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1. Eli Lilly & Co. v. Commissioner, 84 T.C. 996

   Client/matter: -None-

Eli Lilly & Co. v. Commissioner

United States ***Tax*** Court
May 28, 1985; Affirmed in part; Reversed in part and Remanded August 31, 1988 ; May 28, 1985, Filed
Docket No. 5113-76

Reporter: 84 T.C. 996; 1985 U.S. Tax Ct. LEXIS 73; 84 T.C. No. 65

Eli Lilly and Company and Subsidiaries, Petitioners v. Commissioner of Internal Revenue, Respondent

Disposition: **[**1]** *Decision will be entered under Rule 155.*

Core Terms

manufacturing, propoxyphene, pharmaceutical, patent, intangibles, hydrochloride, chemical, capsules, uncontrolled, napsylate, research and development, package, subsidiary, resale, affiliate, arm's-length, ticket, income ***tax***, exemption, team, wholesale, know-how, clinical, stock, personnel, trademark, bulk, finished, bottle, plant

Case Summary

Procedural Posture

Petitioner parent corporation and its subsidiary challenged respondent Commissioner of Internal Revenue's (IRS) ruling, which, pursuant to *I.R.C. § 482*, reallocated gross income from the subsidiary to the parent corporation. The parent corporation alleged, in part, that the IRS erred in not attributing to the subsidiary the income from intangible property ***transferred*** from the parent corporation to the subsidiary pursuant to *I.R.C. § 351*.

Overview

Petitioner parent corporation created a subsidiary corporation in Puerto Rico, ***transferred*** all rights to valuable pharmaceutical patents and trade secrets to the subsidiary pursuant to *I.R.C. § 351*, and contracted to buy the final products for marketing in the United States. Subsequently, respondent Commissioner of Internal Revenue (IRS) held that the subsidiary's income should have been attributed to the parent corporation, and attempted to reallocate that income pursuant to *I.R.C. § 482*. The court held that the parent corporation, for legitimate commercial and ***tax*** reasons, had successfully ***transferred*** the intangible property rights to the subsidiary, which the IRS erred in not taking into account for *§ 482* purposes. However, the court held that the respective corporations had inaccurately calculated their respective incomes but found the amounts as proposed by the IRS unreasonable. The court made its own determination of the ″arms-length″ ***prices*** charged by the subsidiary to the parent corporation as directed by *Treas. Reg. § 1.482-1*, and reallocated the corporations' respective incomes accordingly. However, a decision on the actual ***taxes*** due could not be made from the record.

Outcome

The court held that respondent Commissioner of Internal Revenue erred in not recognizing petitioner subsidiary corporation's ownership of intangible property rights ***transferred*** to it by petitioner parent corporation. The corporations, in turn, did not properly calculate or allocate their incomes derived from that property. The court made its own findings but because ***taxes*** could not be determined entered a judgment pursuant to U.S. ***Tax*** Ct. R. 155.

LexisNexis® Headnotes

Governments > Agriculture & Food > General Overview
Governments > Agriculture & Food > Federal Food, Drug & Cosmetic Act

HN1 The Federal Food, Drug, and Cosmetic Act, *21 U.S.C.S. §§ 301-392*, requires the submission and Food and Drug Administration (FDA) approval of a New Drug Application (NDA) prior to the introduction into interstate commerce of any new drug, including patented drugs. Subsequent to 1962 and throughout the years 1971 through 1973, the process for obtaining an NDA involved as a prior step the filing of a document known as an Investigatory New Drug Application.

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN2 See *I.R.C. § 482*.

Tax Law > Federal Taxpayer Groups > C Corporations > Reorganization of Corporations

HN3 See *I.R.C. § 351(a)*.

Tax Law > International ***Taxes*** > Americans Operating Abroad > Corporations in US Possessions

HN4 See *I.R.C. § 931(a)*.

Tax Law > Federal Taxpayer Groups > C Corporations > Special Corporate Deductions
Tax Law > International ***Taxes*** > General Overview
Tax Law > International ***Taxes*** > Americans Operating Abroad > Corporations in US Possessions
Tax Law > International ***Taxes*** > Foreign Persons in US > US Real Property Investments
Tax Law > State & Local ***Taxes*** > Income ***Taxes*** > General Overview

HN5 *I.R.C. §936* eliminates the ***tax*** exemption for income from foreign investments outside the possessions and permits the intercorporate dividends received deduction for dividends received from a wholly owned possessions subsidiary. *Section 936* essentially transforms the exemption mechanism contained in *I.R.C. § 931* to a credit system whereby the U.S. parent can elect a special ***tax*** credit to offset the U.S. ***tax*** on its wholly owned possessions subsidiary's source income.

Tax Law > Federal Taxpayer Groups > General Overview
Tax Law > International ***Taxes*** > Americans Operating Abroad > Corporations in US Possessions
Tax Law > State & Local ***Taxes*** > Income ***Taxes*** > General Overview

HN6 *I.R.C. § 936* allows the ***tax*** credit to domestic corporations operating in Puerto Rico and all possessions of the United States except the Virgin Islands . *I.R.C. § 931* was retained to provide the possessions source income exclusion to qualifying U.S. individual citizens. For *§ 931* purposes, however, ″possession″ does not include Puerto Rico , Guam , or the Virgin Islands . *I.R.C. § 931(c)*. The Puerto Rican-source income exclusion for qualifying U.S. individual citizens is now contained in *I.R.C. § 933*.

Business & Corporate Law > ... > Corporate Finance > Franchise ***Tax*** > General Overview
Business & Corporate Law > ... > Corporate Finance > Franchise ***Tax*** > Excise ***Taxes***
Tax Law > International ***Taxes*** > Americans Operating Abroad > Corporations in US Possessions
Tax Law > ... > Income ***Taxes*** > Corporations & Unincorporated Associations > General Overview
Tax Law > ... > Income ***Taxes*** > Corporations & Unincorporated Associations > Limitations on Taxation
Tax Law > ... > Personal Property ***Taxes*** > Exemptions > General Overview

HN7 In addition to exempting corporations from Puerto Rican corporate income ***taxes***, Industrial ***Tax*** Exemption Act of 1948, *13 P.R. Laws Ann. §§ 221-238* (1955), also provides exemptions from certain property ***taxes***, excise ***taxes***, and license fees, with a gradual phase-out of exemptions by 1962. The ***tax*** exemptions generally are available for a corporation manufacturing items not produced on a commercial scale in Puerto Rico prior to 1947.

Tax Law > International ***Taxes*** > Americans Operating Abroad > Corporations in US Possessions
Tax Law > ... > Income ***Taxes*** > Corporations & Unincorporated Associations > General Overview
Tax Law > ... > Personal Property ***Taxes*** > Exemptions > General Overview

HN8 In 1954, the Industrial ***Tax*** Exemption Act of 1948, *13 P.R. Laws Ann. §§ 221-238* (1955), was reenacted with an amendment that provided for an additional 10-year exemption for new businesses subsequently locating on the island. Industrial Incentive Act of 1954 (1954 Act), *13 P.R. Laws Ann. §§ 241-251* (1977). The Industrial Incentive Act of 1963, *13 P.R. Laws Ann. §§ 252-252j* (1977), provides completely new exemption grants for periods ranging from 10 to 25 years and retains virtually all the provisions of the 1954 Act.

Mergers & Acquisitions Law > Takeovers & Tender Offers > General Overview
Mergers & Acquisitions Law > Taxable Acquisitions > General Overview
Tax Law > ... > Sales & Exchanges > Like Kind Exchanges > General Overview
Tax Law > ... > Sales & Exchanges > Like Kind Exchanges > Nonrecognition of Gains & Losses
Tax Law > Federal Taxpayer Groups > C Corporations > Reorganization of Corporations

HN9 *I.R.C. § 351* provides for the nonrecognition of gain or loss upon the ***transfer*** of property to a corporation if immediately after the ***transfer*** the corporation is controlled by the transferor. The ***transfer*** of property must be solely in exchange for stock or securities of the transferee corporation. The ***transfer*** of property to an existing controlled corporation will qualify the transaction for nonrecognition treatment even though the transferor did not receive any additional stock at the time of the ***transfer***.

Mergers & Acquisitions Law > Takeovers & Tender Offers > General Overview
Mergers & Acquisitions Law > ***Tax*** Free Acquisitions
Mergers & Acquisitions Law > Taxable Acquisitions > Stock Acquisitions
Tax Law > Federal Taxpayer Groups > C Corporations > Recapitalization of Corporations
Tax Law > Federal Taxpayer Groups > C Corporations > Reorganization of Corporations

HN10 ″Control″ is defined by *I.R.C. § 368(c)* as being the ownership of stock possessing at least 80 percent of the total combined voting power of all classes of stock entitled to vote and at least 80 percent of the total number of shares of all other classes of stock of the corporation. The court mentions control merely as being one of the requirements for nonrecognition under *I.R.C. § 351*.

Administrative Law > Judicial Review > Standards of Review > General Overview
Business & Corporate Law > Foreign Corporations > General Overview
Mergers & Acquisitions Law > ***Tax*** Free Acquisitions
Mergers & Acquisitions Law > Taxable Acquisitions > Stock Acquisitions
Tax Law > Federal Taxpayer Groups > C Corporations > Reorganization of Corporations

HN11 Rev. Rul. 64-155, 1964-1 C.B. (Part 1) 138 provides, in part that X, a domestic corporation, proposes to contribute appreciated property to Y, an existing wholly owned foreign subsidiary. Although X will not receive any additional Y shares, the transaction will be considered an exchange of property for stock described in I.R.C. § 351. Revenue rulings have none of the force or effect of Treasury decisions and do not commit the Internal Revenue Service to a particular interpretation of the law. While a ruling is not controlling, however, it is not without weight and the court will consider it as a statement of respondent's position on a given set of facts.

Mergers & Acquisitions Law > Sales of Assets > General Overview
Mergers & Acquisitions Law > ***Tax*** Free Acquisitions
Mergers & Acquisitions Law > Taxable Acquisitions > Asset Acquisitions
Patent Law > Ownership > Patents as Property
Tax Law > Federal Taxpayer Groups > C Corporations > Reorganization of Corporations

HN12 ***Transfer*** of patents and know-how is a ″***transfer*** of property.″

Tax Law > ... > Retirement Plans > Qualified Retirement Plans > Determination Letters

HN13 A ruling may be modified or revoked by the Internal Revenue Service, effective in rare cases even retroactively. I.R.C. § 7805(b); I.R.C. § 601.201(1).

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Power to Allocate

HN14 I.R.C. § 482 gives the Internal Revenue Service broad authority to allocate between or among commonly controlled corporations their respective gross incomes, deductions, credits, or allowances when necessary either to prevent the evasion of ***taxes*** or in order clearly to reflect the income of such corporations.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > Federal Taxpayer Groups > C Corporations > Recapitalization of Corporations
Tax Law > Federal Taxpayer Groups > C Corporations > Reorganization of Corporations

HN15 The term ″controlled,″ as defined by Treas. Reg. § 1.482-1(a)(3) has a much more expansive meaning than that used in I.R.C. §§ 351 and 368. For the purposes of I.R.C. § 482, ″controlled″ includes any kind of control, direct or indirect, whether legally enforceable, and however exercisable or exercised.

Energy & Utilities Law > Taxation Issues
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN16 An I.R.C. § 482 allocation based upon ***tax*** avoidance grounds is primarily intended to prevent the artificial shifting or milking of profits.

Energy & Utilities Law > Taxation Issues
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > Federal ***Tax*** Administration & Procedures > Criminal Offenses & Penalties > General Overview

HN17 For purposes of I.R.C. § 482, the terms ″***tax*** evasion″ and ″***tax*** avoidance″ are interchangeable.

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > S Corporations > Shareholders > General Overview

HN18 The Internal Revenue Service may compel a reallocation of income under I.R.C. § 482 where the incomes of related parties are not clearly reflected, even in the absence of ***tax*** avoidance motives. The clear reflection of income doctrine has justified an allocation when the challenged transaction shifted income earned by one party to a related party or when it resulted in an artificial mismatching of a party's income and expenses.

Tax Law > Federal Income ***Tax*** Computation > General Overview
Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > State & Local ***Taxes*** > Income ***Taxes*** > General Overview

HN19 Treas. Reg. § 1.482-1(b)(1), provides, in part that the purpose of I.R.C. § 482 is to place a controlled taxpayer on a ***tax*** parity with an uncontrolled taxpayer, by determining, according to the standard of an uncontrolled taxpayer, the true taxable income from the property and business of a controlled taxpayer. The standard to be applied in every case is that of an uncontrolled taxpayer dealing at arm's length with another uncontrolled taxpayer.

Tax Law > ... > Sales & Exchanges > Like Kind Exchanges > General Overview
Tax Law > ... > Sales & Exchanges > Like Kind Exchanges > Nonrecognition of Gains & Losses
Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > Federal Taxpayer Groups > C Corporations > Reorganization of Corporations

HN20 I.R.C. § 482 provides that respondent may make allocations between related parties when necessary either to prevent the evasion of ***taxes***, or in order clearly to reflect their incomes. Moreover, Treas. Reg. § 1.482-1(d)(5) specifically provides that § 482 may, when necessary to prevent the avoidance of ***taxes*** or to clearly reflect income, be applied in circumstances described in

sections of the Internal Revenue Code, such as I.R.C. § 351, providing for nonrecognition of gain or loss.

Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview

HN21 The situations in which courts have upheld I.R.C. § 482 allocations that, in effect, ignored nonrecognition transfers can be separated into two narrowly defined categories: (1) Cases in which property was transferred in a nonrecognition transaction and subsequently disposed of by the transferee, and in which the sole purpose of the transfer was to achieve tax consequences on the disposition of the property by the transferee that were more favorable than the tax consequences of a disposition by the transferor and (2) cases in which the nonrecognition transfer of property resulted in an artificial separation of income from the expenses of earning the income.

Criminal Law & Procedure > ... > Fraud Against the Government > Tax Fraud > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview
Tax Law > State & Local Taxes > Administration & Procedure > Tax Avoidance & Evasion

HN22 It is well established that taking advantage of tax benefits made available by Congress does not constitute tax avoidance.

Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview

HN23 Taxpayers have the right so to arrange their affairs that their taxes shall be as low as possible; that one is not obliged to pursue a course of action giving rise to a greater tax liability if another is open which will give rise to a lesser liability and that what a taxpayer did, rather than what he might have done, determines his liability.

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > Power to Allocate
Tax Law > State & Local Taxes > Income Taxes > General Overview

HN24 A valid business purpose will not preclude the application of I.R.C. § 482 in such a situation when necessary clearly to reflect income. Treas. Reg. §§ 1.482-1(c), 1.482-1(d)(5).

Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > Power to Allocate
Tax Law > Federal Taxpayer Groups > C Corporations > Reorganization of Corporations
Tax Law > ... > S Corporations > Shareholders > General Overview

HN25 Allocation should be available to dissolve the fiction that one entity was unprofitable, and that to achieve the rough matching of expenses and income previously attained, allocation of the expenses to the concern which is to profit by them is the alternative. I.R.C. § 482 will control when it conflicts with I.R.C. § 351 as long as the discretion of the Commissioner of Internal Revenue in reallocating is not abused.

Tax Law > Federal Income Tax Computation > General Overview
Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview

HN26 A fundamental principle of federal income tax law is that income from property is earned by the owner of the property. This principle is recognized by the regulations under I.R.C. § 482 at Treas. Reg. § 1.482-1(b)(1). That section provides that the purpose of § 482 is to place a controlled taxpayer on a parity with an uncontrolled taxpayer by determining the true taxable income from the property and business of a controlled taxpayer.

Patent Law > Ownership > Patents as Property
Patent Law > ... > Damages > Collateral Assessments > Costs

HN27 Under patent law, only the owner of a patent may sue for infringement of that patent.

Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview

HN28 A taxpayer corporation is free to and can use its funds for its own purposes. It is under no obligation to so arrange its affairs and those of its subsidiary as to result in a maximum tax burden. On the other hand, it has a clear right by such a real transaction to reduce that burden.

Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview

HN29 The Internal Revenue Service is authorized under I.R.C. § 482 to make allocations between the parent corporation and its subsidiary if necessary clearly to reflect their respective incomes.

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > Personal Property Taxes > Intangible Personal Property > General Overview

HN30 Treas. Reg. § 1.482-2(d)(1)(i) provides that in general, except as otherwise provided in subparagraph (4), where intangible property or an interest therein is transferred, sold, assigned, loaned, or otherwise made available in any manner by one member of a group of controlled entities, referred to in this paragraph as the transferor, to another member of the group, referred to

in this paragraph as the transferee, for other than an arm's length consideration, the district director may make appropriate allocations to reflect an arm's length consideration for such property or its use. Subparagraph (2) provides rules for determining the form an amount of an appropriate allocation, subparagraph (3) provides a definition of "intangible property", and subparagraph (4) provides rules with respect to certain cost-sharing arrangements in connection with the development of intangible property. An interest in intangible property may take the form of the right to use such property.

Contracts Law > Types of Contracts > Reciprocal Contracts
Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN31 Treas. Reg. § 1.482-2(d)(1)(i) defines arm's-length consideration as royalties, lump-sum payments, or any other form, including reciprocal licensing agreements, consistent with the form adopted by unrelated parties.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN32 Treas. Reg. § 1.482-2(d)(2)(i) provides that an arm's length consideration shall be in a form which is consistent with the form which would be adopted in transactions between unrelated parties under the same circumstances. To the extent appropriate, an arm's length consideration may take any one or more of the following forms: (a) royalties based on the transferee's output, sales, profits, or any other measure; (b) lump-sum payments; or (c) any other form, including reciprocal licensing rights, which might reasonably have been adopted by unrelated parties under the circumstances, provided that the parties can establish that such form was adopted pursuant to an arrangement which in fact existed between them. However, where the transferee pays nominal or no consideration for the property or interest therein and where the transferor has retained a substantial interest in the property, an allocation shall be presumed not to take the form of a lump-sum payment.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > Federal Taxpayer Groups > General Overview
Tax Law > State & Local ***Taxes*** > Income ***Taxes*** > General Overview

HN33 I.R.C. § 482 gives respondent authority to allocate income between or among related corporations when necessary to prevent the evasion of ***taxes*** or clearly to reflect the income of such corporations. The purpose of § 482 is to place a controlled taxpayer on a ***tax*** parity with an uncontrolled taxpayer. Treas. Reg. § 1.482-1(b)(1).

Tax Law > ... > Audits & Investigations > Burdens of Proof > General Overview
Tax Law > ... > Audits & Investigations > Burdens of Proof > Burden of Government
Tax Law > ... > Audits & Investigations > Burdens of Proof > Burden of Taxpayer
Tax Law > Federal ***Tax*** Administration & Procedures > ***Tax*** Court > General Overview
Tax Law > ... > ***Tax*** Credits & Liabilities > Deficiencies > General Overview

HN34 The Internal Revenue Service's determination as set forth in the notice of deficiency is presumptively correct, and the burden of disproving that determination lies with the taxpayer. U.S. ***Tax*** Ct. R. 142(a). The burden of proving the increases in deficiencies is on Internal Revenue Service. U.S. ***Tax*** Ct. R. 142(a).

Administrative Law > Judicial Review > Standards of Review > Arbitrary & Capricious Standard of Review
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Power to Allocate

HN35 In addition to the general presumption of correctness that attaches to the Internal Revenue Service's (IRS) determination as set forth in the notice of deficiency, the IRS has broad discretion in its application of I.R.C. § 482 so that it's determination will be upheld unless the taxpayer proves it to be arbitrary, capricious, or unreasonable. The court's decision as to whether or not the IRS has exceeded or abused its discretion turns upon questions of fact.

Administrative Law > Judicial Review > Standards of Review > Arbitrary & Capricious Standard of Review
Evidence > ... > Presumptions > Particular Presumptions > Regularity
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > ***Tax*** Credits & Liabilities > Deficiencies > General Overview

HN36 Should the taxpayer parent corporation prove the Internal Revenue Services' (IRS) determination as set forth in the notice of deficiency to be arbitrary, capricious, or unreasonable, the general presumption of correctness no longer applies. The taxpayer parent corporation also may overcome the presumption by introducing sufficient evidence proving that the transactions in issue satisfied the arm's-length standard of I.R.C. § 482. In the event that the taxpayer parent corporation does overcome the IRS' presumption of correctness and disproves the deficiencies set forth in the statutory notice, the court must determine from the record before it the proper allocations, if any, of income between the taxpayer parent corporation and its subsidiary corporation. The court may allocate income under the statute in a manner the evidence before it demonstrates to be correct and the IRS' allocation need not be approved or disapproved in toto.

Administrative Law > Judicial Review > Standards of Review > Arbitrary & Capricious Standard of Review
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN37 There are often occasions when, in order to protect the revenue, the Internal Revenue Service (IRS) must make alternative determinations. Moreover, to lock the IRS into one exact methodology or calculation would require the IRS to retain an expert at the time of mailing the deficiency notice, a requirement which would effectively preclude it from ever using outside experts. The court does not think that because the IRS made alternative determinations supported by differing methodologies, its actions were arbitrary, capricious, or unreasonable. Thus, the presumption of correctness would not be lost for that reason, alone.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > Personal Property ***Taxes*** > Tangible Personal Property > General Overview

HN38 Treas. Reg. § 1.482-2(e)(1)(i) provides that when one controlled entity sells tangible property to another controlled entity at "other than an arm's length ***price***," respondent may make appropriate allocations between the seller and the buyer to reflect an arm's length ***price*** for such sale. An "arm's length ***price***" for purposes of that section is defined as the ***price*** that an unrelated party would have paid under the same circumstances for the property involved in the controlled sale. Since unrelated parties normally sell products at a profit, an arm's length ***price*** normally involves a profit to the seller. Treas. Reg. § 1.482-2(e)(1)(i).

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Comparable Uncontrolled ***Price*** Method
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Cost Plus Method
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Resale ***Price*** Method

HN39 The regulations set forth three detailed methods for determining an arm's-length ***price*** when one controlled entity sells tangible property to another controlled entity; the comparable uncontrolled ***price*** method, the resale ***price*** method, and the cost plus method. Treas. Reg. § 1.482-1(e)(1)(ii). A fourth method is provided by Treas. Reg. § 1.482-2(e)(1)(iii) that says where the standards for applying one of the three methods of ***pricing*** are met, such method must, for the purposes of this paragraph, be utilized unless the taxpayer can establish that, considering all the facts and circumstances, some method of ***pricing*** other than those described is more appropriate. Where none of the three methods of ***pricing*** can reasonably be applied under the facts and circumstances as they exist in a particular case, some appropriate method of ***pricing*** other than those described, or variations on such methods, can be used.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Comparable Uncontrolled ***Price*** Method
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Cost Plus Method
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Resale ***Price*** Method
Tax Law > State & Local ***Taxes*** > Income ***Taxes*** > General Overview

HN40 Treas. Reg. § 1.482-2(e)(1)(ii) establishes a priority for the application of ***pricing*** methods. The comparable uncontrolled ***price*** method is the most accurate of the methods, and is to be used whenever there are "comparable uncontrolled sales." Comparable uncontrolled sales are sales of the same or substantially identical property between uncontrolled buyers and sellers. Treas. Reg. § 1.482-2(e)(2). The resale ***price*** method is to be used if there are no comparable uncontrolled sales. Treas. Reg. § 1.482-2(e)(1)(ii). That method involves calculating an appropriate markup by which the resale ***price*** to an uncontrolled buyer is reduced to find the arm's-length ***price*** for the controlled sale. Treas. Reg. § 1.482-2(e)(3). The cost plus method starts from the other end. Instead of reducing the sales ***price*** of the reseller by an appropriate markup, the cost plus method requires the determination of an appropriate gross profit, which is added to the seller's or manufacturer's cost of producing such property. Treas. Reg. § 1.482-2(a)(4).

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Comparable Uncontrolled ***Price*** Method
Tax Law > State & Local ***Taxes*** > Sales ***Taxes*** > General Overview

HN41 If none of the ***pricing*** methods of Treas. Reg. §§ 1.482-2(e)(1)(ii), 1.482-2(e)(1)(ii), 1.482-2(e)(2), or 1.482-2(e)(3), are viable under the facts of a particular case, a fourth "appropriate" method may be used. Treas. Reg. § 1.482-2(e)(1)(iii).

Patent Law > Infringement Actions > Exclusive Rights > General Overview
Patent Law > Infringement Actions > Exclusive Rights > Manufacture, Sale & Use
Patent Law > Ownership > Conveyances > General Overview

HN42 A patent owner has three exclusive rights under a patent: the right to manufacture, use, and sell the pat-

ented product. 35 U.S.C.S. § 154. However, once the product is sold by the patent owner to a third-party purchaser, the purchaser acquires the right to resell the product.

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > Resale Price Method

HN43 The regulations provide that the arm's-length price of a controlled sale determined using the resale price method is equal to the applicable resale price reduced by an appropriate mark-up, Treas. Reg. § 1.482-2(e)(3)(i), and adjusted to reflect any material differences between the uncontrolled purchases and resales used as the basis for the calculation of the appropriate markup percentages and the resales of property involved in the controlled sale. The differences referred to are those differences in functions or circumstances which have a definite and reasonably ascertainable effect on price. Treas. Reg. § 1.482-2(e)(3)(ix).

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > Resale Price Method

HN44 The "applicable resale price" is the price at which it is anticipated that property purchased in the controlled sale will be resold by the buyer in an uncontrolled sale. The "applicable resale price" will generally be equal to either the price at which current resales of the same property are being made or the resale price of the particular item of property involved. Treas. Reg. § 1.482-2(e)(3)(iv). The "appropriate markup" is the gross profit, expressed as a percentage of sales, earned by the buyer or reseller or another party on the resale of property which is both purchased and resold in an uncontrolled transaction, which resale is most similar to the applicable resale of the property involved in the controlled sale. Treas. Reg. § 1.482-2(e)(3)(vi).

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > Resale Price Method

HN45 Treas. Reg. § 1.482-2(e)(3) determines the arm's-length price of property in a controlled sale by reducing the reseller's price of the property to an uncontrolled buyer by an "appropriate markup." Subdivision (vi) of that section clearly requires that the appropriate markup percentage be calculated using gross profit percentages earned by a reseller on the resale of property which is both purchased and resold in an uncontrolled transaction. The regulations state elsewhere their basic assumption that uncontrolled purchases and sales must be used under the resale price method.

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview
Tax Law > State & Local Taxes > Sales Taxes > General Overview

HN46 Treas. Reg. § 1.482-2(e)(3)(vii) states that whenever possible, markup percentages should be derived from uncontrolled purchases and resales of the buyer or reseller involved in the controlled sale.

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview

HN47 Treas. Reg. § 1.482-2(e)(3)(viii) provides that in calculating the markup percentage earned on uncontrolled purchases and resales the same elements which enter into the computation of the sales price and the costs of goods sold of the property involved in the comparable uncontrolled purchases and resales should enter into such computation in the case of the property involved in the controlled purchases and resales.

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview

HN48 Treas. Reg. § 1.482-2(e)(3)(ix) states that in determining an arm's length price appropriate adjustment must be made to reflect any material differences between the uncontrolled purchases and resales used as the basis for the calculation of the appropriate markup percentage and the resales of the property involved in the controlled sale.

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > Resale Price Method

HN49 "Similar" in the context of the resale price method relates to the probable effect upon the markup percentage of any differences between the uncontrolled and controlled purchases and resales. Thus, close physical similarity of the property involved in the sales compared is not required under the resale price method since a lack of close physical similarity is not necessarily indicative of dissimilar markup percentages. Treas. Reg. § 1.482-2(e)(3)(vi).

Tax Law > Federal Income Tax Computation > Tax Accounting > General Overview
Tax Law > ... > Tax Accounting > Allocations of Deductions & Income > General Overview

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Cost Plus Method
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Resale ***Price*** Method

HN50 The cost plus method is equal to the cost of producing the property plus an appropriate profit computed with reference to uncontrolled sales of similar property. *Treas. Reg. § 1.482-2(e)(4)*.

Evidence > ... > Testimony > Expert Witnesses > General Overview

HN51 The court is not bound by the testimony of an expert witness and must reject such testimony where the witness overlooks a significant factor in reaching his conclusion.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN52 The fourth ***pricing*** method is contained in *Treas. Reg. § 1.482-2(e)(1)(iii)* that provides that where none of the three methods of ***pricing*** described in subdivision (ii) of the subparagraph can reasonably be applied under the facts and circumstances as they exist in a particular case, some appropriate method of ***pricing*** other than those described in subdivision (ii) of the subparagraph, or variations on such methods, can be used.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN53 No quantum of evidence as to a taxpayer's internal transactions with its own subsidiaries, standing alone, can be sufficient to establish arm's-length dealing between them. The three ***pricing*** methods prescribed by the regulations under *I.R.C. § 482* required evidence of the transactions of uncontrolled parties. *Treas. Reg. § 1.482-2(e)(1)(iii)*] states that where the standards set out in the regulations indicate that one of the three methods is applicable, the taxpayer may avoid its application only by demonstrating that some other ***pricing*** method is clearly more appropriate.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN54 *Treas. Reg. § 1.482-2(b)(1)* provides that when one member of a group of controlled entities performs services for the benefit of another member without charge or for a charge which is less than arm's length, the District Director of the Internal Revenue Service may make an appropriate allocation to reflect such an arm's-length charge. *Treas. Reg. § 1.482-2(b)(2)(i)*, sets forth the ″benefit test″ relative to those services performed by one member of a controlled group for another. That section provides that in general, allocations may be made if the service, at the time it was performed, related to the carrying on of an activity by another member or was intended to benefit another member, either in the member's overall operations or in its day-to-day activities.

Business & Corporate Law > Corporations > General Overview
Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN55 *Treas. Reg. § 1.861-8(e)(4)* provides that if a corporation renders services for the benefit of a related corporation and the corporation charges the related corporation for such services, the deductions for expenses of the corporation attributable to the rendering of such services are considered definitely related to the amounts so charged and are to be allocated to such amounts. However, the regulations under *I.R.C. § 482* , that is *Treas. Reg. § 1.482-2(b)(2)(ii)*, recognize a type of activity which is not considered to be for the benefit of a related corporation but is considered to constitute ″stewardship″ or ″overseeing″ functions undertaken for the corporation's own benefit as an investor in the related corporation, and therefore, a charge to the related corporation for such stewardship or overseeing functions is not provided for. Services undertaken by a corporation of a stewardship or overseeing character generally represent a duplication of services which the related corporation has independently performed for itself.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN56 *Treas. Reg. § 1.482-2(b)(2)(ii)* referenced in the preceding regulation, provides that allocations will generally not be made if the service is merely a duplication of the service which the related party has independently performed or is performing for itself. In this connection, the ability to independently perform the service, in terms of qualification and ability of personnel, shall be taken into account.

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > International ***Taxes*** > General Overview

HN57 Amounts associated with day-to-day operations cannot be considered as stewardship expenses.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Comparable Uncontrolled ***Price*** Method
Tax Law > State & Local ***Taxes*** > Sales ***Taxes*** > General Overview
Tax Law > State & Local ***Taxes*** > Sales ***Taxes*** > Sales ***Tax*** Defini-

tions

HN58 Under the comparable uncontrolled ***price*** method, the arm's length ***price*** of a controlled sale is equal to the ***price*** paid in comparable uncontrolled sales, adjusted as provided in subsection (ii) of this subparagraph. *Treas. Reg. § 1.482-2(e)(2)(i)*. Uncontrolled sales are defined as sales in which the sellers and the buyers are not members of the same controlled group. *Treas. Reg. § 1.482-2(e)(2)(ii)*.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN59 Uncontrolled sales are considered comparable to controlled sales if the physical property and circumstances involved in the uncontrolled sales are identical to the physical property and circumstances involved in the controlled sales, or if such properties and circumstances are so nearly identical that any differences either have no effect on ***price***, or such differences can be reflected by a reasonable number of adjustments to the ***price*** of uncontrolled sales. For this purpose, differences can be reflected by adjusting ***prices*** only where such differences have a definite and reasonably ascertainable effect on ***price***. If the differences can be reflected by such adjustment, then the ***price*** of the uncontrolled sale as adjusted constitutes the comparable uncontrolled sale ***price***. *Treas. Reg. § 1.482-2(e)(2)(ii)*.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN60 Some of the differences which may affect the ***price*** of property are differences in the quality of the product, terms of sale, intangible property associated with the sale, time of sale, and the level of the market and the geographic market in which the sale takes place. Whether and to what extent differences in the various properties and circumstances affect ***price***, and whether differences render sales noncomparable, depends upon the particular circumstances and property involved. *Treas. Reg. § 1.482-2(e)(2)(ii)*.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Comparable Uncontrolled ***Price*** Method
Tax Law > State & Local ***Taxes*** > Sales ***Taxes*** > General Overview

HN61 Under the comparable uncontrolled ***price*** method of *Treas. Reg. § 1.482-2(e)(2)*, adjustments can be made to reflect differences between the controlled sale and the uncontrolled sale. The only guidance for those adjustments is contained in the regulations which state, in *Treas. Reg. § 1.482-2(e)(2)(ii)*, that differences can be reflected by adjusting ***prices*** only where such differences have a definite and reasonably ascertainable effect on ***price***.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN62 The methods of determining arm's length ***prices*** described in this section are stated in terms of their application to individual sales of property. However, because of the possibility that a taxpayer may make controlled sales of many different products, or many separate sales of the same product, it may be impractical to analyze every sale for the purposes of determining the arm's length ***price***. It is therefore permissible to determine or verify arm's length ***prices*** by applying the appropriate methods of ***pricing*** to product lines or other groupings where it is impractical to ascertain an arm's length ***price*** for each product or sale. *Treas. Reg. § 1.482-2(e)(1)(iv)*.

Tax Law > Federal Income ***Tax*** Computation > ***Tax*** Accounting > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > Comparable Uncontrolled ***Price*** Method
Tax Law > State & Local ***Taxes*** > Sales ***Taxes*** > General Overview

HN63 The terms of sale is one of the factors specifically mentioned in the *I.R.C. § 482* regulations as a cause for adjustment of the comparable uncontrolled ***price***. *Treas. Reg. § 1.482-2(e)(2)(ii)*.

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN64 *Rev. Proc. 63-10* still may be used in such cases if the result is more favorable to the taxpayer than that obtained under the *I.R.C. § 482* regulations. *Rev. Proc. 68-22*, § 4, *1968-1 C.B. 819, 821*.

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview
Tax Law > State & Local ***Taxes*** > Income ***Taxes*** > General Overview

HN65 If all applicable intangibles are treated as belonging to the island affiliate, all of the income produced by the intangibles is allowed to the island affiliate. In this case, gross income of the island affiliate would be determined on the basis of a selling ***price*** equal to the highest ***price*** which a representative independent United States company comparable to the mainland affiliate would pay for the product involved. In principle, this ***price*** would approximate the final United States market ***price*** for the product less (a) the mainland affiliate's costs of distribution, (b) a reasonable margin of profit for distribution, and (c) all costs incident to transportation from the point of sale in Puerto Rico . *Rev. Proc. 63-10*, § 4.03, *1963-1 C.B. 490*.

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN66 If some, but not all intangibles which are significant in a joint operation are treated as belonging to the island affiliate, it would be allowed a ***price***, which assumed the ownership of no intangibles plus an amount representing an estimated payment by the mainland affiliate for those intangibles owned by the island affiliate. This amount would be based on evidence available regarding what an independent company would receive as royalties or fees or as an increased ***price*** in such circumstances. *Rev. Proc. 63-10*, § 4.04, *1963-1 C.B. 490*.

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN67 Not infrequently, the return attributable to intangibles is substantial. Therefore, in cases where significant income-producing intangibles are present the determination whether they belong to the island affiliate or the mainland affiliate is important in the proper application of *I.R.C. § 482*. It is a question to be decided under the facts and circumstances of a particular case (a) whether significant intangibles are present, and (b) if significant intangibles are present, whether they belong to the mainland or the island affiliate. *Rev. Proc. 63-10*, § 4.01, *1963-1 C.B. 490*.

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN68 It may be expected that as to certain intangibles no supportable contention could be made that they belong to the island affiliate. For example, if the mainland affiliate acts as the marketing and servicing organization for products produced by the island affiliate, any market position, consumer acceptance, or similar factors of good will attributable to the distribution and product servicing activities in the United States do not, as a matter of substance, belong to the island affiliate. *Rev. Proc. 63-10*, § 4.01, *1963-1 C.B. 490*.

Tax Law > ... > ***Tax*** Accounting > Allocations of Deductions & Income > General Overview

HN69 The problem of applying *section 482* of the Code is more difficult as a practical matter when directly applicable independent ***prices*** are not available. However, when a product manufactured in Puerto Rico and sold only to a mainland affiliate differs only slightly from other products bought and sold by independent firms, an arm's length ***price*** for the island affiliate may be determined by adjusting these independent ***prices*** to take account of such minor differences as are present. of *Rev. Proc. 63-10*, § 3.02(2), *1963-1 C.B. 490, 493*.

Syllabus

CONTENTS

[2]** 1. Petitioner is engaged in the manufacture and sale of pharmaceutical products. Petitioner created and patented propoxyphene hydrochloride (Darvon) during the early 1950's and propoxyphene napsylate (Darvon-N) during the early 1960's. Darvon was first introduced into the U.S. market in 1957, and was manufactured by petitioner from 1957 to 1966. Darvon-N was not introduced into the U.S. market until 1971 and was never manufactured by petitioner. In 1965, petitioner organized Lilly P.R. as a wholly owned Puerto Rican subsidiary qualifying for the benefits of sec. 931, I.R.C. 1954. In December 1966, petitioner ***transferred*** the Darvon and Darvon-N patents and related manufacturing know-how to Lilly P.R. in a sec. 351, I.R.C. 1954, nonrecognition transaction. After 1966 and throughout the years in issue, Lilly P.R. manufactured Darvon and Darvon-N for sale to petitioner who in turn marketed the products throughout the United States. *Held*, Lilly P.R.'s ownership of the manufacturing intangibles is recognized in determining arm's-length ***prices*** between Lilly P.R. and petitioner. *Held, further*, the **[**3]** ***prices*** Lilly P.R. charged petitioner caused a distortion of income justifying reallocations.

2. *Held*, although reallocations of income were warranted, respondent's adjustments to ***prices*** under *sec. 482*, which denied Lilly P.R. any income from the manufacturing intangibles, were unreasonable.

3. During 1971 and 1972, Lilly P.R. was the sole manufacturer of Darvon and Darvon-N. These drugs were nonnarcotic analgesics which competed in the prescription pain relief market with combinations of codeine with aspirin or acetaminophen. At the end of 1972, the Darvon patent expired and, shortly thereafter, several companies began to compete directly with Darvon by manufacturing and marketing generic propoxyphene hydrochloride products. *Held*, arm's-length ***prices*** determined for 1971 and 1972 under *sec. 1.482-2(e)(1)(iii), Income **Tax** Regs.* *Held, further*, arm's-length ***prices*** for 1973 determined under *sec. 1.482-2(e)(2), Income **Tax** Regs.*

Counsel: *Thomas M. Haderlein, John C. Klotsche, Michael Waris, Jr., Gregg D. Lemein, Paul J. Linstroth, and James M. O'Brien, for the petitioners.*

Joel V. Williamson, Charles S. Triplett, and Joseph R. Goeke, for the respondent.

Judges: Wiles, *Judge.*

Opinion by: WILES

Opinion

[*1000] Respondent determined **[**4]** deficiencies in petitioners' Federal income ***taxes*** as follows:

Year	Deficiency
1971	$ 7,622,449
1972	7,340,867
1973	6,853,816

[*1001] By amendment to his answer, respondent asserted increased deficiencies in the following amounts:

Year	Deficiency [1]
1971	$ 11,711,792
1972	11,626,363
1973	10,882,192

The entire amounts of the deficiencies determined by respondent for 1971 and 1972 are in dispute, and petitioners claim refunds for 1971 and 1972 in the amounts of $ 1,700,038 and $ 1,697,257, respectively. For 1973, all but $ 189,048 of the deficiency determined by respondent is in dispute.

Pursuant to petitioners' motion, this Court severed from the case all issues other than the propriety of respondent's allocations of gross income under *section 482* [2] from Eli Lilly & Co., Inc. (hereinafter Lilly P.R.) to petitioner Eli Lilly Co. (hereinafter petitioner) with respect to Darvon Registered TM and Darvon-N Registered TM products. The severed issues were consolidated with docket No. 19606-80 for purposes of trial, briefing, and opinion; consequently, **[**5]** a final decision as to the income ***tax*** deficiencies of petitioners for the taxable years 1971, 1972, and 1973 will not be possible based upon the opinion of this case.

The *section 482* allocations of gross income from Lilly P.R. to petitioner with respect to Darvon and Darvon-N products determined by respondent in his notice of deficiency and amendment to answer are as follows:

Year	Notice of deficiency	Amendment to answer
1971	$ 18,522,924	$ 26,620,387
1972	17,820,986	26,314,918
1973	10,717,187	18,078,205

These allocations raise the following questions for our consideration:

1. Whether petitioner's 1966 ***transfer*** pursuant to *section 351* of certain Darvon and Darvon-N income-producing intangibles to Lilly P.R., a wholly owned subsidiary cor-

[1] These and the above deficiencies include amounts attributable to the issues severed from this case and consolidated with the case of petitioner in docket No. 19606-80.

[2] Unless otherwise indicated, all section references are to the Internal Revenue Code of 1954 as amended and in effect during the years in issue.

poration **[*1002]** engaged in manufacturing in Puerto Rico and qualifying as a possessions corporation within the meaning of section 931, should be recognized for the purposes of determining arm's-length ***prices*** for Darvon and Darvon-N products purchased by petitioner from Lilly P.R. during 1971, 1972, and 1973;

2. Whether respondent's **[**6]** determinations that gross income should be allocated from Lilly P.R. to petitioner with respect to Darvon and Darvon-N products for the years 1971, 1972, and 1973 were arbitrary, capricious, or unreasonable;

3. Whether Lilly P.R.'s ***prices*** to petitioner for Darvon and Darvon-N products manufactured by Lilly P.R. and sold to petitioner during 1971, 1972, and 1973 were ***prices*** at which those products would have been sold between unrelated parties dealing at arm's length.

FINDINGS OF FACT

Some of the facts have been stipulated and are found accordingly.

I. *History and Background of Eli Lilly & Co.*

A. *Petitioner*

Petitioner is an Indiana corporation whose principal place of business at the time of filing the petition herein was Indianapolis, Indiana. During the years 1971, 1972, and 1973, petitioner and its consolidated subsidiaries maintained their books and records on the accrual method of accounting with taxable years beginning on January 1 and ending on December 31. Petitioner and its consolidated subsidiaries filed consolidated Federal income ***tax*** returns on Forms 1120 for the taxable years 1971, 1972, and 1973, at the Memphis Service Center, Memphis, Tennessee.

Petitioner is engaged in the **[**7]** United States in the invention, development, manufacture, marketing, and sale of a wide variety of ethical (i.e., prescriptions) and other pharmaceutical products, as well as certain agricultural, chemical, and cosmetic products. Petitioner is engaged in similar activities in approximately 145 countries throughout the world through a network of approximately 70 partially and wholly owned domestic and foreign corporations. During the time period **[*1003]** 1960 through 1975, petitioner and its subsidiaries employed from 10,000 to 24,000 individuals.

During the years 1971 through 1973, the relevant divisions and subsidiaries of petitioner and their respective responsibilities were as follows:

(a) Pharmaceutical Division: Marketing and sale of pharmaceutical products in the United States.

(b) Elanco Products Co.: Marketing and sale of animal health and agricultural products in the United States.

(c) Elizabeth Arden, Inc.: Marketing and sale of cosmetic products in the United States.

(d) Lilly Research Laboratories: Fundamental and developmental research in the life sciences.

(e) Production Operations Division: Operation of all manufacturing facilities in the United States.

(f) Lilly P.R.: Manufacture **[**8]** and sale of ethical pharmaceutical products in Puerto Rico.

(g) Lilly Industries Ltd.: Fundamental and developmental research in the life sciences and manufacturing, marketing, and sale of pharmaceutical, animal health, and agricultural products.

(h) Eli Lilly S.A., Geneva: International marketing, licensing, and holding company.

The consolidated net sales (excluding intercompany sales) of petitioner and its worldwide subsidiaries and the United States pharmaceutical net sales of petitioner for the years 1965 through 1973 were as follows (000's omitted):

Year	Consolidated net sales	U.S. pharmaceutical net sales
1965	$ 316,600	$ 176,358
1966	366,700	196,482
1967	408,400	212,829
1968	479,600	257,610
1969	537,200	284,501
1970	592,300	304,933
1971	723,300	338,321
1972	819,700	351,044
1973	972,500	368,915

During the years 1971 through 1973, approximately 60 percent of the consolidated sales of petitioner and its worldwide subsidiaries was attributable to the sale of

pharmaceutical **[*1004]** products. [3] During those years, petitioner marketed approximately 750 pharmaceutical products in the United States. Petitioner's pharmaceutical sales during that time accounted for approximately 7.5 percent of the total pharmaceutical industry **[**9]** sales in the United States, and its pharmaceutical products accounted for approximately 6.5 percent of the new and refilled prescriptions written in the United States.

B. *Lilly P.R.*

Lilly P.R. was organized under the laws of the State of Indiana on June 9, 1965, as a wholly owned subsidiary corporation of petitioner. Lilly P.R.'s principal place of business is located in the Commonwealth of Puerto Rico. During 1971, 1972, and 1973, Lilly P.R. maintained its books and records on the accrual method of accounting with taxable years beginning on January 1 and ending on December 31. Lilly P.R. filed Federal income ***tax*** returns on Forms 1120 for the taxable years 1971 through 1973 with the Office of International Operations, Philadelphia, Pennsylvania.

Lilly P.R. was organized by petitioner, among other reasons, to take advantage of the benefits provided by *section 931* relating to income from sources within possessions of the United States. Since its inception, Lilly P.R. has been engaged in the manufacture of propoxyphene and other pharmaceutical **[**10]** products in the Commonwealth of Puerto Rico. During each of the years in issue, Lilly P.R.'s gross income satisfied the conditions set forth in subsections (1) and (2) of *section 931(a)*.

II. *History and Background of Darvon and Darvon-N Products*

A. *Propoxyphene and Propoxyphene Hydrochloride*

The search for a nonaddictive synthetic analgesic having the pain relieving properties of morphine began in the late 1920's and was accelerated in later years by two events. The first of those events was the scarcity of morphine during World War II. The second came at the close of World War II when American scientific intelligence teams investigated German **[*1005]** wartime work on synthetic analgesics and published a report, referred to as the ″Kleiderer Report,″ summarizing that work for the American scientific community. The Kleiderer Report dealt with a number of synthetic substances, one of which subsequently became known as methadone. Although methadone proved to be as effective an analgesic as morphine, it also proved to be as addictive as morphine. In response to the Kleiderer Report, an intensive research effort was mounted in the United States and abroad for a nonnarcotic, synthetic analgesic **[**11]** of the morphine class. Several major pharmaceutical companies, including petitioner, participated in that effort.

In 1951, Dr. Albert Pohland, a research chemist working at Lilly Research Laboratories, discovered propoxyphene and propoxyphene hydrochloride. Propoxyphene hydrochloride, the principal active ingredient in Darvon products, proved to be the first synthetic analgesic that acted on the central nervous system with only a negligible potential of addiction. U.S. Patent 2,728,779 (hereinafter the propoxyphene patent) was issued to petitioner as Dr. Pohland's assignee on December 27, 1955, pursuant to an application filed on December 3, 1952. The propoxyphene patent covered the chemical substance propoxyphene and the acid addition salts of propoxyphene, including propoxyphene hydrochloride. The propoxyphene patent expired on December 27, 1972.

Propoxyphene is an oral prescription analgesic medication that relieves pain by acting upon the pain receptors in the brain. Propoxyphene is prescribed by physicians for the relief of mild to moderate pain, such as severe headache pain, postsurgical pain, and pain from bone fractures. It is often prescribed for patients with pain who **[**12]** have unsuccessfully self-medicated with over-the-counter drugs such as aspirin and acetaminophen. [4] Aspirin and acetaminophen are peripherally acting analgesics that relieve pain by acting at the site in the body where the pain arises.

Although propoxyphene was discovered in 1951 and the propoxyphene patent was issued to petitioner in 1955, petitioner did not obtain its first approval to market a propoxyphene product in the United States from the Food and Drug Administration, Department of Health and Human Services (hereinafter **[*1006]** the FDA) until September 9, 1957. Petitioner sold its propoxyphene hydrochloride products under the trademark Darvon, which trademark it registered on July 29, 1958.

During the period from 1957 through 1973, petitioner sold the following products containing propoxyphene hydrochloride as their principal active ingredient:

Identification code	Description
PU 364	Darvon 32 mg.
PU 365	Darvon 65 mg.

[3] Of the remaining 40 percent, 30 percent was attributable to the sale of agricultural products and 10 percent was attributable to the sale of cosmetics.

[4] Acetaminophen is sold separately over the counter under such trademarks as Tylenol Registered TM.

Identification code	Description
PU 366	Darvon with A.S.A.
PU 368	Darvon Compound
PU 369	Darvon Compound-65
PU 377	Darvo-Tran Registered TM
TA 1855	Stero-Darvon Registered TM

The letters ″PU″ in the identification code **[**13]** of a product indicate that the product is sold in capsule, or ″Pulvule Registered TM,″ form. The letters ″TA″ indicate that the product is sold in tablet form. The propoxyphene hydrochloride products listed above are hereinafter referred to collectively as ″Darvon products.″

B. *Propoxyphene Napsylate*

Propoxyphene napsylate, another salt of propoxyphene, is a nonnarcotic analgesic closely related to propoxyphene hydrochloride. Propoxyphene napsylate was discovered by Dr. Verlin C. Stephens, a research chemist of Lilly Research Laboratories. U.S. Patent 3,065,261 (hereinafter the napsylate patent) was issued to petitioner as Dr. Stephens' assignee on November 20, 1962, pursuant to an application filed on December 14, 1960. The napsylate patent, covering the napsylate acid addition salts of propoxyphene, expired on November 20, 1979.

Propoxyphene napsylate and propoxyphene hydrochloride are medically identical as far as pain relief is concerned. However, because the molecular weight of propoxyphene napsylate is greater than that of propoxyphene hydrochloride, a dose of 100 milligrams of propoxyphene napsylate is required to supply an amount of propoxyphene equivalent to that present **[**14]** in 65 milligrams of propoxyphene hydrochloride. Also, whereas propoxyphene hydrochloride is freely soluble in water, propoxyphene napsylate is only slightly soluble in **[*1007]** water. As a result of that difference, the napsylate salt has certain advantages over the hydrochloride salt. First, suspension (i.e., liquid) and tablet formulations of the napsylate salt are more stable than those of the hydrochloride salt. The greater stability of the napsylate salt thus makes it easier to disguise propoxyphene's intensely bitter taste. Second, the napsylate salt does not react with aspirin and, as a result, combinations of aspirin and the napsylate salt do not present the same problems as those that occur in combinations of aspirin and the hydrocholoride salt. [5] Finally, because the napsylate salt is less soluble than the hydrochloride salt, it is not absorbed into the bloodstream as quickly as the hydrochloride salt, which results in less stomach irritation than that occurring in some patients using the hydrochloride salt and which allows more time for emergency measures in overdose situations.

Petitioner obtained its first FDA approval to market a propoxyphene napsylate product in the United States on September 9, 1971. Petitioner sold its propoxyphene napsylate products under the trademarks Darvocet-N Registered TM and Darvon-N, which were registered by petitioner on January 1, 1973, and February 6, 1973, respectively.

During the years 1971 through 1973, petitioner sold the following products containing propoxyphene napsylate as their principal active ingredient:

Identification code	Description
TA 1883	Darvon-N
TA 1884	Darvon-N with A.S.A.
MS 135	Darvon-N Suspension
TA 1890	Darvocet-N 50

The letters ″MS″ in the identification code indicate that the product is sold in the form of a liquid suspension. The propoxyphene napsylate products listed above are hereinafter referred to collectively as ″Darvon-N products.″

C. *Success of Darvon and Darvon-N Products*

Darvon and Darvon-N products were the most often prescribed **[*1008]** ethical pharmaceutical products in the United States during the period 1960 through 1973. During each of **[**16]** the years 1958 through 1973, Darvon or Darvon-N products were among the 10 largest selling ethical pharmaceutical products in the United States.

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[5] When propoxyphene hydrochloride is mixed with aspirin (acetylsalicylic acid), the aspirin tends **[**15]** to deteriorate in the presence of moisture into its component parts: acetic acid, which smells like vinegar, and salicylic acid, which is a highly irritating substance.

During the years 1971 through 1973, Darvon and Darvon-N products competed in the market for medications for the relief of mild to moderate pain, and their principal competitors were combinations of codeine with aspirin, acetaminophen, or other peripherally acting analgesics. During the years 1958 through 1972, while the propoxyphene patent was in effect, Darvon and Darvon-N products occupied 100 percent of the propoxyphene market in the United States. In 1973, after the propoxyphene patent expired, Darvon and Darvon-N products occupied approximately 98 percent of the propoxyphene market in the United States.

Petitioner's sales of Darvon and Darvon-N products in the United States during the years 1958 through 1973 were as follows (000's omitted):

Year	Darvon	Darvon-N	Total
1958	$ 6,900	0	$ 6,900
1959	9,700	0	9,700
1960	14,000	0	14,000
1961	19,700	0	19,700
1962	24,800	0	24,800
1963	24,400	0	29,400
1964	36,700	0	36,700
1965	38,800	0	38,800
1966	44,600	0	44,600
1967	50,300	0	50,300
1968	60,400	0	60,400
1969	65,100	0	65,100
1970	69,300	0	69,300
1971	69,800	$ 4,100	73,900
1972	66,500	9,300	75,800
1973	53,400	16,600	70,000

Petitioner's **[**17]** net income before ***taxes*** on U.S. sales of Darvon products for the years 1958 through 1965, based upon petitioner's method of allocating expenses, was as follows (000's omitted): **[*1009]**

Year	Net income before *taxes*
1958	$ 1,600
1959	4,200
1960	5,100
1961	13,000
1962	17,900
1963	22,200
1964	28,200
1965	30,200

Petitioner's and Lilly P.R.'s consolidated net income before ***taxes*** on U.S. sales of Darvon and Darvon-N products (Darvon-N products in 1971 through 1973 only) for the years 1966 through 1973, based upon petitioner's method of allocating expenses, was as follows (000's omitted):

Year	Net income before *taxes*
1966	$ 32,700
1967	37,600
1968	43,700
1969	43,400
1970	47,100
1971	50,500
1972	49,100
1973	40,700

III. *Manufacture of Darvon and Darvon-N Products*

A. *Overview of Petitioner's Manufacturing Operations*

During the 1950's and 1960's, petitioner maintained bulk chemical manufacturing facilities in Indianapolis, Indiana, at which chemical synthesis, antibiotic fermentation, and insulin manufacturing operations were conducted. Pharmaceutical manufacturing operations (i.e., product formulation, encapsulation or tableting, and packaging), were also conducted at the Indianapolis facilities. In 1953, petitioner started an antibiotic **[**18]** fermentation operation at its new Tippecanoe Laboratories facility in West Lafayette, Indiana. Chemical synthesis operations were begun at Tippecanoe Laboratories in 1958.

Because the manufacturing techniques and technology and the training of production personnel in chemical manufacturing are vastly different from those involved in pharmaceutical manufacturing, it is a common industry practice to physically **[*1010]** separate chemical and pharmaceutical manufacturing operations. Chemical synthesis operations involve continuous reactions that cannot be stopped, thereby requiring 24-hour-a-day operations. They also entail water and air pollution problems, the handling of dangerous chemicals, and a substantial demand for utilities such as water and steam. Furthermore, chemical manufacturing operations are capital intensive. In contrast, pharmaceutical manufacturing operations are labor intensive, are conducted in very clean environments, and do not place a great demand on utilities or require 24-hour-a-day operations.

During the years 1971 and 1973, petitioner maintained separate chemical and pharmaceutical manufacturing facilities. Its pharmaceutical manufacturing operations were conducted **[**19]** in its plants on Kentucky Avenue and McCarty Street in Indianapolis, Indiana, and its chemical manufacturing operations for pharmaceutical products were conducted at its plants in West Lafayette and Clinton, Indiana. The Clinton plant became operational in 1971.

B. *Manufacture of Darvon Products*

The manufacture of Darvon products consists of two distinct phases: (a) the chemical manufacturing phase, involving the production of the bulk chemical propoxyphene hydrochloride; and (b) the pharmaceutical manufacturing phase, involving formulating or mixing the bulk chemical with other active and/or inactive ingredients, encapsulating the formulated product or compressing it into tablets, and packaging and labeling the capsules or tablets.

Prior to full-scale commercial production of Darvon products, petitioner developed manufacturing techniques at its chemical and dry products pharmaceutical pilot plants in Indianapolis, Indiana. Petitioner's pilot plants were departments of Lilly Research Laboratories during the years 1955 through 1973.

The functions of petitioner's chemical pilot plant were to scale up the chemical manufacturing processes for new chemicals from laboratory quantities to commercial **[**20]** quantities and to provide materials for clinical trials and toxicological testing. (Clinical trials and toxicological testing, both of which are important in the development and FDA approval of a new **[*1011]** pharmaceutical product, will be discussed later in detail.) When a new chemical is first identified and undergoes its initial testing, only small quantities of the chemical are produced in the laboratory. The new chemical is ***transferred*** to the pilot plant for the development of an economical process for manufacturing the chemical in commercial quantities. The pilot plant development also identifies any special equipment that might be required to perform the process. When the chemical is placed in production at the chemical manufacturing plant, pilot plant personnel ordinarily will participate in the startup of the full-scale manufacturing process.

Upon the completion of pilot plant development of propoxyphene hydrochloride, petitioner in 1957 began full-scale commercial production of propoxyphene hydrochloride at a chemical manufacturing facility in Indianapolis, Indiana. The chemical manufacture of propoxyphene hydrochloride was ***transferred*** from Indianapolis to petitioner's Tippecanoe **[**21]** Laboratories in West Lafayette, Indiana, in 1960. Chemical manufacture of other products had begun at Tippecanoe Laboratories as early as 1958, when petitioner designated that facility as its site for future expansion of chemical manufacturing. Eventually, petitioner closed its Indianapolis chemical manufacturing facility.

From 1960 through 1965, petitioner produced propoxyphene hydrochloride in various buildings at Tippecanoe Laboratories. As a result of its need for additional chemical manufacturing facilities, petitioner, in 1965, constructed a new building (called Building T28) to house the production of propoxyphene hydrochloride, which by then had become a substantial product. Building T28 was constructed at an approximate cost of $ 2 million and occupied 12,000 square feet, excluding warehouse and central services. From January 1, 1966, to December 5, 1966, [6] bulk propoxyphene hydrochloride was produced in Building T28, requiring a total of approximately 20 direct manual and machine operators for all three 8-hour shifts plus numerous support and management personnel.

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[6] Subsequent to Dec. 5, 1966, petitioner manufactured 700 kilograms of propoxyphene hydrochloride pursuant to **[**22]** a license agreement with Lilly P.R., and obtained 2,607.2 kilograms of propoxyphene hydrochloride from recovery, rework, or cleanup of lots of propoxyphene hydrochloride manufactured by petitioner in 1966, prior to its assignment of the propoxyphene and napsylate patents to Lilly P.R.

[*1012] During the years 1957 through 1965, bulk propoxyphene hydrochloride was transported from the chemical manufacturing facility at either Indianapolis or Tippecanoe to petitioner's Kentucky Avenue plant in Indianapolis for use in the pharmaceutical manufacture of Darvon products. During that period, petitioner also manufactured the empty capsules for Darvon products at the Kentucky Avenue plant.

During the period 1957 to December 5, 1966, petitioner manufactured and sold Darvon products only in bottles of 100 and bottles of 500 capsules. The following Darvon products were manufactured and sold by petitioner during that period:

Identification code	Description
PU 364	Darvon 32 mg.
PU 365	Darvon 65 mg.
PU 366	Darvon with A.S.A.
PU 368	Darvon Compound
PU 369	Darvon Compound-65
PU 377	Darvo-Tran

C. *Manufacture of Darvon-N Products*

Darvon-N products were first sold by petitioner in 1971. Petitioner never commercially manufactured **[**23]** bulk propoxyphene napsylate or Darvon-N products in the United States. The Darvon-N products sold by petitioner in 1971, 1972, and 1973 were manufactured solely by Lilly P.R.

D. *Development of Manufacturing Know-How*

1. *Chemical Manufacture*

As stated earlier, petitioner manufactured bulk propoxyphene hydrochloride from 1957 to December 5, 1966. The actual chemical synthesis involved was done in a six -step sequence: (1) Propiophenone, (2) iso butyro phenone derivative base, (3) carbinol derivative crude, (4) dextro carbinol camphor sulfonate, (5) dextro carbinol base, and (6) propoxyphene hydrochloride.

The processes and techniques used by petitioner to manufacture the bulk chemical propoxyphene hydrochloride generally were standard in the pharmaceutical industry. However, over a period of several years, petitioner in the chemical pilot plant of Lilly Research Laboratories and in its chemical manufacturing **[*1013]** plants developed [7] **[**24]** methods of production allowing increased batch size, fewer raw materials, and lower unit costs. As a result of petitioner's efforts, its cost of producing propoxyphene hydrochloride declined from about $ 125 per kilogram in 1957 to about $ 30 per kilogram in 1960.

The basic chemistry underlying each of the chemical reactions involved in the manufacture of propoxyphene hydrochloride is well known in the pharmaceutical industry. A skilled chemist could ascertain the basic chemical reactions involved once he knew the molecular structure of the final product. However, the details of the processes used by petitioner in carrying out those reactions could not be ascertained by analysis of the finished product and is not known outside of petitioner and certain of its subsidiaries.

The processes used by petitioner to manufacture propoxyphene hydrochloride were not discussed in the propoxyphene patent, and, in fact, the patent application was filed in 1952, long before the processes themselves were developed. The propoxyphene patent was not a so-called **[**25]** "process" patent, but rather covered the chemical substances propoxyphene and propoxyphene hydrochloride, which are not produced until the sixth and final step. Petitioner did not attempt to patent the processes it developed to manufacture propoxyphene hydrochloride, which may or may not have been patentable, because process patents disclose the details of the processes they cover and are difficult and costly to enforce. Petitioner, instead, relied upon secrecy to preserve the value of the manufacturing know-how involved in its manufacture of propoxyphene hydrochloride.

Petitioner disclosed its manufacturing know-how to production employees in documents called manufacturing or work tickets, which contained detailed processing instructions. The manufacturing tickets were kept in secure cabinets when not in use by the plan operators, and access to the production areas where the processes were performed was restricted.

The chemical reactions involved in the manufacture of bulk propoxyphene napsylate are precisely the same as those involved in the manufacture of bulk propoxyphene hydrochloride, from the first step through the pro-

[7] The term "developed" as we use it here includes, but is not limited to, the initiation, testing, and modification of the procedures involved.

duction of propoxyphene **[*1014]** base in the final step of the process. **[**26]** The only differences in the manufacture of the two salts are the agents and the manners of acidification of the propoxyphene base used in the last reactions to produce the salts.

The chemical manufacturing processes used in the manufacture of propoxyphene napsylate were developed in the chemical pilot plant of Lilly Research Laboratories during the period 1960 through 1963, soon after the discovery of propoxyphene napsylate. The napsylate patent, like the propoxyphene patent, was not a process patent, but rather covered the chemical substance itself. Accordingly, petitioner relied on secrecy to preserve the value of the manufacturing know-how involved in the manufacture of propoxyphene napsylate.

2. *Pharmaceutical Manufacture*

The last phase in the manufacture of Darvon products is the phase in which the bulk material, propoxyphene hydrochloride, is made into the pharmaceutical product, Darvon (and its various formulations).

Pharmaceutical manufacturing is primarily a mixing operation and rarely involves sophisticated chemical processes. The critical aspect of pharmaceutical manufacturing is the quality control and attention to detail necessary to perform each step accurately so that **[**27]** the final product is precisely what it is intended to be and conforms to the FDA-approved New Drug Application (hereinafter NDA) [8] for that product.

The manufacturing know-how necessary for the pharmaceutical manufacture of Darvon products was developed by petitioner during the years 1957 through 1966. In general, the processes and techniques so used by petitioner during those years were standard in the pharmaceutical industry. During the early 1960's, however, petitioner developed a method allowing it to improve its formulations of Darvon products containing aspirin. In the presence of moisture, propoxyphene hydrochloride causes aspirin to decompose and to form acetic acid and free salicylic acid. The FDA has established limits on the level of free salicylic acid, a highly irritating substance, allowed in products containing aspirin. Moreover, the presence of acetic acid in those products causes them to have the **[*1015]** odor of vinegar. To prevent the decomposition of aspirin, petitioner developed a method whereby the propoxyphene hydrochloride was formed into a coated pellet, called a sphercote, which, when placed in a capsule **[**28]** with aspirin, prevented the interaction of the propoxyphene hydrochloride and the aspirin. Petitioner also developed a mechanical means of inspecting every capsule to insure that every capsule contained one, and only one, pellet of propoxyphene hydrochloride.

The pharmaceutical manufacturing of Darvon-N products is generally the same as that for Darvon products. Their only difference is that Darvon-N products are primarily in tablet, rather than capsule, form.

E. *Foreign Manufacture of Propoxyphene Products*

Propoxyphene products have never been patented in any foreign country. However, since 1963, petitioner and Lilly Industries Ltd. (hereinafter Limited), a wholly owned United Kingdom subsidiary of petitioner, have made available to each other patents, manufacturing know-how, and other scientific and technical data pursuant to a cross license agreement entered into by them on January 1, 1965. In the cross license agreement, petitioner granted to Limited the exclusive license to make, use, and sell petitioner's products in the United Kingdom. Pursuant to that license, Limited manufactured the bulk chemicals propoxyphene hydrochloride and propoxyphene napsylate and sold propoxyphene **[**29]** hydrochloride and propoxyphene napsylate final dosage form products in the United Kingdom through 1973.

IV. *Historical Development of the Puerto Rican Operations of Petitioner and Lilly P.R.*

A. *Puerto Rico's "Operation Bootstrap"*

In the 1940's, an economic development program began in Puerto Rico that later became known as "Operation Bootstrap." At first the program concentrated on land reform, public services, and Government ventures into industry. Later, its emphasis shifted to stimulating private investment. Under the Puerto Rican Industrial Incentive Act of 1954, eligible companies were entitled to a 10-year ***tax*** exemption from **[*1016]** Puerto Rican income ***taxes*** measured from the start of their manufacturing operations in Puerto Rico. In addition, exemptions were provided from certain property ***taxes***, license fees, and excise ***taxes***. A company was eligible for those exemptions if its proposed Puerto Rican operation would manufacture in Puerto Rico a product not manufactured there before January 2, 1947, or if it met other limited criteria.

On June 13, 1963, the Puerto Rican Industrial Incentive Act of 1963 was enacted. The new act retained virtually all of the provisions of the 1954 Act **[**30]** and added a number of new and more liberal provisions. One of the major new provisions provided for exemption periods of longer than 10 years if the Puerto Rican operations were conducted in a less developed area of Puerto Rico.

B. *Petitioner's 1961-62 Study of Possible Puerto Rican Operations*

From approximately June 1, 1961, through June 1, 1962, petitioner studied the possibility of establishing manu-

[8] See pp. 1066-1068 for a definition and discussion of NDAs.

facturing operations in Puerto Rico. Petitioner had, at that time, received numerous visits from representatives of the Economic Development Administration of Puerto Rico attempting to interest petitioner in the economic development of that area. The visits included discussions of the ***tax*** advantages of doing business in Puerto Rico. As a result of those contacts, and in an effort to find out more about the possibilities of operating in Puerto Rico, petitioner designated a three-man team to visit Puerto Rico and to investigate the subject in detail.

During the 1961-62 study, petitioner considered the possible conduct in Puerto Rico of a wide range of manufacturing operations, including the manufacture of bulk chemicals, empty gelatin capsules, and finished capsule products. The study **[**31]** included consideration of the possibility of performing the chemical manufacture of propoxyphene hydrochloride in Puerto Rico.

In January 1962, the project team traveled to Puerto Rico to investigate the establishment of a manufacturing plant there. During that trip, the project team had extensive discussions with the law firm of McConnell, Valdes & Kelley; the accounting firm of Ernst & Ernst; branch banks of First National City Bank and Chase Manhattan Bank, as well as two Puerto Rican **[*1017]** banks, Banco Popular and Banco Ponce; the Economic Development Administration of Puerto Rico; and personnel of the Puerto Rican pharmaceutical manufacturing operations of Parke, Davis & Co. and Baxter Laboratories, Inc.

After returning from Puerto Rico, the project team developed an economic analysis of the proposed Puerto Rican manufacturing operations. In a memorandum dated April 30, 1962, the team recommended that petitioner file an application for a Puerto Rican industrial ***tax*** exemption for the pharmaceutical manufacture of capsule products in general. Although petitioner decided not to proceed with an operation in Puerto Rico at that time, due to the anticipated length of time required to obtain **[**32]** approval of an application for Puerto Rican ***tax*** exemption, it did decide to file an application for such an exemption. Petitioner filed its application for a Puerto Rican industrial ***tax*** exemption on June 20, 1962. The application was broadly drafted to cover the pharmaceutical manufacture of all petitioner's capsule products.

Petitioner's June 20, 1962, application for an industrial ***tax*** exemption was approved and the requested exemption was granted on May 29, 1963. The required commencement date of operations, May 29, 1964, was subsequently extended to May 29, 1965, and later to May 29, 1966.

C. *Petitioner's Second Puerto Rican Study 1965-66*

During 1964, petitioner initiated an exhaustive study project to develop an expansion program to meet adequately its projected 1975 requirements for dry pharmaceutical products. [9] Forecasts were prepared of product needs and the facilities necessary to meet those needs. Several alternatives were developed, including utilizing existing facilities with some additional construction as well as selecting a new plant site for current and future expansion. The presentation of the study to management in February 1965 precipitated a renewed interest **[**33]** in the possibility of Puerto Rico being the site of expanded facilities, although the original study did not contain that suggestion.

[*1018] Petitioner's primary purpose for considering construction of a manufacturing plant in 1965 was to provide additional capacity to meet its projected 1975 production requirements. Petitioner attempted to operate its chemical and pharmaceutical manufacturing facilities at about 80 percent of full capacity. Petitioner traditionally operated its chemical manufacturing facilities three 8-hour shifts per day, five days a week, and its pharmaceutical manufacturing facilities one 8-hour shift per day, five days a week, thereby allowing petitioner to accommodate sudden demands for full capacity resulting from epidemics or the introduction of a new product by working overtime on weekends. In 1964 and 1965, petitioner's chemical and pharmaceutical manufacturing facilities were operating at more than 80 percent of full capacity and were becoming overcrowded.

Petitioner's **[**34]** need for additional manufacturing facilities continued throughout the period 1965 through 1973. As noted previously, Building T28 was built in 1965 at Tippecanoe Laboratories to relieve the overcrowding at that chemical manufacturing facility. Tippecanoe Laboratories again was expanded after 1965 to accommodate the ***transfer*** of chemical manufacturing operations to that facility from Indianapolis. In 1969, petitioner began construction of a new chemical manufacturing facility on a 684-acre site at Clinton, Indiana, which facility became operational in 1971. Petitioner's Kentucky Avenue facility, where all its pharmaceutical manufacturing operations for dry products were located, was especially overcrowded and the extent to which it could be expanded was limited. Therefore in 1973, petitioner began construction of a new manufacturing facility on a 160-acre site adjacent to its existing Kentucky Avenue facility.

Petitioner elected to locate the needed manufacturing operations in Puerto Rico for a variety of reasons. One reason for that decision was petitioner's desire to obtain the ***tax*** benefits provided by the Puerto Rican Industrial Incentive Act of 1963 and *section 931*. In addition, **[**35]** the establishment of manufacturing operations in

[9] The term ″dry pharmaceutical products″ refers to tablets and filled capsules which are taken orally as contrasted with other pharmaceutical products such as syringes, liquids, ointments, and injectable medications.

Puerto Rico would geographically disperse petitioner's manufacturing facilities, which in 1965 were concentrated in Indianapolis and nearby communities in Indiana. During the 1960's, petitioner was concerned that its concentrated manufacturing facilities were overly exposed to **[*1019]** the risks of natural and man-made (i.e., nuclear) disasters. The concentration of all capsule and dry products pharmaceutical manufacturing operations at the Kentucky Avenue plant in Indianapolis was of special concern. A disaster at that location would have severely affected petitioner's ability to supply products to a substantial market segment. The possibility of such a disaster became apparent in April 1965, when a tornado caused great damage to an area just north of Indianapolis.

Finally, the establishment of manufacturing operations in Puerto Rico would allow petitioner to isolate the manufacture of a major product in a separate facility, thereby eliminating the possibility of cross-contamination problems.

From February 1965 to August 1966, petitioner conducted a second study specifically focusing on the development of Puerto Rican manufacturing operations. **[**36]** In March 1965, petitioner appointed a special project team to gather and evaluate information on the establishment and operation of a Puerto Rican manufacturing plant. The project team recognized that there were some disadvantages associated with a Puerto Rican operation. Puerto Rico's distance from the continental United States would create coordination and logistical problems in moving products to the market. There was concern with respect to the availability of a qualified labor force and the extent of training and development of employees that would be required. The team was also aware of the possibilities that natural disaster, political unrest, or labor strife would close the shipping lanes to Puerto Rico. Furthermore, a Puerto Rican operation would create additional governmental reporting requirements with their associated administrative expenses.

In view of the business objectives and the perceived disadvantages of operating in Puerto Rico, the project team recommended that a small number of large volume products should be selected for the Puerto Rican operation. Accordingly, the project team selected for further study Darvon and Ilosone Registered TM products, petitioner's **[**37]** largest volume dry products at that time.

The initial proposal considered by the project team in 1965 was an updated version of the proposal considered by petitioner in 1962. That proposal contemplated the establishment of a facility in Puerto Rico to manufacture empty capsules and **[*1020]** perform the pharmaceutical manufacture of all petitioner's Darvon and Ilosone capsule products for sale to petitioner. Under that proposal, the Puerto Rican operation would purchase its bulk chemicals from petitioner.

One of the significant problems the project team faced was the issue of intercompany ***pricing*** under *section 482*. In 1965, the Internal Revenue Service (hereinafter the Service) had not issued, in either proposed or final form, detailed regulations under *section 482* relating to the sale of goods between related parties. The project team for the 1962 study had also recognized the existence of the *section 482* issue. Essentially, the only guidance available to the 1962 project team was the statutory language of *section 482*, although it hoped that representatives of the Puerto Rican and U.S. Government would issue a set of ground rules relative to intercompany ***pricing*** prior to any actual decision **[**38]** to construct facilities in Puerto Rico. Subsequent to the conclusion of the 1962 study and prior to the inception of the second study in 1965, the Service issued Technical Information Release 441, later reprinted as *Revenue Procedure 63-10*, which set forth guidelines for the application of *section 482* to transactions between mainland parents and Puerto Rican affiliated corporations. While the members of the project team in 1965 were familiar with the revenue procedure, they found that it did not eliminate all the uncertainty with respect to intercompany ***pricing***.

On or about March 30, 1965, shortly after its formation, the project team obtained the assistance of petitioner's outside ***tax*** counsel, the law firm of Baker McKenzie & Hightower, and the accounting firm, Ernst & Ernst. In April 1965, at the suggestion of the outside ***tax*** counsel, the project team considered two variations of the initial proposal. First, the team considered the possible sale of the products manufactured in Puerto Rico direct to unrelated wholesalers in the United States rather than to petitioner for resale to such wholesalers. Second, the project team considered the possible manufacture of bulk chemicals **[**39]** in Puerto Rico by the Puerto Rican operation rather than in Indiana by petitioner. The two variations of the original proposal gave the project team the following four alternatives to analyze:

[*1021] (a) Chemical manufacture in Indiana, pharmaceutical manufacture in Puerto Rico, and sales to petitioner (i.e., the original proposal);

(b) Chemical manufacture in Indiana, pharmaceutical manufacture in Puerto Rico, and sales direct to wholesalers;

(c) Chemical and pharmaceutical manufacture in Puerto Rico and sales to petitioner; and

(d) Chemical and pharmaceutical manufacture in Puerto Rico and sales direct to wholesalers.

For the purpose of analyzing these alternatives, the team assumed that the Puerto Rican operation would be a wholly owned subsidiary corporation, and that it would manufacture Darvon products only.

Members of the project team discussed the four alterna-

tives with petitioner's outside ***tax*** counsel. Alternatives (c) and (d) were viewed as the most desirable because the Puerto Rican corporation would be using the propoxyphene patent in its chemical manufacturing operations, and the patent thus could be ***transferred*** to it in a nonrecognition ***transfer*** under section 351. Because the **[**40]** Puerto Rican corporation would own the patent, the outside ***tax*** counsel opined that it would be deemed to have earned the income attributable to the patent. Also, because the Puerto Rican corporation would own the patent and would manufacture the basic chemicals, the issue of the appropriate intercompany ***prices*** for bulk chemicals sold by petitioner to the Puerto Rican corporation would be eliminated. Furthermore, the ***transfer*** of the patent and chemical process to Puerto Rico would effect a complete separation of the manufacturing and marketing functions with respect to Darvon products, thus petitioner would be performing a pure marketing function and an appropriate ***transfer price*** from Puerto Rico could be determined by reference to third-party evidence of the value of that marketing function.

In comparing alternatives (c) and (d), the project team recognized that both involved the ***transfer*** of the propoxyphene patent to a corporation operating outside the United States. The team did not consider that a disadvantage, however, because the patent: (1) Would be owned by a wholly owned subsidiary corporation; (2) would be physically in the United States; (3) could be recovered by collapsing **[**41]** the subsidiary and merging it into petitioner; and (4) would not be subject to **[*1022]** expropriation. Although alternative (d) (sales direct to wholesalers) would enable the Puerto Rican operation to earn the larger amount of net income and would provide the greater number of arm's-length dealings with petitioner, the fact that wholesalers would have to deal with a second organization (the Puerto Rican operation) whenever they ordered, received, and paid for products manufactured in Puerto Rico was considered a major disadvantage and caused the project team to reject that alternative.

At a special meeting of petitioner's board of directors on May 5, 1965, the project team presented its proposal to establish facilities in Puerto Rico for the manufacture of chemicals and empty capsules and the pharmaceutical manufacture of capsule products. After discussion, the board approved the following resolutions:

Resolved, That the establishment by Eli Lilly and Company (or a subsidiary or subsidiaries thereof) in the Commonwealth of Puerto Rico of facilities for the manufacture of chemicals and capsules and the filling and finishing of Pulvules Registered TM with an investment of up to approximately **[**42]** six and one-half million dollars ($ 6,500,000), be, and it is hereby, approved in principle.

Further Resolves, That the proper officers of the Company be, and they hereby are, authorized for and on behalf of the Company:

a. to make such investigations, formulate such plans and to make such commitments as they may deem necessary to expedite the establishment of such facilities.

b. to negotiate, with the Commonwealth of Puerto Rico, its agencies, subdivisions or municipalities in order to obtain necessary authorizations and a grant or grants of ***tax*** exemption pursuant to the Industrial Incentive Act of 1963, and to execute any and all documents that in their opinion may be necessary or proper for such purposes.

c. to enter into lease(s) of facilities for use in the manufacture of products for a term not exceeding three (3) years.

d. to execute option(s) to purchase real estate in the Commonwealth of Puerto Rico.

Further Resolved, That nothing contained in the foregoing resolutions shall be deemed to authorize or approve the appropriation of funds for capital expenditures.

Shortly after the special board of directors meeting on May 5, 1965, representatives of petitioner traveled to Puerto Rico **[**43]** to investigate possible sites for the construction of manufacturing facilities there. At that time, petitioner planned first to establish pharmaceutical manufacturing operations in a **[*1023]** leased facility in order to gain experience in operating a Puerto Rican plant and to begin taking advantage of the potential ***tax*** savings. Petitioner next intended to establish empty capsule manufacturing and pharmaceutical manufacturing on a permanent site owned by the Puerto Rican operation. To those ends, during May 1965, petitioner selected leased facilities in Hato Rey, Puerto Rico, and a permanent plant site in Carolina, Puerto Rico. Petitioner tentatively planned as its third step to establish chemical manufacturing facilities in a permanent site owned by the Puerto Rican operation; however, no definite decision was made to ***transfer*** all or part of the chemical manufacture of Darvon, or the propoxyphene patent, to the Puerto Rican operation at that time.

On May 25, 1965, members of the project team met with petitioner's outside ***tax*** advisers and discussed three aspects of the Puerto Rican operation: corporate structure, financial structure, and intercompany ***pricing***. At that meeting, it was decided **[**44]** that the Puerto Rican operation would be conducted through a new, wholly owned Indiana subsidiary of petitioner that would qualify as a possessions corporation under section 931. It was also decided that the subsidiary corporation would be sufficiently capitalized so that it could borrow funds to maintain its operations until it was in full production without the necessity of a guarantee from petitioner. Although the issue of intercompany ***pricing*** was discussed extensively at that meeting, final intercompany ***pricing*** decisions were deferred until a decision was made

with respect to the extent of the chemical manufacturing operations that would be conducted by the subsidiary.

Petitioner organized Lilly P.R. on June 9, 1965, as a wholly owned subsidiary corporation. On August 3, 1965, members of the project team and other employees of petitioner met to discuss the scope of Lilly P.R.'s chemical manufacturing operations and the related intercompany ***pricing*** issues. At that meeting it was informally decided that at least the last step in the propoxyphene hydrochloride manufacturing process (step 6 (propoxyphene hydrochloride)) and the propoxyphene patent should be ***transferred*** to Puerto **[**45]** Rico. There was still a question, however, with respect to whether step 1 **[*1024]** (propiophenone), and to a lesser extent steps 2 through 5, should be ***transferred*** to Puerto Rico.

At a meeting on August 19, 1965, members of the project team and other employees of petitioner concluded that the entire chemical manufacturing process for propoxyphene hydrochloride should be ***transferred*** to Puerto Rico. That decision enabled the participants at the meeting to reach final decisions with respect to the ***transfer pricing*** of Lilly P.R.'s products. The participants decided that the Darvon products sold by Lilly P.R. to petitioner should be ***priced*** on a basis that would permit petitioner to recover its selling and distribution expenses plus a profit of 90 to 100 percent of those expenses, which was achieved by discounting petitioner's net wholesale ***prices*** for Darvon products by approximately 27.5 to 35 percent. The participants also decided that Lilly P.R. and petitioner should enter into a sales contract that would be reviewed periodically and would provide for rebates from Lilly P.R. to petitioner for sales of Darvon products by petitioner to the U.S. Government.

Petitioner's project team considered **[**46]** the profit margins of other companies selling finished pharmaceuticals in an attempt to determine an appropriate ***transfer price*** for Lilly P.R.'s products. The project team ideally was looking for a company that purchased finished pharmaceutical products from unrelated manufacturers and marketed such products to unrelated customers. The only company performing those functions that petitioner could identify was Marion Laboratories, Inc. The prospectus of that company indicated that its operating income expressed as a percentage of its operating expenses ranged from 5 to 53 percent for the years 1961 through 1965. The project team also examined the operating income to operating expense ratios of petitioner's international affiliates, which purchased finished pharmaceutical products and sold those products to unrelated customers. The ratios for those affiliates ranged from 65 percent to 108 percent during the years 1961 through 1964. [10] Based on that information, the project team concluded that petitioner should earn operating income on its sales of Darvon products purchased **[*1025]** from Lilly P.R. equal to 90 to 100 percent of its operating expenses related to the marketing of Darvon **[**47]** products.

The project team recognized that, under its three-step plan for commencing manufacturing operations in Puerto Rico, [11] Lilly P.R. would not begin full manufacturing operations in Puerto Rico immediately, and petitioner would have to sell propoxyphene hydrochloride and other raw materials to Lilly P.R. while its permanent facilities were being constructed. Therefore, the team decided that Lilly P.R. should pay petitioner a ***price*** equal to petitioner's standard cost of manufacture, plus 100 percent. The 100-percent markup was chosen to provide petitioner the same markup over costs as it would receive for its marketing functions.

The project team also recognized that petitioner would be providing technical assistance to Lilly P.R. during the transition period while Lilly P.R.'s operations were being established. In June 1965, petitioner had established new procedures for the regular reporting of time spent by petitioner's personnel on Lilly P.R. projects and travel to Puerto Rico on behalf of Lilly P.R., so that the costs of those activities could be charged to Lilly P.R. At the meeting on August 19, 1965, the project team concluded that Lilly P.R. and petitioner should execute a technical assistance agreement pursuant to which Lilly P.R. would reimburse petitioner for its direct costs of providing such assistance.

V. *Lilly P.R.'s Puerto Rican* ***Tax*** Exemptions

As stated previously with respect to petitioner's first Puerto Rican study, an industrial ***tax*** exemption was granted by the Commonwealth of Puerto Rico to petitioner on May 29, 1963, covering the pharmaceutical manufacture of capsule products. The ***tax*** exemption grant was ***transferred*** from petitioner to Lilly P.R. effective as of December 14, 1965. The period of that exemption was **[**49]** 10 years, commencing on April 1, 1966.

[*1026] The May 1963 ***tax*** exemption grant was the first of six such grants under which Lilly P.R. conducted manufacturing operations in Puerto Rico during the years 1966 through 1973. The second industrial ***tax*** exemption, covering the manufacture of empty capsules, was

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[10] The expenses and operating profits, as published, for the four export subsidiaries involved were adjusted by petitioner to better relate intercompany administrative fees to the appropriate sales income. The percentages stated above utilized the adjusted operating figures.

[11] As stated earlier, that plan involved (1) the commencement of pharmaceutical manufacturing operations in a leased facility; (2) the establishment of empty capsule manufacturing and pharmaceutical manufacturing in a permanent facility owned by Lilly P.R.; and (3) the establishment **[**48]** of chemical manufacturing on a permanent site, also to be owned by Lilly P.R.

granted to petitioner on August 5, 1965, pursuant to an application filed by petitioner on May 13, 1965. That exemption grant was ***transferred*** from petitioner to Lilly P.R. effective as of December 24, 1965. The period of the exemption was 10 years, commencing on January 1, 1968.

A Puerto Rican industrial ***tax*** exemption covering the chemical manufacture of propoxyphene hydrochloride and certain other chemicals was granted to Lilly P.R. on October 14, 1966, pursuant to an application filed by Lilly P.R. on March 15, 1966. The period of that exemption was 12 years, commencing on January 1, 1967.

A Puerto Rican industrial ***tax*** exemption covering the pharmaceutical manufacture of tablet products was granted to Lilly P.R. on October 17, 1969, pursuant to an application filed by Lilly P.R. on August 15, 1968. The period of the exemption was 10 years, commencing on June 1, 1969. On March 5, 1973, **[**50]** the exemption was amended to include the production of plastic bottles and containers.

A Puerto Rican ***tax*** exemption covering the pharmaceutical manufacture of liquid products (i.e., suspensions) was granted to Lilly P.R. on September 17, 1969, pursuant to an application filed by Lilly P.R. on August 15, 1968. The period of that exemption was 10 years, commencing on February 1, 1970.

A Puerto Rican industrial ***tax*** exemption covering the chemical manufacture of propoxyphene napsylate and other salts of propoxyphene was granted to Lilly P.R. on October 17, 1969, pursuant to an application filed by Lilly P.R. on August 16, 1968. The period of that exemption was 15 years, commencing on January 1, 1970.

In accordance with the terms of the six Puerto Rican industrial ***tax*** exemption grants mentioned above, Lilly P.R. during the years 1966 through 1973 was exempt from Puerto Rican income ***tax*** on its qualified income (i.e., income from manufacturing activities), municipal, and commonwealth ***taxes*** on real and personal property, license fees, and excise and other municipal ***taxes***. Lilly P.R.'s qualified income included **[*1027]** all income generated by sales of Darvon and Darvon-N products to petitioner.

VI. **[**51]** *Background and Documents Concerning Lilly P.R.*

A. *Organization of Lilly P.R. and Initial Capitalization*

As stated earlier, Lilly P.R. was organized under Indiana law as a wholly owned subsidiary of petitioner on June 9, 1965. Pursuant to the authorization of petitioner's executive committee, Lilly P.R. was initially capitalized with an investment of $ 1,000 on June 11, 1965, at which time 1,000 shares of Lilly P.R. common stock with no par value were issued to petitioner. By the end of 1965, petitioner had contributed a total of $ 500,000 cash to the capital of Lilly P.R.

In 1965, Lilly P.R. negotiated a $ 4.5 million line of credit with the San Juan branch of the Chase Manhattan Bank. Petitioner did not assist Lilly P.R. in those negotiations, nor did it guarantee repayment of any amounts loaned to Lilly P.R. under the line of credit. The purpose of the line of credit was to finance the operations of Lilly P.R. until it commenced the manufacture and sale of products to petitioner. During the years 1965 and 1966, Lilly P.R. borrowed from the Chase Manhattan Bank an aggregate amount of $ 1,650,000. Lilly P.R. repaid the loans in full by July 1966.

B. *Technical Assistance Agreement*

On **[**52]** April 8, 1966, petitioner and Lilly P.R. executed an agreement entitled "Technical Assistance Agreement," which was effective from January 1, 1966, to December 31, 1975. The execution of that agreement was ratified by Lilly P.R.'s board of directors on April 28, 1966.

In article II of the agreement, petitioner stated that it would, so far as practicable without unreasonable interference with its own business:

make available [its] scientists, engineers, technicians, research experts, industrial designers and other technical personnel, including if necessary supervisory personnel, for the purpose of providing to [Lilly P.R.] training for its employees and other technical assistance and advice in connection with the manufacture of [Lilly P.R.] products, including the design, construction and operation of factories and other installations, and the installation, operation, and maintenance of the equipment therein.

[*1028] Article II further provided that petitioner would make its manufacturing facilities available to Lilly P.R. for the training of Lilly P.R. personnel. For the purposes of that agreement, Lilly P.R. products included all products manufactured by Lilly P.R., or which it had a right **[**53]** to manufacture, whether or not manufactured by Lilly P.R. in 1966.

Under article III of the agreement, Lilly P.R. obligated itself to pay petitioner the sum of: (a) The cost to petitioner attributable to the services of its personnel rendering technical assistance to Lilly P.R. in accordance with article II of the agreement, other than engineering services; (b) a technical assistance fee equal to 5 percent of the cost described in (a); and (c) petitioner's standard charge for engineering services performed on behalf of Lilly P.R.

C. *Private Letter Ruling*

On April 7, 1966, petitioner applied to the Service for a ruling that petitioner's proposed assignment to Lilly

P.R., as a contribution to capital, of the patents and manufacturing know-how related to propoxyphene and certain other products would qualify for nonrecognition treatment under *section 351*. The ruling application stated that, because of the current and anticipated demand for certain of its products, petitioner had found it necessary to expand its manufacturing facilities, and that its present plans were to establish full-scale manufacturing facilities in Puerto Rico for Darvon, Darvon-N, and other products. The ruling application **[**54]** notified the Service that during the construction of Lilly P.R.'s permanent manufacturing facilities, Lilly P.R. would purchase its requirements for bulk chemicals from petitioner, but that after such facilities were in operation, Lilly P.R. would manufacture the basic chemicals in Puerto Rico and would no longer purchase such chemicals from petitioner. The ruling application also advised the Service that Lilly P.R. would sell essentially all its finished products to petitioner. Attached to the ruling application were a form of agreement providing for the ***transfer*** of the patents and manufacturing know-how from petitioner to Lilly P.R. and a copy of the technical assistance agreement between petitioner and Lilly P.R.

In a letter dated July 20, 1966, petitioner supplied additional information to the Service with respect to its *section 351* **[*1029]** ruling request and requested a ruling on the source of the income that would be generated by Lilly P.R.'s sales to customers in the United States. In that letter, petitioner described the business reasons for the ***transfer*** of patent rights and manufacturing know-how as follows:

The fundamental business reasons for the ***transfer*** of Eli Lilly Patent Rights **[**55]** and Eli Lilly Technology to [Lilly P.R.] is that [petitioner] has decided to vest in [Lilly P.R.] the complete responsibility for the manufacture of the subject products. Since [Lilly P.R.] will have the complete responsibility for manufacturing the subject products it should have the complete right to do so under the Eli Lilly Patent Rights and Eli Lilly Technology. Thus, the business substance which motivates the ***transfer*** of rights to [Lilly P.R.] is the fact that these rights will be used exclusively by [Lilly P.R.].

In addition, as mentioned in the request for ruling, the formation of [Lilly P.R.] and the location of manufacturing facilities in Puerto Rico was prompted by [petitioner's] need for additional manufacturing facilities. It should be noted that [petitioner] currently has under active consideration further expansion of its manufacturing facilities in other areas in the United States. The ***transfer*** of complete responsibility for the manufacture of the subject products to [Lilly P.R.] will not in any way result in a reduction in the facilities now employed by [petitioner] in the United States. The [Lilly P.R.] facilities will clearly be an expansion of the manufacturing **[**56]** facilities now available to manufacture [petitioner's] products. In this sense, the business motivation was clearly to provide additional manufacturing facilities for [petitioner's] products.

As support for the source of income ruling request, petitioner submitted with that letter the proposed terms of sale for Lilly P.R. sales to petitioner and other U.S. customers.

By a letter dated September 16, 1966, petitioner submitted additional information to the Service regarding the issue of whether the secret processes to be ***transferred*** to Lilly P.R. constituted property within the meaning of *section 351*. Attached to that letter was a memorandum prepared by petitioner's technical personnel which described in detail the secret processes to be ***transferred*** to Lilly P.R.

On December 5, 1966, the Service issued the following private letter ruling to petitioner:

This is in reply to a request for ruling with respect to the Federal income ***tax*** consequences of a proposed transaction. Information was submitted in letters dated April 7, July 20, and September 16, 1966. The pertinent facts may be summarized as set forth below.

[*1030] Eli Lilly and Company (″Lilly″), account number 35-0470950, is an Indiana **[**57]** corporation engaged in the manufacture and sale of pharmaceuticals and related products and agricultural and industrial chemical products.

Due to current and anticipated demand for certain of its drugs, Lilly finds it necessary to establish a plant in Puerto Rico to expand the manufacturing capability for these products. The operation in Puerto Rico will be conducted by Eli Lilly and Company, Inc. (″P.R.″), account number 66-0262012, as a wholly owned subsidiary of Lilly. For its contribution of $ 500,000, Lilly was issued 1,000 shares of no par value common stock of P.R. Additional capital for the purchase of land and the construction of plants will be raised by P.R. by borrowing on its own credit.

P.R. will manufacture Darvon, [12] Dymelor, Valmid and Ultran, which are the trademarks for four of the products presently manufactured and sold in the United States by Lilly. A ten-year ***tax*** exemption has been granted in Puerto Rico for the pharmaceutical formulation of two of these products and application will be made for such exemption for the other two drugs.

Lilly proposes to ***transfer*** to P.R. as a contribution to capital all right, title and interest in and to U.S. Patents

[12] The Service and petitioner both use ″Darvon″ to include Darvon and Darvon-N products.

2,728,779, **[**58]** 2,812,363 and 3,065,261 [13] and U.S. patent application 25,209 (relating to Darvon, Dymelor, Ultran and Valmid). In addition Lilly will grant and assign to P.R. the exclusive and perpetual right to use the existing technical information and manufacturing secrets and processes relating to the manufacture and formulation of these products. By these ***transfers***, Lilly will convey to P.R. the exclusive right to make, use and sell under the patents and technical information and to license others to use such patents and technical information upon terms and conditions as P.R. may decide.

The patents to be ***transferred***, except for Ultran, reveal the chemical reactions employed but do not disclose certain steps or the processes utilized in their manufacture in commercial quantities. These processes, which could generally be patented, are maintained as a secret by Lilly and cannot be learned by an analysis of the finished product. They relate to such aspects of manufacture as the solvent employed, the temperature and time duration of certain steps, the use of dangerous reagents in large quantities, the substitution of less expensive chemicals, and methods of recovering certain costly chemicals **[**59]** from the process. The processes employed in the manufacture of Ultran are completely embodied in its patent.

Lilly will ***transfer*** to P.R. the technical reports on the processes. However, the manufacture of certain of the products is so complex that Lilly does not believe that a written description will be sufficient to accomplish the desired results. Lilly has therefore ***transferred*** to P.R., as a full-time employee, the head of one of its chemical manufacturing plants who was involved as a trouble shooter in these processes. In addition, Lilly has entered into an agreement with P.R. on April 8, 1966, under which Lilly will assist P.R. in the establishment of manufacturing facilities in Puerto Rico and render technical assistance, to the extent requested, in connection with the manufacture of the products. P.R. will reimburse Lilly for all costs incurred **[*1031]** plus five percent and will pay for engineering services on the basis of Lilly's standard charges for such services.

P.R. will manufacture the products in Puerto Rico. Other than what may be sold in Puerto Rico to related and unrelated parties, the products will be sold to Lilly in Puerto Rico for trans-shipment to the United States **[**60]** and resale by Lilly in the ordinary course of its business. The sales by P.R. will be in accordance with a statement of conditions of sale which accompanied the request for ruling and is incorporated in this ruling letter by reference.

Lilly does not intend to cause P.R. to sell or license any of the patent rights or technology to third parties. Lilly intends to operate P.R. as a subsidiary and has no intention of selling or otherwise disposing of the stock of P.R.

Based solely on the information submitted, it is held as follows:

(1) No gain or loss will be recognized to Lilly upon the ***transfer*** to P.R. as a contribution to capital of all substantial rights to the patents, patent application, secret processes and technology relating to the manufacture of Darvon, Dymelor, Ultran and Valmid (*section 351*).

(2) The basis of the stock of P.R. in the hands of Lilly will include the adjusted basis of the property ***transferred*** (section 358(a)(1)).

(3) Based on the assumption that P.R. will be established and operated in accordance with the above representations, and that the sale of its products will be made in the manner indicated, the gross income realized by P.R. from the manufacture and sale **[**61]** of pharmaceutical products to Lilly and other United States purchasers will constitute gross income from sources within a possession of the United States within the meaning of *section 931(a)(1)* of the Code.

No opinion is expressed as to the possible application of *section 482* in the event it is subsequently determined that the amounts to be paid by P.R. for the technical assistance to be provided by Lilly does not represent adequate consideration for such assistance or as to whether part of the stock of P.R. was, in fact, received by Lilly for such assistance.

No opinion is expressed as to the ***tax*** treatment of the transaction under the provisions of any of the other sections of the Code and Regulations which may also be applicable thereto or to the ***tax*** treatment of any conditions existing at the time of, or effects resulting from, the transaction which are not specifically covered by the above rulings.

A copy of this ruling should be attached to the Federal income ***tax*** returns of the taxpayers involved for the taxable year in which the transaction is consummated.

D. *Assignment of Patents and Manufacturing Know-How*

On December 5, 1966, in accordance with the private letter ruling issued to petitioner on that date, petitioner and Lilly P.R. entered into an agreement entitled ″Assignment of Patents and Related Technical Data.″ That agreement provided as follows:

This Agreement, made the 5th day of December, 1966, by and between ELI LILLY AND COMPANY, a corpora-

[13] Patent 3,065,261 is the napsylate patent, **[**62]** not the patent relating to Ultran Registered TM

tion organized and existing under **[*1032]** and by virtue of the laws of the State of Indiana, with offices at 740 South Alabama Street, Indianapolis, Indiana (hereinafter referred to as ″ELI LILLY″), and ELI LILLY AND COMPANY, INC., a corporation organized and existing under and by virtue of the laws of the State of Indiana, with offices at 301 East McCarty Street, Indianapolis, Indiana (hereinafter referred to as ″P.R.″),

Witnesseth:

Whereas, ELI LILLY is engaged in the business of manufacturing and selling pharmaceutical and biological products, and

Whereas, ELI LILLY in the course of its operations in the United States has acquired certain technical data, consisting principally of reports, drawings, specifications, blueprints, written descriptions of manufacturing **[**63]** processes, and production information with respect to the manufacture of its Darvon Registered TM product line and related product lines, including combinations, and

Whereas, ELI LILLY has obtained two United States patents relating to its Darvon Registered TM product line, and

Whereas, ELI LILLY is willing to grant P.R. the exclusive right to use such technical data in conjunction with an assignment of such patents, and

Whereas, P.R. has been formed to conduct the manufacture of the Darvon Registered TM line of products for sale in the United States market, and

Whereas, P.R. desires to acquire said patents and technical data from ELI LILLY as a contribution to its share capital:

Now Therefore

In consideration of the mutual promises and covenants herein contained, the receipt and sufficiency of which are hereby acknowledged, it is understood and agreed by and between the parties as follows:

Article I

ELI LILLY hereby assigns to P.R. all right, title and interest in and to U.S. Patents 2,728,779 [the propoxyphene patent] and 3,065,261 [the napsylate patent]. By such grant, ELI LILLY conveys to P.R. the exclusive right to make, use and sell under said patents for their full lives and any extensions **[**64]** or renewals thereof, and to license others to use the same upon such terms and conditions as P.R. may decide. ELI LILLY agrees to execute any documents and authorizations which may be legally required to enable the use of said patents by P.R.

Article II

Eli Lilly hereby assigns and grants to P.R. the exclusive and perpetual right to use and to license others to use the existing technical information and manufacturing secrets and processes of Eli Lilly relating to the manufacturing and formulation of its Darvon Registered TM product line within the United States and Puerto Rico. By said grant Eli Lilly conveys to P.R. the exclusive and perpetual rights to make, use and sell under said technical data and to license others to use the said technical data upon such terms and conditions as P.R. may decide.

Article III

In consideration for the rights, titles and interests set forth in Articles I and II above, P.R. agrees to receive said patents and related technical data as additional consideration for P.R.'s stock which has already been issued to Eli **[*1033]** Lilly and to reflect in its corporate records said patents and technical data as contributions to share capital provided by Eli Lilly.

In Witness **[**65]** Whereof, the parties hereto have caused this Agreement to be signed and sealed by their duly authorized officers at the places and on the dates set forth below.

Eli Lilly and Company

By: (S) Burton E. Beck

Executive Vice President

Signed and sealed at

Indianapolis, Indiana

this 5th day of December, 1966.

(S) C. H. Bradley, Jr.

Attest

Eli Lilly and Company, Inc.

By: (S) W. B. Fortune

Chairman of the Board of Directors

Signed and sealed at

Indianapolis, Indiana

this 5th day of December, 1966.

(S) Walter C. Taylor, Jr.

Attest

The December 1966 Assignment of Patents and Related Technical Data contained the same terms as the form of assignment attached to petitioner's ruling request dated

April 7, 1966. On December 19, 1966, petitioner's board of directors ratified the assignment to Lilly P.R., as a contribution to capital, of the propoxyphene patent, the napsylate patent, and the related manufacturing know-how. On the same date, Lilly P.R.'s board of directors ratified the acceptance of that assignment. The Assignment of Patents and Related Technical Data was recorded in the U.S. Patent Office on February 14, 1969.

In December 1966, immediately after the execution of the Assignment of Patent Rights **[**66]** and Related Technical Data, petitioner ceased performance of step 6 of the propoxyphene hydrochloride manufacturing process. During the phase-in of Lilly P.R.'s chemical manufacturing facility in 1967, petitioner continued to produce dextro carbinol base (steps 1 through 5) **[*1034]** for sale to Lilly P.R. Petitioner did not perform any of the steps in the production of propoxyphene hydrochloride after 1967.

E. *Distribution Agreements*

In accordance with the decisions made in 1965 and 1966 by petitioner's project team that the distribution of Lilly P.R.'s products would be made through petitioner's U.S. marketing organization, petitioner and Lilly P.R. entered into a ″Distribution Agreement,″ effective as of January 1, 1966. In that agreement, Lilly P.R. appointed petitioner its nonexclusive distributor for the sale of Darvon products throughout the world. The distribution agreement provided that: (a) Petitioner would purchase all its requirements for Darvon products from Lilly P.R. and would promote those products through its marketing organization; (b) Lilly P.R.'s selling ***price*** to petitioner for each of the Darvon products was equal to petitioner's net wholesale ***price*** [14] for such product **[**67]** less a 35 -percent discount; (c) petitioner was entitled to charge back to Lilly P.R. (i.e., receive rebates from Lilly P.R.) 25 percent of the net wholesale ***prices*** of Darvon products sold by petitioner to U.S. Government agencies or exported by petitioner from the United States; (d) petitioner would make payments to Lilly P.R. within 180 days after the dates of Lilly P.R.'s invoices; (e) Lilly P.R. would supply reasonable quantities of Darvon products to petitioner at no charge for use by petitioner as samples; and (f) the agreement was for a term of 5 years, cancelable by either party upon 90 days' notice. The provisions of the distribution agreement regarding the place of sale and passage of title of the products were the same as the terms of sale submitted to the Service as support for petitioner's source of income ruling request in its letter to the Service dated July 20, 1966.

As of January 1, **[**68]** 1971, petitioner and Lilly P.R. entered into a new ″Distribution Agreement,″ which superseded the 1966 distribution agreement. The terms and conditions of the 1971 agreement were the same as in the 1966 agreement, except that it provided that: (a) Lilly P.R.'s selling ***prices*** to petitioner for Darvon products were equal to petitioner's net wholesale **[*1035]** ***prices*** less 45 percent; and (b) petitioner was entitled to chargebacks on Government and export sales of 15 percent of petitioner's net wholesale ***prices***.

During the years 1971 through 1973, petitioner and Lilly P.R. executed 9 amendments to the 1971 distribution agreement. In general, those amendments added new products (e.g., Darvon-N) to be sold by Lilly P.R. to petitioner, modified the selling ***prices*** of products sold by Lilly P.R. to petitioner, [15] and provided that, effective January 1, 1973, Lilly P.R. would supply petitioner with Darvon and Darvon-N products for use as samples at Lilly P.R.'s cost. The selling ***prices*** as applicable to the years before us will be discussed at length in a later portion of our findings.

F. *Joint Research Agreement*

Although the technical assistance agreement between petitioner **[**69]** and Lilly P.R. was sufficiently broad to cover research and development activities performed by petitioner for Lilly P.R., petitioner's research and development expenses related to propoxyphene products were not billed to Lilly P.R. pursuant to that agreement. In 1968, petitioner determined that those research and development expenses should be charged to Lilly P.R., so it entered into an agreement with Lilly P.R. entitled ″Joint Research Agreement.″ The agreement was retroactively effective to January 1, 1967, and had a term of 7 years ending on December 31, 1973.

In pertinent part, the joint research agreement, provided as follows:

ARTICLE I.

RESEARCH COMMITMENTS

Section 1.1. [Petitioner] hereby agrees to undertake projects on behalf of [Lilly P.R.] and to arrange for clinical trials and all related activities in connection with the development and testing of the pharmaceutical and biological products.

Section 1.2. [Petitioner] agrees to undertake research, development and related activities under this Agreement only to the extent that --

(a) [Petitioner's] facilities and personnel permit, without interfering with [petitioner's] own research and devel-

---

[14] ″Net wholesale price″ refers to petitioner's price to drug wholesalers for a particular product. During the years 1965 through 1973, net wholesale prices were determined by discounting petitioner's ″net trade prices,″ which were its suggested prices to retail pharmacies, by 17 percent.

[15] See also pp. 1074-1076.

opment progress, the undertaking **[**70]** of **[*1036]** such activities without requiring any significant capital expenditures for alteration of [petitioner's] existing research and development facilities;

(b) [Petitioner] has complete control over the scheduling of any such activities within its research and development facilities;

(c) [Petitioner] does not become liable or responsible for the results of any such research and development activities.

ARTICLE II

CONSIDERATIONS

Section 2.1. The parties agree that [Lilly P.R.] shall have the exclusive and perpetual right to use any of the data developed by [petitioner] under the terms of this Agreement (including any items of a patentable nature and any patents which may issue thereon) within the United States and the Commonwealth of Puerto Rico and that [petitioner] will have the exclusive and perpetual right to use any of the data developed under the terms of this Agreement (including any items of a patentable nature and any patents which may issue thereon) in all areas of the world outside of the United States and the Commonwealth of Puerto Rico.

Section 2.2. [Lilly P.R.] agrees to pay [petitioner] the cost of any research, development and clinical trials undertaken by [petitioner] at the **[**71]** request of [Lilly P.R.] under this Agreement.

Section 2.3. The cost of the research, development, and clinical trials undertaken by [petitioner] for [Lilly P.R.] shall be determined for the purpose of this Agreement in accordance with accounting practices which are consistent with sound accounting principles generally accepted in the United States. Without in any way limiting the foregoing, it is understood that such ″research expenses″ shall include the following expenses:

2.31. Salaries and wages of all employees working full time on such activities.

2.32. The cost of employee benefits pertaining to such employees.

2.33. Research grants.

2.34. The fees of research consultants.

2.35. The costs of biochemical analyses, chemical analyses, clinical expense, and all veterinary testing relating to such activities.

2.36. Cost of chemicals, accessories, glassware, and other supplies used directly in such activities.

2.37. Legal and other expenses spent in connection with obtaining and maintaining patents covered by this contract or in connection with patent interference proceedings related thereto.

2.38. Communication and travel costs, including stationery, postage, cable, phone, and travel expenses **[**72]** of [petitioner's] personnel when such expenditures are in connection with [petitioner's] research, development, and clinical trials for [Lilly P.R.].

2.39. Depreciation or amortization of capital items used in such activities.

2.391. Any other expenses of occupancy and general administration appropriately attributable to such activities.

[*1037] Section 2.4. [Petitioner] will submit to [Lilly P.R.] twice annually its statement of expenses incurred under the terms of this Agreement, and [Lilly P.R.] agrees to make payment thereof in United States dollars within thirty (30) days after receipt of each such statement.

G. *Agreements Regarding Empty Capsules*

In a license agreement dated January 1, 1968, petitioner granted Lilly P.R. a nonexclusive license to make, use, and sell empty capsules covered by two U.S. patents owned by petitioner. Under that license, Lilly P.R. was obligated to pay petitioner a royalty of 5 cents per 1,000 commercially acceptable empty capsules manufactured by Lilly P.R. and covered by either of the two patents. The agreement provided that it would terminate upon the expiration of both of the licensed patents or 30 days after either party gave written notice of termination **[**73]** to the other party.

During the years 1970 through 1973, petitioner and Lilly P.R. entered into three agreements pursuant to which Lilly P.R. manufactured and sold empty capsules to petitioner.

VII. *Lilly P.R.'s Manufacturing Activities*

A. *Temporary Leased Facility*

In May 1965, and pursuant to the May 5, 1965, resolution of petitioner's board of directors approving the establishment of manufacturing operations in Puerto Rico, petitioner entered into a lease with Valencia Realty Corp. for 67,000 square feet of floor space on two floors in a new five-story building located in the Valencia section of San Juan, Puerto Rico. Petitioner's interest in that lease was assigned to Lilly P.R. in June 1965.

On August 5, 1965, a contract was executed between Lilly P.R. and a Puerto Rican construction company calling for the modification of the leased premises to accommodate the pharmaceutical manufacture of Lilly P.R.'s

products. The first floor of the leased facility was used for office and warehouse space. The fifth floor was used to perform the pharmaceutical manufacture of Lilly P.R.'s products. In addition, Lilly P.R. installed air-conditioning, dehumidification, dust-collection, and power equipment **[**74]** on the roof of the facility.

Pharmaceutical manufacturing operations became completely operational at the Valencia facility in January 1966. **[*1038]** Prior to that time, pilot runs were made at that facility to test equipment and to train personnel.

During 1966, the pharmaceutical manufacture of Darvon products was performed both by Lilly P.R. in Puerto Rico and by petitioner in Indiana. By the end of 1966, petitioner had discontinued all pharmaceutical manufacturing operations for Darvon products with the exception of certain sample packaging operations. During the years 1967 through 1973, the entire pharmaceutical manufacturing process for Darvon and Darvon-N products was performed by Lilly P.R., except for certain sample packaging and, during the years 1968 through 1973, Identidose Registered TM [16] packaging of Darvon and Darvon-N products, which was performed or contracted by petitioner.

The Valencia site was designed to serve as a temporary facility while permanent facilities were under construction.

B. *Carolina Facility*

In May 1965, petitioner entered into an agreement **[**75]** to purchase approximately 13 acres of land in an industrial park in Carolina, Puerto Rico, to be used as the site for Lilly P.R.'s permanent pharmaceutical manufacturing facilities. At a meeting on December 14, 1965, Lilly P.R.'s board of directors approved the acceptance of the assignment of that purchase agreement from petitioner.

In June 1965, Lilly P.R. entered into an agreement with a Puerto Rican architectural firm for the performance of architectural and engineering work in connection with the design and development of the Carolina plant. Construction of the Carolina facility started on September 1, 1966.

The manufacture of empty capsules was begun at the Carolina facility in October 1967. The period between October 1, 1967, and January 1, 1968, was a shakedown period but some marketable products were produced. As of January 1, 1968, Lilly P.R.'s investment in capsule manufacturing machinery and equipment was $ 1,499,739. At the time that empty capsule production was begun, approximately 92,000 square feet of the Carolina facility were completed, consisting of the common service building (the powerhouse), the warehouse, and the empty capsule manufacturing department.

[*1039] Pharmaceutical **[**76]** manufacturing operations were completely operational at the Carolina facility by May 15, 1968. At that time, the facility occupied approximately 175,000 square feet, divided functionally as follows:

	Square feet
Common services	19,000
Warehouse	40,000
Empty capsule manufacturing department	33,000
Office building	17,000
Capsule filling	50,000
Capsule finishing	16,000
Total	175,000

As of June 1, 1968, the total investment in pharmaceutical manufacturing operations at Carolina was $ 2,468,462, of which $ 568,327 represented direct production equipment and $ 1,900,135 represented supportive equipment. As of June 1, 1968, the total cost of the Carolina facility was $ 8,917,499, of which $ 531,276 was invested in land, $ 5,037,098 in buildings, and $ 3,349,125 in machinery and equipment. An additional $ 619,075 of machinery and equipment ***transferred*** from the Valencia operation was also used at the Carolina facility.

C. *Mayaguez Facility*

At a meeting on January 20, 1966, Lilly P.R.'s board of directors authorized the officers of that company to select a plant site in Puerto Rico for Lilly P.R.'s chemical manufacturing facility and to develop plans and cost estimates for that facility. After the meeting, **[**77]** Lilly P.R.'s officers began looking for sites for the proposed chemical manufacturing plant with the assistance of the Puerto Rican government. After negotiations with more than one government agency, Lilly P.R. obtained the necessary government approvals to build a plant at a site in Mayaguez, Puerto Rico, at the western end of the island. In June 1966, Lilly P.R. purchased a 25-acre site in Mayaguez.

[16] "Identi-dose" was petitioner's trademarked name for its individual dosage from packages of Darvon and Darvon-N products.

Construction of the Mayaguez facility was started in August 1966, pursuant to contracts between Lilly P.R. and a Puerto Rican construction firm. The construction of the Mayaguez plant was completed in October 1967.

The performance of step 6 (propoxyphene hydrochloride) in the production of bulk propoxyphene hydrochloride was started **[*1040]** at Lilly P.R.'s Mayaquez facility in December 1966, subsequent to the execution on December 5, 1966, of the Assignment of Patents and Related Technical Data. Lilly P.R. began production of step 1 in August 1967, step 2 in September 1967, and steps 3, 4, and 5 in October 1967.

In December 1966, when production of step 6 began, the Mayaquez facility occupied approximately 14,340 square feet as follows:

	Square feet
Building 1, office building	3,840
Building 2, warehouse	7,000
Building 3, manufacturing	3,500
Total	14,340

Upon **[**78]** completion of the Mayaguez facility in October 1967, the following additional structures were utilized in the manufacturing operation:

	Square feet
Building 4, sewage plant	1,600
Building 5, fire pump house	900
Building 6, major manufacturing building	24,000
Building 7, warehouse	10,000
Tank farm consisting of eighteen 12,000 gallon tanks	30,000
Total	66,500

The total amount invested in the Mayaguez chemical facility as of October 1, 1967, was $ 6,192,257, of which $ 302,316 was invested in land, $ 2,708,028 in buildings, and $ 3,181,913 in machinery and equipment. During the years 1969 through 1973, the manufacturing capacity of both the Mayaguez and Carolina facilities of Lilly P.R. was substantially expanded. Construction of additional facilities for the manufacture of propoxyphene napsylate at Lilly P.R.'s Mayaguez facility began in 1969 and was completed in 1970 at a total cost of approximately $ 1 million. As of December 31, 1973, Lilly P.R.'s total investment in physical facilities was $ 26,404,782, of which $ 978,756 was invested in land, $ 13,945,669 in buildings, and $ 11,480,357 in machinery and equipment.

D. *Personnel*

1. *Organization of Initial Work Force*

The initial management of Lilly **[**79]** P.R. consisted of five former employees of petitioner who moved to Puerto Rico to become **[*1041]** permanent employees of Lilly P.R. One of the principal assignments of that management team was to train the Puerto Rican work force of Lilly P.R. and to develop Puerto Rican employees capable of taking over the management of Lilly P.R.

Soon after the management team arrived in Puerto Rico, it began the process of interviewing and employing Puerto Ricans to staff the temporary facility at Valencia. The team worked closely with the Puerto Rican Employment Service, a government agency which screened all applications to determine which applicants were best qualified to meet the job descriptions supplied by Lilly P.R., and performed background checks and applicant health examinations. By January 1966, Lilly P.R. employed 56 Puerto Ricans; by January 1968, Lilly P.R. employed over 400 Puerto Ricans. The hiring of those employees was accomplished without petitioner's assistance. When Lilly P.R.'s pharmaceutical manufacturing operations were ***transferred*** from Valencia to Carolina in 1968, all the employees at the Valencia facility moved to the Carolina facility.

2. *Training of Employees*

At the beginning **[**80]** of Lilly P.R.'s operations in Valencia, small teams of petitioner's employees traveled to Puerto Rico, at the request of Lilly P.R., for 2 or 3 weeks at a time to assist in the training of the employees at that facility. The teams were small, less than 10 in number, because Lilly P.R.'s management team was experienced in production, and because Lilly P.R. rapidly developed a group of Puerto Rican employees who were capable of assisting in the training function.

The training of the work force at Lilly P.R.'s Mayaguez facility required more assistance from petitioner because the chemical manufacturing process for propoxyphene hydrochloride was complicated and dangerous, and because employees in the Mayaguez area generally were less fluent in English than those in the San Juan area. Consequently, 12 to 14 of petitioner's chemical manufacturing employees were residents in Mayaguez for a period of from 6 to 12 months to train Lilly P.R.'s Puerto Rican chemical manufacturing operators.

In 1968, because the work force at the Valencia facility had over 2 years' experience in the pharmaceutical manufacture of **[*1042]** Lilly P.R.'s products, and because the entire work force moved from Valencia to the **[**81]** Carolina facility in that year, Lilly P.R. did not require any great amount of assistance from petitioner in training its employees at the Carolina facility.

3. *Board of Directors, Officers, and Management Committees*

During the years 1965 through 1973, Lilly P.R.'s board of directors consisted of from 9 to 11 individuals. Throughout that period, two of the directors were management employees, the general manager and treasurer, of Lilly P.R. living in Puerto Rico. The remaining members of Lilly P.R.'s board of directors were officers and/or employees of petitioner.

During the years 1965 through 1973, Lilly P.R. had an executive committee, which had 5 members through 1972 and 6 members in 1973. During the years 1971 through 1973, Lilly P.R. also had the following committees: operations, salary, budget, safety and housekeeping, and benefits and retirement.

During the years 1971 through 1973, Lilly P.R.'s general manager had authority to approve capital expenditures of less than $ 1,000; the operations committee had authority to approve capital expenditures of less than $ 5,000; the executive committee had authority to approve capital expenditures of less than $ 25,000; Lilly P.R.'s board **[**82]** of directors had the authority to approve capital expenditures of between $ 25,000 and $ 50,000; and proposed capital expenditures in excess of $ 50,000 were submitted for approval to petitioner's executive committee or board of directors. The division of authority for the approval of capital expenditures was the same as that followed by every other domestic and foreign subsidiary of petitioner.

4. *1971-73 Lilly P.R. Personnel*

During the years 1971, 1972, and 1973, Lilly P.R. had a total of 608, 612, and 651 employees, respectively. During that period, all employees below the management level were Puerto Rican.

During the years 1971, 1972, and 1973, Lilly P.R. had 22, 25, and 23 management employees, respectively. In 1971, 15 of those management employees were Puerto Ricans.

E. *Manufacturing Activities 1971-73*

1. *Production Planning*

[*1043] The planning and scheduling of Lilly P.R.'s manufacturing operations were conducted in Puerto Rico by employees of Lilly P.R. without the assistance of petitioner. Lilly P.R.'s production planning process involved the scheduling of raw material purchases and the scheduling of production on a day-to-day basis consistent with Lilly P.R.'s policy of keeping **[**83]** a stable and fully occupied work force.

Petitioner's finished stock planning department in Indianapolis provided Lilly P.R. with annual projections of the quantities of each package size of each product that petitioner would purchase from Lilly P.R. during the coming year. [17]

From the annual projections, Lilly P.R.'s production planning group at the Carolina facility prepared production schedules for the pharmaceutical manufacture of the finished products to be sold to petitioner, and determined the quantities of propoxyphene hydrochloride and propoxyphene napsylate necessary to manufacture those products. Based upon the production schedule, the empty capsule manufacturing manager produced a schedule for the manufacture of empty capsules. Also, materials-purchasing personnel determined whether and when to purchase raw materials for the empty capsule manufacturing operation based upon inventory levels of materials on hand.

The projections of annual requirements for propoxyphene hydrochloride and **[**84]** propoxyphene napsylate prepared at Carolina were sent to the Mayaguez facility and used as the starting point for its production planning. Personnel at Mayaguez determined the quantities of intermediate chemicals necessary to produce the final chemicals and projected the amount of basic raw materials needed during the year. The purchasing department of Mayaguez issued purchase orders throughout the year based upon the projected requirements for raw materials.

2. *Chemical Manufacturing at Mayaguez*

During the years 1971 through 1973, propoxyphene hydrochloride and propoxyphene napsylate were manufac-

[17] Petitioner's projected product needs were updated on a monthly basis and, if sales were moving faster than anticipated, changes in product needs were communicated to Lilly P.R. by telephone.

tured in bulk form at Lilly P.R.'s Mayaguez facility and transported to Lilly P.R.'s Carolina facility for use in the pharmaceutical **[*1044]** manufacture of Darvon and Darvon-N products. The chemical manufacturing processes at the Mayaguez facility involved numerous continuous reactions, and as a result, that facility was generally operated 24 hours per day, 5 days per week. The manufacturing activities at Mayaguez were conducted according to a campaigning program. For example, a 2-week campaign might have been conducted to build up stock of propiophenone (step 1) which was then used during a **[**85]** subsequent 2-week campaign to produce iso butyro phenone derivative (step 2).

Each of the steps in the manufacturing process was covered by a separate manufacturing ticket (manufacturing tickets are defined in section F under this heading, *infra*), and generally was performed independently of the other steps. Although each step took only 1 to 3 days to complete, in the normal sequence of operations at Mayaguez, an entire series of campaigns from the beginning (step 1) to the end (step 6) took approximately 60 to 90 days to complete.

The chemical manufacturing processes performed by Lilly P.R. at the Mayaguez facility were complicated. Each of the 6 steps in the production of propoxyphene hydrochloride and propoxyphene napsylate was in itself a multistep process requiring the utilization of approximately 28 reaction tanks and the services of approximately 35 operators, working on a three-shift basis. The processes involved the use of highly corrosive and flammable chemicals, and as a result, Lilly P.R.'s operators wore acid goggles, air line respirators, and rubber gloves while handling those chemicals. Most of the chemical reactions involved in the processes had to be performed within **[**86]** narrow ranges of variables such as temperature and quantity. For example, if too little heat was applied to the reaction of propionic anhydride and dextro carbinol base in the final step of producing propoxyphene hydrochloride, some of the dextro carbinol base would remain in the propoxyphene base as a contaminant. If too much heat was applied to that reaction, the propoxyphene base was decomposed. The operators were required to exercise judgment during the manufacturing processes, such as using a sight glass to determine whether separations of solutions had been made. Operators also were required to perform temperature and pH tests during the processes.

[*1045] Lilly P.R.'s operators involved in the manufacturing processes at Mayaguez were all at least high school graduates. As a result of the complexity of the manufacturing processes, it generally took an operator 1 year to learn the skills necessary to perform properly all the procedures involved in only one of the 6 steps. It was not necessary, however, for each operator to be familiar with every step in order for the processes to function properly.

The intermediate chemicals produced at Mayaguez in steps 1 through 4 were analyzed **[**87]** in the plant laboratory and subjected to as many as 8 quality control tests. Steps 5 and 6 were performed as one continuous process, during which samples were taken to the laboratory for analysis. The final product, propoxyphene hydrochloride or propoxyphene napsylate, was subjected to 28 quality control tests lasting a period of 2 days. After satisfactory completion of the quality control tests, the finished product was shipped to the Carolina facility in accordance with that facility's request for bulk chemicals.

3. *Pharmaceutical Manufacturing at Carolina*

During 1971, 1972, and 1973, Lilly P.R.'s Carolina facility was engaged in the pharmaceutical manufacture of Darvon and Darvon-N products. Its manufacturing operations were divided into the manufacture of empty capsules, the formulation and encapsulation or tableting of the mixed material, [18] and the packaging and labeling of the finished products.

Lilly P.R.'s empty capsule manufacturing department operated 24 hours a day, 7 days a week, and employed approximately 65 to 80 people. The manufacturing process involved the **[**88]** mixture of gelatin melts, using protocols (similar to manufacturing tickets, see pages 1046-1048) prepared and issued by Lilly P.R., and the actual production of the empty capsules on the capsule manufacturing machines. The empty capsules were tested throughout the manufacturing process to ensure the absence of physical defects and bacteria. The capsules passing those tests were stored for later use in Lilly P.R.'s pharmaceutical manufacturing operations.

The pharmaceutical manufacture of capsule products at Carolina entailed mixing the raw chemical materials and **[*1046]** filling the empty capsules with the mixed, or formulated, materials. For the manufacture of tablet products, the dry chemical ingredients were mixed with a lubricant, compressed by machine into tablets, and coated with a colored material. The products were periodically tested and analyzed for physical defects, weight, and the amount of active ingredients.

The finished capsules and tablets were moved to the finishing department, where they were counted and filled into plastic bottles, 10 bottles at a time. The bottles were capped, labeled, and packaged in corrugated boxes for shipment to Indianapolis.

The entire pharmaceutical **[**89]** manufacturing process for capsule products normally took approximately 1 month per lot. The filling operation, alone, took approxi-

[18] The Carolina facility also manufactured one small volume propoxyphene liquid product, Darvon-N Suspension.

mately 10 days per lot on a two-shift operation. Approximately 150 to 175 employees were involved in the production process, although at any one time, as few as 15 people might have been working on a particular lot. The pharmaceutical manufacture of tablet products, because of the additional steps of mixing the ingredients with liquids and coating, required approximately 1 1/2 to 2 months per lot to complete.

F. *Manufacturing Tickets and Related Procedures*

A manufacturing ticket is a document listing the step-by-step procedures for manufacturing one lot of a specific pharmaceutical product. A separate manufacturing ticket was issued by petitioner for each lot of each chemical intermediary and final bulk chemical product manufactured by Lilly P.R. at its Mayaguez facility and for each finished product manufactured at its Carolina facility. The manufacturing tickets, in essence, were oversized recipes listing the names and quantities of all of the ingredients to be used in the manufacturing process, the step-by-step actions required to combine them in perfect **[**90]** order, and the specifications for the final product produced under the manufacturing ticket. They specified the checks and audits to be carried out by production workers and by quality control personnel, as well as the tests to be conducted at critical points by laboratory scientists. Manufacturing tickets for chemical manufacturing processes also indicated temperatures, pressures, and reaction times for the chemical reactions covered by those manufacturing tickets.

[*1047] The manufacturing tickets were numbered to correspond with given lots of the product and were initialed by the operators of Lilly P.R. responsible for each step in the various manufacturing processes so that any problem that arose with respect to a lot could be traced back to the operators involved. FDA regulations required the use of documents such as manufacturing tickets to provide control and accountability in the manufacture of pharmaceutical products. The manufacturing ticket procedures used by petitioner and Lilly P.R. satisfied that FDA requirement, although manufacturing tickets were used by petitioner even before such documents were required by the FDA.

During the years 1966 through 1973, the manufacturing tickets **[**91]** used by Lilly P.R. in its manufacturing processes were issued to Lilly P.R. by petitioner's ticket issuance department in Indianapolis, Indiana. The ticket issuance department was the custodian of the master formula for each product manufactured by petitioner and Lilly P.R. The ticket issuance department produced duplicates of the master formulas using a large [19] copying machine pursuant to instructions from petitioner's finished stock planning department that tickets were needed by Lilly P.R.'s Carolina facility or upon receiving requests for tickets from Lilly P.R.'s Mayaguez facility. The ticket issuance department assigned the lot number to each manufacturing ticket and produced tags or stickers called manufacturing tags which bore the lot number and were to be placed on containers to identify raw and work-in-process materials to that lot. The manufacturing tags, required by FDA regulations, were sent to Lilly P.R. along with the manufacturing tickets for the lot. After the manufacturing tickets were used by Lilly P.R. in its chemical and pharmaceutical manufacturing processes, they were returned to petitioner's ticket issuance department in Indianapolis for microfilming **[**92]** and storage.

The manufacturing tickets used by Lilly P.R. for the production of Darvon products were essentially the same as those developed by petitioner prior to 1967 for use in its manufacture of those products. The manufacturing tickets for Darvon-N products were developed jointly by petitioner and **[*1048]** Lilly P.R. The master manufacturing tickets for Darvon and Darvon-N products were modified from time to time, based upon recommendations by employees of Lilly P.R. Generally, those modifications were made to remedy a problem or implement improved manufacturing procedures developed by Lilly P.R.

During the years 1971 through 1973, Lilly P.R. personnel recommended approximately 55 modifications of the manufacturing tickets for Darvon and Darvon-N products, 2 of which were the subject of a supplemental NDA. (See pages 1067-1068.) All the manufacturing ticket modifications recommended were adopted, even though there were some comments by petitioner that resulted in further testing by Lilly P.R. prior to their adoption.

In addition to the manufacturing tickets, Lilly P.R., during the years in issue, **[**93]** used master packaging orders issued by petitioner's ticket issuance department in Indianapolis. Those master packaging orders were used by Lilly P.R.'s Carolina facility to produce the packaging orders it used in the packaging of Darvon and Darvon-N products.

During the years 1971, 1972, and 1973, Lilly P.R. also used numerous written procedures (called protocols) that had been developed by Lilly P.R. to cover manufacturing and other activities that were not covered by manufacturing tickets or packaging orders. For example, the Mayaguez facility of Lilly P.R. developed protocols to cover the reworking of chemicals it produced that did not meet specifications, and the Carolina facility developed standard procedures for the preparation of gelatin solutions. Both the Mayaguez and Carolina facilities developed procedures that covered virtually every aspect of their operations, including administrative and financial functions. In this respect, Lilly P.R. had the use of numer-

[19] The master formula and manufacturing ticket for a product were often as long as 15 feet.

ous manuals prepared by petitioner in its manufacturing and other operations.

G. *Raw Material Purchases*

During the years 1968 through 1973, Lilly P.R.'s chemical and pharmaceutical manufacturing activities respectively **[**94]** required the use of approximately 35 and 140 different raw materials. Lilly P.R.'s established policy was to purchase most of its raw materials from unrelated suppliers located in Puerto **[*1049]** Rico; to purchase raw materials from unrelated suppliers located outside of Puerto Rico if Puerto Rican suppliers could not be located; and to purchase raw materials from petitioner only in rush situations, when it had trouble locating or obtaining materials from another source, or when petitioner was the only source. Lilly P.R.'s purchases of raw materials from third-party suppliers accounted for 80 percent, 81 percent, and 87 percent of its total raw material purchases in dollars for 1971, 1972, and 1973, respectively. The remainder of Lilly P.R.'s purchases of raw materials in those years were from petitioner. Among the purchases of materials from petitioner were all labels and literature used by Lilly P.R. for its Darvon and Darvon-N products.

Although petitioner provided Lilly P.R. with a list of suppliers of raw materials, Lilly P.R. was not required to purchase only from the suppliers on the list. During the years in issue, Lilly P.R. selected and evaluated its suppliers of raw materials **[**95]** without petitioner's assistance.

H. *Equipment Purchases*

During the years 1965 through 1973, Lilly P.R. purchased equipment and machine parts either directly from third party suppliers or through petitioner. The procedures for those purchases are discussed in detail at pages 1099-1100.

Although equipment purchases by Lilly P.R. in excess of $ 50,000 were submitted to petitioner's executive committee or board of directors for approval, none of Lilly P.R.'s requests for authorization to purchase equipment was rejected during the years 1965 through 1973.

I. *Technical Assistance*

During the years 1971, 1972, and 1973, Lilly P.R. received and paid for certain technical assistance from petitioner under the technical assistance agreement. Such assistance included the following:

a. Installation of new chemical and pharmaceutical manufacturing equipment, and instruction relative to the use of said equipment;

b. Maintenance and repair of chemical and pharmaceutical manufacturing equipment;

c. Managerial assistance relative to industrial health programs;

d. Expert industrial relations assistance;

e. Consultations with personnel relative to Lilly P.R.'s Credit Union;

[*1050] f. Expert assistance relative to the **[**96]** engineering and long term planning of manufacturing operations;

g. Expert assistance and coordination with public officials relative to waste treatment and the environmental impact of facilities;

h. Expert assistance relative to financial organization, payroll accounting and computerization of data;

i. Training in the areas of laboratory testing, accounting and managerial skills;

j. Assistance with problems in quality control laboratory;

k. Review of inventories and assistance in inventory planning;

l. Maintenance of Lilly P.R. aircraft;

m. Supervision of telephone communication system installation; and

n. Assistance in cafeteria and food service operations.

Petitioner provided technical assistance to Lilly P.R. only upon request. Lilly P.R. was free to and did retain unrelated outside consultants and advisers having mechanical, electrical, architectural, accounting, and legal expertise.

J. *Quality Control*

In the normal course of its operations, Lilly P.R. performed all required quality control tests on raw materials and in-process materials without the need for assistance from or coordination with petitioner. With one exception, Lilly P.R. also normally performed all quality control tests **[**97]** on finished products. Lilly P.R.'s Mayaguez facility did not have the capability to perform toxicity tests on the final products, bulk propoxyphene hydrochloride and bulk propoxyphene napsylate. That testing was performed on samples of the products by petitioner's quality assurance department in Indianapolis, Indiana.

While petitioner did not routinely perform quality control tests on materials and products of Lilly P.R., it did perform a limited number of quality control tests at the request of Lilly P.R. For example, if Lilly P.R. encountered problems in performing a particular quality control test, it might have had petitioner perform the same test in or-

der to compare results. The testing performed by petitioner took place in petitioner's quality control laboratories in Lilly Research Laboratories. Lilly P.R. reimbursed petitioner for the cost of the quality control testing performed at its request. In addition, petitioner performed quality control tests on raw materials that it manufactured or purchased for sale to Lilly P.R.

[*1051] During the years in issue, petitioner provided to Lilly P.R. and all its other subsidiaries copies of petitioner's standard procedures for the performance **[**98]** of quality control tests. Lilly P.R., however, developed some of its own procedures for testing raw materials. Also during the years in issue, Lilly P.R. sent copies of its assay reports on the final bulk products propoxyphene hydrochloride and propoxyphene napsylate produced by its Mayaguez facility and on certain raw materials and finished products produced by its Carolina facility to petitioner's quality assurance department in Indianapolis.

K. *Sample and Identi-dose Packaging*

During the years 1966 through 1972, under the terms of the distribution agreement, petitioner received from Lilly P.R. at no charge Darvon and Darvon-N capsules and tablets in bulk which petitioner packaged as samples. Commencing in 1973, petitioner purchased those samples at cost. During the period 1968 through 1973, petitioner purchased from Lilly P.R. at Lilly P.R.'s cost, Darvon and Darvon-N capsules and tablets in bulk which petitioner packaged in Identi-dose packages for resale to wholesalers.

VIII. *Petitioner's Marketing Operations*

A. *Introduction*

The U.S. ethical pharmaceutical industry has three characteristics that distinguish it from other industries. First, the pharmaceutical industry is research **[**99]** intensive. Pharmaceutical companies spend relatively greater amounts on research and development than do companies in many other industries. Second, the pharmaceutical industry is very competitive. Although petitioner has always been a leader in the pharmaceutical industry, its U.S. pharmaceutical sales accounted for only approximately 7 1/2 percent of total pharmaceutical industry sales in the United States during the years 1971 through 1973. Third, the pharmaceutical industry is unique in that promotional efforts for ethical pharmaceutical products are directed to health care professionals such as physicians and dentists, the actual users of the products.

During the years 1971 through 1973, the primary business of petitioner's pharmaceutical division was the sale of ethical pharmaceutical products to wholesale distributors. Unlike **[*1052]** most companies in the pharmaceutical industry, which sell both to wholesalers and direct to certain large accounts, petitioner sold its ethical pharmaceutical products almost exclusively through a network of approximately 400 wholesalers located throughout the United States. The products sold by petitioner in 1971 through 1973 included all those manufactured **[**100]** by Lilly P.R. Petitioner's wholesalers generally paid petitioner's invoices within 30 days, and petitioner rarely had credit problems with its wholesalers.

During the years 1971 through 1973, petitioner's marketing efforts generally involved personal contacts by petitioner's sales representatives (called detail men) with physicians, dentists, hospitals, pharmacists, and wholesalers. In addition, petitioner's marketing operations included supportive promotional activities such as the distribution of printed literature by sales representatives, direct mail advertising, operation of exhibits at medical conventions and schools, and journal advertising.

B. *Organization*

During the years 1971 through 1973, petitioner's pharmaceutical marketing operations in the United States were organized into two functions: the ″inside″ function of marketing research and planning and the ″outside″ function of the sales force calling on health care professionals.

1. *Marketing Research and Marketing Planning*

During the years 1971, 1972, and 1973, petitioner employed approximately 160 individuals in marketing administration at its Indianapolis headquarters. Those individuals were engaged in marketing research, **[**101]** marketing planning, and certain staff functions for petitioner's U.S. pharmaceutical marketing operations. The function of petitioner's marketing research was to study the historical and present conditions in the U.S. pharmaceutical market and to make judgments about the future marketing activities of both petitioner and its competitors. This was done primarily by reviewing statistical data gathered by independent information services. The function of marketing planning was to develop specific strategies for the promotion of petitioner's products based upon the information produced by petitioner's marketing research. The marketing planning function also involved the preparation of printed **[*1053]** advertising materials to be distributed by sales representatives, by direct mail, in medical journals, and at medical conventions.

Petitioner's inside marketing function employed individuals possessing university or graduate degrees, usually in scientific areas such as pharmacy. The majority of petitioner's inside marketing personnel had experience as sales representatives.

2. *Sales Force*

Petitioner's marketing philosophy emphasized the interpersonal interaction between the sales representative

[102]** and the health care professionals. Consequently, petitioner's marketing efforts were concentrated around the activities of its sales representatives. During the years 1971 through 1973, petitioner employed approximately 1,000 sales representatives throughout the United States. Those sales representatives were distributed geographically based upon petitioner's assessment of the market potential for its products in various areas of the country as well as on the distribution of the physician population within the country.

The principal function of petitioner's sales representatives was the presentation of scientific information to health care professionals about the nature and appropriate use of petitioner's pharmaceutical products. Health care professionals are a very select and well-informed group, are highly trained in their fields, and are capable of making discriminating judgments about pharmaceutical products. As a result of the scientific nature of petitioner's pharmaceutical products, and the qualifications of the audience to which petitioner's promotional efforts were directed, petitioner's sales representatives had to have scientific training. Each of petitioner's sales **[**103]** representatives was a college graduate, 80 percent were pharmacists, and the remainder generally had degrees in one of the life sciences. Approximately 6 percent of petitioner's sales representatives had masters degrees.

The process of calling on physicians and other health care professionals is relatively standardized in the pharmaceutical industry. The physician audience for each product is defined, and a regular schedule of periodic visits with the physicians in that audience is developed. Because physicians have a limited amount of time to meet with sales representatives of pharmaceutical **[*1054]** companies, the usual visit of a sales representative with a physician occupies only 5 to 10 minutes. The frequency of such visits ranges from approximately 4 times a year to as many as 10 or 12 times a year. Due to the limited time involved in a call on a physician, the sales representative has to have a well-developed message with respect to the products he is discussing, including both the benefits of the products and their potential side effects. Generally, a sales representative visits a physician with the primary objective of discussing one particular product (called a primary detail). **[**104]** The sales representative also might spend a limited amount of time during the same visit on another product (called a secondary detail).

During the years in issue, petitioner's sales representatives made calls on physicians, interns, and residents in their offices or in hospitals; pharmacists in drug stores and in hospitals; the nonphysician staffs of hospitals, such as hospital administrators, nurses, and laboratory technicians; dentists; industrial clinics and nursing homes; and pharmacy, dental, medical, and nursing schools. The contacts with students in those schools were made to acquaint them with petitioner's name and products, and were informational rather than sales oriented. Petitioner's sales force was considered one of the most effective sales forces in the pharmaceutical industry in the United States.

Approximately 200 of petitioner's 1,000 sales representatives concentrated their knowledge and sales efforts in certain areas of medical specialty in order to become familiar with the special interests, problems, needs, and language of those areas of medicine. Those medical specialities included surgery, internal medicine, pediatrics, and urology. The ″specialty″ sales **[**105]** representatives were responsible for contacting physicians, residents, pharmacists, and paramedical staffs in large multidepartment hospitals, major metropolitan areas, and other places with high concentrations of specialized medical practices.

During 1972, petitioner formed a second sales force in addition to its 1,000 man regular sales force. The new sales force, called Dista, consisted of approximately 150 sales representatives and was formed to market products directed to primary care physicians, that is, general practitioners, family **[*1055]** practitioners, and other physicians working in office-based, non-hospital environments. The management personnel for the Dista sales force came from petitioner's existing sales force. The Dista sales representatives primarily were new employees hired by petitioner, although some Dista sales positions were filled by existing sales representatives of petitioner. The educational background of the Dista sales force was similar to the educational background of petitioner's regular sales force.

C. *Regulation of Promotional Claims*

During the years in issue, the FDA placed specific constraints on the content of promotional claims for ethical pharmaceutical **[**106]** products. When an NDA was approved by the FDA, the FDA and the manufacturer agreed on the content of a document called a ″package insert,″ which accompanied each package of the product sold by the manufacturer. The package insert was a very comprehensive document that described, in scientific terms, the chemical composition of the drug, its medical actions, its indications (i.e., the medical conditions for which it was to be used), and its contraindications (i.e., the medical conditions for which the drug should not be used). The insert also provided information with respect to administration and dosage, the dangers of using the drug, precautions that should be taken by the physician, adverse reactions, interactions with other drugs, and the treatment of overdose situations. The claims for the drug as set forth in the package insert had to be demonstrated to the satisfaction of the FDA on the basis of clinical studies performed with the drug. Federal law prohibited the promotion of a drug for uses other than those included in the package insert.

In addition, pharmaceutical manufacturers submitted to the FDA copies of all promotional materials for clear-

ance prior to use. After **[**107]** the drug was on the market, the FDA periodically reviewed all promotional materials. Package inserts could be amended from time to time to add new uses for the drug established by clinical studies or to add additional warnings and information with respect to adverse reactions. The package inserts used by petitioner were developed by the medical and scientific personnel of petitioner's Lilly Research Laboratories.

[*1056] D. *Marketing of Darvon and Darvon-N Products*

By 1971, Darvon products had been sold for 13 years and were well established in the market place as leading analgesic drugs. During the years 1971 through 1973, petitioner introduced Darvon-N products. Darvon and Darvon-N products together were the most frequently prescribed ethical pharmaceutical products in the United States during the years 1960 through 1973.

During the years 1971 through 1973, Darvon and Darvon-N products were petitioner's largest selling product line and as such received a major share of petitioner's marketing attention and efforts. Physicians at that time knew what Darvon products were and how they fit into their practices of medicine. Consequently, petitioner's marketing efforts for Darvon products during **[**108]** those years were in the nature of advising physicians of new developments concerning Darvon products and attempting to expand their uses of those products. As Darvon-N products had been introduced only recently, petitioner concentrated its marketing efforts for propoxyphene products during the years 1971 through 1973 upon Darvon-N in order to inform physicians and other health care professionals of that new product line.

Petitioner's marketing efforts for Darvon and Darvon-N products were directed principally to primary care physicians, that is, physicians who treat patients initially as opposed to specialists to whom patients are referred. However, almost all physicians were candidates for the promotion of analgesic drugs because of the broad incidence of pain resulting from many types of illnesses and injuries. Consequently, petitioner's target audience for Darvon and Darvon-N products was very broad. Petitioner promoted Darvon and Darvon-N products primarily through its regular sales representatives rather than through its specialty sales representatives or Dista sales force.

E. ***Pricing*** *of Darvon and Darvon-N Products*

Petitioner's ***prices*** to wholesalers for its pharmaceutical **[**109]** products were determined primarily by petitioner's assessments of what the marketplace was willing to pay for those products. Although the profitability of a product was a factor **[*1057]** in ***pricing*** decisions, the ***prices*** of petitioner's products were not directly related to its costs of producing those products.

Health care professionals generally categorize drugs as either relatively expensive or relatively inexpensive. The ***price*** of a drug can be a material concern to the health care professional when choosing among relatively expensive drugs; ***price***, however, is usually not a material concern to the health care professional when choosing among relatively inexpensive drugs. Oral analgesics, and particularly propoxyphene products, were viewed by health care professionals as being relatively inexpensive drugs. During the years in issue, the average prescription ***price*** (i.e., the ***price*** paid by the patient at the drug store) for a bottle of 30 Darvon capsules was approximately $ 4. Thus, Darvon products cost the patient approximately 13 cents per capsule or about 50 cents per day (the recommended dose of Darvon products was four capsules per day).

The reason why health care professionals are **[**110]** not concerned when choosing among relatively inexpensive drugs such as Darvon products is that the differences in the wholesale ***prices*** for the drugs are not fully reflected in their retail ***prices***. Pharmacists in drug stores rarely determine their ***prices*** for less expensive drugs based on a markup over cost, but rather charge a dispensing fee of approximately $ 2 for each prescription. For example, if a prescription for a Darvon products costs the patient $ 4 in the drug store, the pharmacist's ingredient cost would be approximately $ 2 (the $ 4 ***price*** less the $ 2 dispensing fee). Therefore, if the pharmacist's ingredient cost was produced by 50 percent to $ 1, the pharmacist's ***price*** to the patient would be reduced only 25 percent from $ 4 to $ 3.

Although petitioner anticipated that competitors would enter the market with generic propoxyphene products after the propoxyphene patent expired in 1972, petitioner did not decrease its ***prices*** for Darvon products. Petitioner expected that its competitors would ***price*** such generic products at levels lower than petitioner's ***prices*** but no less than half of petitioner's ***prices***. If the ***price*** of a generic propoxyphene product was half that of **[**111]** the Darvon product, the difference in the prescription ***price*** to the patient, using the figures in our example, would be approximately $ 1 for a prescription of 30 capsules or only about 3 cents a capsule. Petitioner believed that, given **[*1058]** the small difference in the prescription ***price*** to the patient, physicians would continue to prescribe the Darvon product, a known product which they had used over several years, rather than a new generic product.

F. *Significance of Marketing Intangibles*

For many years, petitioner has enjoyed a favorable reputation in the marketplace as a result of bringing to the market a succession of therapeutically successful products. Petitioner also has developed over the years a marketing organization that is highly skilled in the promotion of pharmaceutical products. The fact that petitioner marketed several successful pharmaceutical products and enjoyed a good reputation made it easier for petition-

er's sales representatives to obtain access to health care professionals in order to discuss petitioner's other products.

Although petitioner's reputation gave it access to health care professionals, such access was no assurance that a new product marketed by petitioner **[**112]** would be successful. Health care professionals, as stated earlier, are a sophisticated and discriminating audience, and they will not automatically accept any new product marketed by petitioner. Petitioner, in fact, marketed several products during the 1960's and 1970's that were unsuccessful despite the fact that those products were heavily promoted by petitioner's sales force under petitioner's well-known and respected name.

It often takes several years to determine whether a new drug will prove to be successful in the marketplace. In petitioner's experience, health care professionals ordinarily will try a new drug only if it promises to perform more satisfactorily than the drugs already available and used by them. If a health care professional tries the drug and finds that it works satisfactorily, he then gradually may broaden his use of the drug in his practice. In addition, although new drugs undergo extensive clinical testing before marketing, it is not uncommon to discover new information about the drug, such as adverse reactions, after it has been on the market and in general use. Furthermore, as the marketing of a new drug is usually more expensive in the early years **[**113]** due to the marketing effort required to inform health care professionals about **[*1059]** the new drug, a new drug may not produce substantial economic returns to the manufacturer for many years.

It was clear by 1966 that the Darvon product line was an extraordinarily successful product line. It then had an 8-year demonstrated history of substantial sales, establishing its position as a leader in the prescription oral analgesic market. The Darvon product line was well known among health care professionals and others. It was also extremely profitable. For those reasons, the Darvon product line had a substantial intangible value in 1966.

If petitioner had lost the right to use the Darvon trademark at some point during the period 1966 through 1971, the sales and profit performance of petitioner's propoxyphene hydrochloride products would not have been materially affected, provided petitioner had the exclusive right to market those propoxyphene hydrochloride products. Because propoxyphene hydrochloride products had been on the market since 1957, those products were well known in the medical community. Health care professionals were aware that the generic name for the active ingredient in Darvon **[**114]** products was propoxyphene hydrochloride because labels, product information, and other literature regarding Darvon products all prominently displayed that fact.

The loss of the trademark would have caused petitioner to incur only a minor amount of additional marketing costs for a short period of time. Petitioner would have had to inform health care professionals that the propoxyphene hydrochloride products previously marketed by it under the trademark Darvon were no longer available under that trademark but only under a new trademark. More importantly, petitioner would have had to advise retail pharmacists of the trademark change. Pharmacists were legally prohibited during those years from substituting, without the consent of the prescribing physician, a generic drug for the drug prescribed by the physician. If a pharmacist had received a prescription for a Darvon product, he probably would have called the prescribing physician, advised him that propoxyphene hydrochloride products were no longer sold under that trademark but under a new one, and requested permission from the physician to fill the prescription with the new trademarked product. Such a procedure was generally standard **[**115]** among pharmacists. The **[*1060]** physician in most instances would have granted the permission requested because he was interested in prescribing for his patient the therapeutic agent, propoxyphene hydrochloride, and the Darvon trademark as such was of little importance to him.

IX. *Petitioner's Research and Development Activities*

A. *Introduction*

During the years 1971, 1972, and 1973, petitioner's Lilly Research Laboratories conducted research and development in the life sciences with the objectives of inventing, developing, and improving pharmaceutical, agricultural, and cosmetic products. All the products manufactured by Lilly P.R. during those years, as well as most of the ethical pharmaceutical products of petitioner, were developed by Lilly Research Laboratories, a division of petitioner, solely or in conjunction with research facilities of petitioner's subsidiaries.

During the years 1971 through 1973, the research and development facilities of Lilly Research Laboratories were located at McCarty Street in Indianapolis, at the Wishard Memorial Hospital in Indianapolis, and at Greenfield, Indiana.

Petitioner's research and development facilities at McCarty Street in Indianapolis occupied approximately **[**116]** 775,000 square feet of space and had a book value of approximately $ 23.3 million at the end of 1973. In 1972, petitioner completed and occupied a new building at McCarty Street (called Building 88) that approximately doubled petitioner's research facilities. The pharmaceutical pilot plant on Kentucky Avenue in Indianapolis also was considered part of the McCarty Street research facilities.

The Lilly Laboratory for Clinical Research (often called the Lilly Clinic) was located on the seventh floor and

half of the sixth floor of the Wishard Memorial Hospital in Indianapolis and occupied approximately 67,000 square feet of space. Petitioner's assets at that location had a book value of approximately $ 698,000 at the end of 1973. Wishard Memorial Hospital was a government -owned institution staffed by the University of Indiana Medical School. The Lilly Clinic was a 40-bed facility responsible for initial tests of new pharmaceutical compounds in human volunteers. Approximately 125 **[*1061]** employees of Lilly Research Laboratories worked at the Lilly Clinic.

Petitioner's Greenfield Laboratories were located on a 750 -acre site near Greenfield, Indiana. The facility occupied approximately 420,000 **[**117]** square feet of space, and had assets with a book value of approximately $ 11.6 million at the end of 1973.

During the years 1971 through 1973, Lilly Research Laboratories employed approximately 2,000 persons. Approximately 8 percent of those employees were research executives, 13 percent were senior scientists who held Ph.D. degrees, 35 percent were scientists not holding Ph.D. degrees, and the remaining 44 percent were technicians, secretaries, animal caretakers, and other support personnel. The executives and scientists at Lilly Research Laboratories included physicians, chemists, biologists, microbiologists, physiologists, and pharmacologists.

The activities of Lilly Research Laboratories were directed by four general committees during the years 1971 through 1973. Those committees were: (1) The research projects committee; (2) the product development committee; (3) the product introduction committee; and (4) the product addition committee. The objective of those committees was to create new compounds that could be recommended for clinical or field trial testing. The recommendation of those committees was forwarded with accumulated data relative to the compound involved to a research **[**118]** management group. If the research management group agreed with the recommendation of the committees and the evaluations of the chemical work done with respect to the recommendation, the compound was forwarded for development.

The research and development work on each compound was done by designated teams drawn from the four divisions of Lilly Research Laboratories. The divisions were organized into two major categories. The first category contained the research, development, and control divisions. The second category consisted of the medical research division.

The research division of Lilly Research Laboratories was responsible for creating new compounds, screening compounds for potential product development, and studying the initial toxicological effects of those compounds. That division performed **[*1062]** the general or basic research function of Lilly Research Laboratories. A research team was established to search for new compounds in each general area of interest to petitioner, such as cardiovascular drugs, anti-cancer drugs, or analgesic drugs. A research project number was established to cover the work of each of those research teams. The research division synthesized thousands **[**119]** of new chemical compounds every year. In the pharmaceutical industry, approximately 8,000 new compounds are synthesized for each compound that finally is marketed as a new drug.

The development division of Lilly Research Laboratories was responsible for developing compounds that had been screened by the research division and that appeared to have marketing potential. Such development activities included performance of short- and long-term toxicology studies, development of a manufacturing process, production of clinical trial materials, and performance of clinical studies. When a new compound identified by the research division was forwarded by the research committees for development, a product development team was established for that compound and a product development number was established to cover the work of that team.

The control division of Lilly Research Laboratories was responsible for the performance of analytical assays on research materials, purchased materials, and manufactured items. That division was basically a service operation providing analytical testing for the research, development, and medical research divisions of Lilly Research Laboratories. The primary function **[**120]** of the control division was to perform the required quality control tests on each lot of each product manufactured by petitioner in the United States.

The medical research division of Lilly Research Laboratories was responsible for conducting, coordinating, and evaluating human clinical tests to establish the safety and efficacy of new pharmaceutical compounds. Its activities also included the preparation and submission of NDAS.

During the years 1971, 1972, and 1973, the research and development expenses of Lilly Research Laboratories were $ 53,513,000, $ 59,502,000, and $ 65,551,000, respectively. Those amounts represented all of petitioner's research and development expenditures with the exception of certain development **[*1063]** expenditures for petitioner's antibiotic development division that were not incurred by Lilly Research Laboratories. The expenses of the control division of Lilly Research Laboratories were included in the above amounts only to the extent that assays were performed by the control division on materials used or produced by the research, development, or medical research divisions. The remaining expenses of the control division were ***transferred*** to petitioner's production **[**121]** departments and were included in petitioner's cost of products sold.

Petitioner generally performed three types of research. One was fundamental research, which included the basic research necessary to synthesize and screen new chemical compounds. The fundamental research laid the groundwork for the second type of research, product-oriented, or defined, research. That research included activities related to the development of pharmaceutical compounds and the preparation of NDAs. Defined research covered the time period from the establishment of a product development team for a promising compound to the approval of an NDA for that compound. The third type of research, support research, involved activities performed after the compound had been marketed. During the years 1971 through 1973, the fundamental research category accounted for approximately 60 percent of the total research and development expenditures of Lilly Research Laboratories. Defined research accounted for approximately 20 percent of those expenditures, and support research accounted for approximately 20 percent.

The research and development expenses of Lilly Research Laboratories for pharmaceutical, agricultural, **[**122]** and cosmetic research and development projects for the years 1971, 1972, and 1973 were as follows (000's omitted):

Area of research	1971	1972	1973 [20]
Pharmaceutical	$ 40,393	$ 45,397	$ 49,632
Agricultural	12,830	13,979	15,765
Cosmetic	290	126	153
Total	53,513	59,502	65,551

[*1064] B. *Food and Drug Administration Requirements*

HN1 The Federal Food, Drug, and Cosmetic Act (*21 U.S.C. secs. 301-392*) requires the submission and FDA approval of an NDA [21] prior to the introduction into interstate commerce of any new drug, including patented drugs. Subsequent to 1962 and throughout the years 1971 through 1973, the process for obtaining an NDA involved as a prior step the filing of a document known as an Investigatory New Drug Application (hereinafter IND).

An IND contained the background of the new drug at the point in **[**123]** time at which it was filed. It described the method and chemistry of synthesizing the new drug; the procedures and tests for controlling the quality of the drug; summaries of animal pharmacology tests performed to assess the drug's therapeutic potential; results of animal toxicology studies performed to assess the safety of the drug; the labeling the developer intended to use to ship the drug in interstate commerce; the names of the investigators who would be conducting the clinical studies in humans; and the plans or protocols to be used in those studies.

Petitioner's INDs were prepared by the regulatory affairs department of Lilly Research Laboratories' medical research division. During the years in issue, the regulatory affairs department had approximately 60 employees. The preparation of an IND was largely a process of collating finished packages of materials received from other areas of Lilly Research Laboratories. It took two or three of the clerical personnel in that department approximately 2 to 3 days to collate and duplicate an IND.

Assuming that the FDA did not have serious objections with respect to the IND, the pharmaceutical company was free to begin clinical studies **[**124]** in humans after a 30-day waiting period. The clinical studies for a new drug generally were divided into three phases referred to as phase I, phase II, and phase III. Although there were qualitative distinctions in the nature of the clinical studies performed in each phase, the three phases were not performed in strict chronological order and often overlapped in time.

[*1065] Phase I clinical studies consisted largely of dose ranging studies in normal human subjects. During the years in issue, phase I clinical studies usually involved 20 to 50 subjects and took from 3 to 6 months to complete, depending upon the new drug being tested. Petitioner's phase I studies ordinarily were performed in the Lilly Clinic.

Phase II clinical studies were the initial efficacy studies for the new drug. The purpose of those studies was to demonstrate that the drug had some valuable, therapeutic activity. In those studies, the new drug was given to a small number of patients who had the disease or medical condition that the new drug was intended to treat.

At some point during phase II, sufficient information with respect to the efficacy and toxicity of the new drug

[20] The parties have stipulated the amounts of the expenses. We accept them as fact although the amounts do not total $ 65,551,000, as shown.

[21] The required application for new drugs other than antibiotics is called an NDA. The required application for an antibiotic drug is FDA Form 5 and contains essentially the same information as an NDA. For convenience, both NDAs and Forms 5 are referred to herein as NDAs.

was accumulated to permit a decision as **[**125]** to whether the new drug would be able to complete successfully the FDA approval process or whether the testing of the new drug should be abandoned. That point in a new drug's development was referred to as the NDA decision point. The NDA decision point was important because it was at that time that it was decided whether to commit the considerable resources necessary to complete the phase II and phase III clinical studies for the new drug. The amount of time between the end of phase I and the NDA decision point varied greatly depending upon the new drug being tested, but generally ranged between 1 and 2 years.

Phase III studies were similar to and essentially a continuation of phase II studies. Phase III studies, however, were more extensive. They involved more patients than were involved in phase II studies, and more attributes of a new drug were assessed. The drug was tested under various dosage schedules and in conjunction with other drugs. A major objective of phase III studies was to expose large numbers of patients to the new drug to collect information with respect to potential side effects or abnormalities in the patients and for the large body of safety data necessary **[**126]** to support an NDA.

Petitioner generally attempted to have its new drugs investigated by well-known clinical investigators, outside physicians who were paid by petitioner to study the new drugs. The testing usually was done at large teaching hospitals in various locations around the country to provide test data under various conditions. Petitioner contracted with those clinical **[*1066]** investigators and provided them with case report forms on which to report the data produced by the clinical studies. The case report forms completed by the clinical investigators were forwarded to petitioner's regulatory affairs department where they were entered into a computer. The regulatory affairs department worked with petitioner's computer analysts and statisticians to devise computer-generated tables summarizing the clinical data, which tables eventually became part of the applicable NDAs. The time from the NDA decision point to the completion of phase III clinical studies varied greatly depending on the drug being tested but generally ranged between 2 and 3 years.

The NDA was in large part a duplication and elaboration of the material included in an IND. The NDA included the information originally **[**127]** submitted in the IND and all additional information the applicant had collected relative to the new drug, including but not limited to: (1) Detailed descriptions of the manufacturing and quality control procedures; (2) any animal pharmacology studies done subsequent to the filing of the IND; (3) any animal toxicology studies done subsequent to the filing of the IND; (4) all information relative to phases I, II, and III clinical studies on humans during the IND process, including the names of the investigators and the results of their research; (5) the labels and labeling information; and (6) the package insert for the new drug. The NDA material submitted to the FDA generally was voluminous.

By regulation, the FDA had 180 days from the filing of an NDA within which to respond. The FDA could and often did ask questions with regard to the clinical, toxicology, and pharmacology studies reported in the NDA. When such questions were raised with respect to NDAs filed by petitioner, personnel of petitioner's regulatory affairs department or the individuals in Lilly Research Laboratories who prepared the data submitted with the NDA discussed those questions with the FDA. If necessary, petitioner **[**128]** supplied additional information to the FDA. During that interaction period, a regional office of the FDA conducted an inspection of the manufacturing facilities to be used to produce the new drug. Inspections of Lilly P.R.'s manufacturing facilities were conducted by the local Puerto Rican office of the FDA.

[*1067] When the FDA completed its review of the NDA, and if the FDA was satisfied, it issued a letter stating that the new drug was approvable contingent upon a review of final printed labeling and package inserts. When petitioner received an approvable letter from the FDA, it printed final labeling and package inserts for the new drug and submitted those materials to the FDA. At that point, petitioner also submitted to the FDA the promotional materials it planned to use to market the drug. If the FDA found those materials satisfactory, it issued a letter to petitioner approving the NDA and giving petitioner the right to market the new drug.

During the years 1971 through 1973, the average period from the filing of an NDA to its final approval by the FDA was approximately 2 years. Only 1 in every 10 new drugs for which an IND was filed, successfully completed the process and received **[**129]** FDA approval. While the time frame leading to an NDA varied extensively, the entire procedure from the initial chemical synthesis and identification of a new drug to the approval of an NDA for the new drug ranged from approximately 7 years to 13 years.

The approval letters issued by the FDA contained specific provisions and conditions relative to the maintenance of that approval. The pharmaceutical companies were required to maintain certain records and to make certain periodic reports to the FDA. The companies were required to report every 3 months for the first year, every 6 months the second year, and annually thereafter. In addition, the pharmaceutical companies were required to submit to the FDA any information concerning accidents or certain complaints relative to a drug on a priority basis. Immediate notification was required of labeling mix-ups, bacteriological contamination, or chemical degradation; notification was required within 15 days of receiving complaints or learning of serious, unexpected side effects of a drug.

If a pharmaceutical company desired to make any major change in the manufacturing or marketing of a drug, such as the addition of a new indication for **[**130]** the drug or a change in its dosage schedule, additional materials were submitted to the FDA in the form of a supplemental NDA. The supplemental NDA described the desired change and included data supporting that change.

[*1068] FDA approved NDAs cannot be assigned or ***transferred*** by pharmaceutical companies. The approved NDA is peculiar to the pharmaceutical company that obtained it because it contains information specific to that company. A second pharmaceutical company desiring to market the same drug would be required to file and obtain approval of its own NDA for the drug. If the pharmaceutical company that originally obtained FDA approval to market the drug granted the second pharmaceutical company the right to refer to the information in the first company's NDA file, the second company could obtain FDA approval of an NDA simply by submitting to the FDA the appropriate labeling, manufacturing, and quality control information. The first company's NDA file in that situation is referred to as a ″master file.″ During the years 1971 through 1973, a master file could be referred to only with the permission of its sponsor. A ″sponsor,″ in the FDA context, is the company that submitted the **[**131]** IND and NDA, and is the party responsible for maintaining records and submitting the periodic reports to the FDA.

C. *Research and Development of Propoxyphene Products 1967-73*

1. General

During the years 1967 through 1973, Lilly Research Laboratories conducted research and development activities with respect to propoxyphene products for the benefit of Lilly P.R. The expenses of those activities, as determined using Lilly Research Laboratories' accounting system, were billed to and paid by Lilly P.R. pursuant to the joint research agreement.

Because propoxyphene products had been on the market since 1957, the propoxyphene research and development activities of Lilly Research Laboratories generally were categorized by petitioner as support research. The support research primarily consisted of the development of new formulations of propoxyphene products. Lilly P.R. participated by producing some materials for testing by Lilly Research Laboratories, and by working with Lilly Research Laboratories to develop manufacturing processes and manufacturing tickets for the new product formulations.

2. *Research Projects*

During the years 1967 through 1973, the research and **[*1069]** development activities of **[**132]** Lilly Research Laboratories with respect to propoxyphene products primarily were conducted under nine research and product development projects established by Lilly Research Laboratories. [22] Four of the product development projects (PD 1464, PD 1627, PD 2204, and PD 2308) were established by Lilly Research Laboratories prior to 1967. Research and development activities on those projects during the years 1967 through 1973 primarily consisted of formula revisions to improve product stability and the attempted development of a sustained release drug delivery system. Lilly Research Laboratories focused on the use of propoxyphene products in sustained release form from 1971 through 1973, when it terminated all work on sustained release formulations. Petitioner never marketed a propoxyphene product in sustained release form.

The remaining five research and **[**133]** product development projects (PD 3012, PD 3016, RP 1638, 0805, and 0694) were established by Lilly Research Laboratories during the years 1967 through 1973. PD 3012 (Darvon-N and combination products) was established to cover the development of formulations and manufacturing processes for Darvon-N products. Approximately one-half of the research and development expenses of Lilly Research Laboratories incurred with respect to propoxyphene products during the years 1967 through 1973 were incurred under that project number.

PD 3016 (Sphercotes Darvon) was a product development project established after 1966 for the purpose of developing new formulations of Darvon products containing aspirin. Prior to 1970, the interaction of propoxyphene hydrochloride and aspirin in Darvon products was prevented by forming the propoxyphene hydrochloride into a coated tablet, called a sphercote. During the 1960's, it was discovered that that formulation was subject to misuse because the sphercote of propoxyphene hydrochloride could be extracted from the Darvon capsule. The objective of PD 3016 was to eliminate the use of the sphercote by developing new all-powder formulations of Darvon products containing **[**134]** aspirin. In 1970, Dr. **[*1070]** Walter D. Walkling, a research chemist at Lilly Research Laboratories, discovered a method of stablizing aspirin in the presence of propoxyphene hydrochloride by incorporating glutamic acid hydrochloride in pharmaceutical compositions of aspirin and propoxyphene hydrochloride. The addition of glutamic acid hydrochloride to those formulations had a stablizing effect on the formulation and prevented the decomposition of the aspirin. A U.S. patent (4,044,125) covering that formulation was issued to petitioner as assignee of Dr. Walkling on August 23, 1977. The glutamic acid hydrochloride for-

[22] Lilly Research Laboratories also utilized a research project number (RP 1195) for studies of analgesics in general. Some information obtained from studies under RP 1195 was submitted as support for Darvon-N related NDAs during the years 1971 through 1973; however, the studies were not specifically related to propoxyphene products.

mulation was used by Lilly P.R. in the manufacture of Darvon with A.S.A. (PU 366), Darvon Compound (PU 368), and Darvon Compound-65 (PU 369) during the years 1971 through 1973.

RP 1638 was a research project established for the purpose of developing a formulation and manufacturing process for Darvocet Registered TM, a product that petitioner ultimately never manufactured or marketed. Project numbers 0805 and 0694 were short-term projects for the revision of the formulas for Darvon products.

3. *NDAs*

Petitioner filed with the FDA the following NDAs covering its Darvon and Darvon-N **[**135]** products:

Product	NDA number	Date filed	Date approved
Darvon 32 mg. (PU 364)	10-977	Mar. 25, 1957	Sept. 9, 1957
Darvon 65 mg. (PU 365)	10-977	Mar. 25, 1957	Sept. 9, 1957
Darvon with A.S.A. (PU 366)	10-996	Jan. 24, 1964	Sept. 24, 1964
Darvon Compound (PU 368)	10-996	Mar. 25, 1957	Sept. 23, 1957
Darvon Compound-65 (PU 369)	10-996	July 5, 1960	Sept. 22, 1960
Darvo-Tran (PU 377)	12-032	June 26, 1959	Sept. 4, 1959
Stero-Darvon (TA 1855)	14-768	June 17, 1963	May 3, 1967
Darvon-N (PU 391 and PU 392)	16-827	Nov. 13, 1968	Sept. 9, 1971 [23]
Darvon-N (TA 1883)	16-862	May 19, 1969	Sept. 9, 1971
Darvon-N with A.S.A. (TA 1884)	16-863	May 19, 1969	Sept. 9, 1971
Darvon-N Suspension (MS 135)	16-861	May 19, 1969	Sept. 9, 1971
Darvocet-N 50 (TA 1890) [24]	17-122	Dec. 17, 1971	Dec. 19, 1972

[*1071] Petitioner was the sponsor for all the NDAs for Darvon and Darvon-N products. [25] Petitioner informed the FDA in those NDAs or in supplemental NDAs that the products covered by those NDAs would be manufactured in Puerto Rico by Lilly P.R. However, as sponsor, petitioner was still the entity responsible for maintaining records and reports and the entity accountable for problems with Darvon and Darvon-N products.

The NDAs for all Darvon and Darvon-N products approved by the FDA during the years 1965 through 1973 referred, directly of indirectly, to the basic Darvon NDA master file NDA NO. 10-977). Petitioner did not permit a third party seeking to market a new pharmaceutical product to refer to any of its master file NDAs during the years 1971 through 1973.

If Lilly P.R. had had to compile and submit its own NDAs for Darvon and Darvon-N products, the time and expense necessary would have been substantial. The typical NDA submission for a new drug was **[**137]** sizable due to the large number of clinical studies necessary to show its safety and efficacy. For example, petitioner's NDA NO. 16-827 consisted of 23 volumes containing a number of pharmacology, toxicology, and pain studies. Those studies were performed prior to the filing of NDA NO. 16-827 on November 15, 1968.

Although NDA NO. 16-827 was a large submission, it was not as extensive as an NDA for an entirely new drug. NDA NO. 16-827 would have been required to contain substantially more clinical studies if it had been the first NDA for a propoxyphene product. In 1969, petitioner filed an NDA for an oral cephalosporin antibiotic sold under the trademark Keflex Registered TM. The Keflex NDA contained 88 volumes. NDAs for antibiotics ordinarily are less extensive than NDAs for analgesic drugs. There are objective measurements of effectiveness of an antibiotic drug, and as a result it is easier to develop evidence of efficacy. In contrast, the effects of an analgesic drug are more subjective and, therefore, more difficult to measure. If NDA NO. 16-827 had been the first NDA for a propoxyphene product, it probably would have been larger than, and perhaps twice as large as, petitioner's **[**138]** NDA for Keflex.

[*1072] X. *Litigation Related to Propoxyphene Products*

During the years 1966 through 1973, petitioner or Lilly P.R. brought three patent infringement actions to defend the propoxyphene patent. Those actions were *Eli Lilly & Co. v. Generic Formulas, Inc.*, 66 Civil Action File 576 (E.D.N.Y. Sept. 30, 1966); *Eli Lilly & Co. v. Milan Pharmaceutical, Inc.*, No. C-68 13F, *169 U.S.P.Q. 32*

[23] NDA No. 16-827 covered Darvon-N capsules. Petitioner, however, decided not to market Darvon-N in capsule form.

[24] On Mar. 12, 1973, petitioner filed an NDA (No. 17-122) with the FDA covering Darvocet-N 100 (TA 1893). Darvocet-N 100 is the same product as Darvocet-N 50, except that it contains twice the amounts of propoxyphene napsylate and acetaminophen contained in Darvocet-N 50. The NDA was approved on Nov. 12, 1973, but petitioner did not market Darvocet-N **[**136]** 100 until 1974.

[25] All animal and human testing, as well as the preparation of all correspondence, associated with obtaining FDA approval of NDAs for Darvon and Darvon-N products was performed or contracted by Lilly Research Laboratories.

(N.D.W.Va. 1968); and *Eli Lilly & Co. v. Generix Drug Sales, Inc.*, No. 69-1241- Civ., 324 F. Supp. 715 (S.D. Fla. 1971), affd. in part and vacated and remanded in part 460 F.2d 1096 (5th Cir. 1972). The validity of the propoxyphene patent was upheld in each of those actions, and injunctions were issued prohibiting further infringement of the patent by each defendant. The legal fees for the Generic Formulas, Inc., action, which was concluded prior to the execution of the Assignment of Patents and Related Technical Data on December 5, 1966, were paid by petitioner. Lilly P.R. bore the legal fees incurred in connection with the Milan Pharmaceutical, Inc., and Generix Drug Sales, Inc., actions. The legal fees and related costs billed to Lilly P.R. by petitioner with respect to the Milan and Generix **[**139]** actions during the years 1968 through 1973 were as follows:

Action	Year		Amount
Milan	1968		$ 42,822
	1969		35,984
		Total	78,806
Generix	1970		276,149
	1971		473,625
	1972		120,547
	1973		25,744
		Total	[26] 896,065
Total for both Milan and Generix actions			974,871

During the period from 1957 through 1973, a total of six lawsuits were filed against petitioner or Lilly P.R. for damages allegedly resulting from the use of Darvon or Darvon-N products. Petitioner settled the first suit by paying the plaintiff $ 1,000. The remaining five lawsuits were dismissed and no damages were paid to the plaintiffs by petitioner or **[*1073]** Lilly P.R. Petitioner's legal fees paid in defense of all six lawsuits aggregated approximately $ 51,000. Those legal fees were not reimbursed by Lilly P.R. but were included in petitioner's general and administrative expenses.

XI. *Intercompany* ***Pricing*** of Darvon and Darvon-N Products

A. *General*

During the years 1971 through 1973, petitioner purchased its complete line of Darvon and Darvon-N products from Lilly P.R. Listed below are the Darvon and Darvon-N products purchased by petitioner for **[**140]** resale to customers in the United States during those years:

Identification code	Description	Packaging size(s) [27]
PU 364	Darvon 32 mg.	100,500
PU 365	Darvon 65 mg.	100,500, 25/30, 20/50
PU 366	Darvon with A.S.A.	100,500
PU 368	Darvon Compound	100,500
PU 369	Darvon Compound-65	100,500, 25/30, 20/50
PU 377	Darvo-Tran	100,500
TA 1855	Stero-Darvon	50
TA 1883	Darvon-N	100,500, 25/30, 20/50
TA 1884	Darvon-N with A.S.A.	100,500, 25/30, 20/50
TA 1890	Darvocet-N 50	100,500, 20/50
MS 135	Darvon-N Suspension	Pint, ID 10cc

[26] The parties incorrectly stipulated this number as $ 897,065. We have found what we consider to be the correct total.

[27] The 50-, 100-, and 500-package sizes refer to bottles of 50, 100, and 500 capsules or tablets, respectively. The 25/30-package size was a package containing 25 packages of 30 capsules or tablets. The 20/50-package size was a package containing 20 packages of 50 capsules or tablets. The ID 10cc-package size for Darvon-N Suspension was an Identi-dose package of 100 individually labeled bottles each containing one dose.

Petitioner also received finished Darvon and Darvon-N capsules and tablets in bulk packages from Lilly P.R. for use as samples or to be packaged in unit-dose packaging. Petitioner's unit-dose packagings were (a) an ID 100 Identi-dose package consisting of 100 strips of 10 individually **[**141]** labeled blisters, each containing 1 capsule or tablet, and (b) a DS 1000 package containing 10 dispenser rolls, each consisting of 100 capsules in individual unit-dose packages. The unit-dose packaging was performed or contracted in the United States by petitioner and was not performed by Lilly P.R. at any time prior to 1974. **[*1074]** Petitioner's cost of Identi-dose packaging was included in its cost of sales of Darvon and Darvon-N products.

During the years 1965 through 1973, all pharmaceutical products sold by petitioner in the United States were listed in petitioner's published ***price*** lists. The ***prices*** in petitioner's ***price*** lists were its suggested ***prices*** to retail pharmacies and were referred to as "net trade ***prices***." During that period, drug wholesalers of petitioner's products received a standard discount of 17 percent from petitioner's net trade ***prices***. Petitioner's ***prices*** to drug wholesalers were referred to as "net wholesale ***prices***."

Petitioner's net trade ***prices*** and net wholesale ***prices*** for the Darvon and Darvon-N products manufactured and sold by Lilly P.R. during the years 1966 through 1973 were as follows:

Identification code	Package size	Description	Net trade *price*	Net wholesale *price*
PU 364	100	Darvon 32 mg.	$ 3.72	$ 3.10
PU 364	500	Darvon 32 mg.	17.67	14.72
PU 365	100	Darvon 65 mg.	7.02	5.85
PU 365	500	Darvon 65 mg.	33.35	27.79
PU 365	25/30	Darvon 65 mg.	52.53	43.77
PU 365	20/50	Darvon 65 mg.	68.80	57.33
PU 366	100	Darvon with A.S.A.	7.11	5.92
PU 366	500	Darvon with A.S.A.	33.77	28.14
PU 368	100	Darvon Compound	4.02	3.35
PU 368	500	Darvon Compound	19.10	15.92
PU 369	100	Darvon Compound-65	7.32	6.10
PU 369	500	Darvon Compound-65	34.77	28.97
PU 369	25/30	Darvon Compound-65	54.66	45.55
PU 369	20/50 [1]	Darvon Compound-65	71.60	59.67
PU 377	100	Darvo-Tran	5.40	4.50
PU 377	500	Darvo-Tran	25.65	21.37
TA 1855	50	Stero-Darvon	3.62	3.02
TA 1883	100	Darvon-N	7.02	5.85
TA 1883	500	Darvon-N	33.35	27.79
TA 1883	25/30	Darvon-N	52.53	43.77
TA 1883	20/50	Darvon-N	68.80	57.33
TA 1884	100	Darvon-N with A.S.A.	7.11	5.92
TA 1884	500	Darvon-N with A.S.A.	33.77	28.14
TA 1884	25/30	Darvon-N with A.S.A.	53.16	44.30
TA 1884	20/50	Darvon-N with A.S.A.	69.60	58.00
TA 1890	100	Darvocet-N 50	4.10	3.42
TA 1890	500	Darvocet-N 50	19.48	16.23
TA 1890	20/50	Darvocet-N 50	$ 41.00	$ 34.17
MS 135	Pint	Darvon-N Suspension	4.79	3.99
MS 135	ID 10cc	Darvon-N Suspension	21.98	18.32

[142]**

[*1075] During the years 1966 through 1973, Lilly P.R. sold Darvon products to petitioner at the following discounts from petitioner's net wholesale ***prices***:

[1] We have corrected the parties' erroneous stipulation of this package size as 20/30.

Year	Discount [28]
1966	35%
1967	40
1968	40
1969	45
1970	45
1971	40 [1]
1972	46 [1]
1973	58 [1]

Pursuant to the distribution agreement between Lilly P.R. and petitioner, Lilly P.R. granted petitioner "chargebacks," or rebates, for export and U.S. Government sales of Darvon and Darvon-N products by petitioner. During the years 1971 through 1973, the chargebacks were equal to 20 percent of petitioner's net wholesale ***price*** for the volume of material sold in export and to the Government. [29] During the years **[**143]** 1971 through 1973, petitioner's export and Government sales of Darvon and Darvon-N products were 3 to 4 percent of its total sales of those products.

During the years 1966 through 1972, the distribution agreements between petitioner and Lilly P.R. provided that Lilly P.R. would provide free samples of Darvon and Darvon-N products to petitioner. In practice, that was accomplished by Lilly P.R. granting chargebacks to petitioner for Darvon and **[*1076]** Darvon-N products used as samples by petitioner. For samples packaged by petitioner from bulk capsules or tablets purchased from Lilly P.R., the chargeback was equal to the ***price*** petitioner paid Lilly P.R. for the bulk capsules or tablets, plus petitioner's costs of packaging the bulk capsules and tablets in sample packages. For trade packages (such as bottles of 100 capsules or tablets) used as samples, the chargeback was equal to the ***price*** petitioner paid Lilly P.R. for the trade package. Effective January 1, 1973, the distribution agreement was amended to provide that petitioner would reimburse Lilly P.R. for its costs of manufacturing Darvon and Darvon-N products **[**144]** used as samples by petitioner. That provision was effectuated by Lilly P.R. granting petitioner chargebacks for Darvon and Darvon-N products used as samples equal to Lilly P.R.'s manufacturing profit for such products.

In 1973, Lilly P.R. manufactured and sold to petitioner Ilosone products, the ***pricing*** of which is in dispute but has been severed from the trial of this case. Lilly P.R. also manufactured and sold a small amount of certain other pharmaceutical products in 1971, 1972, and 1973, the ***pricing*** of which is not in dispute in this case. In addition, in late 1973, Lilly P.R. manufactured and sold to petitioner Darvocet-N 100 (TA 1893), but that product was not sold by petitioner until 1974.

B. *Initial* ***Pricing*** Policy

In **[**145]** 1965, petitioner's second project team for Puerto Rico decided that Lilly P.R.'s ***prices*** to petitioner should allow petitioner to recover its selling and distribution expenses related to Lilly P.R. products and to earn a profit equal to 90 to 100 percent of those expenses. In accordance with that decision, Lilly P.R.'s ***prices*** to petitioner for Darvon products initially were established at a 35-percent discount from petitioner's net wholesale ***prices*** for those products.

Lilly P.R.'s ***prices*** to petitioner for Darvon products were reduced for 1967 and 1968 to petitioner's net wholesale ***prices***, less a 40-percent discount. That action was taken in order to conform Lilly P.R.'s ***prices*** with the objective of providing petitioner with operating income equal to 90 to 100 percent of its selling and distribution expenses related to those products.

[*1077] During the period from late 1969 through February 1972, the Service audited petitioner's returns for the 1966 through 1968 taxable years. As a result of that audit, the Service and petitioner agreed upon certain allocations of income from Lilly P.R. to petitioner on the basis of adjustments to the ***transfer price*** of Darvon products sold to petitioner by **[**146]** Lilly P.R. in 1966 and 1967. For the taxable year 1968, the Service and petitioner agreed to a ***pricing*** formula for Darvon products (hereinafter the 1968 audit formula), the result of which was to divide the combined profit earned by Lilly P.R. and petitioner and to use such division for purposes of establishing the ***price*** at which Darvon products should be sold by Lilly P.R. to petitioner.

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[28] The parties have stipulated these figures as being the discounts in effect during the years stated. We note, however, that the stipulated discounts often were in effect for only part of the respective years. For example, the discount for 1971 was 45 percent as of Jan. 1, 1971. That discount was reduced to 40 percent for Darvon products in March 1971, and for Darvon-N products in August 1971.

[1] These discounts also applied to Darvon-N products sold by Lilly P.R. to petitioner.

[29] During January and February 1971, the chargeback percentage was 15 percent.

The first step in the application of the 1968 audit formula was a determination of the combined net income of petitioner and Lilly P.R. attributable to the intangible property related to the manufacture and sale of Darvon products. The combined net income attributable to intangibles was determined by subtracting from the total combined net income of petitioner and Lilly P.R. from the manufacture and sale of Darvon products (a) a manufacturing profit equal to 100 percent of Lilly P.R.'s manufacturing costs (i.e., cost of goods sold) less Lilly P.R.'s operating expenses; (b) the cost savings resulting from operating in Puerto Rico rather than in the United States; and (c) a marketing profit equal to 25 percent of petitioner's expenses attributable to its marketing of Darvon products in the United States. **[**147]** The location savings portion of the formula represented the reduced cost of operating in Puerto Rico as compared to the United States and was attributable primarily to lower labor rates in Puerto Rico and Lilly P.R.'s exemptions from Puerto Rican property and other non-income ***taxes***.

Under the 1968 audit formula, 60 percent of the net income attributable to intangibles was considered as being attributable to manufacturing intangibles such as the propoxyphene patent and propoxyphene manufacturing know-how and was allocated to Lilly P.R. The remaining 40 percent of the net income attributable to intangibles was considered to be attributable to marketing intangibles, such as the Darvon trademark and petitioner's name and marketing organization, and was allocated to petitioner.

[*1078] On April 12, 1972, petitioner and the Service entered into a closing agreement for the 1966 through 1968 taxable years, reflecting the adjustments referred to above. As stated, the 1968 audit formula was applied to 1968 only; an alternative method of disposing of the 1966 and 1967 years was agreed to by the Service and petitioner. Petitioner and respondent at no time entered into an agreement that would legally **[**148]** bind the other party to apply the 1968 audit formula to the years 1971 through 1973.

C. ***Pricing*** Policy 1971-73

On June 30, 1972, petitioner and Lilly P.R. amended their distribution agreement in order to adjust Lilly P.R.'s ***prices*** for Darvon and Darvon-N products. The discount from petitioner's net wholesale ***prices*** on Darvon and Darvon-N products was increased from 40 percent to 46 percent effective July 1, 1972. That amendment to the distribution agreement provided, in pertinent part:

Whereas, [petitioner] has agreed with the Internal Revenue Service that the ***price*** [petitioner] will pay for DARVON Registered TM Products manufactured by [Lilly P.R.] cannot exceed certain guidelines; and

Whereas, it has been understood between the two companies that as soon as a preliminary analysis of 1972 results provided some indication that ***prices*** paid for DARVON Registered TM Products were not within such guidelines, adjustments would be made to correct prior ***pricing*** for such Products purchased on or after January 1, 1972, and to establish new intercompany ***prices*** for the remainder of 1972; and

Whereas, it is now apparent that ***prices*** charged [petitioner] for DARVON Registered TM Products during the **[**149]** period January 1, 1972, through June 30, 1972, exceed the agreed upon guidelines, and that to keep the ***prices*** paid for DARVON Registered TM Products within the guidelines for the remainder of 1972, it will be necessary to increase discounts to [petitioner] as set forth in the attached ***price*** schedule.

In February 1972, as the expiration of the propoxyphene patent on December 27, 1972, approached, petitioner began to consider Lilly P.R.'s ***pricing*** of Darvon and Darvon-N products for 1973. Such consideration consisted of several discussions involving officers of petitioner and petitioner's outside ***tax*** advisers.

Petitioner's consideration of the 1973 ***pricing*** of Lilly P.R.'s Darvon and Darvon-N products was conducted in the context of the 1968 audit formula. Because the propoxyphene patent **[*1079]** would no longer be in existence in 1973, petitioner's objective was to determine what intangible property would remain in Lilly P.R. in 1973 and the value of that property. In that respect, petitioner considered the alternative of Lilly P.R. selling directly to wholesalers in the United States, accompanied by the ***transfer*** of the Darvon and Darvon-N trademarks to Lilly P.R. Petitioner rejected that alternative **[**150]** in 1972 as it had in 1965 and 1966.

Petitioner determined that, after the expiration of the propoxyphene patent, three intangible elements would remain in Lilly P.R. Those elements were: (a) Manufacturing know-how, (b) the glutamic acid hydrochloride formula for Darvon compound products, and (c) the napsylate patent.

Petitioner believed that the 100-percent markup allowed Lilly P.R. under the 1968 audit formula probably included compensation to Lilly P.R. for such things as capital investment, going concern value, and goodwill. However, petitioner believed that the 100-percent markup did not allow Lilly P.R. sufficient compensation for the manufacturing know-how that had been developed over the years by Lilly P.R. and petitioner. The manufacturing cost of Darvon products as a percentage of sales historically had declined from a high of 28.2 percent to 13.9 percent, a 14 percentage point difference. Petitioner assumed that part of that cost reduction was attributable to increases in volume and to the savings attributable to operating in Puerto Rico rather than in the United States. Accordingly, petitioner concluded that only 6.9 percent of the 14 percentage point difference was properly **[**151]** attributable to manufacturing know-how. As-

suming sales to wholesalers of Darvon and Darvon-N products of $ 70 million, petitioner concluded that between $ 4.5 million and $ 5 million of income was attributable to Lilly P.R.'s manufacturing know-how.

Petitioner also believed that the glutamic acid hydrochloride formula used by Lilly P.R. in the manufacture of Darvon products containing aspirin had a significant intangible value. That formula allowed Lilly P.R. to make a stable product that was difficult to abuse. Petitioner believed that it was reasonable to attribute a 3-percent royalty value to that formula. Because the Darvon products using that formula respresented approximately 65 percent of $ 54 million of petitioner's total sales of Darvon and Darvon-N products, petitioner estimated **[*1080]** that approximately $ 2 million of income was attributable to the glutamic acid hydrochloride formula.

Petitioner also considered the napsylate patent to be a valuable intangible that would remain in Lilly P.R. in 1973. Sales of Darvon-N products were projected to be approximately 15 to 20 percent of total sales of propoxyphene products in 1973, and total income for 1973 attributable to intangibles **[**152]** under the 1968 audit formula was projected to be $ 30 million. Petitioner concluded that it was reasonable to attribute to the napsylate patent between 5 to 10 percent or $ 1.5 to $ 3 million of the total income attributable to intangibles.

In summary, petitioner concluded that $ 8 to $ 10 million of income could be attributable to the intangibles remaining in Lilly P.R. in 1973. As the income attributable to all intangibles under the 1968 audit formula was projected to be approximately $ 30 million, petitioner concluded that approximately 30 percent [30] of that intangible value could be allocated to Lilly P.R. for the purpose of determining Lilly P.R.'s ***prices*** to petitioner for Darvon and Darvon-N products. Thus, in applying the 1968 audit formula to the 1973 taxable year, petitioner allocated to Lilly P.R. 30 percent of the income attributable to intangibles, rather than 60 percent as in prior years. The distribution agreement between Lilly P.R. and petitioner accordingly was amended to increase the discount from net wholesale ***prices*** for Darvon and Darvon-N products from 46 percent to 58 percent, effective January 1, 1973.

XII. *Financial Information*

A. *Overview of Petitioner's Accounting System*

[*1081] Petitioner's financial statements for the years 1971 through 1973 were a consolidation of the financial records of petitioner and its subsidiaries, including Lilly P.R.

Petitioner and each of its subsidiaries accounted for expenses on a departmental basis. Petitioner maintained a departmental accounting system, with every individual who worked for petitioner assigned to a specific department.

In the departmental accounting system, petitioner maintained three primary groupings of departments and accounts: manufacturing, operating, and service. Petitioner's manufacturing departments worked directly on the manufacture of a product. The accounting for expenses of manufacturing departments was accomplished by establishing cost center rates within each department which were then applied to the product flowing through the department on the basis of time spent or on an absorption -rate **[**154]** basis. When the product was completed, it was placed in inventory. When the product was ultimately sold, it was released from inventory, and its cost was charged to manufacturing cost of sales.

The second grouping was petitioner's nonmanufacturing operating departments. The expenses of those departments were recorded in several separate subledgers such as selling, merchandising, shipping, research and development, and general administration.

The third primary grouping consisted of those departments of petitioner that serviced other departments. The service departments included quality control, engineering, personnel, buildings and ground maintenance, and industrial relations. The expenses of those departments were recorded in service ledger accounts and ultimately were allocated either to a manufacturing cost account or to an operating expense account.

B. *Lilly Research Laboratories' Accounting Systems*

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[30] Petitioner's calculation, as we have deduced it from the **[**153]** record, was as follows:

	In millions of dollars		
	Minimum		**Maximum**
Manufacturing know-how	4.5		5
Glutamic acid hydrochloride	2		2
Napsylate patent	1.5		3
	8.0		10
Expressed as a percentage of $ 30			
attributable to intangibles	26.6%		33.3%
Average of minimum and maximum		29.9%	

Lilly Research Laboratories had two separate but closely related accounting systems: a general departmental accounting system and a project accounting system.

The general departmental accounting system accumulated costs by expense class (e.g., compensation and benefits, supplies, and **[**155]** materials) for each department in Lilly Research Laboratories. Under the project accounting system, expenses **[*1082]** were recast from a departmental basis to a research project basis which enabled petitioner to track, monitor, and manage the various research projects of Lilly Research Laboratories. The system also provided the management of Lilly Research Laboratories with information to assist it in establishing priorities for and planning and control of research activities.

As stated earlier, Lilly Research Laboratories had a general research project for each broad area of interest to petitioner, such as anti-cancer drugs, cardiovascular drugs, and analgesic drugs. Each of those projects was monitored by a research project committee. Projects in the general research area had ″RP″ numbers, that is, research project numbers.

Generally, when a promising compound was identified by one of the research projects, a product development or ″PD″ number was established for the new compound. [31] Thereafter, the research activity carried out with respect to the new compound was to be charged to its PD number rather than to a general RP number. A development project team also was established at that **[**156]** time to monitor the particular project.

There were two basic methods for allocating expenses in the project accounting system. The simplest method was the direct charging method. Certain expenditures, such as materials bought specifically for a particular research project could be identified with and directly charged to specific projects. The determination of which project to charge was not an accounting function but was made by research management personnel. The second method of charging expenses to research projects was based on research time reports. The scientific personnel of Lilly Research Laboratories filled out time sheets on a monthly basis. Those time sheets showed the projects to which the employee charged time the previous month, and contained space **[**157]** for the addition of new projects in the current month. The employee was required to allocate to those projects his total time on the job that month. The total time allocated by all employees to each one of the projects was accumulated at the end of each month. The expenses of each department, **[*1083]** other than those expenses directly charged to projects, were allocated to the various projects based on the time spent on the projects by the employees in that department. The expenses allocated included compensation, benefits, overhead, and utilities.

As a general rule, only the technicians and scientists, that is, the professional researchers working directly on research projects, filled out time sheets. Senior scientists and research management people normally did not fill out time sheets, as they tended to be involved more in supervisory or administrative functions, and their time was allocated on the basis of the time of the people they supervised. The support staff (e.g., secretaries, animal caretakers, and clerical help) also did not fill out time sheets. During the years 1971 through 1973, approximately 800 persons filled out time sheets. There were approximately 1,700 employees **[**158]** in Lilly Research Laboratories (exclusive of the control division) in those years, so approximately 45 to 50 percent of the research and development personnel filled out time sheets.

The Lilly Research Laboratories project accounting system has been in existence since at least 1951. Since that time, there have been no significant changes in the system of reporting time and direct charging of expenses to projects. There have been some refinements and enhancements over the years, however, such as the establishment of more, and more specific, project numbers; the direct charging of clinical grants to the related project; more frequent reporting of time; and computerization.

C. *Propoxyphene Research and Development Expenses*

1. Pre-1967 Research Activities

For the period 1951 through 1966, the total expenses of Lilly Research Laboratories relating to propoxyphene, by project number, were as follows (000's omitted):

			Total
Research project	**1951-57**	**1958-66**	**1951-66**
RP 1195 Analgesics			
General	$ 848	$ 765	$ 1,613
RP 1513 Propoxyphene	0	14	14

[31] RP 1638 (propoxyphene hydrochloride and acetaminophen), established for the purpose of developing the product Darvocet, appears to be an exception to this rule. Petitioner has failed to explain the disparity in treatment of Darvocet and other products. Also, no PD number was established for Darvon-N products until 1967, although propoxyphene napsylate was identified and the patent was approved in the early 1960's.

Research project	1951-57	1958-66	Total 1951-66
PD 1464 Darvon & Novrad	0	797	797
PD 1627 Darvo-Tran	0	6	6
PD 2204 Stero-Darvon	$ 0	$ 604	$ 604
Propoxyphene	0	54	54
Price list items	0	41	41
Compound 31518 Darvon Analog	0	39	39
	848	2,320	3,168

[*1084] During **[**159]** the period 1951 through 1957, there were no PD project numbers for propoxyphene in existence, and only one analgesic project. Therefore, all the propoxyphene activity reported was captured by RP 1195. However, other non-propoxyphene analgesic activity also was charged to RP 1195 during those years, although petitioner is unable to quantify that non-propoxyphene activity in RP 1195.

The propoxyphene expenses for 1951 through 1957 contained in RP 1195 did not include clinical grants to outside investigators relative to propoxyphene products because grants were not charged directly to specific projects during that period. Petitioner's total clinical grants, including propoxyphene-related grants, during 1951 through 1957 averaged approximately $ 200,000 per year or 2 to 3 percent of petitioner's total research and development expenditures. Petitioner is unable to identify specifically the propoxyphene-related clinical grants for those years.

In 1958, research management at Lilly Research Laboratories established additional project numbers for Darvon products in order to isolate propoxyphene expenses from the rest of the general analgesic research. However, RP 1195 continued to include **[**160]** both some propoxyphene and non-propoxyphene research activity; petitioner again is unable to quantify that non-propoxyphene activity in RP 1195. No propoxyphene research was charged to RP 1195 after 1962.

The propoxyphene expenses for 1958 through 1966 did not include clinical grants relative to propoxyphene products because, during that period, grants again were not charged directly to specific projects. Petitioner's total clinical grants, including propoxyphene-related grants, during 1958 through 1966 averaged approximately $ 800,000 to $ 1 million per year, or 3 to 4 percent of total research and development expenditures. Petitioner is unable to identify specifically the propoxyphene-related grants for those years.

[*1085] 2. *1967-73 Research Activities*

In 1968, pursuant to the joint research agreement between Lilly P.R. and petitioner, Lilly P.R. began reimbursing petitioner for certain research and development expenses relative to Darvon and Darvon-N products. The following amounts were billed by petitioner to Lilly P.R. for research performed during the calendar years 1967 through 1973. In 1973, the amount billed included Ilosone-related research performed in 1973.

Year billed	Amounts of petitioner's research and development expenses billed to Lilly P.R.
1968	$ 419,986
1969	485,890
1970	505,156
1971	506,937
1972	661,197
1973	891,963
Total	3,471,129

The **[**161]** research and development expenses billed by petitioner to Lilly P.R. were the expenses attributed by Lilly Research Laboratories' project accounting system to those research projects and clinical grants [32] related to products manufactured by Lilly P.R., including Darvon and Darvon-N products. The expenses incurred in any

[32] Prior to 1970, the project accounting system did not charge clinical grants directly to research projects. For the years 1967 through 1969, petitioner reviewed the clinical grants records of Lilly Research Laboratories to **[**162]** determine which clinical

6-month period attributed to such products and grants were billed to Lilly P.R. during the following 6-month period. For example, expenses incurred by petitioner during the last 6 months of 1972 were billed to Lilly P.R. during the first 6 months of 1973. Research and development expenses shown on the books and records of Lilly P.R. generally exceeded in any year the research and development expenses billed to Lilly P.R. by petitioner because Lilly P.R. charged to research and development expense the expenses of producing materials for use in the research activities of **[*1086]** petitioner and the expenses of research related activities of Lilly P.R.

The research and development expenses of Lilly Research Laboratories billed to Lilly P.R. during the years 1968 through 1973 were attributable to the following research and product development projects, clinical grants, and materials:

Project number	Description	Total
PD 1464	Darvon & Novrad	$ 526,137
PD 1627	Darvo-Tran	3,003
PD 2204	Stero-Darvon with A.S.A.	70,368
PD 2308	Actimets Darvon (1971-73)	195,051
PD 3012	Darvon-N & Combination Products	1,708,055
PD 3016	Sphercotes Darvon	357,267
RP 1638	Darvocet	136,750
0805	Pulvules Darvon	7,144
0694	Pulvules Darvo-Tran	7,250
PD 1544	Ilosone	180,228
	Grants (1967-69)	245,845
	Materials	34,031
		3,471,129

D. *Lilly P.R. Financial Statements 1971-73*

For the years 1971 through 1973, Lilly P.R.'s statement of income, as reflected in its Ernst & Ernst audited financial statements, **[**163]** was as follows:

	1971	1972	1973
Net sales to affiliated companies	$ 55,573,774	$ 57,188,297	$ 50,785,895
Cost of goods sold	12,754,744	14,387,345	18,669,170
	42,819,030	42,800,952	32,116,725
Expenses:			
Administrative and general	1,316,108	1,075,313	1,241,112
Samples	1,042,215	1,297,190	194,762
Research and development	522,891	712,633	929,849
	2,881,214	3,085,136	2,365,723
	39,937,816	39,715,816	29,751,002
Other income:			
Interest on certificates of			
deposit	2,503,034	2,890,985	7,091,162
Income from Government			

grants properly were attributable to Darvon and Darvon-N products. Petitioner billed Lilly P.R. for the costs of the grants it so identified. From 1970 through 1973, all clinical grants determined by petitioner to be attributable specifically to Darvon and Darvon-N products were charged directly to such projects, and thus billed to Lilly P.R., in accordance with the project accounting system.

	1971	1972	1973
guaranteed securities	2,176,049	2,101,277	2,465,225
Sundry	16,270	42,951	50,207
	4,695,353	5,035,213	9,606,594
	44,633,169	44,751,029	39,357,596
Other deductions:			
Prior years' ***price*** adjustments		$ 30,780,507	$ 5,826,399
Amortization of bond premiums and bank fees	$ 103,573	84,450	37,693
Idle plant cost	35,145		
Sundry	35,294	21,828	30,569
	174,012	30,886,785	5,894,661
Income before income ***taxes***	44,459,157	13,864,244	33,462,935
Income ***taxes***:			
Puerto Rico	594,045	(560,816)	845,873
Federal	166,034	139,964	218,882
	760,079	(420,852)	1,064,755
Net income	43,699,078	14,285,096	32,398,180

[*1087] The Forms 1120 filed by Lilly P.R. for the years 1971 through 1973 report ***tax***-exempt possession source income in the following amounts:

Year	Exempt possession source income
1971	$ 40,914,829
1972	42,037,274
1973	36,537,408

For **[**164]** the years 1971 through 1973, Lilly P.R.'s balance sheet, as reflected in its Ernst & Ernst audited financial statements, was as follows:

Assets	At December 31 --		
	1971	1972	1973
Current assets			
Cash	$ 654,639	$ 353,196	$ 1,220,930
Certificates of deposit	41,300,000	85,700,000	107,700,000
Government securities	88,993,655	62,884,710	70,600,000
Accounts receivable:			
Affiliated companies	28,498,967	24,358,172	21,166,295
Interest	1,459,565	2,155,520	2,771,120
Other	37,756	634,333	160,516
	29,996,288	27,148,025	24,097,931

	Assets		
	At December 31 --		
	1971	**1972**	**1973**
Inventories:			
Finished	65,509	13,166	307,361
Work in process	2,141,997	1,206,419	2,220,854
Raw materials	4,788,151	3,795,136	5,348,207
Packaging	$ 264,858	$ 387,476	$ 696,536
Supplies	275,082	434,258	505,289
	7,535,597	5,836,455	9,078,247
Total current assets	168,480,179	181,922,386	212,697,108
Prepaid expenses and other assets	191,212	195,525	196,427
Property, plant, and equipment:			
Buildings	11,718,630	11,787,169	13,945,669
Machinery and equipment	9,046,290	9,609,287	11,480,357
	20,764,920	21,396,456	25,426,026
Allowances for depreciation	(3,436,701)	(4,445,457)	(5,671,741)
	17,328,219	16,950,999	19,754,285
Land	998,541	978,756	978,756
Construction	445,126	1,841,819	522,744
	18,771,886	19,771,574	21,255,785
	187,443,277	201,889,485	234,149,320
	Liabilities		
	At December 31 --		
	1971	1972	1973
Current liabilities			
Accounts payable:			
Parent company	$ 471,489	$ 617,010	$ 70,909
Other	493,488	424,832	533,472
	964,977	1,041,842	604,381
Accrued payrolls, payroll ***taxes*** and amounts witheld from payrolls	319,145	485,523	595,912
Other accrued expenses	17,020	16,182	28,713
Taxes on income:			
Puerto Rico	103,757		
Federal	10,759	33,223	103,857

	Assets		
	At December 31 --		
	1971	1972	1973
	450,681	534,928	728,482
Total current liabilities	1,415,658	1,576,770	1,332,863
Stockholder's equity			
Common stock, no par value:			
Authorized, issued, and			
outstanding 1,000 shares			
at stated capital amount			
(no change)	500,000	500,000	500,000
Reinvested earnings	185,527,619	199,812,715	232,316,457
	186,027,619	200,312,715	232,816,457
	187,443,277	201,889,485	234,149,320

[165] [*1089]** E. *Lilly P.R. Sales of Darvon and Darvon-N Products*

Lilly P.R.'s sales of each Darvon and Darvon-N product marketed by petitioner during the years 1971 through 1973, expressed as percentages of Lilly P.R.'s total sales of Darvon and Darvon-N products to petitioner during those years, were as follows:

Identification code	Description	1971	1972	1973	Total 1971-73
PU 364	Darvon 32 mg.	1.6%	1.1%	1.4%	1.4%
PU 365	Darvon 65 mg.	20.5	22.8	15.2	19.9
PU 366	Darvon with A.S.A.	3.1	2.1	2.0	2.5
PU 368	Darvon Compound	2.3	1.8	2.2	2.1
PU 369	Darvon Compound-65	60.7	60.6	50.7	58.6
PU 377	Darvo-Tran	1.2	1.0	1.0	1.1
TA 1855	Stero-Darvon	0.5	0.4	0.6	0.5
TA 1883	Darvon-N	3.8	3.9	8.7	4.9
TA 1884	Darvon-N with A.S.A.	5.7	4.0	8.1	5.6
MS 135	Darvon-N Suspension	0.6	0.2	(0.3)	0.3
TA 1890	Darvocet-N 50		2.1	10.4	3.1
	Totals	100.0	100.0	100.0	100.0

F. *Petitioner's Pharmaceutical Division Income Statements*

Petitioner's accounting records for sales were maintained on the basis of two divisions, Elanco and the parent (pharmaceutical division). The Elanco division conducted the marketing and sale of animal health and agricultural products while the pharmaceutical division conducted all petitioner's pharmaceutical operations in the United States, including **[**166]** research and development. All petitioner's expenses were charged to one or the other of those two divisions.

For the years 1971 through 1973, the operating income of petitioner's pharmaceutical division was as follows:

	1971	1972	1973
Net sales	$ 338,321,035	$ 351,043,948	$ 368,914,571
Cost of goods sold	135,365,180	135,781,325	136,096,900
Gross profit	202,955,855	215,262,623	232,817,671

	1971	1972	1973
Operating expenses:			
Merchandising	29,449,279	25,492,164	27,508,217
Selling	31,927,371	33,844,269	39,377,260
Shipping	8,586,038	9,658,004	11,243,576
General administrative	31,739,849	35,068,693	38,018,471
Loss on returned goods	2,600,054	3,076,367	3,324,777
Total operating expenses	104,302,591	107,139,497	119,472,301
Operating income	98,653,264	108,123,126	113,345,370

[*1090] The operating income statement above was not prepared contemporaneously with the years 1971 through 1973, but the information contained therein was derived from the contemporaneous financial records of petitioner.

Net sales, cost of goods sold, and gross profit of the pharmaceutical division represented the entire activity of petitioner, exclusive of the Elanco division and those charges that were directly incurred on behalf of sales to petitioner's international operations.

Merchandising **[**167]** and selling expenses of the pharmaceutical division included all expenses of petitioner's merchandising and selling departments assigned to the pharmaceutical division. Excluded from those expenses were the merchandising and selling expenses of departments of the Elanco division, which were incurred directly by that division and charged to its separate general ledger.

Shipping expenses of the pharmaceutical division included principally freight and warehousing. Those expenses were not reported through either the pharmaceutical or Elanco division but rather through the corporate division. The shipping department maintained records of all freight charges and those charges were assigned directly to the proper division based on the nature of the product being shipped. With respect to warehousing, if a facility was used exclusively for a product of either the pharmaceutical or Elanco division, then the cost of the facility was charged directly to such division. If, however, the facility was jointly used, the cost was allocated to the divisions on the basis of the floor space utilized.

General administrative expenses of the pharmaceutical division included the expenses of petitioner's **[**168]** corporate affairs, financial, legal, and data processing departments, plus the expenses of petitioner's top management and all management of the pharmaceutical division. General administrative expenses were gross figures and were not net of administrative and technical service fees from petitioner's subsidiaries, which were booked as "other income," a nonoperating income item.

Also included in the general administrative expenses of petitioner's pharmaceutical division were the activities and services performed for Lilly P.R. which petitioner considered to be stewardship expenses. The following activities were not billed to Lilly P.R. but were charged to general administrative **[*1091]** expense: (a) Services performed for Lilly P.R. by petitioner's corporate ***tax***, legal, [33] corporate insurance, accounting, and financial departments; (b) activities performed in Indianapolis [34] on Lilly P.R. matters by any member of petitioner above the level of assistant division director; [35] and (c) periodic audits, conducted every 12 to 18 months by petitioner's quality assurance department.

During the years in issue, Lilly P.R. had the use of manuals prepared by petitioner in its manufacturing and other operations. The manuals were provided to Lilly P.R. without its reimbursing petitioner for the cost of preparing the manuals. Petitioner charged the cost of developing the manuals to general administrative expenses, but did not specifically delineate them as stewardship expenses.

Loss on returned goods for the pharmaceutical division represented products returned from the field, principally from outdating where the product in the field exceeded its expiration date. Petitioner's returned goods experience with respect to Darvon and Darvon-N products historically has been very favorable due to the products' long dating period and rapid shelf turnover.

G. *Combined Income Statements for Darvon and Dar-*

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[33] See e.g., pp. 1072-1073 *supra*.

[34] If the employees traveled to Puerto Rico, however, their time as well as their travel **[**169]** expenses were billed to Lilly P.R.

[35] Those activities included the serving of petitioner's employees on Lilly P.R.'s board of directors, as all the employees so serving were above the level of assistant director.

von-N Products 1971-73

1. *General*

During the normal course of its business, petitioner did not maintain accounting records that reflected net income for the pharmaceutical **[**170]** division or by various product lines. During the years 1971 through 1973, petitioner contemporaneously prepared consolidated net income statements (hereinafter the combined income statements) for all products, including Darvon and Darvon-N, manufactured and sold by Lilly P.R. Those combined income statements were prepared to enable petitioner's management to determine and evaluate the intercompany ***transfer prices*** for products sold by Lilly P.R. to petitioner.

[*1092] The combined income statements of petitioner and Lilly P.R. for the years 1971 through 1973 with respect to Darvon and Darvon-N products were as follows:

1971				
	Lilly P.R.	Petitioner		
	Sales to petitioner	Sales to Lilly P.R.	Sales of Lilly P.R. produced merchandise	Total
Net sales	$ 53,968,400	$ 654,833	$ 73,861,799	$ 74,516,632
Cost of goods sold	11,569,396	381,102	47,059,792	47,440,894
Gross profit	42,399,004	273,731	26,802,007	27,075,738
Adjustment for change in inventory	(6,258,854)	(140,258)		(140,258)
Adjusted gross income	36,140,150	133,473	26,802,007	26,935,480
Operating expense:				
Research & development	522,891			
General administration	1,295,050	31,159	1,204,177	1,235,336
Selling			4,150,558	4,150,558
Merchandising			3,898,811	3,898,811
Shipping			551,898	551,898
Sample expense	1,041,308			
Total operating expense	2,859,249	31,159	9,805,444	9,836,603
Operating income	33,280,901	102,314	16,996,563	17,098,877
Other income:				
Royalties		86,687		86,687
Net income	33,280,901	189,001	16,996,563	17,185,564

[171]**

1972				
	Lilly P.R.	Petitioner		
	Sales to petitioner	Sales to Lilly P.R.	Sales of Lilly P.R. produced merchandise	Total
Net sales	$ 54,793,500	$ 603,140	$ 75,827,232	$ 76,430,372

	1972			
	Lilly P.R.	Petitioner		
	Sales to petitioner	Sales to Lilly P.R.	Sales of Lilly P.R. produced merchandise	Total
Cost of goods sold	12,697,303	374,591	46,686,723	47,061,314
Gross profit	42,096,197	228,549	29,140,509	29,369,058
Adjustment for change in inventory	(6,984,591)	77,921		77,921
Adjusted gross income	35,111,606	306,470	29,140,509	29,446,979
Operating expense:				
Research & development	712,633			
General administration	1,048,430	31,413	1,530,354	1,561,767
Selling			6,331,787	6,331,787
Merchandising			4,082,419	4,082,419
Shipping			516,894	516,894
Sample expense	1,234,433			
Total operating expense	$ 2,995,496	$ 31,413	$ 12,461,454	$ 12,492,867
Net income	32,116,110	275,057	16,679,055	16,954,112

[*1093]

	1973			
	Lilly P.R.	Petitioner		
	Sales to petitioner	Sales to Lilly P.R.	Sales of Lilly P.R. produced merchandise	Total
Net sales	$ 32,598,070	$ 429,394	$ 70,026,591	$ 70,455,985
Cost of goods sold	10,739,954	258,897	38,387,726	38,646,623
Gross profit	21,858,116	170,497	31,638,865	31,809,362
Adjustment for change in inventory	5,549,170	203,114		203,114
Adjusted gross income	27,407,286	373,611	31,638,865	32,012,476
Operating expense:				
Research & development	749,621			
General administration	845,197	20,751	2,175,799	2,196,550
Selling			8,025,582	8,025,582
Merchandising			[1] 6,378,561	6,378,561
Shipping			498,587	498,587

[1] Includes sample expense of $ 1,872,896.

1973				
	Lilly P.R.	Petitioner		
	Sales to petitioner	Sales to Lilly P.R.	Sales of Lilly P.R. produced merchandise	Total
Total operating expense	1,594,818	20,751	17,078,529	17,099,280
Net income	25,812,468	352,860	14,560,336	14,913,196

[172]**

2. *Lilly P.R.*

Lilly P.R.'s net sales were computed by abstracting from invoices its gross sales less returns and chargebacks. The adjustment for change in inventory was computed by petitioner to remove from the combined income statements any intercompany profit or loss on Lilly P.R.'s sales to petitioner. Lilly P.R.'s general administration expenses were allocated as a percentage of sales, and research and development expenses were calculated in accordance with the joint research agreement.

[*1094] 3. *Petitioner*

Petitioner's net sales, cost of goods sold, and gross profit on the combined income statements were taken directly from the audited books and records of petitioner's pharmaceutical division and no allocations were made.

a. *Cost of Goods Sold*

Cost of goods sold included the ***transfer*** or invoice ***price*** from Lilly P.R., plus pro rata shares of the actual freight and insurance expenses associated with bringing the goods from Puerto Rico to Indianapolis. In 1971, none of the expenses of petitioner's ticket issuance and stock planning departments were included in petitioner's cost of goods sold of Darvon and Darvon-N products. In 1972 and 1973, cost **[**173]** of goods sold included some portion of the expenses of those departments.

The total department expenses of petitioner's ticket issuance department were $ 285,000, $ 300,000, and $ 311,000 in 1971, 1972, and 1973, respectively. In 1972 and 1973, 5 percent ($ 15,000) and 7 percent ($ 22,000), respectively, of the expenses of petitioner's ticket issuance department were charged to and included in petitioner's cost of goods sold of Darvon and Darvon-N products. The percentages of ticket issuance expenses charged to cost of goods sold of Darvon and Darvon-N products were based on the ratio of the number of manufacturing tickets for Darvon and Darvon-N products issued to Lilly P.R. over the total number of manufacturing tickets issued during each year.

The total department expenses of petitioner's finished stock planning department were $ 438,000, $ 425,000, and $ 450,000 in 1971, 1972, and 1973, respectively. In 1972 and 1973, 12 percent ($ 51,000) and 14 percent ($ 63,000), respectively, of those expenses were charged to and included in petitioner's cost of goods sold of Darvon and Darvon-N products. The percentages of finished stock planning expenses charged to Darvon and Darvon-N cost **[**174]** of goods sold were based on the ratio of the number of persons handling all Puerto Rico source products to the total number of persons in the finished stock planning department.

b. *Operating Expenses*

i. *General Administration Expenses*

[*1095] In allocating general administrative expenses, petitioner first obtained the total general administrative expenses for its 1971, 1972, and 1973 pharmaceutical division from its consolidated financial statements. Petitioner then arrived at an "administrative expense factor," which was the percentage of total general administrative expenses relative to certain total expenditures of petitioner. The denominator of that fraction included manufacturing costs less material costs, research and development expenses, and selling, merchandising, and shipping expenses of petitioner. The next step was to total the various expenses that previously had been directly incurred or allocated in the combined income statements, i.e., the selling, merchandising, and shipping expenses. The administrative expense factor percentage then was applied to those expenses, which resulted in a total administrative expense allocable to Darvon and Darvon-N products.

ii. *Selling Expenses*

For **[**175]** 1971, petitioner's selling expenses were allocated to Darvon and Darvon-N products on the basis of the ratio of primary details of those products to total pri-

mary details. [36] The method of allocating selling expenses used by petitioner for the years 1972 and 1973 was as follows.

Petitioner's selling expenses were first analyzed by segregating total calls by sales representatives into six categories. Each sales representative of petitioner reported on a daily call card the number and types of calls he made on various health care representatives. The total calls of the sales representative were categorized as follows: physicians, interns, and residents; drug stores; hospitals; nonmedical; dentists; and miscellaneous. The total number of calls and a percentage of total calls were determined for each category.

The total U.S. selling expenses of petitioner's pharmaceutical division, less selected accounts, [37] then were extracted from the general ledger. That total was multiplied by the percentage factor for each call category to arrive at the total amount of selling expenses for all products properly attributable to each particular category **[**176]** of calls.

[*1096] The next step was a determination of the proper allocation factor or percentage for each call category as it related to Darvon and Darvon-N products. The allocation factor then was multiplied against the total amount of selling expenses for each category to determine the proper Darvon/Darvon-N allocation.

The first type of call category, physicians, interns, and residents, involved calls on physicians, interns, and residents at their private offices or in hospitals. Those calls were allocated on the basis of annual primary detail calls made by petitioner's sales representatives on physicians, interns, and residents for Darvon and Darvon-N products as a percentage of total primary detail calls for all of petitioner's products. The number of such annual primary detail calls was ascertained from the internal call data reports submitted by the sales representatives to petitioner's marketing department. Primary detail calls represented the most reliable information to measure selling activity for **[**177]** physician, intern, and resident calls.

The next category, drug store calls, was determined by reference to petitioner's ***price*** list for its top 100 items (based on sales). The top 100 items represented 92 percent of petitioner's pharmaceutical products sold for 1973. Petitioner determined that, according to the ***price*** list, sales of Darvon and Darvon-N products represented 10 percent of the total number of sales of the top 100 items. Accordingly, a 10-percent allocation factor was applied for drug store calls. Petitioner used that methodology to allocate drug store calls because that type of call was essentially a service call on the pharmacist and, unlike calls on physicians, did not relate to any specific product.

Hospital calls involved calls on hospital pharmacists. Those calls were allocated on the basis of total Darvon and Darvon-N products sales to hospitals as a percentage of total pharmaceutical sales by petitioner to hospitals. Because petitioner had no actual data on sales of its products to hospitals, because it sold only to wholesalers, the data for that method were derived from an external independent audit conducted by International Marketing Services (hereinafter **[**178]** IMS). The audit was based on a significant statistical sample, and IMS used techniques that petitioner believed provided a good representation of the **[*1097]** movement of products from the wholesaler to the hospital. Petitioner believed the IMS data to be accurate and reliable.

Nonmedical calls involved calls in a hospital atmosphere on nonphysician health care individuals, such as hospital administrators or nurses. As with hospital calls, the percentage allocation factor was determined on the basis of total sales of Darvon and Darvon-N products to hospitals as a percentage of total pharmaceutical sales by petitioner to hospitals. Therefore, the source of data used for the allocation was again the IMS audit.

Dentist calls involved calls by petitioner's sales representatives on privately practicing dentists in their offices. Petitioner's methodology was to calculate total Darvon and Darvon-N prescription dollars as a percentage of petitioner's total dental prescription dollars to arrive at an expense allocation for Darvon and Darvon-N products. Because petitioner had no internal records regarding dental prescriptions, it again used data derived from an external independent audit. The audit **[**179]** used was the R.A. Gosselin Prescription Audit (hereinafter the Gosselin audit). Whereas the IMS audit was a breakdown of retail sales, primarily to hospitals, the Gosselin audit was an audit of actual prescription activity. Petitioner believed the Gosselin data to be accurate and reliable.

Miscellaneous calls involved calls by petitioner's sales representatives on industrial clinics; pharmacy, dental, and medical schools; and nursing homes. The methodology used to arrive at an allocation factor for miscellaneous calls was to calculate petitioner's total sales of Darvon and Darvon-N products to wholesalers as a percentage of petitioner's total sales of pharmaceutical products to wholesalers. The data for that allocation were generated internally.

The final item of allocation of selling expenses was administrative support. Administrative support represented

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[36] See p. 1054 for the meaning of primary details.

[37] The record is silent as to what those accounts were in 1972. In 1973, the total pharmaceutical division selling expenses were reduced only by the expenses of the Dista sales force.

expenditures exclusive of direct selling, such as sales management, district and regional sales directors, secretarial support, and sales service training. The methodology used to determine the allocation factor was the same as that used for miscellaneous calls, that is, the percentage factor was calculated based on petitioner's **[**180]** total sales of Darvon and Darvon-N products to wholesalers as a percentage of petitioner's total pharmaceutical **[*1098]** sales to wholesalers. The data for that allocation also were internally generated.

iii. *Merchandising Expenses*

Petitioner's allocation of merchandising expenses in the combined income statements was first determined by identifying the total merchandising expenses reported on the books and records of petitioner's pharmaceutical division as accumulated in its consolidated financial statements for the years 1971, 1972, and 1973. Those figures were comprised of direct promotion expenses and indirect merchandising expenses.

The direct promotion expenses were those expenses directly related to particular product groups. At the time such expenditures were incurred, they were coded in such a manner that they could be accumulated in a promotional group, and, therefore, were identified directly with such group.

The indirect merchandising expenses were those not directly identifiable with any particular product group and represented the balance of the merchandising expenses of the pharmaceutical division. Because petitioner had determined that the indirect expenses were incurred for **[**181]** the benefit of all pharmaceutical products sold by it, those expenses were allocated on the basis of total sales of those particular product groups to total wholesaler sales.

iv. *Shipping Expenses*

Petitioner's total shipping expenses were derived from the consolidated expenses of petitioner's pharmaceutical division for the years 1971 through 1973. From the various distribution departments, data were obtained to determine the total number of shipments made and those shipments then were divided into the total cost of shipping expenses to get a per-unit cost of shipping. The resulting unit number then was applied to the number of units of Darvon and Darvon-N products shipped to determine the portion of shipping expenses allocable to Darvon and Darvon-N products.

H. *Technical Assistance Fees*

During the years 1971, 1972, and 1973, Lilly P.R. was billed for certain technical assistance that it received from petitioner. The amounts of technical assistance fees billed to Lilly P.R. by petitioner for each of those years were as follows: **[*1099]**

Year	Amount
1971	$ 166,481
1972	129,054
1973	131,969

During the years 1965 through 1973, petitioner determined the technical assistance fees charged to Lilly P.R. **[**182]** by multiplying the number of hours of technical assistance reported by petitioner's employees by the technical assistance fee rates applicable to those employees. In addition, an amount equal to 5 percent of those hourly charges was added to each technical assistance invoice. The hourly technical assistance fee rates were equal to the average hourly compensation costs (including benefits and employment ***taxes***) for petitioner's employees. One rate was used for all nonexempt employees, a second rate was used for all exempt employees below the level of director, and individual rates were used for employees at the director levels and above. Petitioner also billed Lilly P.R. for the travel expenses of petitioner's employees who traveled to Puerto Rico and for engineering services according to petitioner's standard rates.

The amounts billed by petitioner to Lilly P.R. during the years 1971 through 1973 represented all the technical assistance rendered by petitioner for the benefit of Lilly P.R. except for certain activities labeled as stewardship functions by petitioner. Petitioner's employees had no incentive to understate the amount of technical assistance fees chargeable to Lilly P.R. **[**183]** Indeed, the opposite was true because all amounts for technical assistance fees charged to Lilly P.R. reduced petitioner's department expenses for budgetary and profit performance purposes.

I. *Lilly P.R. Purchases From Petitioner*

1. Raw Materials

Lilly P.R.'s purchases of raw materials from third-party suppliers accounted for 80 percent, 81 percent, and 87 percent of its total raw material purchases in dollars for 1971, 1972, and 1973, respectively. The remainder of Lilly P.R.'s purchases of raw materials in those years were from petitioner.

Petitioner's ***prices*** for raw materials sold to Lilly P.R. were cost plus 100 percent for materials manufactured by petitioner and petitioner's cost for materials purchased by petitioner. **[*1100]** Petitioner's cost for both manufactured and purchased materials included its costs of

packaging materials and material handling (e.g., freight in, freight to Puerto Rico, analytic assays on incoming materials, and warehousing).

2. *Equipment and Machine Parts*

As stated earlier in our findings of fact, Lilly P.R. purchased equipment and machine parts either directly from third-party suppliers or through petitioner during the years 1971 through 1973.

In cases in which **[**184]** Lilly P.R. purchased equipment directly from third-party suppliers, petitioner had no involvement whatsoever. In cases in which Lilly P.R. purchased equipment and machine parts through petitioner, Lilly P.R. was billed by petitioner for the requested items plus transportation and related services of petitioner (i.e., handling charges and costs of purchasing and engineering personnel) without any additional charges.

XIII. *Generic Propoxyphene Products*

A. *General*

In 1973, after the propoxyphene patent expired, at least 24 pharmaceutical manufacturers and/or distributors entered the United States market with generic propoxyphene hydrochloride products. The suggested ***prices*** to retail pharmacies for the generic propoxyphene hydrochloride products generally were about one-half of petitioner's net trade ***prices*** for the comparable Darvon products.

In February 1973, Lilly Research Laboratories began a program of evaluating generic propoxyphene hydrochloride products that were in direct competition with Darvon 65 mg. (PU 365) and Darvon Compound-65 (PU 369). The quality of the generic products was compared with that of petitioner's Darvon products by examining specifications such as (a) uniformity **[**185]** of drug content, (b) uniformity of weight, (c) decomposition of aspirin in compound products into acetic acid and salicylic acid, and (d) purity (i.e., presence of nonpropoxyphene chemicals generated by the chemical manufacturing process). The results of that study indicated that petitioner's Darvon products were equal or superior to the **[*1101]** generic propoxyphene hydrochloride products. Two particular defects were found in the generic compound products. First, x-ray examination of generic products having a pellet formulation (i.e., containing an encased pellet of propoxyphene hydrochloride to prevent the interaction of propoxyphene hydrochloride and aspirin) showed that some of the lots of the generic products contained capsules that contained either no pellet or two pellets. Second, examination of generic products having an all-powder formulation (i.e., products in which the propoxyphene hydrochloride was mixed directly with the aspirin) showed greater disintegration of aspirin into acetic acid and free salicylic acid than in Darvon compound products.

Three of the pharmaceutical firms that entered the U.S market in 1973 with generic propoxyphene products were Zenith Laboratories, Inc., **[**186]** Rachelle Laboratories, Inc., and Smith Kline & French Laboratories. Each company sold both propoxyphene hydrochloride and a propoxyphene hydrochloride compound in 65 milligram strengths. We will discuss each company in turn below.

B. *Zenith Laboratories, Inc.*

Zenith Laboratories, Inc. (hereinafter Zenith) is a manufacturer of generic pharmaceuticals with facilities in northern New Jersey and the Virgin Islands. Its sales are divided evenly between private label manufacturing and sales under its own label, and are made both to large pharmaceutical companies and to drug distributors.

Zenith purchases rather than produces the basic chemical substances used in its products. Zenith's activities, then, are limited to the pharmaceutical manufacturing activities of formulation, encapsulation or tableting, and packaging. During the early 1970s, it had approximately 190 employees, including 3 employees assigned to work full-time in obtaining FDA approval for its products. Zenith does not promote its products directly to physicians.

Zenith's net sales for the years 1971, 1972, and 1973, respectively, were $ 9,436,000, $ 9,032,000, and $ 11,593,000. There is no evidence in the record indicating **[**187]** what proportion of its 1973 net sales were attributable to sales of generic propoxyphene hydrochloride products.

[*1102] C. *Rachelle Laboratories, Inc.*

Rachelle Laboratories, Inc. (hereinafter Rachelle), is a subsidiary of International Rectifier Corp. located in Long Beach, California. Rachelle is largely a chemical company and produces basic substances as well as final pharmaceutical products. Rachelle produces products for sale not only to the human market, but to the veterinary market as well.

Rachelle chemically manufactures most of the substances used in the manufacture of its final pharmaceutical products. In 1973, Rachelle produced the propoxyphene hydrochloride used in its plain propoxyphene

hydrochloride capsules; [38] it purchased, however, finished propoxyphene hydrochloride compound-65 capsules from the Caribe Chemical Co., Inc., of the Virgin Islands.

During 1973, Rachelle employed approximately 200 persons at its Long Beach facility. As of June 1973, 67 of those employees were involved in the chemical and pharmaceutical manufacture of products, **[**188]** and 29 were involved in the sale and marketing of Rachelle's products.

Rachelle's net sales were $ 5,944,000, $ 12,254,000, and $ 11,228,000 for 1971, 1972, and 1973, respectively. Rachelle's sales of propoxyphene hydrochloride products were approximately $ 50,000 in fiscal year ending June 30, 1973, and approximately $ 60,000 in fiscal year ending June 30, 1974.

D. *Smith Kline & French Laboratories*

Smith Kline & French Laboratories (hereinafter SKF) marketed a line of branded prescription pharmaceutical products on which patent protection had expired called the SK line. The SK line included a fairly wide range of antibiotics and mild tranquilizers as well as two propoxyphene hydrochloride products. SKF manufactured the plain propoxyphene hydrochloride product it marketed, but purchased its SK-65 Compound (a combination of propoxyphene hydrochloride and APC) from Milan Pharmaceuticals, Inc.

1. *Milan Pharmaceuticals, Inc.*

Milan Pharmaceuticals, Inc. (hereinafter Milan), of Morgantown, West Virginia, is a generic pharmaceutical manufacturing **[*1103]** firm similar to Zenith and Rachelle. Milan purchases the basic chemical substances used in its products, and has no chemical manufacturing facilities. **[**189]** Its sales, like those of Zenith, are made both under its own label and under those of the largest pharmaceutical houses. During the latter part of 1973, Milan employed approximately 235 persons, 4 of whom were involved in research and development and obtaining FDA approval for Milan's products.

Milan's net sales for the years 1971, 1972, and 1973 were $ 4,253,000, $ 7,826,000, and $ 10,818,000, respectively. Of the 1973 net sales amount, approximately $ 1,200,000 were attributable to sales of propoxyphene hydrochloride compound.

2. *SK-65 Compound*

The SK-65 Compound manufactured for SKF by Milan contained an encased pellet of propoxyphene hydrochloride to prevent the propoxyphene hydrochloride from interacting with and decomposing the aspirin in that product. Because SKF did not have the capability of inserting the propoxyphene hydrochloride pellets into the capsules of SK-65 Compound, SKF decided to purchase SK-65 Compound from Milan, which had already developed that capability. In addition, Milan had obtained FDA approval to manufacture the SK-65 Compound, and, therefore, the use by SKF of Milan as the source of SK-65 Compound was the most expeditious way for SKF to enter the propoxyphene **[**190]** hydrochloride market.

Milan's basic ***price*** to SKF in 1973 for SK-65 Compound was $ 14.50 per 1,000 filled capsules. Milan also charged SKF $ 0.15 per bottle for packaging the SK-65 Compound capsules in bottles of 100 capsules and $ 0.3 for packaging the SK-65 Compound capsules in bottles of 500 capsules. Thus, Milan's ***price*** to SKF for a bottle of 100 SK-65 Compound capsules was $ 1.60, and Milan's ***price*** to SKF for a bottle of 500 SK-65 Compound capsules was $ 7.55.

During 1973, SKF purchased 47,399,654 filled SK-65 Compound capsules from Milan at a total invoice cost of $ 742,865. Milan's sales to SKF of SK-65 Compound capsules in bottles of 100, bottles of 500, sample packages, and bulk during 1973 were as follows: **[*1104]**

Type of package	1973 Sales
Bottle of 100 capsules	$ 295,072
Bottle of 500 capsules	346,689
Sample package of 4 capsules	34,094
Bulk	67,010
Total	742,865

SKF sold the SK-65 Compound products purchased from Milan to drug wholesalers in the United States. SKF's net trade ***price*** and ***price*** to wholesalers for bottles of 100 SK-65 Compound capsules were $ 3.75 and $ 3.09, respectively. SKF's net trade ***price*** and ***price*** to wholesalers for bottles of 500 SK-65 Compound capsules were $ 16.50 and **[**191]** $ 13.61, respectively.

[38] Rachelle purchased propiophenone and began its chemical manufacture of propoxyphene hydrochloride at the equivalent of petitioner's step 2.

SKF supplied to Milan at no charge the empty capsules, package inserts, labels, and bottle caps used by Milan in making SK-65 Compound for SKF. SKF's cost of providing those materials for Milan were $ 0.26 for a bottle of 500 SK-65 Compound capsules.

During 1973, Lilly P.R. manufactured the empty capsules it used to make Darvon Compound-65 and purchased from suppliers the package inserts, labels, and bottle caps for Darvon Compound-65. [39] During the period 1971 through 1973, petitioner sold billions of empty capsules to unrelated customers throughout the world. Petitioner's ***price*** per thousand for empty capsules of the type used by Lilly P.R. in manufacture of Darvon Compound-65 was about $ 1.60. During that period, Lilly P.R. lost, in the manufacturing process, approximately 3 percent of the empty capsules it used in the filling and finishing of Darvon Compound-65. Thus, the effective market ***price*** for empty capsules for Darvon Compound-65 was approximately $ 0.82 per bottle of 500 capsules. Lilly P.R.'s standard cost per bottle of 500 Darvon Compound-65 capsules for labels, package inserts, and bottle caps was approximately $ 0.04 in 1973.

Milan's credit terms to SKF in 1973 relative to Milan's sales of SK-65 Compound to SKF were a 1-percent discount for payment within 10 days and net for payment in 30 days.

SKF also purchased SK-65 Compound capsules from Milan for use as samples. Approximately 20 percent of the SK-65 Compound capsules used as samples by SKF in 1973 were **[*1105]** packaged by Milan in packages of four capsules. Milan's ***price*** to SKF for such a sample package was $ 0.135 per package. The remaining SK-65 Compound capsules purchased by SKF from Milan for use as samples were purchased in bulk at the basic ***price*** of $ 14.50 per thousand capsules and packages by SKF.

SKF loaned to Milan, at no charge, equipment used by Milan in 1973 to package SK-65 Compound capsules in sample packages. That equipment was excess old equipment owned by SKF which was not being used by it at the time the equipment was made available to Milan.

Milan had its own quality control personnel who performed all required FDA checks on products it produced. SKF, however, performed complete quality control analysis on the first **[**193]** several commercial batches of SK-65 Compound it purchased from Milan. After that time, SKF accepted Milan's quality control assay reports, but continued to perform a physical quality control check upon receipt of the SK-65 capsules.

SKF also retained from each lot of SK-65 Compound capsules purchased from Milan a sampling of capsules for stability testing. In addition, during each of the production runs of SK-65 Compound at Milan, SKF had from 1 to 3 of its own quality control personnel at Milan's plant to observe the production process. SKF's quality control personnel were present at Milan's plant for the duration of each production run which, depending on the size of the run, was approximately 1 week.

SKF paid the freight costs related to shipments of SK-65 Compound from Milan to SKF in 1973. SKF did not maintain any FDA required records for Milan; Milan maintained all the required records relative to its production of SK-65 Compound. SKF did not make any patent or manufacturing know-how relative to SK-65 Compound available to Milan. SKF did not perform any research and development, pilot plant testing, or process development testing for Milan.

XIV. *Respondent's Proposed Adjustments*

A. **[**194]** *Notice of Deficiency*

In his notice of deficiency dated March 26, 1976, respondent allocated gross income from Lilly P.R. to petitioner under *section 482* in the amounts of $ 18,522,924, $ 17,820,986, and $ 10,717,187 for 1971, 1972, and 1973, respectively, with respect **[*1106]** to Lilly P.R.'s sales of Darvon and Darvon-N products to petitioner in those years.

The allocations of income in the notice of deficiency were based upon a multi-step method of determining Lilly P.R.'s gross income on sales of Darvon and Darvon-N products to petitioner. Under that method, Lilly P.R.'s gross income on sales to petitioner of Darvon and Darvon-N products was equal to the sum of the following amounts:

(a) Lilly P.R.'s cost of goods sold;

(b) Lilly P.R.'s location savings (i.e., the cost savings resulting from operating in Puerto Rico rather than in the continental United States);

(c) a gross profit for the Mayaguez facility of Lilly P.R. determined by respondent; and

(d) a gross profit for the Carolina facility of Lilly P.R. determined by respondent.

The location savings of the Mayaguez and Carolina facilities of Lilly P.R. for the years 1971, 1972, and 1973 were as follows:

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[39] Lilly P.R. purchased **[**192]** from petitioner all labels and literature, as well as some bottle caps, used in its packaging of Darvon and Darvon-N products.

	1971	1972	1973
Mayaguez	$ 1,464,359	$ 1,354,798	$ 1,211,242
Carolina	3,263,957	3,910,644	2,602,491
Total	4,728,316	5,265,442	3,813,733

[195]** In the notice of deficiency, respondent determined the gross profit for Lilly's P.R.'s Mayaguez facility by constructing ***prices*** for the bulk propoxyphene hydrochloride and propoxyphene napsylate ***transferred*** by the Mayaguez facility to Lilly P.R.'s Carolina facility. Respondent determined that those ***prices*** were $ 88, $ 86, and $ 77 per kilogram for 1971, 1972, and 1973, respectively. The gross profit of the Mayaguez facility as determined by respondent was the excess of those ***prices*** over Lilly P.R.'s cost of manufacturing propoxyphene hydrochloride and propoxyphene napsylate.

In the notice of deficiency, respondent determined that the gross profit of the Carolina facility was 25 percent of the sum of (a) the Carolina facility's ″cost″ of acquiring the propoxyphene hydrochloride and propoxyphene napsylate from the Mayaguez facility at the ***transfer prices*** constructed by respondent, (b) the manufacturing cost of the Carolina facility (exclusive of the actual cost of propoxyphene hydrochloride **[*1107]** and propoxyphene napsylate), and (c) the location savings attributable to the Carolina facility.

B. *Amendment to Answer*

In an amendment to answer filed April 14, 1981, respondent increased the *section 482* **[**196]** allocation of gross income from Lilly P.R. to petitioner with respect to Darvon and Darvon-N products by $ 23,952,413 for the period 1971 through 1973, as indicated by the following table:

	Sec. 482 allocation		
	Amendment to answer	Notice of deficiency	Increase in allocation
1971	$ 26,620,387	$ 18,522,924	$ 8,097,463
1972	26,314,918	17,820,986	8,493,932
1973	18,078,205	10,717,187	7,361,018
Total	71,013,510	47,061,097	23,952,413

The increase in *section 482* allocations in the amendment to answer resulted from a new method of computing Lilly P.R.'s gross income from sales of Darvon and Darvon-N products to petitioner. In the amendment to answer, respondent asserted that such gross income should be limited to 130 percent of the sum of Lilly P.R.'s manufacturing costs and location savings. The notice of deficiency ***pricing*** method was asserted by respondent as an alternative position to the amendment to answer ***pricing*** method.

OPINION

Introduction

The issues before this Court involve respondent's reallocations of gross income from Lilly P.R. to petitioner for the taxable years 1971, 1972, and 1973.

Petitioner is engaged in the manufacture and sale of pharmaceutical products. Petitioner invented and patented propoxyphene **[**197]** hydrochloride (Darvon) during the early 1950s and propoxyphene napsylate (Darvon-N) during the early 1960s. Darvon was first introduced into the U.S. market in 1957, and was manufactured by petitioner in Indiana from 1957 through 1966. Darvon-N was not introduced into the U.S. market until 1971 and was never manufactured by petitioner.

[*1108] During 1965, petitioner organized Lilly P.R. as a wholly owned Puerto Rican subsidiary. In December 1966, petitioner ***transferred*** ″all right, title and interest in and to″ the propoxyphene and napsylate patents to Lilly P.R., as well as the exclusive right to use petitioner's manufacturing know-how. The transaction qualified for nonrecognition under *section 351* and, therefore, Lilly P.R. reported no gain or loss on the transaction in 1966. After the ***transfer*** in 1966 and throughout the years in issue, Lilly P.R. was the sole manufacturer of Darvon and Darvon-N; Lilly P.R. sold its products to petitioner, who in turn marketed the products throughout the United States.

In the statutory notice of deficiency and in the amended answer, respondent, through adjustments in intercorporate ***pricing***, reallocated the income attributable to the propoxyphene and napsylate **[**198]** patents and related manufacturing know-how from Lilly P.R. to petitioner under the authority of *section 482*. Respondent's methods of determining the *section 482* allocations in the notice of deficiency, the amended answer, and at trial treat Lilly P.R. as a contract manufacturer and do not

take into account Lilly P.R.'s ownership of the manufacturing intangibles.

The first issue we must decide is whether Lilly P.R. should be considered the owner of the propoxyphene and napsylate patents and manufacturing know-how for purposes of determining arm's-length ***prices*** to petitioner under *section 482*. We must then determine whether respondent's *section 482* adjustments were arbitrary, capricious, or unreasonable. Finally, we must make a determination of arm's-length ***prices*** between petitioner and Lilly P.R.

Issue 1. Ownership of Intangibles for Section 482 Purposes

The first issue for decision is whether, for purposes of determining arm's-length ***prices*** under *section 482*, [40] the **[*1109]** income attributable to the manufacturing intangibles should be allocated to petitioner or Lilly P.R.

Petitioner contends that it ***transferred*** complete ownership of the propoxyphene and napsylate patents and manufacturing know-how to Lilly P.R., and that, therefore, the income from such patents and know-how belongs to Lilly P.R. Although respondent concedes that Lilly P.R. acquired legal title to the patents and know-how in 1966 in a valid *section 351* ***transfer***, [41] he maintains that for purposes of *section 482*, legal ownership of the intangibles can be disregarded and all income attributable to them reallocated from Lilly P.R. to petitioner. During all relevant years, Lilly P.R. was a qualifying *section 931* possessions corporation and was exempt from U.S. **[**200]** ***tax*** on the income earned from its manufacture and sale of Darvon and Darvon-N products.

A. *Background of Relevant Provisions*

1. ***Tax*** Incentives for Companies Operating in Puerto Rico

a. *Section 931*

Section 931, in effect during the years in issue, provided in relevant part:

HN4 *SEC. 931*. INCOME FROM SOURCES WITHIN POSSESSIONS OF THE UNITED STATES.

(a) General Rule. -- In the case of citizens of the United States or domestic corporations, gross income means only gross income from sources within the United States if the conditions of both paragraph (1) and paragraph (2) are satisfied:

> (1) 3-year period. -- If 80 percent or more of the gross income of such citizen or domestic corporation (computed without the benefit of this section) for the 3-year period immediately preceding the close of the taxable year (or for such part of such **[**201]** period immediately preceding the close of such taxable year as may be applicable) was derived from sources within a possession of the United States; and
>
> (2) Trade or business. -- If --
>
> > (A) in the case of such corporation, 50 percent or more of its gross income (computed without the benefit of this section) 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.

[*1110] *Section 931* had its genesis 64 years ago in section 262 of the Revenue Act of 1921, ch. 136, 42 Stat. 271, which first exempted from Federal ***taxes*** the incomes of U.S. corporations operating in a possession. [42] Section 262(c) provided the requirements for qualification as a possessions corporation later set forth in *section 931*. The section was reenacted without any material change by section 251 of the Revenue Act of 1928, ch. 852, 45 Stat. 850, and *section 931 of the Internal Revenue Code of 1954*. It was not until enactment of the ***Tax*** Reform Act of 1976, that any material changes were made in the basic ***tax*** exemption for possessions corporations, and then Congress substituted an equally favor-

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[40] ***HN2*** Sec. 482. ALLOCATION OF INCOME AND DEDUCTIONS AMONG TAXPAYERS.

In any case of two or more organizations, trades, or businesses **[**199]** (whether or not incorporated, whether or not organized in the United States, and whether or not affiliated) owned or controlled directly or indirectly by the same interests, the Secretary may distribute, apportion, or allocate gross income, deductions, credits, or allowances between or among such organizations, trades, or businesses, if he determines that such distribution, apportionment, or allocation is necessary in order to prevent evasion of taxes or clearly to reflect the income of any such organizations, trades, or businesses.

[41] ***HN3*** SEC. 351. TRANSFER TO CORPORATION CONTROLLED BY TRANSFEROR.

(a) General Rule. -- No gain or loss shall be recognized if property is transferred to a corporation by one or more persons solely in exchange for stock or securities in such corporation and immediately after the exchange such person or persons are in control (as defined in section 368(c)) of the corporation.

[42] For an overview of the tax relationship between the United States and its possessions and territories, see Hoff, "U.S. Federal Tax Policy Towards the Territories: Past, Present and Future," 37 Tax L. Rev. 53 (1981).

able ***tax*** credit mechanism. See section 936, ***Tax*** Reform **[**202]** Act of 1976, Pub. L. 94-455, 90 Stat. 1643.

The congressional intent for *section 931* and its predecessors consistently has been the encouragement of American business investments in possessions of the United States. American companies operating in the possessions originally were subjected to double taxation by the imposition of both the Federal corporate income ***tax*** and the ***taxes*** levied by the possessions governments. Section II of the Tariff Act of 1913, ch. 16, 38 Stat. 166; Revenue Act of 1918, ch. 18, 40 Stat. 1058. Congress perceived that the ***tax*** burden so created placed American businesses at a competitive disadvantage when compared with their British and French counterparts, which were not subject to taxation on the profits earned abroad unless they were paid back to the home company. Congress consequently enacted *section 931* and its predecessors to remove that competitive disadvantage and to encourage American business activity in the U.S. possessions. H. Rept. **[**203]** 350, 67th Cong., 1st Sess. 1 (1921), 1939-1 C.B. (Part 2) 168, 174.

Generally, *section 931* provided corporations an exclusion of possession source income if they met the 80-percent source test and 50-percent active trade or business test. Because of that exclusion, and because dividends received by a domestic corporation from its wholly owned possessions subsidiary were not eligible for the intercorporate dividends received deduction of section 246(a)(2)(B), possessions corporations amassed **[*1111]** large amounts of income which were not repatriated to the United States. To encourage investment of possessions source earnings in the United States, in 1976 Congress enacted new section 936. ***HN5*** That section eliminated the ***tax*** exemption for income from foreign investments outside the possessions and permitted the intercorporate dividends received deduction for dividends received from a wholly owned possessions subsidiary. Section 936 essentially transformed the exemption mechanism contained in *section 931* to a credit system whereby the U.S. parent can elect a special ***tax*** credit to offset the U.S. ***tax*** on its wholly owned possessions subsidiary's source income. [43]

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, at least on the part of the United States, by its enactment of section 936. As the Senate Finance Committee and the House of Representatives Committee on Ways and Means stated, 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 **[**205]** 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.

[*1112] *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 **[**206]** *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.

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[43] ***HN6*** Sec. 936 allows the tax credit **[**204]** to domestic corporations operating in Puerto Rico and all possessions of the United States except the Virgin Islands. Sec. 931 was retained to provide the possessions source income exclusion to qualifying U.S. individual citizens. For sec. 931 purposes, however, ″possession″ does not include Puerto Rico, Guam, or the Virgin Islands. Sec. 931(c); sec. 1.931-1(a), Income Tax Regs. The Puerto Rican-source income exclusion for qualifying U.S. individual citizens is now contained in sec. 933.

[S. Rept. 94-938 (1976), 1976-3 C.B. (Vol. 3) 315, 315-316; H. Rept. 94-658 (1975), 1976-3 C.B. (Vol. 2) 945, 946-947. Emphasis added and fn. refs. omitted.] [44]

(The excerpt quoted is from the Senate report; the House report version differs by two words.)

b. *Puerto Rico's Operation Bootstrap*

In 1948, as part of its Operation Bootstrap, the Commonwealth of Puerto Rico matched the U.S. ***tax*** exemption for possessions corporations. Industrial ***Tax*** Exemption Act of 1948, *P.R. Laws Ann. tit. 13, secs. 221-238* (1955). ***HN7*** In addition to exempting corporations from Puerto Rican corporate income ***taxes***, the legislation also provided exemptions from certain property ***taxes***, excise ***taxes***, and license fees, with a gradual phase-out of exemptions by 1962. The ***tax*** exemptions generally were available for a corporation manufacturing items not produced on a commercial scale in Puerto Rico prior to 1947.

HN8 In 1954, the 1948 Act was reenacted with an amendment providing for an additional 10-year exemption for new businesses subsequently locating on the island. Industrial Incentive Act of 1954, *P.R. Laws Ann. tit. 13, secs. 241-251* (1977). **[**208]** Later, as the 1950s drew to a close and some of the original investors approached the end of their exemption periods, pressure mounted for further extensions of, and **[*1113]** liberalizations in, the industrial incentives. The Industrial Incentive Act of 1963, *P.R. Laws Ann. tit. 13, secs. 252-252j* (1977), as subsequently enacted, provided completely new exemption grants for periods ranging from 10 to 25 years and retained virtually all the provisions of the 1954 Act.

2. *Nonrecognition Provision of Section 351*

HN9 *Section 351* provides for the nonrecognition of gain or loss upon the ***transfer*** of property to a corporation if immediately after the ***transfer*** the corporation is controlled [45] by the transferor. The ***transfer*** of property must be "solely in exchange for stock or securities" of the transferee corporation. The ***transfer*** of property to an existing controlled corporation will qualify the transaction for nonrecognition treatment even though the transferor did not receive any additional stock at the time of the ***transfer***. [46]

Petitioner **[**210]** ***transferred*** the propoxyphene and napsylate patents and manufacturing know-how to Lilly P.R., a wholly owned subsidiary. [47] It is undisputed that petitioner's ***transfer*** of the patents and know-how to Lilly P.R. qualified for nonrecognition under *section 351*. Respondent not only has issued a private ruling letter (as set out in pp. 1029-1031 of our findings of fact) to petitioner in which he ruled that no gain or **[*1114]** loss on the ***transfer*** would be recognized under *section 351*, [48] but has emphasized through counsel on brief that he

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[44] On Sept. 3, 1982, Congress enacted the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Pub. L. 97-248, 96 Stat. 324. TEFRA contains new provisions dealing specifically with the issue before us involving the tax-free transfer of intangibles to a possessions corporation. **[**207]** However, no inference can be drawn from those provisions and the fact of their enactment can have no effect on our decision herein. See H. Rept. 97-760 (Conf.) (1982), 1982-2 C.B. 600, 617 n. 1. Moreover, the provisions are effective, with two exceptions not relevant herein, only for taxable years beginning after Dec. 31, 1982.

[45] ***HN10*** "Control" is defined by sec. 368(c) as being "the ownership of stock possessing at least 80 percent of the total combined voting power of all classes of stock entitled to **[**209]** vote and at least 80 percent of the total number of shares of all other classes of stock of the corporation." There is no question of control being present in the case as Lilly P.R. was at all times the wholly owned subsidiary of petitioner. We mention control merely as being one of the requirements for nonrecognition under sec. 351.

[46] ***HN11*** Rev. Rul. 64-155, 1964-1 C.B. (Part 1) 138 provides, in pertinent part:

"X, a domestic corporation, proposes to contribute appreciated property to Y, an existing wholly owned foreign subsidiary. Although X will not receive any additional Y shares, the transaction will be considered an exchange of property for stock described in section 351 of the Internal Revenue Code of 1954."

Revenue rulings "have none of the force or effect of Treasury decisions" and do not commit the Service to a particular interpretation of the law. *Helvering v. New York Trust Co.*, 292 U.S. 455 (1934). While a ruling is not controlling, however, it is not without weight and we will consider it as a statement of respondent's position on a given set of facts. *Groves v. United States*, 533 F.2d 1376 (5th Cir. 1976), affg. an unreported District Court opinion, cert. denied 429 U.S. 1000 (1976).

[47] Petitioner's ***HN12*** transfer of patents and know-how was a "transfer of property." See, e.g., *Hooker Chemicals & Plastic Corp. v. United States*, 591 F.2d 652 (Ct. Cl. 1979); *DuPont de Nemours & Co. v. United States*, 471 F.2d 1211 (Ct. Cl. 1973); *Bell International Corp. v. United States*, 381 F.2d 1004 (Ct. Cl. 1967); Rev. Rul. 71-564, 1971-2 C.B. 179; Rev. Rul. 64-56, 1964-1 C.B. (Part I) 133. See also generally **[**211]** Beschell, Taxation of Patents, Trademarks, Copyrights & Know-How, par. 6.3, 6.3A, at 6-5 -- 6-14 (1974).

[48] ***HN13*** A ruling may be modified or revoked by the Service, effective in rare cases even retroactively. Sec. 7805(b); sec. 601.201(1), Statement of Procedural Rules; *Automobile Club of Michigan v. Commissioner*, 353 U.S. 180, 184 (1957). The record in this case clearly indicates that the representations of fact by petitioner upon which the Service's ruling to petitioner was based were accurate. The ruling issued to petitioner has not been revoked and thus is controlling. See *Wisconsin Nipple & Fabri-*

does not challenge the validity of the section 351 ***transfer***. Thus, petitioner recognized no gain or loss upon its ***transfer*** of patents and know-how to Lilly P.R. in 1966 and, after such ***transfer***, Lilly P.R. was the legal owner of those patents and know-how.

B. *Interrelationship of Section 482 and Sections 351 and 931*

1. *Introduction*

a. *History and Purpose of Section 482*

Section 482 had its origin in Regulation 41, Articles 77 and 78 of the War Revenue Act of 1917, ch. 63, 40 Stat. 300, which gave the Commissioner the authority to require related corporations to file consolidated returns "Whenever necessary to more equitably determine the invested capital or taxable income." It reappeared in section 240(d) of the Revenue Act of 1921, ch. 136, 42 Stat. 260, as part **[**212]** of the provisions liberalizing the consolidated return rules. [49] Section 240(d) permitted the Commissioner to consolidate the accounts of affiliated corporations "for the purpose of making an accurate distribution or apportionment of gains, profits, income, deductions, or capital between or among such related trades or business." Section 240(d) of the Revenue Act of 1921 was successively reenacted as section 240(d) of the Revenue Act of 1924, ch. 234, 43 Stat. 288, and as section 240(f) of the Revenue Act of 1926, ch. 27, 44 Stat. 46, both of which permitted taxpayers to request the Commissioner to consolidate the accounts of related businesses.

Section 45 of the Revenue Act of 1928, ch. 852, 45 Stat. 806, gave the predecessor of section 482 **[**213]** independent status by **[*1115]** eliminating the taxpayer's power to invoke the section and emancipating it from the consolidated return provisions. The language in the new section 45 was essentially the same as that contained in the present section 482. The legislative history of the provision indicated that:

> Section 45 is based upon section 240(f) of the 1926 Act, broadened considerably in order to afford adequate protection to the Government made necessary by the elimination of the consolidated return provisions of the 1926 Act. The section of the new bill provides that the Commissioner may, in the case of two or more trades or businesses owned or controlled by the same interests, apportion, allocate, or distribute the income or deductions between or among them, as may be necessary in order to prevent evasion (by the shifting of profits, the making of fictitious sales, and other methods frequently adopted for the purpose of "milking"), and in order clearly to reflect their true ***tax*** liability. [H. Rept. 2, 70th Cong., 1st Sess. (1927), 1939-1 C.B. (Part 2) 395; see also S. Rept. 960, 70th Cong., 1st Sess. (1928), 1939-1 C.B. (Part 2) 426.]

b. *Scope of Respondent's Authority*

HN14 Section 482 gives **[**214]** respondent broad authority to allocate between or among commonly controlled [50] corporations their respective gross incomes, deductions, credits, or allowances when necessary either to prevent the evasion of ***taxes*** or in order clearly to reflect the income of such corporations. [51] We emphasize that these are alternate bases for application of the section.

HN16

A section 482 allocation based upon ***tax*** avoidance grounds is primarily intended to prevent the artificial shifting or milking of profits. [52] Thus, **[**215]** respondent's application of section 482 has been upheld when the challenged transaction was arranged by the related parties without a valid business purpose and solely in order to avoid ***taxes***. E.g., *Asiatic Petroleum Co. v. Commissioner*, 79 F.2d 234 (2d Cir. 1935), affg. *31 B.T.A. 1152 (1935)*, **[*1116]** cert. denied *296 U.S. 645*, rehearing denied *296 U.S. 664 (1935)*; *Northwestern National Bank of Minneapolis v. United States*, an unreported case (D. Minn. 1976, 38 AFTR 2d 76-1400, 76-1 USTC

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cating Corp. v. Commissioner, 67 T.C. 490, 497 (1976), affd. 581 F.2d 1235 (1978).

[49] Sec. 240 allowed affiliated corporations, which were previously required to file consolidated returns, to file separate returns. Corporations entitled to the benefits of sec. 262 (the predecessor of sec. 931), however, were treated as foreign corporations by sec. 240(d) and thus were prevented from filing consolidated returns. Sec. 1504 (b)(4), I.R.C. 1954, continues the possessions corporation proscription from filing consolidated returns.

[50] ***HN15*** The term "controlled," as defined by sec. 1.482-1(a)(3), Income Tax Regs., has a much more expansive meaning than that used in secs. 351 and 368. See n. 44 *supra*. For the purposes of sec. 482, "'controlled' includes any kind of control, direct or indirect, whether legally enforceable, and however exercisable or exercised." Lilly P.R. was at all times the wholly owned subsidiary of, and was controlled by, petitioner.

[51] See generally B Bittker & J. Eustice, Federal Income Taxation of Corporations and Shareholders, par. 15.06, at 15-16 (4th ed. 1979); Eustice, "Tax Problems Arising From Transactions Between Affiliated or Controlled Corporations," 23 Tax L. Rev. 451, 460-462, 480-496 (1968).

[52] ***HN17*** For purposes of sec. 482, the terms "tax evasion" and "tax avoidance" are interchangeable. See *Asiatic Petroleum Co. v. Commissioner*, 79 F. 2d 234, 236 (2d Cir. 1935); *Foster v. Commissioner*, 80 T.C. 34, 158 (1983), affd. on this issue 756 F. 2d 1430 (9th Cir. 1985).

par. 9408), affd. 556 F.2d 889 (8th Cir. 1977).

HN18 Respondent also may compel a reallocation of income under section 482 where the incomes of related parties are not clearly reflected, even in the absence of ***tax*** avoidance motives. This aspect of the section is concerned with properly allocating income to the person who earns the income and the deduction to the person who, in substance, incurred the expenses and obtained the benefits of the **[**216]** correlative deduction. Accordingly, the clear reflection of income doctrine has justified an allocation when the challenged transaction shifted income earned by one party to a related party (Baldwin-Lima-Hamilton Corp. v. United States, 435 F.2d 182 (7th Cir. 1970), affg. in part and revg. and remanding in part an unreported District Court decision), or when it resulted in an artificial mismatching of a party's income and expenses. Rooney v. United States, 305 F.2d 681 (9th Cir. 1962), affg. 189 F. Supp. 733 (N.D. Cal. 1960); Central Cuba Sugar Co. v. Commissioner, 198 F.2d 214 (2d Cir. 1952), revg. and remanding on this issue 16 T.C. 882 (1951), cert. denied 344 U.S. 874 (1952).

2. *Income From Manufacturing Intangibles*

a. *Section 482 Allocations Involving Nonrecognition* ***Transfers***

The issue now before us is whether Lilly P.R. should be considered the owner of the propoxyphene and napsylate patents and manufacturing know-how for purposes of determining arm's-length ***prices*** to petitioner for Lilly P.R.'s Darvon and Darvon-N products. [53] Respondent concedes the validity of petitioner's section 351 ***transfer*** of the manufacturing intangibles to Lilly P.R. and that Lilly P.R. is the legal **[**217]** owner of the intangibles. Respondent alleges, however, that he has the authority under section 482 to disregard the legal ownership **[*1117]** of the intangibles and to reallocate the income attributable to the intangibles from Lilly P.R. back to petitioner in order to prevent the evasion of ***taxes*** or clearly to reflect petitioner's income.

Petitioner agrees that respondent may use section 482 to reallocate income from property received in a section 351 ***transfer*** back to the transferor. Petitioner contends, however, that allocations ignoring nonrecognition ***transfers*** are upheld by the courts in only two narrow factual situations, discussed hereinafter, neither of which applies in this case. **[**218]** Therefore, petitioner asserts that respondent has no authority to disregard completely petitioner's 1966 ***transfer*** of the manufacturing intangibles to Lilly P.R. by reallocating the income attributable to those intangibles to petitioner. For the reasons discussed below, we agree with petitioner.

As we stated earlier, ***HN20*** section 482 provides that respondent may make allocations between related parties when necessary either to prevent the evasion of ***taxes***, or in order clearly to reflect their incomes. Moreover, section 1.482-1(d)(5), Income ***Tax*** Regs., specifically provides:

Section 482 may, when necessary to prevent the avoidance of ***taxes*** or to clearly reflect income, be applied in circumstances described in sections of the Code (such as section 351) providing for nonrecognition of gain or loss. See, for example, National Securities Corporation v. Commissioner of Internal Revenue, 137 F. 2d 600 (3rd Cir. 1943), cert. denied 320 U.S. 794 (1943).

National Securities Corp. v. Commissioner, 137 F.2d 600 (3d Cir. 1943), affg. 46 B.T.A. 562 (1942), and its progeny delineate ***HN21*** the situations in which courts have upheld section 482 allocations that, in effect, ignored nonrecognition ***transfers***. **[**219]** Those situations can be separated into two narrowly defined categories: (1) Cases in which property was ***transferred*** in a nonrecognition transaction and subsequently disposed of by the transferee, and in which the sole purpose of the ***transfer*** was to achieve ***tax*** consequences on the disposition of the property by the transferee that were more favorable than the ***tax*** consequences of a disposition by the transferor (see, e.g., National Securities Corp. v. Commissioner, supra; Southern Bancorporation v. Commissioner, 67 T.C. 1022 (1977); *Northwestern National Bank of Minneapolis v. United States*, an unreported case (D. Minn. 1976, 38 AFTR 2d 76-1400, 76-1 USTC par. **[*1118]** 9408), affd. 556 F.2d 889 (8th Cir. 1977)); [54] and (2) cases in which the nonrecognition ***transfer*** of property resulted in an artificial separation of income from the expenses of earning the income. See, e.g., Rooney v. United States, 305 F.2d 681 (9th Cir. 1962); Central Cuba Sugar Co. v. Commissioner, 198 F.2d 214 (2d Cir. 1952). But see Heaton v. United States, 573 F. Supp. 12 (E.D. Wash. 1983); Fanning v. United States, 568 F. Supp. 823 (E.D. Wash. 1983). The leading cases in each category are discussed in detail below.

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[53] ***HN19*** Sec. 1.482-1(b)(1), Income Tax Regs., adopted in 1968, provides, in pertinent part:

(b) *Scope and purpose*. (1) The purpose of section 482 is to place a controlled taxpayer on a tax parity with an uncontrolled taxpayer, by determining, according to the standard of an uncontrolled taxpayer, the true taxable income from the property and business of a controlled taxpayer. * * * The standard to be applied in every case is that of an uncontrolled taxpayer dealing at arm's length with another uncontrolled taxpayer.

[54] But **[**220]** see Ruddick Corp. v. United States, 226 Ct. Cl. 426, 643 F.2d 747 (1981), remanded 3 Cl. Ct. 61 (1983), affd. 732 F.2d 168 (Fed. Cir. 1984).

(i) *National Securities Corp. and Avoidance of **Taxes***

The leading case in the first category is *National Securities Corp. v. Commissioner, supra.* In that case, a parent corporation ***transferred*** shares of stock in an unrelated corporation, Standard Gas & Electric Co. (Standard), to the taxpayer, its wholly owned subsidiary, in exchange for additional shares of the taxpayer's stock. The transaction qualified as a nonrecognition exchange under the predecessor of *section 351*. [55] The parent's basis in the Standard stock was approximately $ 140,000, but the stock had only a market value of approximately $ 8,500 at the time of the ***transfer***. At the end of the ***transfer*** year, the taxpayer sold the stock for $ 7,175 and reported on its return a loss of $ 133,202, the difference between the parent's basis in the stock (the taxpayer's carryover basis under *section 362*) and the amount realized by the taxpayer. The parent, having already realized a net capital loss for that year in excess of the amount deductible under the relevant revenue provision, could **[**221]** not have derived any ***tax*** benefit from the loss on the sale if it had retained and then sold the Standard stock itself.

Acting pursuant to *section 482*, the Commissioner disregarded the nonrecognition ***transfer*** of stock and allocated the entire loss on the sale from the taxpayer to the parent. [56] The taxpayer contended that the nonrecognition and basis provisions of *sections 351* and *362*, respectively, precluded the application of *section 482* to the taxpayer. The Court of **[*1119]** Appeals for the Third Circuit upheld the Commissioner's allocation from the taxpayer to the parent under *section 482* of the deduction for the portion of the loss sustained before the ***transfer***.

The Court of Appeals based its holding in *National Securities Corp*. upon the clear reflection of income standard rather than the ***tax*** avoidance test of *section 482*. Factually, however, the case involved a ***tax*** avoidance situation in which a nonrecognition **[**222]** transaction was used solely to shift to the taxpayer the ***tax*** consequences of a preconceived disposition of stock in order to obtain a ***tax*** benefit that could not be obtained by the parent. Because there was no valid business purpose for the ***transfer***, we view *National Securities Corp*. and all members of the first category primarily as ***tax*** avoidance cases. See *Southern Bancorporation v. Commissioner*, 67 T.C. 1022, 1027 (1977).

The facts of the case before us are readily distinguishable from those discussed above. Petitioner's ***transfer*** of the patents and manufacturing know-how to Lilly P.R. was motivated by bona fide business reasons, and Lilly P.R. did not thereafter dispose of the ***transferred*** assets. Petitioner in 1965 needed to expand its chemical and pharmaceutical manufacturing facilities in order to meet the projected 1975 U.S. requirements for its products. After considering several alternatives, petitioner decided to locate two such facilities in Puerto Rico. That decision allowed petitioner to take advantage of the congressionally sanctioned ***tax*** incentives, Puerto Rican ***tax*** exemptions, and lower labor costs available in Puerto Rico. In addition, petitioner was able to diversify **[**223]** geographically its manufacturing facilities.

Once petitioner determined that the products it would manufacture in Puerto Rico were Darvon and Darvon-N, it consulted with its ***tax*** counsel to ascertain the most desirable means of doing so. Petitioner was advised that it could minimize its Federal income ***taxes*** by ***transferring*** ownership of the patents and the manufacturing intangibles relating to the production of Darvon and Darvon-N to a subsidiary possessions corporation that qualified for the benefits of *section 931*. On the basis of that advice, petitioner organized Lilly P.R. to operate the manufacturing facilities and executed the Assignment of Patent and Related Technical Data.

[*1120] ***HN22*** It is well established that taking advantage of ***tax*** benefits made available by Congress does not constitute ***tax*** avoidance. In *Barber-Green Americas, Inc. v. Commissioner*, 35 T.C. 365 (1960), this Court held that the organization of a subsidiary to take advantage of the Western Hemisphere Trade Corporation provisions of sections 921 and 922, and the organization of the business and sales procedures of the subsidiary to qualify for the benefits of sections 921 and 922, did not constitute ***tax*** avoidance under **[**224]** the predecessor of section 269. See also *Baldwin-Lima-Hamilton Corp. v. United States*, 435 F.2d 182 (7th Cir. 1970). Sections 921 and 922 provided a special deduction for corporations making sales in the Western Hemisphere. The purpose of the ***tax*** incentives provided in those sections is similar to the purpose of *section 931*, namely, to promote commerce and economic development in the targeted areas.

What we stated in *Barber-Greene* is equally applicable here:

When the Congress offered certain ***tax*** benefits as an inducement to United States corporations to engage in foreign trade, it was to be expected that some corporations would seek to avail themselves of these benefits. The creation of a subsidiary to carry on the business in the Western Hemisphere area of an existing domestic corporation does not constitute ***tax*** avoidance within the meaning of [the predecessor of section 269], * * * and there

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[55] To facilitate our discussion of the cases, we will hereafter refer to the sections involved solely by their current designations.

[56] At trial, the Commissioner conceded that the taxpayer was entitled to deduct the portion of loss sustained during the period in which it held the stock.

seems to be no good reason why the deliberate organizing of such a corporation's business and sales procedures to meet the other conditions specified by the legislation and thereby to qualify for the ***tax*** benefits offered should be regarded as ***tax*** avoidance. Otherwise the purpose of organizing **[**225]** a subsidiary would be lost and the congressional objective would not be carried out.

It has repeatedly been stated that ***HN23*** taxpayers have the right so to arrange their affairs that their ***taxes*** shall be as low as possible, *Gregory v. Helvering*, 293 U.S. 465 (1935); that one is not obliged to pursue a course of action giving rise to a greater ***tax*** liability if another is open which will give rise to a lesser liability, *Fruit Belt Telephone Co.*, 22 B.T.A. 440 (1931), * * * and that what a taxpayer did, rather than what he might have done, determines his liability. *Seminole Flavor Co.*, 4 T.C. 1215, 1230 (1945). * * *

[*35 T.C. at 386*.]See also *Achiro v. Commissioner*, 77 T.C. 881 (1981); *Rev. Rul. 76-363, 1976-2 C.B. 90*; *Rev. Rul. 70-238, 1970-1 C.B. 61*.

In enacting *section 931*, Congress intended to encourage American business investments in U.S. possessions. Responding to that congressional invitation, petitioner organized Lilly P.R. as a wholly owned Puerto Rican subsidiary qualifying for the ***tax*** benefits of *section 931*. Such action was motivated by **[*1121]** valid business purposes and does not constitute ***tax*** avoidance. [57] Accordingly, *National Securities Corp. v. Commissioner, supra*, and the ***tax*** **[**226]** avoidance standard of *section 482* are inapplicable.

ii. *Central Cuba Sugar, Rooney, and Clear Reflection of Income*

Central Cuba Sugar Co. v. Commissioner, 198 F.2d 214 (2d Cir. 1952), and *Rooney v. United States*, 305 F.2d 681 (9th Cir. 1962), are typical of the second category of cases noted earlier, i.e., cases in which nonrecognition **[**227]** ***transfers*** or property resulted in artificial separations of income from the expenses of earning that income. In each of those cases, the taxpayer ***transferred*** a planted crop, together with other assets, to a newly formed corporation in exchange for all the stock of the corporation. [58] The crop was harvested and the profit from the sale of the crop was reported as income by the new corporation. The taxpayer deducted the expenses incurred in growing the crop prior to its ***transfer*** and as a result, sustained a net operating loss which it sought to carry back to prior years. In each case, the Court of Appeals upheld the Commissioner's allocation of all the expenses of raising the crop from the taxpayer to the transferee corporation.

In *Central Cuba Sugar*, the Court of Appeals for the Second Circuit rejected the taxpayer's argument that *section 482* **[**228]** was inapplicable in the face of the nonrecognition reorganization provisions. It observed that *section 482* had its origin in the consolidated returns provisions, and that consolidation would have shown the income which accrued during the year for the business as a whole. It stated that ***HN25*** allocation likewise should be available to dissolve the fiction that one entity was unprofitable, **[*1122]** and that "to achieve 'the rough matching of expenses and income previously attained,' allocation of the expenses to the concern which is to profit by them is the alternative." *198 F.2d at 216*; citations omitted. The Ninth Circuit Court of Appeals in *Rooney* followed suit, concluding that "*section 482* * * * will control when it conflicts with *section 351* * * * as long as the discretion of the Commissioner in reallocating is not abused." *305 F.2d at 686*. Citing *Central Cuba Sugar*, the Court held that there was no abuse of discretion by the Commissioner.

Both *Central Cuba Sugar* and *Rooney* dealt with bifurcations of a single taxable year. Both cases involved nonrecognition ***transfers*** of unharvested crops to new corporations, with the transferee corporations reporting the crop income and the transferors deducting **[**229]** the crop growing expenses and, consequently, suffering net operating losses. [59] Both cases also involved ***transfers*** which the Courts acknowledged were motivated by valid

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[57] Because of the lack of tax avoidance motives herein, petitioner states that *Ruddick Corp v. United States*, 226 Ct. Cl. 426, 643 F.2d 747 (1981), remanded 3 Cl. Ct. 61 (1983), affd. 732 F.2d 168 (Fed. Cir. 1984), is controlling. In that case, the Court of Claims held that, absent the taint of tax avoidance or tax evasion, the Commissioner is not authorized by sec. 482 to allocate income on the ground of clear reflection of income in a situation involving a specific nonrecognition provision. However, *National Securities* and subsequent law make it clear that ***HN24*** a valid business purpose will not preclude the application of sec. 482 in such a situation when necessary clearly to reflect income. Secs. 1.482-1(c), 1.482-1(d)(5), Income Tax Regs.; *Rooney v. United States*, 305 F.2d 681 (9th Cir. 1962); *Central Cuba Sugar Co. v. Commissioner*, 198 F.2d 214 (2d Cir. 1952).

[58] *Central Cuba Sugar Co. v. Commissioner*, 198 F.2d 214 (2d Cir. 1952), revg. and remanding this issue 16 T.C. 882 (1951), involved a tax-free reorganization under the predecessor of sec. 368(a)(1)(F); the taxpayers in *Rooney v. United States*, 305 F.2d 681 (9th Cir. 1962), affg. 189 F. Supp. 733 (N.D. Cal. 1960), transferred their crop under sec. 351.

[59] Contra *Heaton v. United States*, 573 F. Supp. 12 (E.D. Wash. 1983); *Fanning v. United States*, 568 F. Supp. 823 (E.D. Wash. 1983). In each of those cases, the District Court held the Commissioner abused his discretion in allocating planting expenses claimed by individual farmers to their newly formed farm corporation because the farmers, unlike **[**230]** the taxpayers in *Central Cuba Sugar* and *Rooney*, did not generate a net operating loss.

business reasons. [60] Also, in both it was the subsequent dispositions of the ***transferred*** crops by the successor corporations that triggered the application of *section 482*. In *Central Cuba Sugar* and *Rooney* the Courts focused on the timing of the ***transfers***, which, coupled with the taxpayers' methods of accounting for growing crops, bifurcated the taxpayers' taxable years and artificially separated the expenses and the income attributable thereto. The Courts in both cases approved respondent's authority under *section 482* to, in essence, ignore the nonrecognition provisions by treating the transferee corporations as having planted and incurred the expenses of growing the crops.

Several of the factors mentioned above distinguish those cases from the one before us. In our case, petitioner's ***transfer*** of the intangibles in 1966 effected a change of ownership of those intangibles to Lilly P.R. Lilly P.R. did not sell or otherwise dispose of the intangibles in the year of the ***transfer***, **[*1123]** or in any other year, but held them and used them in the active conduct of its business of manufacturing and selling Darvon and Darvon-N products. [61] It is the income from the conduct of that business in 1971, 1972, and 1973, *not* the income (or loss) realized upon the disposition of the ***transferred*** assets, that respondent is attempting to allocate from Lilly P.R. to petitioner.

Respondent's reallocations conflict with ***HN26*** a fundamental principle of Federal income ***tax*** law: that income from property is earned by the owner of the property. See *Helvering v. Horst*, 311 U.S. 112 (1940); *Blair v. Commissioner*, 300 U.S. 5 (1937). This principle is recognized by the regulations under *section 482* at *section 1.482-1(b)(1), Income **Tax*** Regs. That section provides that "the purpose of *section 482* is to place a controlled taxpayer on a parity with an uncontrolled taxpayer by determining * * * the true taxable income *from the property and business* of a controlled taxpayer." (Emphasis added.) Therefore, the income produced by Lilly P.R. attributable to its use of the ***transferred*** property cannot be allocated to petitioner under *section 482* because it is income *earned* by Lilly P.R. from the use of *its* property in *its* business.

Our conclusion is supported by *Bank of America v. United States*, an unreported case (N.D. Cal. 1979, 44 AFTR 2d 79-5013, 79-1 USTC par. 9170). In that case, a wholly owned subsidiary ***transferred*** the assets of its foreign branches to its parent bank in consideration for the parent's assumption of the branches' liabilities **[**232]** plus the payment of an additional amount of cash. The transaction qualified for nonrecognition treatment under section 311. The parent bank did not dispose of the branches but continued to operate them. The District Court for the Northern District of California rejected the Commissioner's attempt to allocate income from the parent to the subsidiary under *section 482*. The Court stated that:

No * * * distortion of income [is] produced by this ***transfer*** which is not sanctioned by section 311. The income from the branches goes to the [parent] instead of to [the subsidiary] but that is because the income producing capital assets were ***transferred***. [44 AFTR 2d at 79-5106, 79-1 USTC par. 9170, at 86,253.]

[*1124] Moreover, we note that nothing in *National Securities Corp. v. Commissioner, supra*, is to the contrary. In that case, the Commissioner conceded, and the Court concurred, that the subsidiary was entitled to deduct that portion of the loss on the sale of the ***transferred*** stock sustained after the *section 351* ***transfer*** of that stock.

Finally, *Central Cuba Sugar* and *Rooney* each involved the mismatching of income and expenses occurring within a single taxable year. The mismatching resulted **[**233]** from the ***transfer*** of a crop midway through the taxable year. The expenses of growing the crop were paid by the transferor and the transferee had only to sell the crop to realize the income. Respondent argues that petitioner's ***transfer*** of the intangibles to Lilly P.R. under *section 351* without reimbursement for the expenses incurred in connection with the research and development of Darvon and Darvon-N created a distortion of income. However, no mismatching of income and expenses, as occurred in *Central Cuba Sugar* and *Rooney*, resulted from petitioner's 1966 ***transfer*** of patents and know-how to Lilly P.R. The income in question was income earned by Lilly P.R., using the patents and know-how in its business during 1971, 1972, and 1973. The only expenses of petitioner even remotely related to that income were the expenditures petitioner incurred in developing the patents and know-how, largely in the 1950s. Those expenditures were incurred by petitioner not only long before the years in issue but also long before the 1966 ***transfer***. Moreover, the net income earned by petitioner from the manufacture and sale of Darvon products during the years prior to the ***transfer***, greatly exceeded **[**234]** petitioner's research and development expenses related to Darvon and Darvon-N prod-

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[60] In *Central Cuba Sugar*, the taxpayer received from the Service an advance ruling under the predecessor of sec. 367 that the proposed transaction was "not in pursuance of a plan having as one of its principal purposes the avoidance of Federal income taxes."

[61] The level of activity carried on by Lilly P.R. and the amount of its capital investment were set out in detail in our findings of fact. No purpose would be served **[**231]** by restating that information here.

ucts during that period. [62] Clearly, all expenses related to petitioner's research and development of the Darvon and **[*1125]** Darvon-N intangibles were recovered by petitioner prior to the ***transfer*** of those intangibles.

In any event, we believe the expenses giving rise to the development of the patents and know-how simply are too remote in time to be matched with the income earned by Lilly P.R. during the years in issue. [63] To attempt to match income and expenses at this point would cause a distortion of petitioner's income no less severe than that which respondent seeks to remedy by his application of *section 482*. Petitioner's ***transfer*** of intangibles to Lilly P.R. did not create a mismatching of income and expenses, and respondent's actions disregarding that ***transfer*** were improper.

iii. *Substance Over Form*

Respondent maintains that our conclusion would effectively foreclose his application of *section 482* whenever a domestic parent ***transfers*** property to a subsidiary. Respondent argues that, although he is not attacking the validity of the *section 351* ***transfer***, he is authorized by *section 482* to allocate the income from the ***transferred*** property back to petitioner. In essence, respondent **[**236]** is making the ubiquitous "substance over form" argument: he acknowledges the valid "form" of the transaction but challenges the "substance" thereof because of the alleged income distortion resulting from the ***transfer***. Quoting extensively from *Gregory v. Helvering*, 293 U.S. 465 (1935), and its progeny, respondent contends that the technical form of a transaction cannot control its true nature where that form does not accord with economic reality.

We find that both the form and the substance of petitioner's ***transfer*** of assets to Lilly P.R. comported with economic reality. Petitioner ***transferred*** patents and know-how to its newly formed subsidiary, Lilly P.R., by its Assignment of Patents and Related Technical Data dated December 5, 1966. Such a ***transfer*** of intangibles to a wholly owned subsidiary is a common *section 351* transaction. See sec. 1.351-1(a)(2), example (*1*), Income ***Tax*** Regs., relating to a *section 351* ***transfer*** of a patent, which has been part of the regulations for over 50 years. See art. 1572(c), Regs. 65. As pointed out in *Rev. Rul. 64-56, 1964-1* C.B. (Part 1) 133, the establishment of a **[*1126]** new subsidiary to conduct manufacturing operations outside the United States typically **[**237]** involves the ***transfer*** of manufacturing intangibles to the subsidiary.

Petitioner's assignment ***transferred*** ownership of the patents and know-how in substance as well as in form. The assignment was ratified by the boards of directors of petitioner and Lilly P.R. on December 19, 1966. The assignment was recorded in the U.S. Patent Office on February 14, 1969. After the ***transfer*** of the patents and know-how on December 5, 1966, and during the years in issue, Lilly P.R. was the only manufacturer of Darvon and Darvon-N products in the United States and Puerto Rico and, therefore, was the only user of the patents and know-how in those locations. Moreover, after the 1966 ***transfer*** of the patents and know-how, Lilly P.R. initiated two patent infringement suits in its own name to protect the propoxyphene patent and bore the cost of prosecuting those suits. ***HN27*** Under patent law, only the owner of a patent may sue for infringement of that patent. *Waterman v. Mackenzie*, 138 U.S. 252 (1891).

Additionally, respondent's argument, that petitioner, having originally developed the patents and know-how, is forever required to report the income from those intangibles, is without merit. Respondent ignores **[**238]** the fact that petitioner, as developer and owner of the intangible property, was free to and did ***transfer*** the property to Lilly P.R. in 1966. Respondent's case actually is based upon his belief that because petitioner could have retained the ownership of the patents and know-how and realized all the income attributable thereto, petitioner's ***transfer*** of the ownership of the patents and know-how can be ignored for income ***tax*** purposes. That argument was rejected by this Court 40 years ago. In overturning a *section 482* allocation in *Seminole Flavor Co. v. Commissioner*, 4 T.C. 1215, 1235 (1945), we stated:

Actually, the principal force behind all of the Commissioner's argument is that the petitioner could as well have done all the things that the partnership did and reaped all of the earnings of the related enterprises. *Since petitioner could have had the earnings, the Commissioner would make it so by exercising the authority conferred by* [*the predecessor of section 482*]. The same type of argument was made in the *Koppers* case, *supra*, which rejected the argument in language equally apt to the pres-

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[62] Petitioner's research and development expenses related to Darvon and Darvon-N products for the years 1951 through 1966 were $ 3,168,000 (see p. 1084). That figure, however, does not include the expenses during that period for propoxyphene-related clinical grants. Petitioner's best estimate of the amounts expended for those clinical grants during the years 1951 through 1957 is $ 200,000 per year, or $ 1,400,000 for the 7-year period. Petitioner estimates that its propoxyphene-related clinical grants for the years 1958 through 1966 averaged $ 1 million per year, or $ 9 million for the 9-year period. Petitioner's total propoxyphene-related research and development expenses, therefore, were approximately $ 13,568,000. Petitioner's net income before taxes on U.S. sales of Darvon products for the years 1958 through 1966 totaled $ 155,100,000. (See p. 1009.) (1966 sales of Darvon included some **[**235]** sales by Lilly P.R.)

[63] We do not imply that respondent's authority to invoke sec. 482 is limited to within a 1 year period. See *G.U.R. Co. v. Commissioner*, 117 F.2d 187 (7th Cir. 1941), affg. 41 B.T.A. 223 (1940).

ent contention * * *

[*1127] ″The answer to this argument is that petitioner did not do this. ***HN28*** It **[**239]** was free to and did use its funds for its own purposes. It was under no obligation to so arrange its affairs and those of its subsidiary as to result in a maximum ***tax*** burden. On the other hand, it had a clear right by such a real transaction to reduce that burden.″

[Emphasis added and citations omitted.]The above reasoning in *Seminole Flavor* has been consistently applied in later cases. See *Hospital Corp. of America v. Commissioner*, 81 T.C. 520, 583 (1983); *Polak's Frutal Works, Inc. v. Commissioner*, 21 T.C. 953, 976 (1954). Accordingly, we will not disregard petitioner's ***transfer*** of the intangibles to Lilly P.R. on the basis of substance over form.

b. *Arm's-Length Consideration*

Notwithstanding the fallacies of respondent's other arguments, [64] ***HN29*** he is authorized under *section 482* to make allocations between petitioner and Lilly P.R. if necessary clearly to reflect their respective incomes. *Baldwin-Lima-Hamilton Corp. v. United States*, 435 F.2d 182 (7th Cir. 1970). Respondent argues that petitioner's ***transfer*** of valuable income-producing intangibles under *section 351* to Lilly P.R., without receiving arm's-length consideration as defined under *section 1.482-2(d)(2), Income **Tax*** Regs., **[**240]** for such intangibles, created a distortion of income. On the other hand, petitioner contends that *section 351* permits a ***tax***-free ***transfer*** of the intangibles, and that any distortion which results was contemplated and authorized by Congress.

Although we agree with petitioner that the purpose of *section 351* is to facilitate the incorporation of businesses, [65] we **[*1128]** recognize that *section 482* authorizes respondent to make allocations among related taxpayers clearly to reflect income even in the context of a nonrecognition provision. However, the mere existence of a *section 351* ***transfer*** of property does not, per se, require a *section 482* allocation by respondent. Accordingly, we must decide whether the ***prices*** Lilly P.R. charged petitioner for Darvon and Darvon-N products during 1971, 1972, and 1973 caused an unclear reflection of income. For the reasons set forth below, we believe they did.

Respondent maintains that, because petitioner did not receive arm's-length consideration as defined in *section 1.482-2(d)(2), Income **Tax*** Regs., in exchange for its ***transfer*** of the propoxyphene and napsylate patents in 1966, he can totally disregard the ***transfer*** in making ***pricing*** allocations for the years in issue. In support of his argument, respondent relies on *section 1.482-2(d), Income **Tax*** Regs., which specifically addresses the ***transfer*** of intangible property to a related party for other than an arm's-length consideration. ***HN30*** *Section 1.482-2(d)(1)(i), Income **Tax*** Regs., provides:

(d) ***Transfer*** or use of intangible property. -- (1) *In general*. (i) Except as otherwise provided in subparagraph (4) of this paragraph, where intangible property or an interest therein is ***transferred***, sold, assigned, loaned, or otherwise made available in any manner by one member of a group of controlled entities (referred to in this paragraph as the transferor) to another member of the group (referred to in this paragraph as the transferee) for other than an arm's length consideration, *the district director may make appropriate* **[**243]** *allocations to reflect an arm's length consideration for such property or its use. Subparagraph (2) of this paragraph provides rules for determining the form an amount of an appropriate allocation*, subparagraph (3) of this paragraph provides a definition of ″intangible property″, and subparagraph (4) of this paragraph provides rules with respect to certain cost-sharing arrangements in connection with the development of intangible property. For purposes of this paragraph, an interest in intangible property may take the form of the right to use such property. [Emphasis added.]

HN31 *Section 1.482-2(d)(2)(i), Income **Tax*** Regs., defines arm's-length consideration as royalties, lump-sum payments, or any other form, including reciprocal licensing agreements, consistent with the form adopted by un-

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[64] In addition to the arguments discussed above, respondent argues that petitioner's transfer of the intangibles should be ignored for sec. 482 purposes under *Foglesong v. Commissioner*, 621 F.2d 865 (7th Cir. 1980), revg. and remanding a Memorandum Opinion of this Court, on remand, 77 T.C. 1102 (1981), revd. 691 F.2d 848 (7th Cir. 1982). We, however, find *Foglesong* clearly distinguishable from the present case. In *Foglesong* the Seventh Circuit held that a sec. 482 allocation of income from a one-man personal service corporation to the shareholder-employer was improper because the taxpayer as employee could not be considered a separate trade or business. Respondent's determinations herein do not involve allocations of income and deductions from a personal service corporation to the sole shareholder-employer. Accordingly, *Foglesong* is not on point and does not control disposition of the issues in the present case. *Golsen v. Commissioner*, 54 T.C. 742, 757 (1970), **[**241]** affd. 445 F. 2d 985 (10th Cir. 1971); *Arnwine v. Commissioner*, 76 T.C. 532, 544-545 (1981).

[65] See *Portland Oil Co. v. Commissioner*, 109 F.2d 479, 488 (1st Cir. 1940), affg. 38 B.T.A. 757 (1938):

″It is the purpose of [the predecessor of section 351] to save the taxpayer from an immediate recognition of gain, or to intermit the claim of a loss, in certain transactions where the gain or loss may have accrued in a constitutional sense, but where in a popular economic sense there has been a mere change in form of ownership and the taxpayer **[**242]** is not really 'cashed in' on the theoretical gain or closed out of a losing venture.″

related parties. [66] Although **[*1129]** respondent may have utilized this regulation to impute a royalty or lump-sum payment from Lilly P.R. to petitioner, he chose not to do so. Instead, respondent argues that the regulation supports his disregarding completely the 1966 ***transfer*** in determining arm's-length ***prices*** during 1971, 1972, and 1973. With this we disagree.

Respondent has no authority under *section 1.482-2(d), Income **Tax** Regs.*, to disregard completely the 1966 ***transfer***. We emphasize that respondent is not attempting to impose a royalty or lump-sum payment upon Lilly P.R. under this **[**245]** regulation. Were he to do so, he most certainly would recognize the ***transfer*** and allow Lilly P.R. a return on the manufacturing intangibles after payment of the royalties or lump sum. Indeed, both parties agree that this is a ***pricing*** case and that, for purposes of determining arm's-length ***prices***, *section 1.482-2(e), Income **Tax** Regs.*, controls. Accordingly, we believe that respondent's use of *section 1.482-2(d), Income **Tax** Regs.*, to disregard completely petitioner's ***transfer*** of intangibles is inappropriate. We do believe, however, that the lack of a royalty, lump-sum payment, or bona fide cost-sharing arrangement is a relevant factor to be considered in determining arm's-length ***prices*** between Lilly P.R. and petitioner during 1971, 1972, and 1973.

Although we reject respondent's argument that the ownership of the intangibles should be disregarded in making ***pricing*** allocations, we agree with him that, during the years in issue, there was a distortion of petitioner's income warranting reallocations of income from Lilly P.R. to petitioner.

The distortion of income in this case was caused primarily because petitioner's ***transfer*** of the intangibles to Lilly P.R., without receiving arm's-length **[**246]** consideration as defined in the regulations under *section 482*, enabled it, through the mechanism of intercorporate ***pricing***, to shift profits to Lilly P.R. **[*1130]** Petitioner, a pharmaceutical company, competes in a research-intensive industry and spends a substantial amount of its annual budget on ongoing research and development. Such expenditures yield relatively few marketable products. Pharmaceutical companies, including petitioner, are dependent upon the profits derived from the few marketable products they invent to fund their current research and development functions. In the instant case, the ***prices*** petitioner paid Lilly P.R. for the Darvon and Darvon-N products did not enable petitioner to realize sufficient profit to fund a proportionate share of its ongoing research and development expenses. Had petitioner been dealing with an unrelated third party at arm's length, the fact that it did not receive arm's-length consideration for the ***transfer*** of the intangibles would have been reflected in lower ***prices*** from the transferee to petitioner, thus permitting petitioner to realize more profit. That this is true is illustrated by the testimony of respondent's expert accounting witness, **[**247]** Dr. James Wheeler. Dr. Wheeler testified that, if petitioner had ***transferred*** to Lilly P.R. the rights to manufacture its nine most profitable products and had purchased those products from Lilly P.R. at ***prices*** consistent with the ***prices*** it paid for the Darvon and Darvon-N products, petitioner would have been operating at a loss.

It is inconceivable that petitioner, negotiating at arm's length, would have ***transferred*** valuable income-producing intangibles without a royalty, lump-sum payment, or other agreement that would enable petitioner to continue its general research and development activities. In the absence of such an agreement, petitioner was able to structure its ***pricing*** so as to divert needed profits to Lilly P.R. Accordingly, we must conclude that the ***prices*** petitioner paid Lilly P.R. did cause a distortion of income which respondent may correct by making appropriate allocations under the authority of *section 482*. We must now determine whether respondent's allocations are arbitrary, capricious, or unreasonable.

Issue 2. Respondent's Section 482 Adjustments

HN33 *Section 482* gives respondent authority to allocate income between or among related corporations when necessary to prevent **[**248]** the evasion of ***taxes*** or clearly to reflect the income of such corporations. The purpose of *section 482* is to place a **[*1131]** controlled taxpayer on a ***tax*** parity with an uncontrolled taxpayer. See *sec. 1.482-1(b)(1), Income **Tax** Regs.*

HN34 Respondent's determination as set forth in the notice of deficiency is presumptively correct, and the burden of disproving that determination lies with petitioner. Rule 142(a), [68] *Welch v. Helvering, 290 U.S. 111 (1933)*. The burden of proving the increases in deficiencies alleged in the amended answer, however, is on re-

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[66] ***HN32*** Sec. 1.482-2(d)(2)(i), Income Tax Regs., **[**244]** provides:

(2) *Arm's length consideration.* (i) An arm's length consideration shall be in a form which is consistent with the form which would be adopted in transactions between unrelated parties under the same circumstances. To the extent appropriate, an arm's length consideration may take any one or more of the following forms: (a) royalties based on the transferee's output, sales, profits, or any other measure; (b) lump-sum payments; or (c) any other form, including reciprocal licensing rights, which might reasonably have been adopted by unrelated parties under the circumstances, provided that the parties can establish that such form was adopted pursuant to an arrangement which in fact existed between them. However, where the transferee pays nominal or no consideration for the property or interest therein and where the transferor has retained a substantial interest in the property, an allocation shall be presumed not to take the form of a lump-sum payment.

[68] All Rule references are to the Tax Court Rules of Practice and Procedure.

spondent. Rule 142(a).

HN35 In addition to the general presumption of correctness that attaches to respondent's determination, respondent has broad discretion in his application of *section 482* (*Spicer Theatre, Inc. v. Commissioner*, 346 F.2d 704, 706 (6th Cir. 1965), affg. *44 T.C. 198 (1964))*, so that his determination will be upheld unless petitioner proves it to be arbitrary, capricious, or unreasonable. [69] See, e.g., *Phillip Bros. Chemicals, Inc. (N.Y.) v. Commissioner*, 435 F.2d 53, 57 (2d Cir. 1970), affg. *Phillip Bros. Chemicals, Inc. (Md.) v. Commissioner*, 52 T.C. 240 (1969); **[**249]** *Ach v. Commissioner*, 42 T.C. 114, 125-126 (1964), affd. *358 F.2d 342 (6th Cir. 1966)*; *Grenada Industries, Inc. v. Commissioner*, 17 T.C. 231, 255 (1951), affd. *202 F.2d 873 (5th Cir. 1953)*; *National Securities Corp. v. Commissioner*, 46 B.T.A. 562, 565 (1942), affd. *137 F.2d 600 (3d Cir. 1943)*. Our decision as to whether or not respondent has exceeded or abused his discretion turns upon questions of fact. See, e.g., *Ballentine Motor Co. v. Commissioner*, 324 F.2d 796 (4th Cir. 1963), affg. *39 T.C. 348 (1962)*; *American Terrazzo Strip Co. v. Commissioner*, 56 T.C. 961 (1971).

HN36 Should petitioner prove respondent's determination to be arbitrary, capricious, or unreasonable, the general presumption of correctness no longer applies. See, e.g., *Woodward Governor Co. v. Commissioner*, 55 T.C. 56 (1970). Petitioner also may overcome the presumption by introducing sufficient evidence proving that the transactions in issue **[**250]** satisfied the arm's-length standard of *section 482*. In the event that petitioner does overcome respondent's presumption of correctness and disproves the deficiencies set forth in the statutory notice, we must determine from the record before us the **[*1132]** proper allocations, if any, of income between petitioner and Lilly P.R. See *Nat Harrison Associates, Inc. v. Commissioner*, 42 T.C. 601, 617 (1964): *Ach v. Commissioner, supra.* As we stated in *Nat Harrison*, "this Court may allocate income under the statute in a manner the evidence before us demonstrates to be correct and * * * respondent's allocation need not be approved or disapproved *in toto*." *42 T.C. at 617-618*.

Petitioner argues that, because respondent has espoused different *section 482* determinations supported by totally disparate methodologies, respondent's determinations are arbitrary, capricious, and unreasonable. We disagree.

In the notice of deficiency, respondent's determination was based upon a method which allowed Lilly P.R. its cost of goods sold, location savings, and a gross profit for each of the Mayaguez and Carolina manufacturing facilities. In his amended answer, respondent asserted increased deficiencies by eliminating **[**251]** the intracompany profit on the ***transfer*** of chemicals from the Mayaguez to the Carolina facility and allowing Lilly P.R. a gross profit equal to 30 percent of manufacturing costs and location savings. At trial, respondent relied on his expert witness Dr. William S. Comanor who did not testify regarding the methods used in the notice of deficiency or amended answer. Instead, Dr. Comanor used two other methods for allocating income which involved averages of third-party ***prices*** and gross profits.

HN37 There are often occasions when, in order to protect the revenue, respondent must make alternative determinations. *Nat Harrison Associates, Inc. v. Commissioner, supra* at 617. Moreover, as respondent's counsel argued at trial, to lock him into one exact methodology or calculation would require the Service to retain an expert at the time of mailing the deficiency notice, a requirement which would effectively preclude it from ever using outside experts. Accordingly, we do not think that because respondent made alternative determinations supported by differing methodologies, his actions were arbitrary, capricious, or unreasonable. See *Nat Harrison Associates, Inc. v. Commissioner, supra.* Thus, **[**252]** the presumption of correctness would not be lost for that reason, alone.

Although we do not take issue with respondent's conclusion that, during the years in issue, there was a distortion of income justifying some reallocation, we do disagree with **[*1133]** respondent's determination of the amount of income to be allocated. In making the various allocations of income from Lilly P.R. to petitioner, respondent never permitted Lilly P.R. any income attributable to the manufacturing intangibles [70] which it owned and utilized in the manufacture of the Darvon and Darvon-N products. Because we have found Lilly P.R. is entitled to the income attributable to those intangibles, we must conclude that respondent's determination, which denied Lilly P.R. *any* income from the manufacturing intangibles, was unreasonable. *Baldwin-Lima-Hamilton Corp. v. United States*, 435 F.2d 182, 187 (7th Cir. 1970); *American Terrazzo Strip Co. v. Commissioner.*, 56 T.C. 961, 973 (1971); *P.P.G. Industries, Inc. v. Commissioner*, 55 T.C. 928, 993 (1970); *Nat Harrison Associates, Inc. v. Commissioner, supra* at 617-618; *Seminole Flavor Co. v. Commissioner*, 4 T.C. 1215, 1235

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[69] The fact that some cases express the taxpayer's burden of proof in the conjunctive rather than the disjunctive is of no consequence as the terms used are synonymous. See *Foster v. Commissioner*, 80 T.C. 34, 142 n. 59 (1983), affd. on this issue 756 F.2d 1430 (9th Cir. 1985).

[70] The income attributable to the manufacturing intangibles is, by definition (see our discussion at p. 1151), the excess of Lilly P.R.'s net operating profit over its manufacturing profit and location savings. Our determination that petitioner's intercorporate pricing structure caused a distortion of income, necessitates a downward adjustment in the prices petitioner paid Lilly P.R. for the Darvon and Darvon-N products. Such an adjustment results in a commensurate diminution of Lilly P.R.'s income attributable to the manufacturing intangibles.

(1945). We must therefore make a determination of the **[**253]** proper allocation of income from Lilly P.R. to petitioner, without the benefit of any presumptions, in a manner the evidence before us demonstrates to be correct. *American Terrazzo Strip Co. v. Commissioner, supra; Nat Harrison Associates, Inc. v. Commissioner, supra; Ach v. Commissioner, supra* at 126.

*Issue 3. Determination of Arm's-Length **Prices*** Between Petitioner and Lilly P.R.

We turn now to the third and final issue of this case: whether Lilly P.R.'s ***prices*** to petitioner for the Darvon and Darvon-N products sold by it during the years in question were ***prices*** at which those products would have been sold between unrelated parties dealing at **[**254]** arm's length. We have found that Lilly P.R. is the owner of, and entitled to, the income from the manufacturing intangibles. Consequently, we must determine the applicable arm's-length ***prices*** from all the evidence submitted by the parties, and, if necessary, we may make our own best estimate as to the proper amounts under the principles of *Cohan v. Commissioner*, 39 F.2d 540 (2d Cir. 1930), **[*1134]** modifying *11 B.T.A. 743 (1928)*. See *Nat Harrison Associates, Inc. v. Commissioner*, 42 T.C. 601 (1964); *Ach v. Commissioner*, 42 T.C. 114 (1964).A. *Section 482 Regulations*

1. *1971 and 1972 Taxable Years*

HN38 *Section 1.482-2(e)(1)(i), Income **Tax*** Regs., provides that, when one controlled entity sells tangible property to another controlled entity at ″other than an arm's length ***price***,″ respondent may ″make appropriate allocations between the seller and the buyer to reflect an arm's length ***price*** for such sale.″ An ″arm's length ***price***″ for purposes of that section is defined as:

the ***price*** that an unrelated party would have paid under the same circumstances for the property involved in the controlled sale. Since unrelated parties normally sell products at a profit, an arm's length ***price*** normally involves a **[**255]** profit to the seller. *[Sec. 1.482-2(e)(1)(i), Income **Tax*** Regs.]

HN39 The regulations set forth three detailed methods for determining an arm's-length ***price***: the comparable uncontrolled ***price*** method, the resale ***price*** method, and the cost plus method. *Sec. 1.482-1(e)(1)(ii), Income **Tax*** Regs. A fourth method is provided by the following language in *section 1.482-2(e)(1)(iii), Income **Tax*** Regs.:

Where the standards for applying one of the three methods of ***pricing*** * * * are met, such method must, for the purposes of this paragraph, be utilized unless the taxpayer can establish that, considering all the facts and circumstances, some method of ***pricing*** other than those described * * * is more appropriate. *Where none of the three methods of **pricing*** * * * can reasonably be applied under the facts and circumstances as they exist in a particular case, some appropriate method of ***pricing*** other than those described * * *, or variations on such methods, can be used. [Emphasis added.]

Petitioner argues that the ***prices*** charged it by Lilly P.R. for the years 1971 and 1972 satisfy the resale ***price*** method or a variation of such method. Respondent, apart from his other arguments concerning his own ***pricing*** formulas **[**256]** (which, as we already have held, erroneously failed to allocate any income **[*1135]** attributable to the manufacturing intangibles to Lilly P.R.), [71] argues that the 1971 and 1972 ***prices*** did not satisfy the resale ***price*** method because the appropriate markup was determined by reference to petitioner's own sales of other products. Respondent also alleges that petitioner's allocations of income and expenses between petitioner and Lilly P.R. with respect to Darvon and Darvon-N products were erroneous. For the reasons stated below, we agree with respondent.

a. ***Pricing*** Methods

HN40 *Section 1.482-2(e)(1)(ii), Income **Tax*** Regs., establishes a priority for the application of the ***pricing*** methods listed above. The comparable uncontrolled ***price*** method is the most accurate of the methods, and is to be used whenever there are ″comparable uncontrolled sales.″ Comparable uncontrolled sales are sales of the same or substantially identical property between uncontrolled buyers and sellers. *Sec. 1.482-2(e)(2), Income **Tax*** Regs. The resale ***price*** method is to be used if there are no comparable uncontrolled sales. *Sec. 1.482-2(e)(1)(ii), Income **Tax*** Regs. That method involves calculating an appropriate markup by which the resale ***price*** to an uncontrolled buyer is reduced to find the arm's-length **[**258]** ***price*** for the controlled sale. *Sec. 1.482-2(e)(3), Income **Tax*** Regs.

The cost plus method starts from the other end. Instead

[71] Respondent advocates a ″functional analysis″ of petitioner's and Lilly P.R.'s activities vis-a-vis general pharmaceutical companies' operations. Respondent separates the functions performed into (1) research and development, (2) manufacturing, and (3) marketing. He argues that petitioner did all of (1) and (3), and part of (2), but was never reimbursed fully for the services and materials provided to Lilly P.R. Respondent thus recomputes their ″true taxable income″ based upon the functions performed by each over a period of more than 25 years. Respondent's argument ignores the fact that income is earned not only through the performance **[**257]** of specified functions, but also through the use of tangible and intangible property in the performance of such functions. Thus, respondent has disregarded a fundamental principle of taxation that income from property is earned by the owner of the property. This principle is recognized in sec. 1.482-1(b), Income Tax Regs., which provides that the purpose of sec. 482 is to determine the ″true taxable income from the property and business of a controlled taxpayer.″

of reducing the sales ***price*** of the reseller (marketing company) by an appropriate markup, the cost plus method requires the determination of an appropriate gross profit, which is added to the seller's (manufacturer's) cost of producing such property. *Sec. 1.482-2(a)(4), Income **Tax*** Regs.

HN41 If none of the above methods is viable under the facts of a particular case, a fourth ″appropriate″ method may be used. Sec 1.482-2(e)(1)(iii), Income ***Tax*** Regs.

[*1136] i. *Comparable Uncontrolled **Price*** Method

During the years 1971 and 1972, there were no comparable uncontrolled sales of Darvon and Darvon-N products in the United States. Because of the existence of the propoxyphene and napsylate patents, no one other than Lilly P.R. could manufacture or sell Darvon or Darvon-N products in the United States. [72] Although the record does disclose that sales of propoxyphene in bulk form took place outside the United States in markets that were not covered by U.S. patent protection, those sales were not comparable uncontrolled sales because they occurred in a different, unprotected market. **[**259]** Moreover, no sales were found of the final dosage form of the product at a comparable distribution level.

During the years in issue, Darvon and Darvon-N products were among the 10 largest selling ethical pharmaceutical products in the United States. Darvon and Darvon-N products were prescribed for the relief of mild to moderate pain, and their principal competitors were combinations of codeine with either aspirin or acetaminophen. Those combinations were not substantially identical to Darvon and Darvon-N products. Therefore, no comparable uncontrolled sales of Darvon and Darvon-N products are available for 1971 and 1972.

ii. *Resale **Price*** Method

The next ***pricing*** method prescribed by the regulations under *section 482* is the resale **[**260]** ***price*** method. ***HN43*** The regulations provide that the arm's-length ***price*** of a controlled sale determined using the resale ***price*** method is equal to ″the applicable resale ***price*** * * * reduced by an appropriate mark-up″ (*sec. 1.482-2(e)(3)(i), Income **Tax*** Regs.), and adjusted ″to reflect any material differences between the uncontrolled purchases and resales used as the basis for the calculation of the appropriate markup percentages and the resales of property involved in the controlled sale. The differences referred to * * * are those differences in functions or circumstances **[*1137]** which have a definite and reasonably ascertainable effect on ***price***.″ *Sec. 1.482-2(e)(3)(ix), Income **Tax*** Regs.

HN44 The ″'applicable resale ***price***' is the ***price*** at which it is anticipated that property purchased in the controlled sale will be resold by the buyer in an uncontrolled sale. The 'applicable resale ***price***' will generally be equal to either the ***price*** at which current resales of the same property are being made or the resale ***price*** of the particular item of property involved.″ *Sec. 1.482-2(e)(3)(iv), Income **Tax*** Regs. In this case, the applicable resale ***price*** is petitioner's sales ***price*** to its unrelated customers, i.e., **[**261]** its wholesale distributors. The ″appropriate markup″ is the gross profit, expressed as a percentage of sales, ″earned by the buyer (reseller) or another party on the resale of property which is both purchased and resold in an uncontrolled transaction, which resale is most similar to the applicable resale of the property involved in the controlled sale.″ *Sec. 1.482-2(e)(3)(vi), Income **Tax*** Regs.

Prior to the publication of the regulations under *section 482*, petitioner adopted an approach similar to the resale ***price*** method by attempting to measure an appropriate margin to petitioner for the resale of Darvon and Darvon-N products and by calculating that margin as a percentage discount from petitioner's net wholesale ***prices***. Petitioner contends that the discounts granted by Lilly P.R. to petitioner were comparable to discounts which would have prevailed had the parties been unrelated and dealing at arm's length. Petitioner thus asserts that the discounts constituted an appropriate markup within the meaning of the resale ***price*** method.

In support of its position, petitioner submitted the testimony of three economic experts: Dr. Yale Brozen of the University of Chicago Graduate School of **[**262]** Business, and Drs. William J. Baumol and Charles H. Berry of Princeton University. Respondent submitted the testimony of economic expert Dr. William S. Comanor of the University of Southern California at Santa Barbara. We found all these individuals qualified in the field of economics for the purposes of rendering expert opinions.

Petitioner's economic experts were retained in this case to analyze the intercompany ***transfer pricing*** arrangement between petitioner and Lilly P.R. The experts testified individually, but they submitted a joint report stating their group **[*1138]** analyses and conclusions. Unless otherwise indicated, we will refer to petitioner's economic experts, Drs. Brozen, Baumol, and Berry, in the collective.

Petitioner's experts concluded that the ***transfer prices*** charged by Lilly P.R. for its Darvon and Darvon-N products during 1971 and 1972 were considerably less than

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[72] ***HN42*** A patent owner has three exclusive rights under a patent: the right to manufacture, use, and sell the patented product. 35 U.S.C. sec. 154. However, once the product is sold by the patent owner to a third-party purchaser, such as petitioner in this case, the purchaser acquires the right to resell the product. *Duplan Corp. v. Deering Milliken, Inc.*, 444 F. Supp. 648 (D.S.C. 1977), affd. in part, revd. in part on other grounds 594 F.2d 979 (4th Cir. 1979).

the ***transfer prices*** that would have been charged between unrelated parties. [73] Petitioner's experts also concluded that the ***transfer prices*** proposed by respondent were undefensibly low and completely unrelated to ***prices*** that would have been charged by parties dealing at arm's length.

For 1971 and 1972, petitioner's experts were unable to locate any reasonably comparable uncontrolled transactions involving similar products to determine an arm's-length ***price***. They thus concluded that an arm's-length ***price*** should be determined by reference to the profit generating assets and activities of each of the related companies. The assets and activities relative to Darvon and Darvon-N products considered by the experts were as follows:

	Petitioner			Lilly P.R.	
1.	Market activity and		1.	Manufacturing activity and	
	tangible assets			tangible manufacturing assets	
2.	Intangible assets		2.	Intangible assets	
	a.	Petitioner's name		a.	Propoxyphene patent -- expired
					at end of 1972
	b.	Petitioner's marketing		b.	Napsylate patent
		organization			
	c.	Marketing know-how		c.	Process know-how
	d.	Darvon and Darvon-N		d.	Formula know-how
		trademarks			

Petitioner's experts correctly viewed the ownership of the manufacturing intangibles as an important factor in determining an arm's-length **[**264]** ***price***. For the purposes of their analyses, the experts assumed that Lilly P.R. was the owner of the propoxyphene and napsylate patents during 1971 and 1972, and that petitioner was the owner of the Darvon and Darvon-N trademarks. Based on those assumptions, however, petitioner **[*1139]** could not have sold propoxyphene products under the Darvon and Darvon-N trademarks in 1971 and 1972 unless it had purchased those products from Lilly P.R. If petitioner had been unable to use the Darvon and Darvon-N trademarks in 1971 and 1972, petitioner's economic experts concluded that the value of those trademarks would have fallen substantially. In other words, the experts concluded that the intangible value was attributable primarily to the propoxyphene and napsylate patents because the initial ***transfer*** of the patents to Lilly P.R. must have carried with it the right and the power to acquire all foreseeable propoxyphene profits.

Viewed from another perspective, if Lilly P.R. had sold its propoxyphene products to another pharmaceutical company for distribution in the United States in 1971 and 1972, that other company could have established a new trademark for Lilly P.R.'s propoxyphene products in a market **[**265]** environment protected by Lilly P.R.'s propoxyphene and napsylate patents from the competition of petitioner's Darvon and Darvon-N trademarks. Accordingly, in the opinion of the economic experts, the value of petitioner's Darvon and Darvon-N trademarks was minimal during the years 1971 and 1972, and the bulk of the profit contribution of intangibles related to propoxyphene products in 1971 and 1972 was attributable to the propoxyphene and napsylate patents and the other manufacturing intangibles owned by Lilly P.R.

Because the experts believed the Darvon and Darvon-N trademarks had no especially significant independent value in 1971 and 1972, they estimated an arm's-length ***price*** to petitioner in those years on the basis of the profit contribution of petitioner's marketing activities and intangible marketing assets.

Petitioner's economic experts concluded that the contribution of petitioner's intangible assets and activities related to the marketing of Darvon and Darvon-N products could best be estimated by reference to the ***price*** that petitioner would have been willing to pay Lilly P.R. for the right to market those products in the United States under the circumstances of this case. They **[**266]** believed that in arm's-length negotiations with Lilly P.R., petitioner would have been willing to pay Lilly P.R. a ***price*** that produced a return on its resources devoted to marketing Darvon and Darvon-N products equal to what it **[*1140]** could have earned by devoting those resources to the marketing of other products. To measure that return, the experts concluded that the opportunity cost to petitioner of marketing Darvon and Darvon-N products could be determined by looking at the profitability of the other products that petitioner could have promoted during the years 1971 and 1972 and, further, that the profitability of petitioner's nine leading products provided

[73] "Less than" an arm's-length **[**263]** price in this situation is beneficial to petitioner inasmuch as respondent argues that Lilly P.R.'s prices were greater than arm's-length prices and, therefore, allowed petitioner to transfer too much income to Lilly P.R. See Rev. Proc. 63-10, 1963-1 C.B. 490, 491.

the best estimate of the maximum opportunity cost of marketing Darvon and Darvon-N products.

Petitioner's nine leading products in 1972 were (1) Keflin Registered TM, (2) Keflex, (3) Ilosone, (4) Iletin Registered TM (including Dymelor Registered TM and Tes-Tape Registered TM, (5) Loridine Registered TM, (6) V-Cillin-K Registered TM, (7) Cordran Registered TM and Cordran-N Registered TM, (8)Mi-Cebrin Registered TM and Mi-Cebrin T Registered TM, and (9) Trinsicon Registered TM.

Petitioner's economic experts examined the profitability **[**267]** to petitioner of those products for the period 1964 through 1973. Because petitioner, with one exception, both manufactured and sold the nine leading products, [74] in order to determine the ***price*** at which the experts believed it would have been willing to market those products, a "purchase ***price***" had to be established. The experts established that purchase ***price*** by treating petitioner's manufacturing cost as the ***price*** to petitioner's pharmaceutical marketing division.

The economic experts' initial comparison of petitioner's nine leading products with Darvon and Darvon-N products indicated that the ratio of operating income to operating expense for Darvon and Darvon-N products was 151 percent, but that the ratio of operating income to operating expense for the nine leading products was 144 percent. Thus, the marketing of Darvon and Darvon-N products in 1971 and 1972 was about as profitable to petitioner as the marketing of the nine leading products during that same period. Petitioner's economic experts concluded that their analysis of the nine leading products **[**268]** provided an appropriate evaluation of all the assets owned and activities performed by petitioner in connection with the marketing of Darvon and Darvon-N products. The nine leading products were promoted by the same detail force that promoted the Darvon and Darvon-N products; they were all sold under the "Eli Lilly and Company" trade name using **[*1141]** petitioner's marketing organization and marketing know-how; and each of the nine leading products had its own distinctive trademark.

The economic experts concluded that the comparison of operating income to operating expense, however, clearly overstated the profit attributable solely to the marketing activities devoted to the nine leading products. The operating income figures for the nine leading products included profits attributable to petitioner's capital investment, manufacturing know-how, and patent rights associated with those products. In the case of Darvon and Darvon-N products, however, the profits attributable to the manufacturing activities and the corresponding manufacturing intangibles belonged to Lilly P.R. Petitioner's experts made a conservative adjustment to the operating incomes of the nine leading products to take into **[**269]** account the profits attributable to manufacturing costs and manufacturing intangibles: 30 percent of manufacturing costs and a 5-percent royalty for manufacturing intangibles. This resulted in a ratio of operating income to operating expense for the nine leading products of 99 percent.

Considering the fact that the nine leading products were petitioner's most profitable products, it was the economic experts' view that it would be more realistic to attribute a profit of 100 percent of manufacturing costs for manufacturing activity and a royalty of 10 percent of net sales for manufacturing intangibles with the remaining profit being attributable to the marketing of the product. If those adjustments were made, the calculation of the nine leading products reduced the figure of operating income to operating expense still further to 15 percent.

On the basis of that analysis, the economic experts concluded that Lilly P.R.'s ***transfer prices*** for Darvon and Darvon-N products in 1971 and 1972 were not only within the range of arm's-length ***prices*** but that petitioner earned significantly more profit from the marketing of those products in 1971 and 1972 than it could have earned by directing its **[**270]** resources to its other leading products. Thus, the experts concluded that Lilly P.R.'s ***transfer prices*** for 1971 and 1972 were clearly lower than arm's-length ***prices*** for those years.

Petitioner's economic experts tested the results of their analysis by using several other approaches to valuing the **[*1142]** manufacturing intangibles owned by Lilly P.R. in 1971 and 1972. [75] Each of those approaches produced an estimation of the profit contribution of the manufacturing intangibles owned by Lilly P.R. ranging between 30 percent and 50 percent of petitioner's sales of Darvon and Darvon-N products in 1971 and 1972.

Petitioner **[**271]** asserts that the approach taken by its economic experts tracks the methodology laid down by the *section 482* regulations' resale ***price*** method. Petitioner argues that, because no comparable uncontrolled sales existed, its experts determined that the next best approach to estimating an arm's-length ***price*** would be to

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[74] The exception was the raw material ingredient of Cordran products, which petitioner purchased from an unrelated third party.

[75] Petitioner's economic experts utilized: (1) A comparison of Darvon and Darvon-N gross profits to gross profits of all other pharmaceutical products of petitioner; (2) a comparison of Darvon and Darvon-N operating income to operating income from all other pharmaceutical products of petitioner; and (3) an analysis of 1973 prices for generic propoxyphene products sold in the United States. A fourth method, analyzing propoxyphene market prices in various foreign markets where no patent protection exists, was used, but Dr. Brozen admitted that that test was almost meaningless.

determine the ***price*** (or absent a ***price***, the margin) at which petitioner would be willing to market the products produced by Lilly P.R., and that that approach was the equivalent of a resale ***price*** approach focusing on the gross margin and net profit of the reseller.

Petitioner argues that, by choosing petitioner's nine leading products for comparison with Darvon and Darvon-N, its experts followed the mandate of the regulations to focus on transactions, if possible, of the specific reseller involved in the controlled transaction (in this case, petitioner). See *sec. 1.482-2(e)(3)(vii), Income **Tax*** Regs. Petitioner argues further that, by focusing on those other products of petitioner, the experts were able to neutralize completely the significance of the marketing intangibles on the sale of the Darvon and Darvon-N products because petitioner sold all the nine leading products **[**272]** using its Eli Lilly & Co. trade name, and promoted those products by its marketing force to the same customers through the same distribution channels. In addition, each of the nine leading products had its own distinctive trademark.

On the other hand, respondent maintains that the approach taken by petitioner's economic experts does not satisfy the resale ***price*** method of *section 1.482-2(e)(3), Income **Tax*** Regs., because petitioner's nine leading products were not purchased by petitioner in uncontrolled sales. Moreover, because the **[*1143]** regulations provide a listing of the methods to be used in ***pricing*** cases in strict order of their priority, respondent argues that the next method, the "cost plus" method, must be used before any variation on the resale ***price*** method can be utilized. Accordingly, respondent argues that petitioner's attempted use of the resale ***price*** method is in error in this case. Apart from that "initial obstacle," respondent also finds fault with the assumptions made by the experts regarding the constructed purchase ***prices*** for the nine leading products, and with the operating income to operating expense ratios as calculated from petitioner's statements and records. We **[**273]** will address respondent's arguments in turn.

Respondent correctly challenges the use of the resale ***price*** method based solely on evidence of internal transactions of the reseller. ***HN45*** *Section 1.482-2(e)(3), Income **Tax*** Regs., determines the arm's-length ***price*** of property in a controlled sale by reducing the reseller's ***price*** of the property to an uncontrolled buyer by an "appropriate markup." Subdivision (vi) of that section clearly requires that the appropriate markup percentage be calculated using gross profit percentages earned by a reseller "on the resale of property *which is both purchased and resold in an uncontrolled transaction*." (Emphasis added.) The regulations state elsewhere their basic assumption that uncontrolled purchases and sales must be used under the resale ***price*** method. ***HN46*** *Sec. 1.482-2(e)(3)(vii), Income **Tax*** Regs., states as follows:

Whenever possible, markup percentages should be derived from *uncontrolled purchases and resales* of the buyer (reseller) involved in the controlled sale. * * * [Emphasis added.]

HN47 *Section 1.482-2(e)(3)(viii), Income **Tax*** Regs., provides:

In calculating the markup percentage earned on *uncontrolled purchases and resales* * * * the same elements which **[**274]** enter into the computation of the sales ***price*** and the costs of goods sold of the property involved in the comparable *uncontrolled purchases and resales* should enter into such computation in the case of the property involved in the controlled purchases and resales. * * * [Emphasis added.]

And, finally, ***HN48*** *section 1.482-2(e)(3)(ix), Income **Tax*** Regs., states:

In determining an arm's length ***price*** appropriate adjustment must be made to reflect any material differences between the *uncontrolled purchases* **[*1144]** *and resales* used as the basis for the calculation of the appropriate markup percentage and the resales of the property involved in the controlled sale. * * * [Emphasis added.]

We recognize that there simply were no similar uncontrolled purchases and resales in 1971 or 1972. [76] Because of petitioner's failure to establish similar uncontrolled sales, the resale ***price*** method cannot be utilized to determine arm's-length ***prices***. Subsequent case law confirms our literal reading of the regulation. In *Lufkin Foundry & Machine Co. v. Commissioner*, 468 F.2d 805 (5th Cir. 1972), revg. a Memorandum Opinion of this Court, [77] a machine manufacturing corporation sold its machinery to various wholly owned **[**275]** subsidiaries for resale throughout the Western Hemisphere, exclusive of the United States. The ***prices*** it charged the subsidiaries were based on discounts from list ***prices***, as well as on commissions on net invoice ***prices***. The Com-

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[76] ***HN49*** "Similar" in the context of the resale price method relates to the probable effect upon the markup percentage of any differences between the uncontrolled and controlled purchases and resales. Thus, close physical similarity of the property involved in the sales compared is not required under the resale price method since a **[**276]** lack of close physical similarity is not necessarily indicative of dissimilar markup percentages. Sec. 1.482-2(e)(3)(vi), Income Tax Regs. Darvon and Darvon-N products were among the 10 largest selling ethical pharmaceutical products in the United States during 1971 and 1972; the other largest selling products on the market apparently were marketed by their manufacturing companies, as petitioner did with its other product lines, and were not resold for marketing and distribution by an independent company.

[77] T.C. Memo. 1971-101.

missioner, exercising his power under *section 482*, allocated to the parent 50 percent of the discounts given and 50 percent of the commissions paid to the subsidiaries. In this Court, the parent introduced evidence of the reasonableness of the discounts and commissions prepared by an independent certified public accountant using data from the parent's own internal marketing arrangements. We held that the evidence was sufficient to overcome the Commissioner's presumption of correctness and, because he had failed to introduce any evidence on his own behalf, that the Commissioner had abused his discretion in making the above allocations.

Citing *section 1.482-2(e), Income **Tax** Regs.*, the Court of Appeals for the Fifth Circuit reversed. In holding that evidence of the transactions of uncontrolled parties is necessary to determine an arm's-length ***price***, the Court stated:

[*1145] No amount of self-examination of the taxpayer's internal transactions alone could make it possible to know what ***prices*** or terms unrelated parties would have charged or demanded. We think it palpable that if the standard set by these unquestioned regulations is to be met evidence of transactions between uncontrolled corporations unrelated to Lufkin must be adduced in order to determine what charge would have been negotiated for **[**277]** the performance of such marketing services. [*468 F.2d at 808*.]

The method of determining arm's-length ***prices*** employed by petitioner's experts thus fails to satisfy the resale ***price*** method. Petitioner contends in the alternative that the methodology used by its economic experts was a permissible variation of the resale ***price*** method which was required by the particular facts of this case. Petitioner argues that, although the regulations under the resale ***price*** method call for the establishment of an appropriate markup using the actual purchases and resales of comparable property, there is no reason why this markup could not be arrived at by an analysis of the profit of products manufactured and sold, rather than of products purchased and sold. Furthermore, petitioner maintains that, although the regulations outline three methods valid in the order in which they are prescribed, the evidentiary rules for establishing any method should be applied flexibly by the Court citing *United States Steel Corp. v. Commissioner*, 617 F.2d 942 (2d Cir. 1980), revg. two Memorandum Opinions of this Court. We do not agree.

Unquestionably, there are problems with applying the regulations as they stand **[**278]** today; [78] however, to approve the use of variations of the methods *within* their order merely would add to the problems and confusion surrounding intercompany ***pricing***. In addition, adopting such an approach would render the delineation of each method, and its order of priority, meaningless. Moreover, neither the Commissioner nor the taxpayers would have an objective means of determining whether or not one of the three methods applied.

iii. *Cost Plus Method*

Because the facts of the case before us do not lend themselves **[*1146]** to application of the resale ***price*** **[**279]** method, the next method to be examined is the cost plus method described in *section 1.482-2(e)(4), Income **Tax** Regs.* ***HN50*** The cost plus method, as previously described, is equal to the cost of producing the property plus an appropriate profit computed with reference to uncontrolled sales of similar property. It is this method that respondent urges upon us, and towards which his notice of deficiency, amendment to answer, and experts' testimony and reports are directed.

Respondent's notice of deficiency and amendment to answer used a ***pricing*** formula allowing Lilly P.R. its manufacturing cost and location savings plus a manufacturing profit. [79] Respondent's calculations, however, do not allocate to Lilly P.R. any of the income associated with its manufacturing intangibles.

Respondent's expert economic witness, Dr. William S. Comanor, examined the "functions" performed by petitioner and Lilly P.R. and attempted to determine an allowable level of profits based on those functions. Dr. Comanor used two separate **[**280]** methods to determine what he believed to be acceptable profits for Lilly P.R. His first method observed certain third-party ***prices*** for the sale of propoxyphene products which occurred during 1973. Based on those observations, Dr. Comanor determined a weighted average for the market ***prices*** and then determined the percent differential between those ***prices*** and the ones charged by Lilly P.R. to petitioner. Based on that percent differential, he thus determined the amounts of profit reported by Lilly P.R. which were, in his opinion, in excess of the profits that would have been earned by it had the parties been unrelated.

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[78] The following list is but a sampling of the critical commentary regarding the pricing regulations: Eustice, "Tax Problems Arising From Transactions Between Affiliated or Controlled Corporations," 23 Tax L. Rev. 451 (1968); Fuller, "Problems in Applying the 482 Intercompany Pricing Regs. Accentuated by *DuPont* Case," 52 J. Tax. 10 (1980); Fuller, "Section 482 Revisited," 31 Tax L. Rev. 475 (1976); Jenks, "Treasury Regulations Under Section 482," 23 Tax Law. 279 (1970); Simon, "Section 482 Allocations," 46 Taxes 254 (1968); Webb, "*DuPont* and *U.S. Steel* Exacerbate Section 482 Intercompany Pricing Regulations," 10 J. Corp. Tax. 152 (1983).

[79] The two methods differ in that the notice of deficiency also allows Lilly P.R. an intracompany profit on the transfer of chemicals from the Mayaguez facility to the Carolina facility.

Dr. Comanor's second method compared Lilly P.R.'s reported gross profits with the gross profits earned by three unrelated pharmaceutical companies deemed comparable by Dr. Comanor. Dr. Comanor determined an average gross profit margin for all three companies for each of the years 1971, 1972, and 1973, and, based on those averages, he recalculated the amount of gross profits realized by Lilly P.R. as a result of its dealings with petitioner.

[*1147] Dr. Comanor's ***pricing*** methods do not provide Lilly P.R. with any income from the patents and manufacturing know-how, something **[**281]** we have held necessary in this case. ***HN51*** This Court is not bound by the testimony of an expert witness and must reject such testimony where the witness overlooked a significant factor in reaching his conclusion. See *South Texas Rice Warehouse Co. v. Commissioner*, 366 F.2d 890, 898 (5th Cir. 1966), affd. *43 T.C. 540 (1965)*. Moreover, after observing Dr. Comanor's demeanor on the witness stand, we must substantially discount his report and testimony. We therefore reject Dr. Comanor's ***pricing*** methods with respect to the 1971 and 1972 taxable years.

The regulations under *section 482* were promulgated for the purpose of providing specific guidelines and a degree of certainty to the realm of intercompany ***pricing***. *31 Fed. Reg. 10394 (1966)*. Such purpose would be ill-served by our use of the cost plus method herein. There is no evidence in the record (other than petitioner's attempt in 1972 to value the napsylate patent) (see page 1080), concerning the value of the manufacturing intangibles. Petitioner's economic experts assigned a possible royalty value to the napsylate patent for 1973, but did not state how they arrived at their figure or what their qualifications for valuing a pharmaceutical **[**282]** patent were. Respondent has not suggested any method whereby we could allocate income attributable to the intangibles to Lilly P.R. while using the cost plus method to determine arm's-length ***prices*** for the Darvon and Darvon-N products it sold. Our use of the cost plus method in such circumstances is unwarranted and we decline to use it. [80]

b. *Profit Split Approach*

We have rejected the ***pricing*** methods and conclusions advocated by petitioner's and respondent's expert witnesses, and have found the use of all three ***pricing*** methods specified by the regulations under *section 482* to be inappropriate. However, based upon the evidence before us, we must determine arm's-length ***prices*** for the Darvon and Darvon-N products purchased by petitioner from Lilly P.R. during 1971 and **[*1148]** 1972. *American Terrazzo Strip Co. v. Commissioner*, 56 T.C. 961, 973 (1971); *Nat Harrison Associates, Inc. v. Commissioner*, 42 T.C. 601 (1964). Although petitioner has met its burden of proving that such arm's-length **[**283]** ***prices*** would allow Lilly P.R. to earn the income attributable to the manufacturing intangibles, it has not proven what these arm's-length ***prices*** would be. Consequently, we must use our best judgment in determining arm's-length ***prices*** from the evidence submitted, bearing heavily against petitioner, "whose inexactitude is of [its] own making." *Cohan v. Commissioner*, 39 F.2d 540, 544 (2d Cir. 1930); *Ach v. Commissioner*, 42 T.C. 114, 126-127 (1964).

The use of a ***pricing*** method other than the three methods previously discussed is contemplated by the regulations under *section 482*. ***HN52*** The fourth method is contained in *section 1.482-2(e)(1)(iii), Income **Tax*** Regs. That section provides that:

Where none of the three methods of ***pricing*** described in subdivision (ii) of this subparagraph can reasonably be applied under the facts and circumstances as they exist in a particular case, some appropriate method of ***pricing*** other than those described in subdivision (ii) of this subparagraph, or variations on such methods, can be used.

This provision is clearly applicable to the facts of this case. We note that a study of more than 500 U.S. companies in 1970 and 1971 indicated that 36 percent of the *section 482* **[**284]** allocations made by Service field agents were based on some method other than the three described in the regulations. See Duerr, "***Tax*** Allocations and International Business," Conference Board Report No. 555 (1972), portions reprinted in O'Connor & Russo, "A Study of Corporate Experience With *Sec. 482*," 3 ***Tax*** Adviser 526 (1972). Another study, made by the Service of its 1968 and 1969 audits involving ***transfer pricing***, showed that agents used some other method 41 percent of the time. Treasury Department, "Summary Study of International Cases Involving *Section 482 of the Internal Revenue Code (1973)*," reprinted in 2 Rhoades, Income Taxation of Foreign Related Transactions 7-91 to 7-95 (1977). A third study, conducted by a private individual, was based on the experiences in 1977 of approximately 60 companies. The participants reported that, for intercompany exports audited since 1965, the Service used some other method 32 percent of the time; for those assessments that were settled, the figure rose to 35 percent. Burns, **[*1149]** "How IRS Applies the Intercompany ***Pricing*** Rules of *Section 482*; A Corporate Survey," 52 J. ***Tax***. 308 (1980).

While the other methods mentioned by the companies consist **[**285]** of everything from customs valuations to royalty agreements, the method most widely recognized by courts is the reasonable profit split approach. A lead-

[80] See sec. 1.482-2(e)(3)(iii), examples (*1*) & (*2*), Income Tax Regs., where the manufacturer's use of a patent made difficult the determination of an appropriate gross profit percentage under the cost plus method.

ing case in this area is *PPG Industries, Inc. v. Commissioner*, 55 T.C. 928 (1970). [81] In *PPG*, respondent allocated to the taxpayer a portion of the income of PPGI, its wholly owned foreign subsidiary, from sales of glass products. As an indication of the arm's-length nature of its sales to PPGI, the taxpayer introduced evidence of the reasonableness of the net profits earned on those sales. [82] This Court determined that "When the profit earned by both [the taxpayer] and PPGI on export sales is combined to give us a consolidated export sales figure * * * it appears PPGI is only receiving a fair percent of such consolidated profit." *55 T.C. at 997*. The profit split was about 55 percent to the taxpayer and 45 percent to PPGI. We stated further:

The relevance in *sec. 482* cases of the division of profits realized on export sales is illustrated in *Eli Lilly & Co. v. United States*, 372 F.2d 990 (Ct. Cl. 1967), where the court, in upholding the reallocation of profits between a domestic parent and its Western Hemisphere corporation subsidiary, **[**286]** pointed out that prior to the reallocation the subsidiary received a share of total profits from Western Hemisphere sales ranging from 92.84 percent of 97.68 percent while the parent corporation's share of such profits ranged from 0.61 percent to 5.65 percent, whereas after the reallocation the subsidiary's share of the profits ranged from 62.07 percent to 74.56 percent while the parent corporation's share increased to a range of from 22.90 percent to 28.30 percent. (A second subsidiary was also involved in the reallocation of profits.) [*55 T.C. at 997 n. 10*.]

This Court again approved a profit split in *Lufkin Foundry & Machine Co. v. Commissioner*, T.C. Memo. 1971-101, revd. **[**287]** *468 F.2d 805 (5th Cir. 1972)*. There the taxpayer showed, through the analyses of a certified public accountant, that about 52 percent of the combined profit was income to Lufkin **[*1150]** and 48 percent was income to its selling subsidiaries. Lufkin, however, introduced no evidence of uncontrolled transactions, and this Court relied solely upon the reasonable profit split analysis. [83] The Service decided to appeal the decision [84] and the Court of Appeals for the Fifth Circuit reversed on the ground that ***HN53*** "No quantum of evidence as to a taxpayer's internal transactions with its own subsidiaries, standing alone, [can] be sufficient to establish arm's-length dealing between them." *468 F.2d at 805*. In its discussion of arm's-length ***pricing***, however, the Court of Appeals stated briefly that the three ***pricing*** methods prescribed by the regulations under *section 482* required evidence of the transactions of uncontrolled parties, then went on to say:*[section 1.482-2(e)(1)(iii)]* states that where the standards set out in the regulations indicate that one of the three methods is applicable, the taxpayer may avoid its application only by demonstrating that some other ***pricing*** method is clearly more appropriate. **[**288]** Lufkin has not shown that each of the three methods is inapplicable, nor has it shown that a more appropriate method ought to be utilized. [*468 F. 2d at 808*.]

From this language, we believe that the reversal of *Lufkin* is distinguishable. In the instant case, we are faced here with the task of approximating, as best we can, the arm's-length ***prices*** for Darvon and Darvon-N products in 1971 and 1972. The three preferred ***pricing*** methods detailed in the regulations are clearly inapplicable due to a lack of comparable or similar uncontrolled transactions. Petitioner's evidence amply demonstrates **[*1151]** that some fourth method not only is more appropriate, but is inescapable.

Petitioner's method of allocating income between itself and Lilly P.R. during 1972, although presented to us at trial and on brief as satisfying the arm's-length dealing test under the resale ***price*** method, was, in substance, based upon a profit split formula. By applying that formula to the amounts determined using petitioner's system **[**290]** of allocating expenses, petitioner derived its dis-

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[81] See also *Baldwin-Lima-Hamilton Corp. v. United States*, 435 F.2d 182, 185 (7th Cir. 1970), affg. in part an unreported District Court opinion; *Woodward Governor Co. v. Commissioner*, 55 T.C. 56, 66 (1970); *Nat Harrison Associates, Inc. v. Commissioner*, 42 T.C. 601, 622 (1964); *Eli Lilly & Co. v. United States*, 372 F.2d 990, 997 (Ct. Cl. 1967).

[82] The taxpayer also introduced sufficient evidence to satisfy the comparable uncontrolled price method. *PPG Industries, Inc. v. Commissioner*, 55 T.C. 928, 993-995 (1970).

[83] The Court noted that, because the taxpayer did not have the benefit of the regulations under sec. 482 (adopted Apr. 15, 1968) for the tax years in issue (1961 and 1962), it did not attempt to consider the case within the confines of those regulations.

[84] The author states in Fuller, "Section 482 Revisited," 31 Tax L. Rev. 475, 513 (1976), with respect to this case, that the Service decided to prosecute an appeal in *Lufkin* apparently only after careful consideration was given to the profit split analysis of the opinion. As he explains in note 158:

"The Service appealed the Tax Court's decision on October 20, 1971, but on November 9, 1971 the court granted the Service's motion to extend the time for transmission of the record to the Fifth Circuit to January 8, 1972 to give the Service time to determine whether the appeal should be further prosecuted. See Aland, Section 482: 1971 Version, 49 Taxes 815, 826 (1971). The Treasury Department was working at that time on a revised approach to intercompany pricing and it was understood **[**289]** by some tax practitioners that 'the Treasury [was] devoting its most intensive efforts' to developing an income spliting approach. See Hammer, Morrione & Ryan, Concepts and Techniques in Determining the Reasonableness of Intercompany Pricing Between United States Corporations and Their Overseas Subsidiaries, 30 N.Y.U. Inst. 1407, 1437-1438 (1972)."

count from net wholesale ***prices*** to be applied to Lilly P.R.'s sales to petitioner.

During 1972, petitioner's profit-split formula resulted in Lilly P.R. earning a manufacturing profit of 100 percent of its manufacturing costs (less operating expenses), plus its location savings from operating in Puerto Rico[85] and 60 percent of the combined net income attributable to the intangibles. Petitioner thereby earned a gross profit of 125 percent of its expenses related to the marketing of Darvon and Darvon-N products and the remaining 40 percent of the net income attributable to the intangible property. [86] While postponing for now the question of the appropriate intangible profit divisions, we note our acceptance of petitioner's use of a location savings. Respondent, in computing his allocations of income in both the notice of deficiency and the amended answer, allowed Lilly P.R. a location savings. Because petitioner has introduced no evidence showing that respondent's figures were erroneous, we will, accordingly, use those stated in the notice of deficiency.

We also approve of the 100-percent manufacturing profit allowed Lilly P.R. Respondent, in his notice of deficiency, constructed ***prices*** at which the Mayaguez facility would ***transfer*** bulk propoxyphene hydrochloride and napsylate chemicals to the Carolina pharmaceutical manufacturing plant. The excess of those ***prices*** over Mayaguez's actual costs was allowed as manufacturing profit; Carolina received a manufacturing profit of 25 percent of its costs. Respondent's amended answer eliminated the intra-company profit and **[*1152]** allowed Lilly P.R. only a manufacturing gross profit of 130 percent of the sum of Lilly P.R.'s manufacturing **[**292]** costs and the location savings. Respondent has the burden of proof with respect to his amended answer and did not introduce any evidence to show the reasonableness of his method. Accordingly, our options are limited to petitioner's formula or respondent's notice of deficiency method. Based on our judgment that the results of the two are substantially equivalent, [87] and because respondent has focused his concern on the income from the intangibles, we will use petitioner's manufacturing profit of 100 percent.

With respect to petitioner's marketing profit, we decline to use petitioner's profit split formula. Under that formula, petitioner would earn a marketing profit of 25 percent of its marketing expenses. Such a profit differs substantially from petitioner's **[**293]** initial ***pricing*** policy established in 1965 by the second Puerto Rican project team, which recommended that petitioner earn profits equal to 90 to 100 percent of its marketing expenses based upon an analysis of the operating income to operating expense ratios of Marion Laboratories, Inc., and petitioner's foreign affiliates. See pp. 1024-1025 *supra*. Were we to apply the 25-percent figure to petitioner's 1971 and 1972 taxable years, petitioner's marketing profit for each year would be approximately $ 2,455,000 and $ 3,154,000 respectively. Such a profit in our judgment is unreasonably low considering petitioner's extensive marketing operations and net sales of Darvon and Darvon-N products in excess of $ 55 million and $ 73 million during 1971 and 1972. Consequently, we believe that petitioner should earn a marketing profit of 100 percent (of its marketing expenses) as originally recommended by its own project team. [88]

As previously stated, petitioner's profit split formula was applied to the amounts determined on the **[**294]** basis of allocations of expenses made by petitioner relative to its Darvon and Darvon-N operations. See Combined Income Statements for **[*1153]** Darvon and Darvon-N Products at pages 1092-1093. Respondent alleges that certain of those allocations of expense items to income are erroneous and not in conformity with arm's -length dealings. We agree with respondent in principle but not as to specifics.

i. *Cost of Goods Sold*

The first category of expenses is the cost of goods sold. In 1971, petitioner's cost of goods sold for Darvon and Darvon-N products did not include any expenses of petitioner's ticket issuance department. However, petitioner's cost of goods sold for 1972 and 1973 included an increasing percentage of the expenses of petitioner's

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[85] The location savings portion of the formula represented the reduced cost of operating **[**291]** in Puerto Rico as compared to the United States and was attributable primarily to lower labor rates and Lilly P.R.'s exemptions from Puerto Rican property and other nonincome taxes.

[86] The combined net income attributable to the intangibles (e.g. patents, manufacturing know-how, trademarks, tradenames, reputation, and goodwill) was calculated as the combined net profit excluding Lilly P.R.'s manufacturing profit and location savings, and petitioner's marketing profit. Petitioner owned the marketing intangibles, and was entitled to the income attributable thereto.

[87] Lilly P.R.'s manufacturing profit for 1971 as computed using petitioner's formula would be $ 14,549,000 (100 percent of Lilly P.R.'s manufacturing costs less operating expenses -- $ 9,821,000 (see p. 1163 *infra*) plus Lilly P.R.'s location savings allowed by respondent -- $ 4,728,000); Lilly P.R.'s gross profit for 1971 per respondent's notice of deficiency was $ 13,671,275 (Mayaguez -- $ 7,732,538 plus Carolina -- $ 5,938,737).

[88] Generally, by increasing petitioner's marketing profits we are decreasing Lilly P.R.'s prices to petitioner for Darvon and Darvon-N products. See pp. 1078-1080 *supra*.

ticket issuance department. [89] The ticket issuance department retained, copied, and sent to Lilly P.R. the manufacturing work tickets needed for its manufacture of chemical and pharmaceutical products. Petitioner determined that, based on the ratio of the number of manufacturing tickets for Darvon and Darvon-N products issued to Lilly P.R. for a year to the total number of manufacturing tickets issued during that year, 5 percent ($ 15,000) of the **[**295]** total department expenses for 1972 and 7 percent ($ 22,000) of the total department expenses for 1973 should be charged to petitioner's cost of goods sold for Darvon and Darvon-N products for those respective years.

Petitioner's Darvon and Darvon-N cost of goods sold for 1971 did not include any portion of the expenses of petitioner's finished stock planning department. As with the ticket issuance department expenses, some expenses of petitioner's finished stock planning department were included in petitioner's cost of goods sold for 1972 and 1973. Petitioner based its allocation for those years on the ratio of the number of persons handling Puerto Rican source products to the total number of persons in the finished stock planning department. The expenses charged to cost of goods sold for 1972 and 1973 were 12 percent ($ 51,000) and 14 percent ($ 63,000), **[**296]** respectively, of the total expenses of the finished stock planning department for those years.

[*1154] ***HN54*** *Section 1.482-2(b)(1), Income **Tax*** Regs., provides that when one member of a group of controlled entities performs services for the benefit of another member without charge or for a charge which is less than arm's length, the District Director may make an appropriate allocation to reflect such an arm's-length charge. *Section 1.482-2(b)(2)(i), Income **Tax*** Regs., sets forth the "benefit test" relative to those services performed by one member of a controlled group for another. That section provides as follows:

In general, allocations may be made if the service, at the time it was performed, related to the carrying on of an activity by another member or was intended to benefit another member, either in the member's overall operations or in its day-to-day activities * * *

In 1971, petitioner, through its ticket issuance and finished stock departments, provided Lilly P.R. with services for which it was not compensated. An adjustment must therefore be made to provide petitioner arm's-length compensation for those services. Exercising our best judgment, we allocate 3 percent of petitioner's 1971 **[**297]** ticket issuance department expenses ($ 285,000), or $ 8,550, and 10 percent of petitioner's 1971 finished stock planning department expenses ($ 438,000), or $ 43,800, from Lilly P.R. to petitioner. [90]

Petitioner charged for 1972 expenses stated above to cost of goods sold and did not bill Lilly P.R. or seek reimbursement for them on the ground that they were "stewardship" expenses. We believe that petitioner's characterization of the ticket issuance and finished stock planning functions as stewardship activities is in error and caused petitioner's 1972 cost of goods sold to be inflated.

Stewardship activities have been recognized both by the regulations and **[**298]** in case law as an exception to the rule that services between controlled entities must be reimbursed. Those activities are not defined by the *section 482* regulations. However, the regulations under section 861 are somewhat analogous, and contain a specific cross-reference to the *section* **[*1155]** 482 regulations. ***HN55*** *Section 1.861-8(e)(4), Income **Tax*** Regs., provides as follows:

If a corporation renders services for the benefit of a related corporation and the corporation charges the related corporation for such services * * *, the deductions for expenses of the corporation attributable to the rendering of such services are considered definitely related to the amounts so charged and are to be allocated to such amounts. However, the regulations under *section 482* (*section 1.482-2(b)(2)(ii)*) recognize a type of activity which is not considered to be for the benefit of a related corporation but is considered to constitute "stewardship" or "overseeing" functions undertaken for the corporation's own benefit as an investor in the related corporation, and therefore, a charge to the related corporation for such stewardship or overseeing functions is not provided for. Services undertaken by a corporation **[**299]** of a stewardship or overseeing character generally represent a duplication of services which the related corporation has independently performed for itself. * * *

HN56 *Section 1.482-2(b)(2)(ii), Income **Tax*** Regs., referenced in the preceding regulation, provides:

Allocations will generally not be made if the service is merely a duplication of the service which the related party

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[89] Because of the amounts of expenses of the ticket issuance and finished stock planning departments included in petitioner's cost of goods sold of Darvon and Darvon-N products increased from 1972 to 1973, we will consider this aspect of 1973 for the purpose of determining the expenses properly chargeable to cost of goods sold in 1971.

[90] The amounts petitioner charged to cost of goods sold of Darvon and Darvon-N products for 1972 and 1973, respectively, were 5 percent and 7 percent of the total ticket issuance department expenses, and 12 percent and 14 percent of the finished stock planning department expenses. We believe that petitioner's methods of determining those charges are reasonable and appropriate. It follows that the allocations for 1971 should be 3 percent (ticket issuance) and 10 percent (stock planning) of the actual expenses of those departments.

has independently performed or is performing for itself. In this connection, the ability to independently perform the service (in terms of qualification and ability of personnel) shall be taken into account. * * *

In a line of cases dealing with the deductibility of expenses claimed by one corporation when the expenses were incurred in connection with the activities of a related corporation, it has been held that ***HN57*** amounts associated with day-to-day operations cannot be considered as stewardship expenses. See *Austin Co. v. Commissioner*, 71 T.C. 955 (1979); *Columbian Rope Co. v. Commissioner*, 42 T.C. 800 (1964). See also Feinschreiber, "Stewardship Expenses," 3 International ***Tax*** J. 344 (1977). In *Austin Co*., the issue concerned whether or not the taxpayer was entitled to a deduction under section 162 for reimbursing **[**300]** a foreign subsidiary for foreign ***taxes*** it paid on salaries of loaned technical personnel. The taxpayer attempted to justify the deductibility of its payment of such ***taxes***, claiming that it benefited by protecting its foreign investment and also by reducing its overhead burden of the salaried personnel. This Court responded to that claim as follows:

Petitioner's argument that it loaned, on a full-time basis, supervisory and administrative personnel to safeguard its foreign investment simply does not **[*1156]** withstand analysis * * *. No doubt this relationship enhanced the successful operation of Mexicanos which benefited petitioner as its owner, but this type of indirect and incidental benefit is not enough to justify petitioner's deduction. *Columbian Rope Co. v. Commissioner, supra* at 815-816. Petitioner simply cannot claim as its own expense, amounts paid for activities that were concerned with the day-to-day operation of the subsidiary's business. *Young & Rubicam, Inc. v. United States*, [187 Ct. Cl. 635, 410 F.2d 1233 (1969)] *supra* at 1239. [*71 T.C. at 967-968*.]

Petitioner herein cannot claim as its own expenses amounts attributable to the ticket issuance and finished stock planning **[**301]** functions performed for Lilly P.R. The activities were not of an "overseeing" nature and were not carried out to benefit petitioner in its capacity as an investor in Lilly P.R. The ticket issuance and finished stock planning activities were necessary to and part of Lilly P.R.'s day-to-day manufacturing operations. As Dr. Frederic Lloyd, Vice President-Production, Operations Division of petitioner, testified with respect to the ticket issuance function, a "manufacturing ticket is the key to the whole technique of control of a manufacturing operation and the quality of the product that is produced" and "Some kind of a ticket kind of procedure is an FDA requirement." Dr. Lloyd described the function that produced those tickets as being "clerical" in nature. Moreover, the services performed by petitioner were not duplications of those independently performed by Lilly P.R. for itself. [91]

The ticket issuance and finished stock planning functions **[**302]** were not stewardship functions. Accordingly, the amounts petitioner charged to its cost of goods sold for Darvon and Darvon-N products during 1972 (and 1973, though we discuss that year separately) for those functions must be reallocated from petitioner to Lilly P.R.

ii. *Operating Expenses*

The next category we consider is operating expenses, which includes the expenses of general administration, selling, merchandising, shipping, samples, and research and development. Respondent attacks the manner in which petitioner allocates those expenses, alleging that petitioner's method does not reflect the actual expenses borne by the revenue to which the **[*1157]** allocations are made. Respondent finds particular fault with petitioner's allocations of general administrative and research and development costs. We will discuss each of these in turn.

Petitioner's general administrative expenses were allocated on the basis of a percentage of the selling, merchandising, and shipping expenses which it determined were incurred relative to its marketing of Darvon and Darvon-N products. The percentage was determined by dividing the total general administrative expenses of petitioner's pharmaceutical division **[**303]** by its (1) manufacturing costs less material costs; (2) total research and development expenses, and (3) selling, merchandising, and shipping expenses. Respondent presented the testimony of Dr. James Wheeler, an expert accounting witness, to prove that the percentage factor resulted in unreasonably low allocations of general administrative expenses to petitioner's Darvon and Darvon-N products. Dr. Wheeler based his opinion on the fact that, in an industry like the pharmaceutical one, general and administrative expenses are closely related to the direct costs of materials. Petitioner, however, excluded materials cost from the denominator of its ratio, and used instead only labor costs and overhead, overhead already being an allocated figure. Dr. Wheeler also testified that the use of the research and development figure in the denominator of the administrative expense factor caused some portion of the administrative expenses to be allocated away to research and development expenses, but none of petitioner's general research and development expenses were allocated to any of the product lines.

Dr. Wheeler tested the allocations in question by comparing petitioner's and Lilly P.R.'s **[**304]** rates of return

[91] We have considered the fact that Lilly P.R. could have performed the ticket issuance function during the years in issue had it had the necessary copy machine, but find it of no importance. The day-to-day character of the function remains unchanged.

on employed assets, rates of return on net sales, and percentages of operating expenses to sales. While we agree with the logic and correctness of Dr. Wheeler's conclusions regarding the allocation factor, we will not substitute his results for petitioner's inasmuch as his calculations ignore any manufacturing return of Lilly P.R. which might be attributable to its intangible assets. We will, however, adjust petitioner's allocation factors to include the materials costs in the cost of goods sold figures.

Also, petitioner allowed Lilly P.R. the free use of its administrative manuals and paid the legal expenses connected with suits by persons claiming injuries caused by Darvon or **[*1158]** Darvon-N products (see pp. 1072-1073). The costs to petitioner were included in petitioner's general and administrative expenses. Petitioner has allocated its general and administrative expenses as a percentage of its Darvon and Darvon-N marketing expenses, a method which we understand to include only those expenses allocable to the burden and overhead of petitioner's Darvon and Darvon-N selling, merchandising, and shipping activities. To capture the expense of the manuals, legal fees, **[**305]** and all other nonmarketing general and administrative expenses, we must increase the allocation factor. Petitioner has introduced no evidence on this matter. Therefore, using our best judgment we have concluded that a 10-percent increase is appropriate. Accordingly, using petitioner's formula for allocation of general and administrative expenses, with modifications, [92] we have determined that petitioner's general and administrative expenses with respect to Darvon and Darvon-N products should be adjusted to $ 1,222,097 and $ 1,685,532 for 1971 and 1972, respectively. [93] Thus, petitioner must include an additional $ 17,920 and $ 155,178 as general **[*1159]** administrative expenses for the respective years 1971 and 1972.

The next types of expenses included in petitioner's operating expenses are selling, merchandising, and shipping, i.e., petitioner's marketing expenses. Respondent does not seriously challenge the allocation methods of those expenses, nor can we find any error in such methods. Petitioner's expert accounting witness, Howard L. Shearon, testified at length and in great detail concerning petitioner's allocation methods. We found him to be an impressive witness who explained the methodologies used in connection with the ascertainment of the marketing expense items, carefully, and in a readily comprehensible manner. We agree that **[**307]** those methodologies were reasonable, and make no allocations with respect thereto.

We next consider research and development expenses. Up to this point we have dealt with what are considered by accountants to be strictly operating costs. Accounting methodology is concerned with associating, or matching, expenses with the appropriate time period as well as with the appropriate income. Operating expenses relate to the current operating period and are those costs currently chargeable against the principal revenue sources. While Lilly P.R.'s payments for the expenses of the support research and development activities [94] carried out for it under the joint research agreement were currently chargeable against its sales income, research and development expenses ordinarily are not considered operating

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[92] Besides including material costs in petitioner's cost of goods sold and increasing the allocation factor by 10 percent, we are using only petitioner's pharmaceutical division research and development expenses, rather than the total research and development expenses used by petitioner.

[93] The amounts were calculated as follows (000's omitted):

[(Total G & A) [1]/(COGS n2 + R&D n3 + Mrktg.) n4 100%] X Mrktg. allocated to Darvon/Darvon-N n5 = Darvon/Darvon-N G&A

1971

[(31,740)/(135,365 **[**306]** + 40,393 + 69,963) 110%] X 8,601 = 1,222.097

1972

[(35,069)/(135,781 + 45,397 + 68,994) 110%] X 10,931 = 1,685.532

[1] General and administrative expenses of petitioner's pharmaceutical division, p. 1089.

n2 Cost of goods sold of petitioner's pharmaceutical division, p. 1089.

n3 Research and development expenses of petitioner's pharmaceutical division, p. 1063.

n4 Selling, merchandising, and shipping expenses of petitioner's pharmaceutical division, p. 1089.

n5 Selling, merchandising, and shipping expenses with respect to Darvon and Darvon-N products, pp. 1092-1093.

[94] As discussed in our findings of fact, petitioner's research and development activities were categorized according to the nature **[**308]** of the work involved. The three categories were (1) general, involving the search for new pharmaceutical products; (2) defined, involving development of a specific new product; and (3) continuing or support, involving the ongoing research for, e.g., improved formulations or delivery systems of established products. The expenses allocated to Darvon and Darvon-N during the years in issue were primarily for support activities.

expenses, but are other current income deductions. [95] This is because, as petitioner's Controller, Richard A. Warne, testified, general research and development expenses do not apply to present operations or to any defined period, but apply only to future operations.

During the years in issue, Lilly P.R. was charged by petitioner for certain research and development expenses under the terms of the joint research agreement. Those **[*1160]** expenses were for research and development activities carried out by petitioner that petitioner determined related specifically to Darvon and Darvon-N products. Similarly, petitioner recorded and allocated to its other product lines the research and development expenses it determined related specifically to those product lines. No allocation, however, was made of the general **[**309]** research and development expenses. [96] Those expenses were borne by petitioner's total revenues.

We have carefully considered the testimony of both parties' expert accounting witnesses. Petitioner's witnesses maintained that, because the general research and development expenses did not relate to any specific time period or **[**310]** pharmaceutical product, no allocation of those expenses to Darvon and Darvon-N products in 1971 and 1972 was necessary. Respondent and his experts believe that, given the research-intensive nature of the pharmaceutical business, no independent entity could fail to do otherwise. For the reasons discussed below, we agree with respondent.

Research and development is the lifeblood of the pharmaceutical industry. Pharmaceutical companies rely for their long-range survival on the research and development of new chemical products as well as on the maintenance and upgrading of their existing patents. The time and cost of inventing and developing new drugs and testing them in order to receive FDA approval to market them is a complex, risky, [97] and expensive [98] process. A pharmaceutical company must fund that process through the revenues of its successfully marketed products.

In this case, petitioner invented and developed two highly successful products. Petitioner ***transferred*** the patents and **[*1161]** know-how for those products to Lilly P.R. in a *section 351* exchange. Petitioner did not receive royalties, a lump-sum payment, or other arm's-length consideration to take the place of the prospective revenues those patents would have produced. Petitioner thus deprived itself of the means to carry on a portion of its general research and development activities, or at least, was forced to fund those activities with income that would otherwise have gone elsewhere (e.g., shareholders' dividends, capital investments). As respondent's expert accounting witness, Dr. James Wheeler, testified, using petitioners' allocation methods, were petitioner to ***transfer*** the patents and know-how for its nine most profitable products to a related entity for manufacture and sale of those products to petitioner, petitioner would not receive sufficient income from the marketing of such products to sustain its operations.

Dr. Wheeler stated, and we agree, that no independent company would market **[**312]** a product for an amount insufficient to cover its own ongoing expenses. Petitioner's research and development has contributed greatly to its success in the pharmaceutical industry, and is not a function that we believe petitioner would discontinue under any circumstances. Accordingly, some allocation of research and development expenses must be made. We conclude that $ 7,054,856 and $ 7,844,778 should be included in petitioner's operating expenses for 1971 and 1972, respectively, to cover a proportionate share of its general research and development expenses. [99]

Petitioner's remaining potential problem areas can be dealt with summarily. The technical assistance fees it

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[95] See R. Wixon, W. Kell & N. Bedford, Accountants' Handbook 2-49 -- 9-51 (5th ed. 1970); American Institute of Certified Public Accountants, Inc., 2 APB Accounting Principles, APB Opinion No. 9, at 6557, 6560-6561 (June 30, 1973).

[96] Although the parties stipulated that 60 percent of petitioner's research and development expenses related to general (not defined or support) research and development activities, petitioner's expert accounting witness, Howard L. Shearon, testified that 80 percent of petitioner's research and development expenses were not allocated to particular products or product lines. Because petitioner has not proven that all the expenses connected with its provision to Lilly P.R. of FDA-related services, including, but not limited to, the maintenance of Darvon and Darvon-N NDAs, the retention and storage of lot samples, and the allowance of the right to refer to petitioner's NDAs in subsequent and supplemental NDAs, were allocated to and reimbursed by Lilly P.R., we will use the 80-percent figure as the amount of petitioner's unallocated research and development expenses.

[97] Only 1 in 8,000 new synthesized compounds is finally marketed as a new drug. Only 1 in 10 new drugs for which INDs are filed ever receives final FDA approval for marketing.

[98] Joint Exhibit 73-BT, titled "Research and Development Intensity in Pharmaceutical Industry -- A Composite Profile of Six Major Companies," states **[**311]** that, for 1971, research and development expenses as a percentage of net income was 42.4 percent.

[99] The figures above were based upon the percentage of petitioner's sales of Darvon and Darvon-N products to petitioner's total pharmaceutical sales, and were calculated as follows:

Darvon/Darvon-N sales (from pp. 1092-1093)/total sales (from p. 1089) X 80% pharm. R&D (from p. 1063) = Darvon and Darvon-N general R&D

billed to Lilly P.R. during the years in issue were determined according to the number of **[**313]** hours reported by petitioner's employees **[*1162]** multiplied by the technical assistance fee rates applicable to those employees, plus 5 percent of the hourly charge. The technical assistance fee rates were equal to the average hourly compensation costs, including benefits and employment ***taxes***, for petitioner's employees. Petitioner also billed Lilly P.R. for traveling expenses and the standard charge for engineering services. The amounts billed represented all the technical assistance rendered to Lilly P.R. during 1971 and 1972, except for the ticket issuance and finished stock planning services mentioned previously. Accordingly, no allocation with respect to the technical assistance fees is warranted.

During the years 1971 and 1972, Lilly P.R. purchased 20 percent and 19 percent, respectively, of its raw materials from petitioner. Lilly P.R. also purchased some of its equipment and machine parts through petitioner during those years. In the case of raw materials, petitioner charged Lilly P.R. at its cost for manufactured items and at its materials cost for items purchased by it. In the case of the equipment and machine parts, petitioner accumulated all costs with respect to its purchase **[**314]** of an item under a job cost number; when the item was received by petitioner, it shipped the item to Lilly P.R. and invoiced Lilly P.R. for the total costs accumulated. We believe the amounts billed to Lilly P.R. were reasonable and represented all the costs associated with the supplying of the materials and equipment to Lilly P.R., except for the clerical costs of the actual billings themselves. Those costs, however, can be viewed as falling under the umbrella of general and administrative services, a portion of which has already been included in petitioner's operating costs relative to Darvon and Darvon-N products. We conclude no revision is necessary with respect to the clerical costs of the actual billings.

The fees associated with the joint research agreement covered the research and development activities performed by petitioner for Lilly P.R. but not billed to Lilly P.R. under the technical assistance agreement. Under the joint research agreement, Lilly P.R. was invoiced for and paid the costs of Darvon and Darvon-N research and development activities performed by petitioner. Such activities were classified as support work, and consisted of the expenses attributed by Lilly **[**315]** Research Laboratories' project accounting system to the research projects and clinical grants related to Darvon and **[*1163]** Darvon-N products. Any activities not related directly to a specific product and thereby slipping outside of petitioner's project development system were billed to general research. Inasmuch as we already have revised petitioner's Darvon and Darvon-N expenses to include a portion of such general research and development expenses, no allocation is necessary here.

iii. *Applicable Profit Split Percentage*

We turn now to the application of the profit split approach to the revised income and expense items of petitioner and Lilly P.R. [100] Petitioner has stated at various times throughout the **[*1164]** trial and on brief that Lilly P.R.'s ***prices*** to it were based upon and satisfied a profit split approach. To support its claim, petitioner introduced testimony pertaining to the relative value of pat-

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1971

73,861,799/338,321,035 X .80 (40,393,000) = 7,054,856

1972

75,827,232/351,043,948 X .80 (45,397,000) = 7,844,778

[100] A summary of such items, and their places in the financial statements, are set forth **[**316]** below:

1971				
Financial statements Lilly P.R. (from p. 1086)		**With adjustments Lilly P.R.**		
Net sales	$ 55,573,774	Net sales	$ 55,573,774	
Cost of goods sold	12,754,744	Cost of goods sold	12,754,744	
Gross profit	42,819,030	Gross profit		$ 42,819,030
Operating expenses	2,881,214	Operating expenses	2,881,214	
Operating profit	39,937,816	Adjustments:		
		Ticket issuance	8,550	
		Finished stock planning	43,800	

ents and trademarks, as well as the testimony of its pharmaceutical industry expert witness regarding the profit

1971				
Financial statements Lilly P.R. (from p. 1086)		**With adjustments Lilly P.R.**		
				2,933,564
		Operating profit		39,885,466
Petitioner (from p. 1092)		Petitioner		
Net sales	$ 73,861,799	Net sales	$ 73,861,799	
Cost of goods sold	47,059,792	Cost of goods sold	47,059,792	
Gross profit	26,802,007	Gross profit		$ 26,802,007
Operating expenses	9,805,444	Operating expenses	9,805,444	
Operating profit	16,996,563	Adjustments:		
		General		
		administration	17,920	
		Research &		
		development	7,054,856	
				16,878,220
				9,923,787
		Other operating		
		income:		
		Ticket issuance	8,550	
		Finished stock		
		planning	43,800	
				52,350
		Operating profit		9,976,137

1972				
Financial statements Lilly P.R. (from p. 1086)		**With adjustments Lilly P.R.**		
Net sales	$ 57,188,297	Net sales	$ 57,188,297	
Cost of goods sold	14,387,345	Cost of goods sold	14,387,345	
Gross profit	42,800,952	Gross profit		$ 42,800,952
Operating expenses	$ 3,085,136	Operating expenses	$ 3,085,136	
Operating profit	39,715,816	Adjustments:		
		Ticket issuance	$ 15,000	
		Finished stock		
		planning	51,000	
				$ 3,151,136

level at which an unrelated company would be willing to market Darvon and Darvon-N products.

[317]** Eugene L. Step, president of petitioner's pharmaceutical division and possessing an impressive background in the pharmaceutical industry, testified concerning the marketing efforts of petitioner. Mr. Step stated that he considered petitioner's marketing force to be the leader among the approximately 30 pharmaceutical manufacturers in the United States, but that petitioner's name, reputation, and sales force were no guarantees of promoting a successful product if the product could not ″sell itself.″ Mr. Step stressed the quality of a product and the discerning nature of the health care professionals who prescribe that product as being the deciding factors in its success rather than a trademark. He testified that health care professionals knew a successful product such as Darvon by its generic name of propoxyphene hydrochloride, and that, had the Darvon trademark name been lost, the professionals would have been alerted to a new trademark by pharmacists and petitioner's marketing force and would have simply prescribed the product under its new **[*1165]** name. Thus, the Darvon and Darvon-N trademarks had relatively less value as opposed to the patents, which gave Lilly P.R. the exclusive right **[**318]** to manufacture propoxyphene products in the United States.

This concept of the patent value exceeding the value of the trademark was reiterated by Dr. Baumol, one of petitioner's expert economic witnesses. Dr. Baumol was very familiar with the pharmaceutical industry, and became involved in this case in 1971. Dr. Baumol viewed the trademark for a product as having a negligible value so long as the patent for that product was in effect. He testified that any successful marketing operation, given the opportunity to market a high sales volume pharmaceutical product, could have created an identical demand for the sale of ″Carvon,″ or whatever they chose to call it, with only minor expenditures for the establishment of the new trademark. We find the testimony of Mr. Step and Dr. Baumol very convincing in support of the proper profit split between the manufacturing and marketing intangibles.

Petitioner also introduced the testimony of Lawrence C. Hoff, Executive Vice President, World Wide Pharmaceutical Operations, Upjohn Co. As a result of his employment with the Upjohn Co. and his involvement in industry associations, Mr. Hoff developed throughout a 30-year career an extensive knowledge **[**319]** of the manufacturing and marketing of pharmaceutical products

1972				
Financial statements Lilly P.R. (from p. 1086)		**With adjustments Lilly P.R.**		
		Operating profit		39,649,816
Petitioner (from pp. 1092-1093)		Petitioner		
Net sales	$ 75,827,232	Net sales		$ 75,827,232
Cost of goods sold	46,686,723	Cost of goods sold	$ 46,686,723	
Gross profit	29,140,509	Adjustments:		
		Ticket issuance	(15,000)	
		Finished stock planning	(51,000)	
				46,620,723
		Gross profit		29,206,509
Operating expenses	12,461,454	Operating expenses	12,461,454	
Operating profit	16,679,055	Adjustments:		
		General administration	155,178	
		Research & development	7,844,778	
				20,461,410
		Operating profit		8,745,099

in the United States. Accordingly, Mr. Hoff was qualified as an expert witness on the U.S. pharmaceutical industry. Prior to trial, Mr. Hoff reviewed the sales history of Darvon and Darvon-N products for the years 1958 through 1973, the distribution agreement between petitioner and Lilly P.R., and also the combined income statements for Darvon and Darvon-N products set out in this opinion at pages 1092 and 1093.

Mr. Hoff became familiar with propoxyphene products when petitioner introduced Darvon in the late 1950s. In his opinion, petitioner's Darvon and Darvon-N products filled a significant therapeutic need for a product providing relief from mild to moderate pain. During the 1950s, there was a large gap between the narcotics used to treat severe pain and the over-the-counter drugs such as aspirin used to treat mild pain. For that reason, Mr. Hoff believed petitioner's Darvon and Darvon-N products were well accepted by physicians and were important products in the pharmaceutical industry.

[*1166] It was Mr. Hoff's opinion that a product line such as Darvon and Darvon-N would be of substantial value to any pharmaceutical company. **[**320]** Petitioner's propoxyphene product line was well respected by health care professionals in the United States; propoxyphene products were used by health care professionals ranging from the rural general practitioner to the most experienced urban neurosurgeon. Moreover, the marketing of prescription pharmaceutical products is a sample -oriented business and, under the terms of the distribution agreement, Lilly P.R. provided petitioner with samples free in 1971 and 1972 and at manufacturing cost in 1973. Mr. Hoff believed that the ability to provide large numbers of samples of Darvon and Darvon-N products to a broad range of health care professionals, who respected and were interested in those products, would be extremely valuable to any pharmaceutical company because it would provide additional access to the offices of health care professionals. [101]

Mr. Hoff was also of the opinion that the promotion of Darvon and Darvon-N products by sales representatives would consume a minimal amount of time of those representatives, because the products were ″doorknob detail″ products, i.e., the promotion of the products was sample oriented and health care professionals already were interested in those products.

Mr. Hoff believed that the distribution of Lilly P.R.'s propoxyphene products would provide a pharmaceutical company a substantial return on its marketing efforts at the ***transfer prices*** charged by Lilly P.R. during the years in issue. Mr. Hoff, however, based his belief upon the profits afforded petitioner according to the pro forma combined income statements for Darvon and Darvon-N products. Those statements, as we previously discussed, were incorrect in several respects concerning petitioner's allocation of expenses. Accordingly, our adjustment of those statements requires a correlative adjustment of petitioner's profits for 1971 and 1972.

Mr. Hoff, as well as Mr. Step and Dr. Baumol, testified to the minimal value of the trademark while the patent protection remained in effect. The three agreed on the quality of **[**322] [*1167]** petitioner's marketing force, but emphasized the value that a product line such as the Darvon and Darvon-N product lines would have for the marketing force promoting it, especially, as Messrs. Hoff and Step noted, in terms of increased access for its sales representatives to the offices of health care professionals. The three witnesses believed that the ***prices*** petitioner paid Lilly P.R. for its propoxyphene products were arm's-length ***prices*** based upon the *profit* petitioner received on their resale. Under the ***pricing*** formula petitioner used in determining Lilly P.R.'s ***prices***, that profit was approximately 40 percent of the net intangible income.

We concur with Mr. Hoff, Mr. Step, and Dr. Baumol that the propoxyphene patents had relatively greater value than the Darvon and Darvon-N trademarks. We note, however, that those witnesses did not give enough weight to goodwill and the value of the Lilly name. The witnesses also failed to consider the short life remaining on the propoxyphene patent in 1971 and 1972. We question their assumption that an unrelated marketing company would have paid the same ***prices*** as petitioner for the propoxyphene products, knowing it had at best 2 years **[**323]** in which to develop the market recognition for its trademark before the patent expired. Mr. Hoff, Mr. Step, and Dr. Baumol agreed that, after the patent's expiration, the trademark was the intangible with the greater value.

Petitioner has failed to prove what the arm's-length ***prices*** for Lilly P.R.'s products should be, and we must bear heavily against petitioner in our determination. Using our best judgment, we conclude that petitioner should receive 45 percent of the net intangible income as its income attributable to the marketing intangibles. Consequently, we allocate $ 11,317,000 and $ 12,547,000 from Lilly P.R. to petitioner for the years 1971 and

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[101] Mr. Step agreed with this aspect of the marketing intangibles. While he was not sure whether good products create a good company, or vice versa, he was sure that a good product enhances the reputation of a company, and makes it easier for that company's sales representatives to get in to see a health care professional about the company's **[**321]** other products.

1972, respectively. [102]

[324] [*1168]** 2. *1973 Taxable Year*

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[102] The following figures are taken from the adjusted financial statements on pp. 1163 and 1164, and from the findings of fact at p. 1106. The allocated amounts are in addition to those allocated from Lilly P.R. to petitioner for ticket issuance and finished stock planning expenses, and are calculated as follows (000's omitted):

1971				
Lilly P.R.'s operating profit			$ 39,885	
Petitioner's operating profit			9,976	
Combined operating profit			49,861	
Less:				
Manufacturing profit -- 100% Lilly P.R.'s COGs less operating expenses		$ 9,821		
Location savings (from notice of deficiency)		4,728		
Marketing profit -- 100% petitioner's marketing expenses		9,823		
Total profit excluding intangibles			$ 24,372	
Profit due to intangibles			25,489	
Division of intangible profit				
Manufacturing -- 55% Lilly P.R.				$ 14,019
Marketing -- 45% Petitioner				11,470
Lilly P.R.		Petitioner		
Allocated profit	$ 14,019	Allocated profit		11,470
Manufacturing profit	9,821	Marketing profit		9,823
Location savings	4,728			21,293
	28,568			
Actual profit	39,885	Actual profit		9,976
	(11,317)			11,317
1972				
Lilly P.R.'s operating profit			$ 39,650	
Petitioner's operating profit			8,745	
Combined operating profit			48,395	
Less:				
Manufacturing profit -- 100% Lilly P.R.'s COGs less operating expenses		$ 11,236		
Location savings (from notice of deficiency)		5,265		
Marketing profit -- 100% petitioner's				

Because of the expiration of the propoxyphene patent at the end of 1972 and the entry into the U.S. market of at least 24 pharmaceutical companies which sold propoxyphene hydrochloride products in 1973, petitioner contends that in 1973 the most appropriate method for ascertaining arms'-length ***prices*** for Lilly P.R.'s products is to look to the market ***prices*** for such products in uncontrolled sales. It is petitioner's position that Lilly P.R.'s ***prices*** satisfy the comparable uncontrolled ***price*** **[*1169]** method of *section 1.482-2(e)(2), Income **Tax** Regs.* [103] While respondent agrees that the comparable uncontrolled ***price*** method is available for 1973, he takes issue with petitioner's adjustments to third-party ***prices*** for propoxyphene hydrochloride products.

a. *Comparable Uncontrolled **Price*** Method

HN58 Under the comparable uncontrolled ***price*** method, "the arm's length ***price*** of a controlled sale is equal to the ***price*** paid in comparable uncontrolled sales, adjusted as provided in subsection (ii) of this subparagraph." *Sec. 1.482-2(e)(2)(i), Income **Tax** Regs.* **[**325]** Uncontrolled sales are defined as "sales in which the sellers and the buyers are not members of the same controlled group." *Sec. 1.482-2(e)(2)(ii), Income **Tax** Regs.* The *section 482* regulations also determine the comparability of uncontrolled sales, as follows:

HN59 Uncontrolled sales are considered comparable to controlled sales if the physical property and circumstances involved in the uncontrolled sales are identical to the physical property and circumstances involved in the controlled sales, or if such properties and circumstances are so nearly identical that any differences either have no effect on ***price***, or such differences can be reflected by a reasonable number of adjustments to the ***price*** of uncontrolled sales. For this purpose, differences can be reflected by adjusting ***prices*** only where such differences have a definite and reasonably ascertainable effect on ***price***. If the differences can be reflected by such adjustment, then the ***price*** of the uncontrolled sale as adjusted constitutes the comparable uncontrolled sale ***price***. ***HN60*** Some of the differences which may affect the ***price*** of property are differences in the quality of the product, terms of sale, intangible property associated with **[**326]** the sale, time of sale, and the level of the market and the geographic market in which the sale takes place. Whether and to what extent differences in the various properties and circumstances affect ***price***, and whether differences render sales noncomparable, depends upon the particular circumstances and property involved. *[Sec. 1.482-2(e)(2)(ii), Income **Tax** Regs.]*

Thus, ***HN61*** under the comparable uncontrolled ***price*** method of *section 1.482-2(e)(2), Income **Tax** Regs.*, adjustments can be made to reflect differences between the controlled sale and the uncontrolled sale. The only guidance for those adjustments is contained in the regulations which state, in *section 1.482-2(e)(2)(ii), Income **Tax** Regs.*, "differences can be reflected **[*1170]** by adjusting ***prices*** only where such differences have a definite and reasonably ascertainable effect on ***price***."

During 1973, Lilly P.R. sold its Darvon and Darvon-N products to petitioner at ***prices*** equal to a 58-percent discount from petitioner's net wholesale ***prices*** for those products. The discount from net wholesale ***prices*** was increased from its previous 1972 level of 46 percent to reflect the expiration of the propoxyphene patent at the end of 1972.

marketing expenses		12,617		
Total profit excluding intangibles			29,118	
Profit due to intangibles		19,277		
Division of intangible profit				
Manufacturing -- 55% Lilly P.R.				$ 10,602
Marketing -- 45% Petitioner				8,675
Lilly P.R.		Petitioner		
Allocated profit	$ 10,602	Allocated profit		$ 8,675
Manufacturing profit	11,236	Marketing profit		12,617
Location savings	5,265			21,292
	27,103			
Actual profit	39,650	Actual profit		8,745
	(12,547)			12,547

[103] As stated previously, that method, when available, is the preferred approach to arm's-length pricing. Sec. 1.482-2(e)(1)(ii), Income Tax Regs.

Throughout the **[**327]** years in issue, Smith Kline & French Laboratories, Inc. (hereinafter SKF) marketed a line of branded prescription pharmaceutical products on which patent protection had expired called the SK line. In 1973, after the expiration of the propoxyphene patent, the SK line included two propoxyphene hydrochloride products: plain propoxyphene hydrochloride which was manufactured by SKF, and SK-65 Compound (propoxyphene hydrochloride with a combination of aspirin, phenacetin, and caffeine) which was manufactured for SKF by Milan Pharmaceuticals, Inc. (hereinafter Milan), of Morgantown, West Virginia. SK-65 Compound was competitive with petitioner's Darvon Compound-65 (PU 369).

During 1973, SKF purchased 47,399,654 filled SK-65 Compound capsules from Milan at a total invoice cost of $ 742,865. Milan's ***price*** to SKF for a bottle of 500 SK-65 Compound capsules was $ 7.55. Milan and SKF are unrelated. Petitioner contends that, if the Milan ***prices*** to SKF are properly adjusted to reflect the differences between those sales and sales by Lilly P.R. to petitioner, the Milan ***prices*** to SKF fully support Lilly P.R.'s ***pricing*** for 1973. [104]

[*1171] i. *Petitioner's Adjustments to Milan's **Prices***

Petitioner's economic experts compared the $ 7.55 ***price*** SKF paid for its SK-65 Compound with the $ 12.17 ***price*** petitioner paid Lilly P.R. for its Darvon Compound -65. [105] The experts identified seven adjustments which they believed had to be made to the Milan ***price*** in order to make the transactions between Milan and SKF comparable to the sales by Lilly P.R. to petitioner.

The first adjustment identified by petitioner's experts related to the raw materials furnished to Milan by SKF. SKF supplied to Milan at no charge the empty capsules, package inserts, labels, and bottle caps used by Milan to make SK-65 Compound for SKF. Lilly P.R. manufactured its **[**330]** own empty capsules, but purchased from petitioner the package inserts, labels, and some bottle caps needed for its Darvon Compound-65. [106] Petitioner's experts concluded that Milan's ***price*** should be adjusted for this difference by adding the costs that Milan would have incurred if it had purchased those materials. The experts determined that that adjustment should be $ 0.85 per bottle, although petitioner introduced evidence at trial to show that the actual cost of those materials to Milan was $ 1.14 per bottle.

The second factor which petitioner's economic experts identified for adjustment was the difference in credit terms provided by Milan versus those provided by Lilly P.R. Milan's credit terms to SKF were a 1-percent discount for payment in 10 days and net in 30 days. Lilly P.R.'s terms to petitioner were net in 180 days, and petitioner, as a practice, took the full 180 days to pay. Petitioner's experts valued the differences in those credit terms using the interest costs **[**331]** that petitioner would have saved by receiving from Lilly P.R. what amounted to a 5-month interest-free loan of $ 12.17 (the 1973 ***transfer prices*** of a bottle of 500 Darvon Compound-65 capsules). That value was determined to be $ 0.40 at an interest rate of 8 percent.

[*1172] The third significant difference identified by petitioner's experts between the Milan sales to SKF and the Lilly P.R. sales to petitioner was that Lilly P.R. provided a substantial quantity of samples to petitioner at cost during 1973. Milan charged SKF $ 14.50 per thousand bulk capsules used by SKF as samples, and $ 0.135 for a sample pack of four capsules. Petitioner's experts thus increased Milan's ***prices*** by $ 1.56 per bottle to reflect the additional value of providing samples on the terms and in the relative amount provided by Lilly P.R.

The fourth adjustment described by petitioner's experts involved equipment loaned by SKF to Milan at no cost.

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[104] Neither party places much emphasis on the determination of **[**328]** arm's-length prices for all of Lilly P.R.'s Darvon and Darvon-N products based upon the prices for plain propoxyphene hydrochloride and propoxyphene hydrochloride compound products marketed by SKF and others. The reason for this is contained in sec. 1.482-2(e)(1)(iv), Income Tax Regs.:

HN62 "(iv) The methods of determining arm's length prices described in this section are stated in terms of their application to individual sales of property. However, because of the possibility that a taxpayer may make controlled sales of many different products, or many separate sales of the same product, it may be impractical to analyze every sale for the purposes of determining the arm's length price. It is therefore permissible to determine or verify arm's length prices by applying the appropriate methods of pricing to product lines or other groupings where it is impractical to ascertain an arm's length price for each product or sale." * * *

Petitioner determined Lilly P.R.'s prices according to a standard discount from net wholesale prices, applied to both Darvon and Darvon-N products. If the prices charged petitioner by Lilly P.R. for its Darvon Compound-65 were arm's-length prices, it follows that **[**329]** the prices charged petitioner on Lilly P.R.'s other products likewise were arm's-length prices. This reasoning is particularly persuasive here, as Darvon Compound-65 accounted for 50.7 percent of petitioner's Darvon and Darvon-N sales in 1973. (See p. 1089.)

[105] Petitioner's net wholesale price for Darvon Compound-65 in 500-capsule bottles was $ 28.97 (see p. 1074). Petitioner's discount from net wholesale prices for 1973 was 58 percent (see p. 1075). Fifty-eight percent of $ 28.97 is $ 12.17.

[106] For materials manufactured by petitioner, Lilly P.R. paid petitioner its cost plus 100 percent; for materials purchased by petitioner, Lilly P.R. paid petitioner its cost (including packaging and handling).

The equipment was used by Milan in the packaging of SK-65 Compound capsules in packages of four capsules. Because Lilly P.R. owned all the equipment it used to manufacture Darvon products, petitioner's experts believed that Milan's ***price*** should be adjusted to reflect that **[**332]** difference by adding to that ***price*** the rental value of the equipment loaned by SKF to Milan.

The fifth item of adjustment related to the quality control operations for Milan's products carried out by SKF both at Milan's plant and at SKF's facilities. Lilly P.R. carried out its own quality control operations in Puerto Rico and reimbursed petitioner for certain sample tests performed by it in Indianapolis. Petitioner's experts determined that the cost of SKF's quality control activities should be added to the Milan ***price***, but were unable to quantify this cost.

The sixth difference identified by petitioner's experts was the difference in quality of the Milan product as opposed to that manufactured by Lilly P.R. The Darvon compound product manufactured by Lilly P.R. during the years 1971 through 1973 utilized the glutamic acid hydrochloride formulation to avoid both the misuse and odor problems associated with other formulations of those products. Lilly P.R. bore the cost of developing that formulation, which was a trade secret owned by Lilly P.R. In contrast, the SK-65 Compound sold by Milan to SKF contained a propoxyphene pellet and, therefore, was subject to misuse. Furthermore, **[**333]** SK-65 Compound had a slightly greater variability of active ingredient per capsule than the Darvon Compound-65 produced by Lilly P.R.

The final adjustment by petitioner's experts was made with respect to the continued existence of the napsylate patent. The **[*1173]** $ 12.17 ***transfer price*** of Darvon Compound-65 in 1973 was computed by a formula [107] that spread the value of Lilly P.R.'s napsylate patent over all the Darvon and Darvon-N products produced by Lilly P.R. [108] Thus, the $ 12.17 ***price*** in part reflected the value of the napsylate patent. The experts concluded that either the Milan ***price*** or the Lilly P.R. ***price*** should be adjusted for that factor in order to make the Milan ***price*** comparable to that of Lilly P.R.

On the basis of the foregoing, the adjustments to the Milan ***price*** made by petitioner's experts can **[**334]** be summarized as follows:

Milan ***price***	$ 7.55
Adjustments	
a. Raw materials	0.85
b. Credit terms	0.40
c. Samples	1.56
d. Equipment	
e. Quality control	
f. Quality differences	
g. Darvon-N patent	
Items d -- g (estimate)	n1 1.81
Adjusted Milan ***price***	12.17

Petitioner's experts concluded that, because the adjusted Milan ***price*** was roughly equivalent to the ***price*** petitioner paid Lilly P.R. for the same product, the ***prices*** petitioner paid Lilly P.R. during 1973 for Darvon Compound-65, as well as all the other ***prices*** petitioner paid Lilly P.R. during 1973 for Darvon and Darvon-N products, were arm's-length ***prices***. Petitioner relies upon the conclusions of its expert witnesses to support its contention that Lilly P.R.'s 1973 ***prices*** satisfied the comparable uncontrolled sales method of *section 1.482-2(e)(2), Income **Tax** Regs.*, and thus were arm's-length ***prices***.

ii. *Respondent's Expert Economic Evidence*

Respondent argues that petitioner's 1973 ***prices*** were not at **[*1174]** arm's length based upon his review of comparable sales of generic propoxyphene hydrochloride products in 1973. Respondent's **[**335]** evidence compares ***prices*** that Milan, Zenith Laboratories, Inc., Rachelle Laboratories, Inc., and Caribe Chemical Co., Inc., charged for manufacturing propoxyphene hydrochloride products. Respondent's approach to specific ***price*** evidence also differs from petitioner's by rejecting any add-ons to the ***prices*** uncontrolled manufacturing companies charged for the same products manufactured by Lilly P.R., and by encompassing a broader spectrum of propoxyphene products.

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[107] In recognition of the propoxyphene patent's expiration on Dec. 27, 1972, petitioner revised its pricing formula so that petitioner would receive 70 percent of the intangible income for its possession of the Darvon trademark and other marketing intangibles, and Lilly P.R. would receive the remaining 30 percent as income attributable to its manufacturing intangibles.

[108] See note 104.

Respondent's expert economic witness, Dr. William Comanor, utilized two methods to determine what he believed to be arm's-length ***prices*** for the years 1971 through 1973. Both methods involved comparing the activities of three unrelated pharmaceutical companies with those of Lilly P.R. While we already have discussed the inherent flaws in Dr. Comanor's report and testimony (i.e., no rate of return computed for intangible property), we will consider such evidence insofar as it relates to third-party ***prices*** of propoxyphene products.

Dr. Comanor's first method observed third-party ***prices*** for propoxyphene hydrochloride products, using a weighted average of the ***prices*** to determine the percent differential between those ***prices*** and **[**336]** the ones charged by Lilly P.R. His second method involved observations of the gross profit margins earned by three pharmaceutical companies, Milan, Rachelle Laboratories, Inc., and Zenith Laboratories, Inc. Dr. Comanor determined an average gross margin for all three companies and then compared such margins to those actually earned by Lilly P.R.

Rachelle Laboratories, Inc. (hereinafter Rachelle), is a subsidiary of the International Rectifier Corp. and is located in Long Beach, California. In 1973, Rachelle had in its pharmaceutical line a plain propoxyphene hydrochloride product and a propoxyphene hydrochloride compound. The propoxyphene hydrochloride, sold in 65 mg. capsules, was produced by Rachelle; the propoxyphene hydrochloride compound-65 capsules were purchased as finished products from Caribe Chemical Co., Inc. (hereinafter Caribe), of the Virgin Islands.

A large part of Dr. Comanor's information concerning the three pharmaceutical companies previously mentioned was **[*1175]** obtained through interviews conducted by Dr. Comanor with company officials. The information pertaining to Rachelle and Caribe was provided at trial by Rachelle's president, Dr. Melvin Hochberg. [109] Dr. Hochberg **[**337]** produced records and letters which showed that Caribe's 1973 ***prices*** for the propoxyphene hydrochloride compound-65 mg. in 500-capsule bottles was $ 6.50 per bottle.

Rachelle employed approximately 200 persons in its Long Beach facility during 1973. Only 29 of those employees were involved in sales and marketing. Rachelle's net sales were $ 11,228,000 in 1973; its sales of propoxyphene hydrochloride products were approximately $ 50,000 in fiscal year ending June 30, 1973, and approximately $ 60,000 in fiscal year ending June 30, 1974.

Zenith Laboratories, Inc. (hereinafter Zenith), is a manufacturer of generic pharmaceutical products with facilities in New Jersey and in the Virgin Islands. Zenith purchases rather than produces the basic chemical ingredients needed for its pharmaceutical manufacturing activities. During the early 1970's Zenith employed approximately 190 persons. Zenith does not promote its products directly to physicians. Zenith's net sales for 1973 were $ 11,593,000; there is no evidence in the record indicating what proportion of those sales were attributable to sales of generic propoxyphene **[**338]** hydrochloride products.

Smith Kline & French, or SKF, a leading pharmaceutical company, has already been discussed in pertinent part.

Respondent argues that the information relative to the above companies, and Dr. Comanor's conclusions based thereon, clearly show that Lilly P.R's 1973 ***prices*** to petitioner were greater than arm's length. Although we agree with Dr. Comanor's ultimate conclusion, we disagree with his methods. Dr. Comanor's approach to ***pricing*** failed to take into account the presence of any intangibles held by Lilly P.R., specifically, in 1973, the glutamic acid hydrochloride formulation, and the napsylate patent. Respondent argues that Dr. Comanor purposely was told to evaluate the ***pricing*** relationship between petitioner and Lilly P.R., with no instructions given as to the ownership of intangibles, so as to achieve a fresh and untainted view of the situation, as opposed to petitioner's experts who **[*1176]** from the start assumed the presence of intangibles. Such an argument is specious and completely ignores the ownership of the intangibles by Lilly P.R.

Moreover, the ***pricing*** data relied upon by Dr. Comanor are not supported by evidence in the record. The data were derived from **[**339]** interviews conducted by Dr. Comanor with company officials of Milan, Zenith, and Rachelle. The ***prices*** are not supported by a single document in the record in this case and constitute hearsay evidence. The data were also inconsistent with the actual sales data introduced by petitioner with respect to SKF's purchases from Milan. Finally, the record is completely devoid of any facts regarding the circumstances of the sales by the three companies that would allow comparability to be determined, other than with respect to SKF's purchases from Milan. Rachelle and Zenith employed far fewer persons than did petitioner and had substantially lower net sales. Rachelle in particular had sales of propoxyphene hydrochloride products of only $ 50,000 in fiscal year ending June 30, 1973, and $ 60,000 the next year, as opposed to petitioner's sales of Darvon and Darvon-N products in 1973 of approximately $ 70 million (see page 1093). Mr. Hochberg's testimony with respect to Rachelle thus does not support the use of its sales as comparables.

Dr. Comanor, on direct examination, was responsive to the questions advanced by respondent's counsel; however, on cross-examination he refused to answer many

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[109] Dr. Comanor did not use the information with respect to Caribe in his reports.

[340]** of the hypothetical questions asked by petitioner's attorneys, which questions, in the Court's opinion, were very reasonable under the circumstances. In short, the substance of his testimony fell apart on cross-examination. Accordingly, we have discounted much of Dr. Comanor's report and testimony.

iii. *Determination of Arm's-Length **Price***

We turn now to petitioner's adjustments to Milan's ***price*** for SK-65 Compound. The underlying rationale of the increases made by petitioner's experts is that Milan enjoyed a more advantageous relationship with SKF than Lilly P.R. enjoyed with petitioner. In order to equalize the positions, and ***prices***, of the two, petitioner's experts believed it was necessary to adjust the Milan ***price*** before comparing it to the Lilly P.R. ***price*** for similar products.

[*1177] The first add-on identified by petitioner's experts relates to raw materials that SKF provided free to Milan but which Lilly P.R. purchased for itself. Petitioner's experts determined an add-on of $ 0.85, and petitioner introduced evidence showing that the actual cost to Milan was $ 1.14. Respondent takes issue with any add-on whatsoever. He argues that the amount of materials provided to Milan was not **[**341]** great, [110] and that petitioner's experts merely speculated that the same materials would still have been provided free to Milan if it had produced the same volume of propoxyphene hydrochloride products as did Lilly P.R.

Respondent also alleges that petitioner's experts failed to consider certain favorable circumstances that petitioner extended Lilly P.R. with respect to the same raw materials. Petitioner originally granted Lilly P.R. two licenses to U.S. patents, together with manufacturing know-how, so that Lilly P.R. could manufacture empty capsules. Petitioner provided packaging materials, bottles, and labels to Lilly P.R. at cost. In addition, petitioner designed and obtained all FDA approvals for labels and package inserts with respect to Lilly P.R.'s products. In contrast, the costs associated with Milan's obtaining FDA approval of its product, including the approval of labels and package inserts, were borne by Milan and not SKF.

We believe some adjustment is necessary for the raw materials provided Milan by SKF. The amount of materials provided may not have been large by petitioner's standards, but it apparently represented **[**342]** 100 percent of Milan's needs, and Milan benefited therefrom accordingly. Respondent censures petitioner's experts for a "highly speculative" assumption that Milan would still receive free materials from SKF were Milan to produce the same volume of products as petitioner. However, in comparing the ***prices*** it is impossible to neutralize completely the effect caused by the differences in size and sales of Milan and Lilly P.R. Whether Milan's terms and ***prices*** would or would not differ depending on an increased volume, the fact remains that Milan did receive free materials. We too would be speculating if we refused to adjust Milan's ***price*** upwards for this difference based upon a notion that it is normal for small volume manufacturers to receive **[*1178]** some raw materials free of charge from their purchasers. An adjustment is necessary, but not in the amount of $ 1.14, which was the actual cost of the materials provided Milan, or $ 0.85, the amount estimated by petitioner's experts. To reflect more accurately the cost of the materials at the volume of sales carried on by Lilly P.R., the adjustment should be Lilly P.R.'s own cost of purchasing the raw materials. During 1973, Lilly P.R. manufactured **[**343]** the empty capsules it used to make Darvon Compound-65. During that time, petitioner manufactured and sold billions of empty capsules to unrelated customers throughout the world at a ***price*** of $ 1.60 per thousand capsules. Lilly P.R. lost approximately 3 percent of its capsules in the filling and finishing of Darvon Compound-65. Thus, the market ***price*** for Lilly P.R.'s empty capsules was approximately $ 0.82 per bottle of 500 capsules. Lilly P.R.'s standard cost per bottle of 500 Darvon Compound-65 capsules for labels, package inserts, and bottle caps was approximately $ 0.04 in 1973. Accordingly, Milan's ***price*** should be increased by $ 0.86.

Respondent argues that the Milan ***price*** should be reduced to take into account the favorable conditions Lilly P.R. enjoyed over Milan, namely, the licenses to manufacture capsules, the packaging and other materials provided at cost, and petitioner's design of, and obtainment of, FDA approval for Lilly P.R.'s labels and package inserts. Respondent's argument with respect to empty capsules is without merit inasmuch as Lilly P.R. agreed under the license agreements to pay petitioner a royalty of 5 cents per 1,000 commercially acceptable empty capsules **[**344]** manufactured by Lilly P.R. and covered by either of the two U.S. patents owned by petitioner. Respondent has neither argued nor introduced any evidence to prove that such license agreements were not at arm's length. Accordingly, Lilly P.R.'s manufacture of empty capsules is not cause for a downward adjustment to Milan's ***price***. As for respondent's position that an adjustment is necessitated by petitioner's providing certain raw materials to Lilly P.R. at cost, we already have compensated for this factor by adjusting Milan's ***price*** upward to reflect Lilly P.R.'s own cost per 500-capsule bottles of labels, package inserts, and bottle caps.

Respondent urges us to reduce Milan's ***price*** to reflect its costs associated with Milan's obtaining FDA ap-

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[110] The total value of those raw materials was $ 39,435.

proval of its product, labels, and package inserts. We addressed the question **[*1179]** of Lilly P.R.'s reimbursing petitioner for research and development expenses, of which FDA work is a part, at an earlier time. We concluded that it is inappropriate to charge Lilly P.R. now for research and development activities carried on by petitioner in the past. Research and development activities performed by petitioner in 1973 with respect to Darvon and Darvon-N **[**345]** products (i.e., support research) were charged to Lilly P.R. under the joint research agreement. Petitioner has not proven that those amounts included the costs associated with maintaining FDA approval for the products, storing samples, and with updating and securing approval for the labels, packaging, and package inserts for those products. However, because those costs would be included in petitioner's general research and development expenses, which we discuss at pages 1159-1161, and *infra* at pages 1185-1186, we make no adjustment at this time.

Respondent next alleges that the adjustment made by petitioner's experts for the difference in credit terms was erroneous because petitioner and Lilly P.R. were related entities attempting to allow petitioner the ***tax***-free use of Lilly P.R. funds in the United States. [111] We agree with petitioner's experts that such an adjustment is appropriate. Indeed, ***HN63*** the terms of sale is one of the factors specifically mentioned in the *section 482* regulations as a cause for adjustment of the comparable uncontrolled ***price***. *Sec. 1.482-2(e)(2)(ii), Income **Tax*** Regs. Milan required payment from SKF of the net ***price*** in 30 days while Lilly P.R.'s terms were **[**346]** net in 180 days. However, instead of an adjustment of $ 0.40, based upon the interest saved by petitioner upon a 5-month loan of $ 12.17 with interest at 8 percent, we conclude the adjustment should be calculated using an interest rate of 5 percent. See *sec. 1.483-1(c)(2)(ii), Income **Tax*** Regs. Such a calculation would yield a $ 0.25 adjustment, were we to work our way backwards from Lilly P.R.'s actual ***price*** as petitioner's experts did. Our task, however, is to work forward and adjust Milan's ***price*** of $ 7.55 to the ***price*** we believe Lilly P.R. would have charged to an unrelated pharmaceutical company. Using our best judgment, we conclude the adjustment for the difference in credit terms is $ 0.20.

[*1180] The third item of adjustment deals with samples. Petitioner's experts adjusted Milan's ***price*** to reflect the value of the samples provided to petitioner at cost during 1973, as opposed to the normal bulk ***price*** SKF paid Milan for capsules it used as samples. Respondent argues that petitioner's experts erroneously adjusted for this difference, which was not based on an advantage SKF **[**347]** received due to its terms of sale with Milan, but rather on Lilly P.R.'s relationship with petitioner. Respondent also argues that, because both SKF and petitioner packaged the majority of capsules used as samples, no difference exists and hence no adjustment is necessary. We agree with respondent that the add-on determined by petitioner's experts is incorrect. The add-on of $ 1.56 was calculated using petitioner's cost of purchasing samples at Lilly P.R.'s ***transfer price*** of $ 12.17 per 500-capsule bottles rather than at cost. In other words, petitioner's experts again are working backwards from Lilly P.R.'s ***transfer price*** in order to arrive at the components making up the differences between Lilly P.R.'s and Milan's ***prices***. That approach is in error.

If Milan were to sell bulk capsules for samples to SKF at its cost rather than at its normal trade ***prices***, Milan indeed would realize less income for so doing. The difference in income, however, merely would be Milan's lost profit on the transactions. Consequently, an add-on in the amount of the profit lost is appropriate in the instant case. Milan's ***price*** for bulk capsules was $ 14.50 per thousand capsules. Lilly P.R.'s ***prices*** **[**348]** to petitioner for bulk products were "consistent with its ***prices*** to Petitioner for products in trade packages." (Petitioner's requested finding of fact number 389, n. 12.) Petitioner's cost for purchasing the capsules it used as samples was $ 1,872,896. From the above information, one cannot definitely ascertain the correct adjustment, although we believe some adjustment is necessary. Because petitioner's inexactitude is of its own making, we must bear heavily against it in making our adjustment. *Cohan v. Commissioner*, 39 F.2d 540, 544 (2d Cir. 1930). Keeping in mind that both petitioner and SKF performed most of their own sample packaging activity, for which, as respondent points out, no adjustment is necessary, we conclude that Milan's ***price*** should be adjusted upward by $ 0.50.

[*1181] The final four differences identified by petitioner's experts were free equipment, quality control, quality difference, and the napsylate patent. Petitioner's experts were unable to quantify the values of these four factors, and so provided what they determined was a conservative adjustment of $ 1.81. The equipment was excess sample packaging equipment loaned by SKF to Milan free of charge during 1973. **[**349]** Respondent correctly argues that no adjustment should be made to the purchase ***price*** paid by SKF for this alleged advantage of Milan because no evidence was presented as to the value of the equipment. Petitioner's witness, Mr. Brian McLarnon, was Director of Corporate Facilities for SKF at the time of trial and manager of the SK line during 1971, 1972, and the first half of 1973. Mr. McLarnon testified that the sample packaging equipment provided to Milan was excess equipment not being used by SKF at that time. He stated that the equipment was relatively old and that he did not know its original cost. In light of the fact that the only equipment loaned to Milan was old surplus equipment used only for the packaging

[111] Petitioner, in 1973, could not receive dividends from Lilly P.R. without substantial tax consequences.

of samples, and because there was no testimony or other evidence in the record of the value of that equipment, we believe an adjustment to Milan's ***price*** for SKF's provision of equipment is inappropriate.

Petitioner's experts determined an add-on to Milan's ***price*** for the quality control activities performed by SKF. Because SKF had certain of its quality control personnel at Milan's facility during each of SKF's production runs of SK-65 Compound, the experts concluded that **[**350]** Milan's relationship with SKF was more favorable than that of Lilly P.R.'s with petitioner. Respondent states, however, and we agree, that that analysis overlooks the fact that Milan was still required to employ and utilize its own quality control personnel. Milan's quality control personnel performed all required FDA checks on the SK-65 Compound produced. After the first several production runs of the compound, SKF accepted Milan's quality control assay reports. SKF did not maintain any FDA required records for Milan; Milan maintained all of the required records relative to its production of SK-65 Compound.

We believe that SKF's quality control activities on behalf of Milan were duplicative at best and did not relieve Milan of any of the costs of providing its own quality control. Accordingly, **[*1182]** petitioner's add-on for the difference in quality control is without merit.

The sixth adjustment by petitioner's experts was made with respect to quality differences between the Darvon Compound-65 manufactured by Lilly P.R. and the SK-65 Compound manufactured by Milan. We believe petitioner's experts correctly determined that some add-on to Milan's ***price*** is necessary for these differences. **[**351]** The Darvon Compound-65 manufactured by Lilly P.R. during 1973 utilized the glutamic acid hydrochloride formulation to avoid both the misuse and odor problems associated with other formulations of those products. Lilly P.R. developed and owned the know-how relative to the glutamic acid hydrochloride process. Lilly Research Laboratories in 1973 had begun evaluating generic propoxyphene hydrochloride formulations that were in direct competition with petitioner's Darvon 65 mg. and Darvon Compound-65. The quality of the generic products was compared with that of petitioner's Darvon products by examining specifications such as (a) uniformity of drug content, (b) uniformity of weight, (c) decomposition of aspirin in compound products into acetic acid and salicylic acid, and (d) purity, i.e., presence of nonpropoxyphene chemicals generated by the chemical manufacturing process.

One of the products evaluated by Lilly Research Laboratories was the SK-65 Compound manufactured by Milan. Milan at that time utilized the encased propoxyphene hydrochloride pellet to prevent its interaction with the aspirin in the formulation. Lilly Research Laboratories identified two problems with that formulation. **[**352]** First, the pellet easily was removed from the capsule and therefore was subject to misuse. Second, x-ray examination of the capsules showed a greater variability of active ingredient per capsule than in Darvon Compound -65, as some SK-65 Compound capsules contained either two pellets or no pellet at all.

Petitioner has demonstrated to the Court's satisfaction that Darvon Compound-65 was a better product than SK-65 Compound. It has not, however, demonstrated what the adjustment to Milan's ***price*** should be for that difference. When petitioner was attempting to determine arm's-length ***prices*** for Lilly P.R.'s products for 1973, when the propoxyphene patent no longer would be in existence, petitioner valued the glutamic **[*1183]** acid hydrochloride formula as providing Lilly P.R. a 3-percent royalty. Because the Darvon Compound products using that formula represented approximately 65 percent or $ 54 million of petitioner's 1973 estimated sales of Darvon and Darvon-N products of $ 70 million, petitioner estimated that approximately $ 2 million of income was attributable to the glutamic acid hydrochloride formula. See p. 1079. Bearing this in mind, and in light of all other pertinent facts, we conclude **[**353]** that Milan's ***price*** should be increased by $ 0.21.

The seventh and final adjustment involves the value of the unexpired napsylate patent owned by Lilly P.R. Because Lilly P.R. calculated its ***transfer prices*** on the basis of a standard discount from net wholesale ***price***, the retained value of Lilly P.R.'s napsylate patent was spread across Lilly P.R.'s entire Darvon and Darvon-N product lines. Petitioner's experts thus believed that some adjustment to Milan's ***price*** was necessary to reflect the ownership of that valuable patent by Lilly P.R. Working backwards from Lilly P.R.'s ***transfer price*** of $ 12,17, and taking into consideration the increases previously determined, petitioner's experts arrived at a total figure of $ 1.81 for the last four adjustments. We are provided with no breakdown of that estimated, lump-sum amount, and petitioner has compounded our dilemma further by stating on brief that, because Milan's actual raw materials cost was proven at trial to be $ 1.14 rather than $ 0.85, the aggregate adjustment for the final four items need only be $ 1.52.

As with the glutamic acid hydrochloride formula, petitioner considered the value of the napsylate patent when it was attempting **[**354]** to set Lilly P.R.'s ***prices*** for 1973. See p. 1080. Petitioner at that time concluded that a reasonable royalty on the napsylate patent would be $ 1.5 to $ 3 million of the estimated $ 30 million attributable to intangibles under petitioner's method of allocations. On projected sales of $ 70 million, with sales of napsylate products projected to be approximately 20 percent of total sales, the napsylate royalty then was approximately 10 to 20 percent of total propoxyphene sales. Petitioner's expert, Dr. Brozen, testified that the napsylate patent royalty could go as high as 30 percent. Because Darvon-N sales in 1973 actually were approximately 25 percent of total sales, these figures represent possible

royalties of 2.5, 5, and 7.5 percent of all propoxyphene sales. **[*1184]** Petitioner argues that the 7.5 percent factor (multiplied against the net wholesale ***price*** for Darvon Compound-65 of $ 28.97) would yield an adjustment of $ 2.17, which alone was well in excess of the aggregate adjustments of $ 1.81 or $ 1.52 determined by its experts as being the add-on for all four of the final four differences. The smaller 2.5- and 5-percent factors stated above yield adjustments of $ 0.72 and $ 1.45, **[**355]** respectively, when applied against petitioner's net wholesale ***price*** of $ 28.97.

While petitioner's evidence as to the value of the napsylate patent was uncontroverted by respondent, and it is clear that some adjustment is necessary, we cannot accept the figures above. Dr. Brozen was one of petitioner's economic witnesses: he has not shown that he had the necessary expertise in the pharmaceutical industry to value the napsylate patent. Also, the figures are based upon petitioner's method of allocating expenses between it and Lilly P.R.

Additionally, respondent argues that petitioner's experts failed to consider some important differences between the petitioner-Lilly P.R. and SFK-Milan sales relationships which would reduce the Milan ***price*** to SFK. During 1973, SFK's market for Milan's SK-65 Compound was in the range of $ 1 million, while petitioner's purchases of Lilly P.R.'s products were in excess of $ 30 million. Respondent contends that basic economics would provide for an adjustment to the ***prices*** where, as here, one of the parties was a large volume purchaser; and that petitioner's experts failed to take into account that an arm's-length purchaser paying $ 30 million for products **[**356]** would demand a substantial quantity discount. Respondent also argues that Lilly P.R., as opposed to Milan, bore none of the risk associated with manufacturing propoxyphene hydrochloride compound. SKF made no guarantees in the event Milan could not manufacture the product economically or if SKF could not successfully market the product against petitioner and other competitions. On the other hand, respondent alleges that Lilly P.R. had a guaranteed market for its products, and that production levels were determined by petitioner and Lilly P.R. assumed no risk in manufacturing Darvon and Darvon-N products.

We agree with respondent that the above factors must be taken into account when determining the adjustment for the **[*1185]** napsylate patent. The levels of market were greatly different between Lilly P.R. and Milan, and such a difference clearly is contemplated by the *section 482* regulations as being susceptible to evaluation and adjustment. *Sec. 1.482-2(e)(2)(ii), Income **Tax*** Regs. Although we would not characterize Lilly P.R.'s relationship with petitioner as being one in which Lilly P.R. had a guaranteed purchaser for its products, the fact remains that petitioner notified Lilly P.R. of **[**357]** its anticipated product needs and Lilly P.R.'s production planning personnel then determined Lilly P.R.'s production schedules and output based upon that information. The likelihood of Lilly P.R. producing products for which it had no purchaser (petitioner) at the time, thus was highly remote.

Finally, in our discussion of the years 1971 and 1972, we stated that petitioner improperly classified some expenses and failed entirely to include others (i.e., general research and development expenses) in its pro forma combined income statements for Darvon and Darvon-N products. Such treatment artificially inflated the income resulting from Lilly P.R.'s ownership of the manufacturing intangibles. Irrespective of the total lack of connection between sales dollars and dollars spent on research, in the ″real world″ a research-intensive company such as petitioner simply would not purchase for resale a product that did not allow a sufficient return to cover a proportionate share of its research expenses. In keeping with our earlier holding concerning petitioner's current general research and development expenses, some adjustment is necessary to reflect that portion of petitioner's general research **[**358]** and development activities the cost of which is borne by Darvon and Darvon-N revenues.

Respondent has proven that, in making our adjustment with respect to the value of Lilly P.R.'s napsylate patent, we must consider the additional factors of market level, risk, technical assistance, and research and development. However, he has offered no evidence or estimation of what the adjustment should be. That task is left to us. Using our best judgment, we conclude that Milan's ***price*** should be increased by $ 0.48.

The following is a summary of the Court's adjustments to Milan's ***price*** for the reasons and in the amounts set out above. **[*1186]**

Milan ***price***	$ 7.55
Adjustments	
a. Raw materials	0.86
b. Credit terms	0.20
c. Samples	0.50
d. Equipment	
e. Quality control	
f. Quality difference	0.21
g. Napsylate patent, market level, risk, technical	0.48

assistance, and research and development	
Adjusted Milan ***price***	9.80

The Milan ***price***, as adjusted, yields an arm's-length ***price*** of $ 9.80 for Darvon Compound-65 in 500 capsule bottles. Petitioner's net wholesale ***price*** for such product was $ 28.97. Accordingly, Lilly P.R.'s ***prices*** for Darvon and Darvon-N products are adjusted to petitioner's net wholesale ***price*** less a discount of **[**359]** 66 percent. [112]

In accordance with our earlier discussion and holding concerning the expenses of petitioner's ticket issuance and finished stock planning activities performed for Lilly P.R., we also allocate from Lilly P.R. to petitioner the amounts of $ 22,000 (ticket issuance) and $ 63,000 (finished stock planning) in 1973.

B. *Revenue Procedure 63-10*

1. *1971 and 1972 Taxable Years*

Petitioner argues in the alternative that its ***prices*** for 1971 and 1972 can be measured under section 4.03 and 4.04 of *Rev. Proc. 63-10, 1963-1 C.B. 490* (based upon Technical Information Release (T.I.R.) 441, dated January 11, 1963), and that under either of those subsections Lilly P.R.'s ***prices*** to petitioner satisfy the arm's-length standard. Respondent argues that *Rev. Proc. 63-10* is not applicable to a situation where the mainland affiliate has ***transferred*** intangibles to its island affiliate without receiving in exchange adequate compensation.

[*1187] *Rev. Proc. 63-10* was issued prior to the promulgation of the 1968 *section 482* regulations and set forth guidelines for the application **[**360]** of *section 482* in cases involving U.S. companies with Puerto Rican manufacturing affiliates. ***HN64*** *Rev. Proc. 63-10* still may be used in such cases if the result is more favorable to the taxpayer than that obtained under the *section 482* regulations. *Rev. Proc. 68-22*, sec. 4, *1968-1 C.B. 819, 821*. Sections 4.03 and 4.04 of *Rev. Proc. 63-10* provide in their entirety as follows:

.03 All Income-Producing Intangibles Belong to the Island Affiliate.

HN65 If all applicable intangibles are treated as belonging to the island affiliate, all of the income produced by the intangibles is allowed to the island affiliate. In this case, gross income of the island affiliate would be determined on the basis of a selling ***price*** equal to the highest ***price*** which a representative independent United States company comparable to the mainland affiliate would pay for the product involved. In principle, this ***price*** would approximate the final United States market ***price*** for the product less (a) the mainland affiliate's costs of distribution, (b) a reasonable margin of profit for distribution, and (c) all costs incident to transportation from the point of sale in Puerto Rico.

.04 Some Income-Producing Intangibles Belong to **[**361]** the Island Affiliate.

HN66 If some, but not all intangibles which are significant in a joint operation are treated as belonging to the island affiliate, it would be allowed a ***price***, which assumed the ownership of no intangibles plus an amount representing an estimated payment by the mainland affiliate for those intangibles owned by the island affiliate. This amount would be based on evidence available regarding what an independent company would receive as royalties or fees or as an increased ***price*** in such circumstances.

[*1963-1 C.B. at 496-497*.]

Respondent argues that *Rev. Proc. 63-10* applies only to cases in which the island affiliate itself has developed an intangible, or where it has purchased an intangible for arm's-length consideration. As support for his argument, respondent cites section 1 of the revenue procedure, which section provides in relevant part:

The guidelines concern what may be considered as the standard type of allocation problem that has arisen in these cases. They do not deal with *other* problems that may be involved in particular cases, including those which may be present in cases involving the ***transfer*** of income producing intangibles from the United States to an affiliate **[**362]** located in Puerto Rico. [*1963-1 C.B. at 490*; emphasis added.]

[*1188] We believe that *Rev. Proc. 63-10* is clear on its face and that it does apply to the situation at hand. Contrary to respondent's assertion, the quoted language does nothing more than restate the obvious -- that *Rev. Proc. 63-10* does not provide guidelines for problems other than *section 482* problems that could be in-

[112] Computed as follows:

Net wholesale price -	(net wholesale price x discount) =
	Lilly P.R.'s transfer price
	28.97 - (28.97 x) = 9.8 x = .66

volved in cases in which intangibles are ***transferred*** to Puerto Rican affiliates. The principle nonsection 482 problem involved in such cases is the determination of whether or not the intangibles in fact have been ***transferred***.

Our interpretation is supported by a realistic view of the legal and factual environment in which *Rev. Proc. 63-10* applies. The ***tax*** incentives provided by the government of Puerto Rico generally apply only to income from manufacturing operations in Puerto Rico. A Puerto Rican affiliate can qualify for the ***tax*** incentives of *section 931* only if it earns 80 percent or more of its gross income from sources within Puerto Rico and 50 percent or more of its gross income from the active conduct of a trade or business in Puerto Rico. To qualify for those ***tax*** incentives, taxpayers must conduct **[**363]** their Puerto Rican operation according to certain well-defined patterns. Generally, mainland affiliates organize new wholly owned domestic subsidiaries to manufacture products in Puerto Rico, with the marketing and distribution functions retained and performed by the mainland affiliate. Moreover, except in unusual cases, any significant intangibles related to products manufactured by the Puerto Rican affiliate are first developed or acquired by the mainland affiliate.

In this context, the only realistic cases in which the Puerto Rican affiliate can own significant intangibles are those in which the intangibles have been ***transferred*** to the Puerto Rican affiliate from its mainland affiliate. If sections 4.03 and 4.04 of *Rev. Proc. 63-10* do not apply to intangibles ***transferred*** to Puerto Rican affiliates, it is difficult to conceive of a case in which they would apply. Our interpretation of the language quoted by respondent is buttressed by section 4 of *Rev. Proc. 63-10*, entitled "Application of *Section 482* in Cases Involving Intangibles." Subsection 4.01 states as follows:

HN67 Not infrequently, the return attributable to intangibles is substantial. Therefore, in cases where significant income-producing **[**364]** intangibles are present the determination whether they belong to the island affiliate or the **[*1189]** mainland affiliate is important in the proper application of *section 482* of the Code.

* * * *

It is a question to be decided under the facts and circumstances of a particular case (a) whether significant intangibles are present, and (b) if significant intangibles are present, whether they belong to the mainland or the island affiliate.

[1963-1 C.B. 496.]

Furthermore, on January 15, 1963, 4 days after the issuance of T.I.R. 441, the Service issued Manual Supplement 42G-86, which provided instructions to Service personnel for applying the guidelines of T.I.R. 441. Section 4.02 of Manual Supplement 42G-86, entitled "Determination of the Party to Whom Intangibles Belong," provided as follows:

It is a question to be decided under the facts and circumstances of a particular case (a) whether significant intangibles are present and (b) if significant intangibles are present, whether they belong to the mainland or to the island affiliate.

* * * *

As to other intangibles, such as patents, trademarks, trade names, etc., originally developed or owned by the mainland affiliate, an examination must be made to **[**365]** determine whether there is evidence that they have been ***transferred*** to the island affiliate. Taxpayers may claim that there has been a sale at a fair market ***price*** or a ***tax***-free ***transfer*** under *section 351*, with section 367 clearance if the island affiliate is a foreign corporation rather than a *section 931* domestic corporation.

Examination may show that there is in fact no substantial evidence that intangibles have been ***transferred*** or may show that the island affiliate has merely been permitted to use the mainland affiliate's intangibles as, for example, by manufacturing patented products and affixing to them the mainland affiliate's trademark. The lack of formal documents ***transferring*** the intangibles, continued use of the intangibles by the mainland affiliate in its own operations, and the retention by the mainland affiliate of protective and exploitative activities related to the intangibles, such as the conduct of infringement proceedings and supervision of licensing programs, would indicate that the intangibles have not, in substance, been ***transferred*** to the island affiliate and are still owned by the mainland affiliate.

Manual Supplement 42G-166, which was issued on April 8, 1968, **[**366]** was intended to supplement the provisions of Manual Supplement 42G-86. Section 5 of Manual Supplement 42G-166 provided that "the Service will continue to apply the **[*1190]** guidelines of Manual Supplement 42G-86." Section 5.03(8) of Manual Supplement 42G-166 provided in pertinent part as follows:

In final analysis, however, as Section 4.02 of Manual Supplement 42G-86 points out, "It is a question to be decided under the facts and circumstances of a particular case (a) whether significant [income-producing] intangibles are present and (b) if significant intangibles are present, whether they belong to the mainland or to the island affiliate."

It thus is clear that *Rev. Proc. 63-10* applies to the case in which the Puerto Rican subsidiary owns intangibles ***transferred*** to it by the U.S. parent. Petitioner argues that section 4.03 provides a resale-***price*** method by which

an arm's-length ***price*** can be determined. Without addressing any of petitioner's other contentions, we conclude that section 4.03 is not applicable to petitioner's case. Petitioner ***transferred*** to Lilly P.R. only the manufacturing intangibles; it retained and used the marketing intangibles associated with its sales of Darvon and **[**367]** Darvon-N products. Petitioner has made no claim otherwise. The value of its marketing intangibles was not an insubstantial amount, and we held that petitioner earned 45 percent of the net income attributable to intangibles through its promotion and sales of the trademarked Darvon and Darvon-N product line.

In short, because petitioner continued to own the marketing intangibles throughout the years in issue, Lilly P.R. did not own all of the income-producing intangibles as required by section 4.03 of *Rev. Proc. 63-10*. This result is contemplated in section 4.01, which provides as follows:

HN68 It may be expected that as to certain intangibles no supportable contention could be made that they belong to the island affiliate. For example, if the mainland affiliate acts as the marketing and servicing organization for products produced by the island affiliate, any market position, consumer acceptance, or similar factors of good will attributable to the distribution and product servicing activities in the United States do not, as a matter of substance, belong to the island affiliate.

Consequently, section 4.03 is unavailable for our purposes herein. Section 4.04, however, provides guidelines for **[**368]** a case such as this, where ″some, but not all intangibles which are significant in a joint operation are treated as belonging to the island affiliate.″ The guidelines are extremely brief and **[*1191]** basically provide that the island affiliate is to receive a ***price*** for its products as if it owned no intangibles, plus an amount representing an estimated payment from the mainland affiliate for the use of the intangibles owned by the island affiliate. This method is similar to the cost plus method of the regulations under *section 482*. We previously rejected the use of that method for 1971 and 1972 due to the lack of evidence with respect to unrelated companies and estimated royalty values. On the facts of this case, we conclude the method provided by *Rev. Proc. 63-10*, sec. 4.04, would not result in either a more accurate or more favorable estimate of Lilly P.R.'s arm's-length ***prices*** than the profit split approach we used under the *section 482* regulations. We thus decline to apply it.

2. *1973 Taxable Year*

Petitioner argues in the alternative that Lilly P.R.'s ***prices*** satisfy the independent ***prices*** for similar products method under section 3.02(2) of *Rev. Proc. 63-10, 1963-1 C.B. 490, 493*. That **[**369]** section provides as follows:

2. Independent ***Prices*** for Similar Products. -- ***HN69*** The problem of applying *section 482* of the Code is more difficult as a practical matter when directly applicable independent ***prices*** are not available. However, when a product manufactured in Puerto Rico and sold only to a mainland affiliate differs only slightly from other products bought and sold by independent firms, an arm's length ***price*** for the island affiliate may be determined by adjusting these independent ***prices*** to take account of such minor differences as are present.

Rev. Proc. 63-10 thus provides for adjustments to the independent ***prices*** just as *section 1.482-2(e)(2)* of the regulations does. Accordingly, our adjustments, adjusted ***price***, and discount from petitioner's net wholesale ***prices*** would be the same under *Rev. Proc. 63-10*.

To reflect the foregoing,

Decision will be entered under Rule 155.