedChem U.S.A. substantially completes the construction of that facility.

APPENDIX B

PROCESSING AGREEMENT

PROCESSING AGREEMENT dated as of December 18, 1987 by and between MEDCHEM PUERTO RICO, INC. ("MedChem [P.R.]", a Delaware corporation, and ALCON (PUERTO RICO) INC. ("Alcon [P.R.]", a Delaware corporation.

In consideration of the mutual covenants and agreements contained in this Agreement, MedChem [P.R.] and Alcon [P.R.] covenant and agree as follows:

1. Definitions. As used in this Agreement, the following terms have the meanings set forth below:

1.1 Acceptance Tests -- chemical, physical and performance tests conducted in accordance with the analytical procedures described in \* \* \* [a referenced schedule], to be applied to Avitene in order to determine whether Avitene conforms to the Product Specifications.

\* \* \* \* \*

1.4 Conversion Process -- the manufacturing process by which raw materials are converted into the finished Avitene product.

\* \* \* \* \*

1.6 Delivery -- the delivery by Alcon [P.R.] of Avitene processed under this Agreement.

1.7 Equipment -- the machinery and equipment owned by MedChem [P.R.] and required for the processing of Avitene.

1.8 Humacao Plant - Alcon[ P.R.]'s Avitene processing facility in Humacao, Puerto Rico.

\* \* \* \* \*

1.10 Order -- a writing from MedChem [P.R.] authorizing or directing Alcon [P.R.] to process and Deliver Avitene.

1.11 Product Specifications -- the specifications for Avitene set forth \* \* \* [in a referenced schedule].

1.12 Proprietary Information -- all patents, trademarks, trade secrets, copyrights, inventions, designs, logos, and any other proprietary rights owned by MedChem [P.R.] which relate to the production and processing of Avitene.

1.13 Processing Fee and Option C Processing Fee -- the fees paid by MedChem [P.R.] to Alcon [P.R.] for each Order filled by Alcon [P.R.] pursuant to Section 9.

\* \* \* \* \*

2. Processing.

2.1 In General. Subject to the provisions of Section 5, and in return for a Processing Fee as defined in Section 9, Alcon [P.R.] agrees to process from raw materials owned and supplied by MedChem [P.R.] all of MedChem[ P.R.]'s requirements of Avitene for sale by MedChem [P.R.] to third parties. The raw materials used in the Conversion Process as well as the finished Avitene Product will remain the sole property of MedChem [P.R.] throughout Alcon[ P.R.]'s physical possession thereof. Alcon [P.R.] agrees to commit its Humacao Plant for the processing of Avitene to satisfy MedChem[ P.R.]'s requirements, subject to the provisions of Section 5. In the event that MedChem[ P.R.]'s requirements of Avitene ever exceed the capacity of the Humacao Plant as of the date hereof, MedChem [P.R.] shall, at its expense, obtain such additional Equipment as is necessary to increase production capacity at the Humacao Plant, or shall use reasonable efforts to obtain access elsewhere to additional production capacity in order to meet the requirements that the Humacao Plant is unable to satisfy.

2.2 Specifications. Alcon [P.R.] agrees to process Avitene in accordance with the Product Specifications and Good Manufacturing Practices as defined by applicable laws and regulations \* \* \*.

2.3 Processing Method. To assist Alcon [P.R.] in satisfying its obligations under this Agreement, MedChem [P.R.] shall grant to Alcon [P.R.] pursuant to the terms of Section 4 the right to use the Equipment, without charge therefor. Alcon [P.R.] shall furnish all labor, variable and fixed overhead and quality assurance required for the processing of Avitene hereunder. MedChem [P.R.] will employ a plant manager and other appropriate personnel who will inspect, advise and make corrections when appropriate with respect to the Conversion Process; however, MedChem [P.R.] employees will not participate in the Alcon [P.R.] management process. Alcon [P.R.] shall be responsible for all maintenance of the Equipment used in the Conversion Process and for the compliance of such Equipment with applicable regulations of governmental agencies, including but not limited to regulations promulgated by the U.S. Food and Drug Administration and the Environmental Protection Agency; the cost of such maintenance and compliance shall be borne initially by Alcon [P.R.] but shall be included in the Processing Cost (as such term is defined in Section 9). Alcon [P.R.] shall also be responsible for required validation studies on devices, formulae or processes used in the Conversion Process. In the event that Alcon [P.R.] is required by a regulatory authority to perform additional validation studies for purposes of validating new devices, new manufacturing procedures and/or new raw material and finished product assay procedures in order to continue lawfully to engage in the processing of Avitene for MedChem [P.R.] (and MedChem [P.R.], after notice from Alcon that such additional validation studies are required, directs Alcon [P.R.] to continue such processing), all expenses borne by Alcon [P.R.] in the conduct of any such validation studies shall be paid by Alcon [P.R.] and shall be included in the Processing Cost. To the extent that MedChem [P.R.] makes direct expenditures (not described in the preceding sentence) with regard to (a) the purchase of machinery or equipment, (b) the compliance of existing machinery or equipment with all applicable laws and regulations or (c) the performance of validation studies or any matter relating to the Conversion Process, such expenditures shall not be included in the Processing Cost.

3. License.

3.1 Grant. MedChem [P.R.] shall grant to Alcon [P.R.] a royalty-free nonexclusive, nontransferable license to use the Proprietary Information solely in connection with the processing of Avitene for MedChem [P.R.] pursuant to this Agreement.

3.2 Ownership. Title to, and ownership of, the Proprietary Information shall at all times remain solely and exclusively with MedChem [P.R.], and Alcon [P.R.] shall not take any action inconsistent with such title and ownership.

3.3 Protection. Alcon [P.R.] hereby covenants to hold such Proprietary Information in confidence. Alcon [P.R.] shall not, without the prior written consent of MedChem [P.R.], disclose or otherwise make available such Proprietary Information in any form to any person, except to Alcon [P.R.]'s employees. \* \* \*

3.4 Equitable Relief; Indemnification. Since an unauthorized use or transfer of the Proprietary Information will substantially diminish the value to MedChem [P.R.] of its rights with respect thereto, if Alcon [P.R.] breaches any of its obligations under this Section 3, MedChem [P.R.] shall (without limiting its other rights or remedies) be entitled to equitable relief (including but not limited to injunctive relief) to protect its interests. Alcon [P.R.] shall indemnify and hold MedChem [P.R.] harmless for any losses or damages which MedChem [P.R.] may suffer as a result of any unauthorized use, transfer or disclosure of the Proprietary Information caused by the acts or omission of Alcon [P.R.].

4. Machinery and Equipment. For the duration of this Agreement, MedChem [P.R.] shall grant to Alcon [P.R.] the right to use, free of charge, all Equipment owned by MedChem [P.R.] and required in the Conversion Process, provided that Alcon [P.R.] shall use such Equipment solely for the purpose of processing Avitene pursuant to this Agreement. Title to and ownership of the Equipment shall remain at all times solely and exclusively with MedChem [P.R.]. Alcon [P.R.]'s rights with respect to the use of the Equipment shall be nontransferable. Alcon [P.R.] shall take reasonable

precautions to preserve the physical condition of the Equipment, and upon the termination of this Agreement pursuant to Section 12, shall return the Equipment to MedChem [P.R.] in good working order and in the same condition (taking into account normal wear and tear) as it was initially provided to Alcon [P.R.]. In the event of any damage to the Equipment covered by insurance maintained by MedChem [P.R.], MedChem [P.R.] shall be obligated to apply any proceeds received in respect of such insurance, and Alcon [P.R.] shall be relieved from liability to the extent of such proceeds.

5. Ordering Procedure.

5.1 Initial Annual Forecast. MedChem [P.R.] shall be responsible for directing the quantity and types of Avitene processed by Alcon [P.R.]. In that regard, MedChem [P.R.] shall, within 60 days of the date of this Agreement, deliver to Alcon [P.R.] an annual forecast (the "Initial Forecast Amount") of MedChem [P.R.]'s projected requirements for each Avitene product for each calendar quarter or fraction thereof during the period commencing on the date of this Agreement and ending on December 31, 1988. \* \* \*

5.2 Subsequent Annual Forecast. No later than August 15, 1988 and 1989, MedChem [P.R.] shall submit to Alcon [P.R.] its preliminary annual forecast of its quarterly requirements of Avitene for the next calendar year (the "Current Annual Forecast Amount"). Such preliminary annual forecast shall be updated on November 30, 1988 and 1989.

5.3 Annual Commitment. MedChem [P.R.] shall order at least 80% of the Initial Forecast Amount or the Current Annual Forecast Amount and Alcon [P.R.] shall be required to process up to 250% of the Initial Forecast Amount or the Current Annual Forecast Amount. In this regard, Alcon [P.R.] shall be given a reasonable amount of time to meet any increases over the Initial Forecast Amount. Alcon [P.R.] agrees, upon reasonable notice, to act in good faith to meet any such increases. In addition, in connection with MedChem [P.R.]'s efforts to establish the MedChem [P.R.] Plant pursuant to Section 13, Alcon [P.R.] agrees, upon reasonable notice to use good faith efforts to process such reasonable amounts in excess of 250% of the Current Annual Forecast Amount during the

ninety (90) day period prior to the effective termination of this Agreement so that MedChem [P.R.] may maintain sufficient inventory to continue normal sales activity while it commences operation at the MedChem [P.R.] Plant. \* \* \*

5.4 Orders and Quarterly Updates. Within a reasonable time after the date of this Agreement, and at least 15 days prior to January 1, April 1, July 1 and October 1 of each year thereafter, MedChem [P.R.] shall furnish to Alcon [P.R.] (i) a binding order for Avitene to be processed and Delivered by Alcon [P.R.] on a date of Delivery specified by MedChem [P.R.], which will allow Alcon [P.R.] at least 30 days from the date of receipt of such Order before such Delivery is required, and (ii) a forecast of MedChem [P.R.]'s projected requirements of Avitene for the three calendar months following the calendar quarter covered by the relevant Order \* \* \*. Alcon [P.R.] shall Deliver the specified quantity and type of Avitene within not more than seven days after the Delivery date specified in the Order. It is understood and agreed that in the event Alcon [P.R.] is unable or unwilling through no fault of MedChem [P.R.] to process Avitene ordered by MedChem [P.R.] in the amount forecast and/or ordered, MedChem [P.R.] is free, without thereby restricting any rights or remedies it may have against Alcon [P.R.] as a result of such nonperformance hereunder, to seek the contract services of third parties to process the incremental quantities which Alcon [P.R.] is unable or unwilling to provide.

5.5. Invoices. Alcon [P.R.] shall submit to MedChem [P.R.] an invoice as soon as practicable after delivery of Avitene to MedChem [P.R.]. Such invoice shall specify the amount and type of Avitene Delivered pursuant to the relevant Order, the date of shipment, and the Processing Cost, and a calculation of the Processing Fee allocable to the Order.

\* \* \* \* \*

6. Packaging and Labeling.

6.1 Design of Package. MedChem [P.R.] shall be responsible for preparing and providing to Alcon [P.R.] labeling copy and/or artwork, as appropriate, for Avitene, and MedChem [P.R.] hereby warrants that

such labeling shall be, in content, in compliance with all applicable governmental regulations. In determining the labeling for Avitene, MedChem [P.R.] shall have the right to use its corporate and/or trade name(s) and its own trademark(s), and to determine the general design and appearance of such labeling.

6.2 Packaging. Utilizing the labeling copy and/or artwork provided by MedChem [P.R.], Alcon [P.R.] shall be responsible initially for producing finished labeling and/or materials, and attaching or accompanying such labeling to or with Avitene. MedChem [P.R.] shall have the option of changing the labeling copy and/or artwork for Avitene packaging at any time, upon 90 days prior written notice to Alcon [P.R.]. MedChem [P.R.] shall further have the option of assuming responsibility at any time for producing the finished labeling and packaging materials and delivering such materials to Alcon [P.R.] for association with Avitene, provided that Alcon [P.R.] has received 90 days prior written notice of such a change.

7. Delivery; Storage.

7.1 Delivery. Alcon [P.R.] shall ship Avitene ordered by MedChem [P.R.] to such destination(s) as MedChem [P.R.] shall designate in its Order. All Deliveries of Avitene under this Agreement shall be F.O.B. common carrier designated by MedChem [P.R.]. Any potential liability for loss or damage that Alcon [P.R.] may maintain by reason of its physical possession throughout the Conversion Process of the raw materials and finished Avitene owned by MedChem [P.R.] shall cease upon Delivery of such Avitene to a common carrier. MedChem [P.R.] shall be responsible for (i) the payment of all transportation charges, taxes, and other charges incident to the storage and movement of Avitene in commerce subsequent to such transfer of the risk of loss to MedChem [P.R.], and (ii) the cost of all insurance relating to the Equipment, raw materials, inventory and the processing and storage of such Avitene, and such costs and charges shall not be included in the calculation of the Processing Costs.

7.2 Storage; Related Documentation. At MedChem [P.R.]'s request and for so long as this

Agreement is in effect, Alcon [P.R.] shall make available to MedChem [P.R.] adequate warehouse space at the Humacao Plant for the storage of Avitene processed pursuant to this Agreement or purchased by MedChem [P.R.] pursuant to the Asset Purchase Agreement. MedChem [P.R.] shall have the right to inspect such warehouse space upon reasonable prior notice and during normal business hours.

8. Acceptance and Rejection of Avitene by MedChem [P.R.].

8.1 In General. Except as set forth below, MedChem [P.R.] shall have the right, within 30 working days following actual receipt by MedChem [P.R.] of any Delivery, to reject any Avitene so Delivered which does not conform in any material respect with the Product Specifications, provided that such nonconformity did not result from contamination or other physical damage cause by MedChem [P.R.] or third parties occurring after Delivery (other than contamination caused by subsequent Delivery by Alcon [P.R.] of contaminated Avitene.) [sic] \* \* \*

8.2 Changes in Conversion Process; Alternative Suppliers. Upon written consent by MedChem [P.R.], Alcon [P.R.] may alter the Conversion Process or obtain Avitene from alternative suppliers for Delivery to MedChem [P.R.]. \* \* \*

8.3 Testing by Alcon [P.R.]. Alcon [P.R.] shall submit to MedChem [P.R.], together with each shipment, batch or lot of Avitene Delivered to MedChem [P.R.] a written notice (i) certifying that such shipment, batch or lot of Avitene meets in every material respect the Product Specifications and (ii) specifying the results of Alcon[ P.R.]'s analysis of such shipment, batch or lot.

8.4 Testing by MedChem [P.R.]. MedChem [P.R.], at its option, may perform the Acceptance Tests on random sample packages of Avitene in order to determine whether such Avitene conforms in every material respect with the Product Specifications.

8.5 Notice; Return; Retesting; Replacement. MedChem [P.R.] shall not be obligated to remit the Processing Fee to Alcon [P.R.] for, and shall notify

Alcon [P.R.] in writing of, the failure of any sample, shipment or lot of Avitene to meet in any material respect the Product Specifications. MedChem [P.R.] shall return to Alcon [P.R.] any such rejected sample, shipment or lot of Avitene, at Alcon [P.R.]'s expense. Alcon [P.R.], at its expense, shall replace any properly rejected sample, shipment or lot of Avitene. Alcon [P.R.] shall also reimburse MedChem [P.R.] for any inventory loss due to warehouse damage, damage resulting from the failure of the Conversion Process (except for damage resulting from changes in the Conversion Process requested by MedChem [P.R.] and instituted by Alcon [P.R.]) or the expiration of the expiration date of any Avitene products stored by MedChem [P.R.] in warehouse space provided by Alcon [P.R.], provided that such expiration of the expiration date is as a result of actions or omissions by Alcon [P.R.] with respect to the management of the inventory. Alcon [P.R.] will not be responsible for inventory losses due to product obsolescence.

8.6 Product Recalls. If any Avitene product is subjected to a recall by a governmental agency, or in the event MedChem [P.R.], after notification to and consultation with Alcon [P.R.], elects to make such a recall based on MedChem [P.R.]'s good faith belief that such Avitene is defective or not in conformity with Alcon [P.R.]'s warranties, Alcon [P.R.] shall pay the actual out-of-pocket costs in connection with such recall, including without limitation the replacement of recalled Avitene. The payment of such costs by Alcon [P.R.] shall not be included in the computation of the Processing Fee pursuant to Section 9 hereof. However, if Alcon [P.R.] was not in breach of its warranties, MedChem [P.R.] shall hold Alcon [P.R.] harmless and shall bear all costs and expenses in connection with such recall.

9. Payment.

9.1 Processing Cost. In return for the processing services performed by Alcon [P.R.] for MedChem [P.R.], MedChem [P.R.] shall pay to Alcon [P.R.] a Processing Fee in connection with each Order for Avitene Delivered pursuant to this Agreement. The Processing Fee shall be equal to Alcon [P.R.]'s Processing Cost (as such term is defined below) plus ten percent (10%). However, the Processing Fee will be

adjusted at year end to account for manufacturing variances, which shall be calculated pursuant to the terms of this Section 9.

The Processing Fee shall be determined in two steps. First, on or before December 31 of each year, Alcon [P.R.] shall determine the estimated Processing Cost for the coming year. Processing Costs shall be composed of Standard Cost less the cost of raw materials owned by MedChem [P.R.] and supplied to Alcon [P.R.] for processing and the depreciation on machinery and equipment owned by MedChem [P.R.] and used in the Conversion Process. Standard Cost shall consist of the sum of estimated direct labor, direct materials, variable overhead, fixed overhead, and quality assurance cost, and is defined in \* \* \* [a referenced schedule]. Standard Cost shall not include costs associated with insurance provided by MedChem [P.R.], freight or shipping costs which shall be separately billed to MedChem [P.R.] by third parties. Standard Cost also shall not include any direct labor costs incurred by MedChem [P.R.] in connection with the provision of services by MedChem [P.R.] employees at the Humacao Plant. Such estimated Processing Cost plus 10% will then be used as the estimated Processing Fee throughout the year for purposes of billing MedChem [P.R.] for the quantity of Avitene produced each month.

Second, at the end of each year the parties shall determine any manufacturing and/or processing variances by comparing the Processing Cost for such year with the actual cost and volumes of Avitene during such year. If the variances indicate that the cost to Alcon [P.R.] to process the Avitene was greater than the Processing Cost, then MedChem [P.R.] shall pay to Alcon [P.R.] an amount of money equal to the total amount of such variance plus 10% within 30 days of MedChem [P.R.]'s receipt of written notice setting forth the amount of such variance. If the variance indicates that the cost to Alcon [P.R.] was less than the Processing Cost, then MedChem [P.R.] shall receive from Alcon [P.R.] an amount of money equal to the total amount of such variance plus 10% within 30 days of the end of the year. \* \* \* MedChem [P.R.] shall have the right to engage an independent auditor, upon reasonable written notice, to examine the relevant books and records of Alcon [P.R.] in order to confirm the accurate calculation of Processing Cost.

9.2 Option C Processing Fee. In addition to the Processing Fee payable pursuant to Section 9.1 above, MedChem [P.R.] shall pay to Alcon [P.R.] an Option C Processing Fee in connection with the processing of Corium to Option C Flour pursuant to this Agreement. The Option C Processing Fee shall be determined in two steps. First, on or before December 31 of each year, Alcon [P.R.] shall determine the Option C Processing Cost of the Option C Flour. The Option C Processing Cost shall be composed of the Option C Standard Cost less the cost of raw materials owned by MedChem [P.R.] and supplied to Alcon [P.R.] for processing and the depreciation on machinery and equipment owned by MedChem [P.R.] and used in the Conversion Process. Option C Standard Cost shall consist of direct labor, direct materials, variable overhead, fixed overhead and quality assurance cost, and is defined in \* \* \* [a referenced schedule]. Option C Standard Cost shall not include costs associated with insurance provided by MedChem [P.R.], freight or other costs which shall be separately billed to MedChem [P.R.] by third parties. Option C Standard Cost also shall not include any direct labor costs incurred by MedChem [P.R.] in connection with the provision of services by MedChem [P.R.] employees at the Humacao Plant. The Option C Processing Cost plus 10% will then be used throughout the year for the purposes of billing MedChem [P.R.] for the quantity of Option C Flour produced each month.

The second step in determining the Option C Processing Fee shall take place at the end of each year. At that time, Alcon [P.R.] shall determine any manufacturing and/or processing variances by comparing the Option C Processing Cost for such year with the actual cost and volumes of Option C Flour during such year. If the variances indicate that the cost to Alcon [P.R.] to process the Option C Flour was greater than the Option C Processing Cost, then MedChem [P.R.] shall pay to Alcon [P.R.] an amount of money equal to the total amount of such variance plus 10% within 30 days of MedChem [P.R.]'s receipt of written notice setting forth the amount of such variance. If the variance indicates that the cost to Alcon [P.R.] was less than the Option C Processing Cost, then MedChem [P.R.] shall receive from Alcon [P.R.] an amount of money equal to the total amount of such variance plus 10% within 30 days of the end of the year. MedChem [P.R.] shall have

the right to engage an independent auditor, upon reasonable written notice, to examine the relevant books and records of Alcon [P.R.] in order to confirm the accurate calculation of the Option C Processing Cost.

10. Payment. MedChem [P.R.] shall pay Processing Fees pursuant to Alcon [P.R.]'s invoice for Avitene Delivered under any Order within 30 days following receipt by MedChem [P.R.] of such invoice. Payment by MedChem [P.R.] of any invoice submitted by Alcon [P.R.] to MedChem [P.R.] shall not be required with respect to any shipment or lot of Avitene which has been properly rejected and returned by MedChem [P.R.] in accordance with Section 8.5. Payment of any disputed amount (but only to the extent of the disputed amount) shall be deferred until resolution of such dispute.

11. Warranty.

11.1 General Warranty; Inspection. Alcon [P.R.] warrants that any Avitene Delivered under this Agreement shall meet the Product Specifications in every material respect, and that at the time of Delivery such Avitene shall be uncontaminated and free from defects in materials and workmanship. MedChem [P.R.] may make changes in the Product Specifications, but such changes must be made known to and agreed to by Alcon [P.R.], which agreement shall not be unreasonably withheld or delayed, and Alcon [P.R.] shall promptly incorporate said change(s) in such products, consistent with Good Manufacturing Practices and regulatory requirements. MedChem [P.R.] shall have the right to inspect the Humacao Plant during mutually agreed upon times when the processing of Avitene is in progress to insure that Alcon [P.R.]'s processing of Avitene is in compliance with the Product Specifications. This right of inspection granted to MedChem [P.R.] shall not be deemed as granting to MedChem [P.R.] access to any trade secrets retained by Alcon [P.R.] subsequent to the closing of the transactions contemplated by the Asset Purchase Agreements.

11.2 MedChem [P.R.] Indemnity. MedChem [P.R.] will indemnify and hold Alcon [P.R.] harmless from any and all claims, damages, costs and/or expenses, including, but not limited to attorneys fees, arising directly from (i) any change required by

MedChem [P.R.] in the Product Specifications or the Conversion Process from the manner in which such procedures were carried out by Alcon [P.R.] as of the date of this Agreement, if such change is the proximate cause of such claim, damages, costs or expenses, (ii) the promotion, distribution, sale and/or internal use by MedChem [P.R.] of Avitene processed by Alcon [P.R.] hereunder unless at the time of Delivery such Avitene did not meet the warranty set forth in Section 11.1 hereof and (iii) any breach by MedChem [P.R.] of its warranties and obligations under this Agreement. Upon the filing of any such claim or suit, Alcon [P.R.] shall immediately notify MedChem [P.R.] thereof and shall permit MedChem [P.R.], at its cost, to handle and control such claim or suit provided, however, that Alcon [P.R.] may, at its own expense, retain such additional attorneys as it may deem necessary, which attorneys will be permitted to reasonably observe and/or participate in all aspects of (but not control) the defense of such claims or suits. MedChem [P.R.] shall have the right, after consultation with Alcon [P.R.], to resolve and settle any such claims or suits. This Indemnity shall not abrogate or in any way modify the obligations of Alcon [P.R.] pursuant to the representations and warranties contained in the Asset Purchase Agreement.

11.3 Alcon [P.R.] Indemnity. Alcon [P.R.] will indemnify and hold MedChem [P.R.] harmless from and against any and all liability, damage, loss, cost, or expense resulting from any third party claims made or suits brought against MedChem [P.R.] which arise from Alcon [P.R.]'s breach of any provision of this Agreement, including, but not limited to, claims of product defect relating to Avitene which is not in conformity with the warranty set forth in Section 11.1 hereof. Upon the filing of any such claim or suit, MedChem [P.R.] shall immediately notify Alcon [P.R.] thereof and shall permit Alcon [P.R.], at its cost, to handle and control such claim or suit; provided, however, that MedChem [P.R.] may, at its own expense, retain such additional attorneys as it may deem necessary, which attorneys will be permitted to reasonably observe and/or participate in all aspects of (but not control) the defense of such claims or suits. Alcon [P.R.] shall have the right, after consultation with MedChem [P.R.], to resolve and settle any such claims or suits.

12. Term and Termination.

12.1 Term of Agreement. The term of this Agreement shall commence on the date hereof and shall end on December 31, 1990 (unless sooner terminated pursuant to this Section 12), and may be renewed on terms and conditions mutually satisfactory to the parties hereto.

12.2 Insolvency. \* \* \*

12.3 Default.

(a) In General. Except as otherwise provided in this Section 12, either party, at its option, may terminate this Agreement upon the occurrence of any breach by the other party, provided however (i) that the nonbreaching party shall have delivered to the breaching party a written notice specifying such breach in reasonable detail, (ii) that the breaching party shall not have cured such breach within 60 days after receipt of the notice and (iii) that the nonbreaching party must exercise its option to terminate this Agreement within 60 days after the expiration of the cure period.

(b) Failure to Deliver by Alcon [P.R.]. Subject to the provisions of Section 12.3(c) of this Agreement, MedChem [P.R.] may terminate this Agreement if Alcon [P.R.] fails to Deliver Avitene ordered by MedChem [P.R.] under this Agreement, provided, however, (i) that MedChem [P.R.] shall have delivered to Alcon [P.R.] a written notice of such failure to Deliver, (ii) that Alcon [P.R.] shall have failed to make Delivery within 60 days after receipt of such written notice and (iii) that MedChem [P.R.] must exercise its option to terminate this Agreement within 60 days after the expiration of the cure period. Alcon [P.R.] acknowledges and agrees that if Alcon [P.R.] fails to Deliver Avitene ordered by MedChem [P.R.] under this Agreement, MedChem [P.R.] may make alternative arrangements, at Alcon [P.R.]'s expense, for the processing of Avitene for the then remaining term of this Agreement. However, Alcon [P.R.] shall not be liable for any incidental or consequential damages sustained by MedChem [P.R.] due to such failure to deliver.

(c) Force Majeure. \* \* \*

12.4 Establishment of MedChem [P.R.] Plant. MedChem [P.R.] may terminate this Agreement pursuant to the provisions of Section 13.

12.5 Remedies Not Exclusive. In the event of a breach of this Agreement, the rights of termination provided in this Section 12 shall not be exclusive of any remedies to which either party may be entitled at law or in equity (as limited by the express terms of this Agreement), provided, however, that such other remedies shall not be subject to the time limitations set forth in Sections 12.3(a) and (b).

\* \* \* \* \*

13. MedChem [P.R.] Plant. The parties acknowledge and agree that, during the term of this Agreement, MedChem [P.R.] will take steps designed to establish alternative facilities (the "MedChem [P.R.] Plant") that will enable MedChem [P.R.] to undertake the Conversion Process. In connection with the establishment of the MedChem [P.R.] Plant, MedChem [P.R.] shall bear the costs of removing the Equipment from the Humacao Plant, including, but not limited to, the costs of repairing any damage to the Humacao Plant caused by such removal. Alcon [P.R.] covenants that it will provide reasonable assistance to MedChem [P.R.] in establishing the MedChem [P.R.] Plant, including training of the Humacao Plant Manager and other appropriate MedChem [P.R.] personnel in all aspects of the Conversion Process. In this regard, appropriate MedChem [P.R.] employees shall have the right, during the term of this Agreement, to observe with regard to the Conversion Process carried out by Alcon [P.R.] at the Humacao Plant. However, such MedChem [P.R.] employees will not participate in Alcon [P.R.]'s management process. In addition, upon the construction of the MedChem [P.R.] Plant, Alcon [P.R.] will assist with the validation of three initial Avitene production batches of each Avitene product produced at the MedChem [P.R.] Plant. When MedChem [P.R.] has successfully established the necessary machinery, equipment and quality control procedures, implemented the Conversion Process at the MedChem [P.R.] Plant and, in the sole opinion of MedChem [P.R.], conducted satisfactory validation tests and received all applicable

governmental approvals relating to the operation of the MedChem [P.R.] Plant, MedChem [P.R.] shall have the right to terminate this Agreement prior to December 31, 1990 upon at least ninety (90) days prior written notice to Alcon [P.R.].

\* \* \* \* \*

17. Applicable Law. The validity, performance and construction of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts.

\* \* \* \* \*

19. Notices. Notices and other communications by a party under this Agreement shall be in writing and hand-delivered, deposited with an overnight carrier for next day delivery, or deposited in the United States mail as certified mail, return receipt requested, postage prepaid, addressed to the parties as follows (or to such other addresses as either party may designate from time to time in writing):

If to Alcon [P.R.]:

Alcon Laboratories, Inc.  
6201 South Freeway  
Forth Worth, TX 76134  
Attention: Henry Meadows  
Vice President and Controller  
Surgical Specialty Division

If to MedChem [P.R.]:

MedChem Puerto Rico, Inc.  
43 Nagog Park  
Acton, MA 01720  
Attention: President

and shall be deemed given when received.

20. No Agency Relationship. Neither party shall be deemed to be the agent of the other party for any purpose. Alcon [P.R.] shall be deemed an independent contractor for the purposes of its performance of services for MedChem [P.R.]. \* \* \*

\* \* \* \* \*

The parties hereto have executed this Agreement as a sealed instrument and this Agreement becomes duly effective, as of the date first written above.

MEDCHEM PUERTO RICO, INC.

By: /s David A. Swann

Title: CEO

ALCON (PUERTO RICO) INC.

By: /s

Title: Vice President