OFFICE OF
CHIEF COUNSEL

DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
WASHINGTON, D.C. 20224
December 21, 1999

Number: **200013013**
Release Date: 3/31/2000
UILC: 174.00-00

TL-N-2453-99
CC:DOM:FS:P&SI

INTERNAL REVENUE SERVICE NATIONAL OFFICE FIELD SERVICE ADVICE

MEMORANDUM FOR FT. LAUDERDALE DISTRICT COUNSEL

FROM: Assistant Chief Counsel (Field Service)
CC:DOM:FS

SUBJECT: Research and Experimentation Expense

This Field Service Advice responds to your memorandum dated September 23, 1999. Field Service Advice is not binding on Examination or Appeals and is not a final case determination. This document is not to be cited as precedent.

LEGEND:

T	=
Year 1	=
Year 2	=
$x	= $
$y	= $

ISSUE:

Whether T is entitled to a deduction under section 174(a) for expenses incurred related to the development or improvement of a device prior to the approval of the new or improved device by the .

CONCLUSION:

T is entitled to a deduction under section 174(a) to the extent the expenditures were research and development costs in the experimental or laboratory sense.

FACTS:

T is engaged in product development and improvement programs for the purpose of manufacturing and selling finished devices. A division of T considers commercial design concepts for product areas beyond those that T currently produces. Such activities are done in the following three phases:

- Product conceptualization. Includes statement of product market and needs, list of technologies that satisfy needs, existing patents, competitor products, and technical risk information. Surveys all possible technologies, demonstrates new technologies, updates product assumptions, and identifies impact on other devices.

- Technical concept demonstration. Selects best technology and performs trade-off analysis, develops engineering model to demonstrate simultaneous operation of all features, determines human study criteria, identifies all required instruments and equipment, and identifies all risks and contingencies.

- Technical concept validation. Identifies all critical design parameters, characterizes all issue effects versus design parameters, builds and tests prototype, considers industrial design strategy, ergonomic requirements, and human factors.

Another division of T conducts product feasibility studies for the product concepts. The activities included in such studies are as follows:

- Feasibility/design review. Develops design and assembly of product, prototype design and construction, engineering invitro and/or in-vivo testing, compatibility testing, technical review, engineering drawings.

- Regulatory submission. Proves product safe and effective to builds submission, submission testing, submission, export requests, builds tests, testing, trials.

- Process and design validation. Verifies design and assembly of product, tests shelf life, tests quality build, and prepares quality testing report.

- Production start-up. Establishes tooling and production line, and initial shelf inventory requirements.

- Sales release. International and domestic marketing.

In the feasibility/design review activity referred to above, the product is researched, developed, and evaluated until the design is complete and the specifications are determined. Typically, as part of the feasibility/design review activity, the following activities are conducted:

- Engineering report of the technical feasibility of the required performance, including basic engineering drawings with functional aspects of given and known tolerances pertaining to those aspects; engineering in-vitro testing; address reliability/quality characteristics and demonstrate product system biocomparability; address feasibility of all currently anticipated failure modes, develop and test prototype models, begin prototype tooling; develop design drawings and documentation.

- Determination of the customer's need for the product, including usage, market potential, performance requirements and risk assessment, as well as any analysis of competitor's products and how T's product design meets or exceeds competitors' design; develop in-vivo performance on human and/or animal subjects with 3-4 prototypes.

- Evaluation of competitive products through purchase and testing.

- Determination of manufacturing plans, expected productability with potential manufacturing flow, early process requirements, potential risk associated with new processes and production costs.

- Evaluation of risks associated with legal, regulatory, and patent infringement issues.

All of the devices which are manufactured by T must receive clearance by the before they may be sold.

T capitalizes all fixed assets (property, plant, and equipment) and all tooling costs for production of prototype devices used in the submissions and testing.

T deducted under section 174(a) $x in fiscal year ending Year 1, and $y in fiscal year ending Year 2. The expenses T deducted included costs incurred from the product concept review initiation through the sales release date.

LAW AND ANALYSIS

Congress enacted the (Act) “to provide for the safety and effectiveness of devices intended for human use.” Under the Act, before a device can be made available for use by the community, the manufacturer must first gain approval or permission for marketing by the

The Act classifies devices into three categories based on the risk that they pose to the public. includes devices that present no unreasonable risk of illness or injury. They are subject only to minimal regulation by “general controls.” includes devices that are potentially more harmful. They may be marketed without advance approval, but manufacturers of such devices must comply with federal performance regulations known as “special controls.” includes devices that either “present a potential unreasonable risk of illness or injury,” or which are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.“ Before a new device may be introduced to the market, the manufacturer must provide the with a “reasonable assurance” that the device is both safe and effective through the process. Manufacturers must conduct and scientific studies to demonstrate that the device is safe and effective for its intended uses and submit detailed information regarding the of their devices. The reviews the submission, spending an average of 1,200 hours on each submission.

There are two exceptions to the requirement. The first exception addresses existing devices. Such devices could not be withdrawn from the market while the completed its analysis. The statute therefore includes a “grandfathering” provision which allows pre-1976 devices to remain on the market without approval until such time as the initiates and completes the requisite . The second exception addressed devices that are “substantially equivalent” to pre-existing devices. The intent of this exception was to prevent manufacturers of grandfathered devices from monopolizing the market while new devices went through the process.

All new and devices and devices which fall under the “substantially equivalent” exception to the requirement can be marketed

without the review but are subject to a premarket notification process. Under the process, a limited form of review is imposed on every manufacturer intending to market a new device. If, based on the notification, the concludes that the device is not new, that it is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis until the initiates the process for the underlying device to which the new device is "substantially equivalent." The assumption behind the process is that the new product is safe and effective for the intended use, performs consistently, and is as good as what is currently available on the market. The role of the is to review the device by assessing the similarities to a device already on the market. This review is completed in an average of only 20 hours. [1]

Even if a device goes through the process, a device is only as safe as the information known at the time the device was submitted for review. professionals cannot assume that the has definitively determined that a device cleared for marketing is absolutely safe for human use. Rather, once the premarketing process is completed and a device goes into widespread use, unforseen problems can still rise. devices continue to be tested by the manufacturer even after approval. Also, the performs in-house laboratory research to further analyze problems related to device safety.

Section 174

A taxpayer may treat research or experimental expenditures which are paid or incurred by it during the taxable year in connection with its trade or business as expenses which are not chargeable to the capital account. I.R.C. § 174(a)(1). A taxpayer is generally allowed the election of either currently deducting its research and experimental expenditures or amortizing those expenditures over a period of not less than 60 months. I.R.C. §§ 174(a)(1), (b)(1); Treas. Reg. § 1.174-1.

---

[1] To reduce the reliance on the process while continuing to ensure that particularly risky devices were reviewed under the procedure, in Congress enacted amendments to the Act.

Research expenses which are neither treated as expenses nor deferred and amortized must be charged to the capital account. Treas. Reg. § 1.174-1.

Treas. Reg. § 1.174-2(a)(1) provides:

> The term *research or experimental expenditures*, as used in section 174, means expenditures incurred in connection with the taxpayer's trade or business which represent research and development costs in the experimental or laboratory sense. The term generally includes all such costs incident to the development or improvement of a product. The term includes the costs of obtaining a patent, such as attorneys' fees expended in making and perfecting a patent application. Expenditures represent research and development costs in the experimental or laboratory sense if they are for activities intended to discover information that would eliminate uncertainty concerning the development or improvement of a product. Uncertainty exists if the information available to the taxpayer does not establish the capability or method for developing or improving the product or the appropriate design of the product. Whether expenditures qualify as research or experimental expenditures depends on the nature of the activity to which the expenditures relate, not the nature of the product or improvement being developed or the level of technological advancement the product or improvement represents.

"Product" includes any pilot model, process, formula, invention, technique, patent, or similar property and includes products to be used by the taxpayer in its trade or business as well as products to be held for sale, lease or license. Treas. Reg. § 1.174-2(a)(2). It does not include ordinary testing or inspection of materials for quality control, efficiency surveys, advertising or promotions, or the acquisition of another's production or process. Treas. Reg. § 1.174-2(a)(3). Quality control testing does not include testing to determine if the design of the product is appropriate. Treas. Reg. § 1.174-2(a)(4).

Section 174 covers costs incurred in developing the concept of a product. Rev. Rul. 73-275, 1973-1 C.B. 134. It does not include expenditures for the acquisition or improvement of depreciable property. I.R.C. § 174(c); Treas. Reg. § 1.174-2(b). See also Mayrath v. Commissioner, 41 T.C. 582, 590 (1964), aff'd, 357 F.2d 209 (5th Cir. 1966) (regulatory definition of research or experimental expenditures is reasonable and consistent with the intent of the statute to limit deductions to those

expenditures of an investigative nature expended in developing the concept of a model or product).

Under the facts provided, there is no disagreement that the expenses at issue were incurred by T during the taxable year in carrying on its trade or business. In addition, there is no disagreement that the expenditures incurred during the feasibility/design review activity, wherein the product is researched, developed, and evaluated until the design is complete and the specifications are determined, qualify as section 174 expenses. The only issue is whether expenses incurred after the feasibility/design activity qualify as section 174 expenses.

CASE DEVELOPMENT, HAZARDS AND OTHER CONSIDERATIONS:

The fact that T has completed the feasibility/design activity and has determined a design for a medical device does not result in all subsequently incurred expenses being not qualified as research and experimental expenditures. Rather, such expenditures must be considered in light of the definition of research and experimental expenditures and the facts and circumstances. Specifically, to the extent the expenditures are part of T's continuing experiments in its attempts to finish developing its medical device, they are deductible under section 174(a).

At the end of the feasibility/design activity, T generally had determined the medical device design specifications. Nevertheless, additional testing and research had to be conducted to obtain approval from the FDA. Furthermore, as noted by the FDA, research on medical devices often continues even after FDA approval.

Expenses attributable to clinical tests, preclinical testing, and clinical trials of a medical device are costs incident to the development or improvement of the medical device. In addition, such expenditures are intended to discover information to eliminate uncertainty concerning the development or improvement of the medical device. These expenditures assist T in establishing the capability or method for developing or improving the medical device or determining the appropriate design of the device. Similarly, while expenses for ordinary testing or inspection of materials for quality control do not qualify as section 174 expenses, testing to determine if the design of the product is appropriate is not considered quality control. Accordingly, to the extent T incurred validation testing expenses, such expenses would not be considered quality control and would qualify as section 174 expenses. Treas. Reg. § 1.174-2(a)(4). The fact that the final product would likely receive approval from the FDA does not change this result because uncertainty in

developing the product, not uncertainty in receiving FDA approval, is the relevant issue.

Expenses attributable to design and assembly verification, shelf life, and quality of build are likely costs incident to the development or improvement of the medical device. Such expenditures eliminate uncertainty concerning the development or improvement of the medical device in that they assist T in establishing the capability or method for developing or improving the medical device or determining the appropriate design of the device. Similarly, while expenses for ordinary testing or inspection of materials for quality control do not qualify as section174 expenses, testing to verify design and assembly, shelf life and quality of build are not considered quality control. Accordingly, such expenses would not be considered quality control and would qualify as section 174 expenses. Treas. Reg. § 1.174-2(a)(4).

It is unclear how expenses associated with export requests are costs incident to the development or improvement of the medical device. Similarly, it is unclear how expenses associated with production start-up or sales release are research and development costs incident to the development or improvement of the medical device. Accordingly, to be deductible under section 174, T must provide more information which would establish that such expenses qualify as section 174 expenses.

Finally, it appears that T claimed various overhead expenses (*i.e.*, utilities) and non-research and development expenses (*i.e.*, marketing, production supervision, quality assurance) as expenses deductible under section 174(a). Generally, such expenses are not considered research and development costs incident to the development or improvement of a product. Accordingly, to be deductible under section 174, T must provide more information which would establish that such expenses qualify as section 174 expenses.

A taxpayer is allowed a credit against tax for qualified research expenses paid or incurred in a trade or business. I.R.C. §§ 38(a); 41(a). The credit for increasing research activities was added to the Internal Revenue Code by the Economic Recovery Tax Act of 1981 and was codified as section 44F. The credit was subsequently amended by the Tax Reform Act of 1984 and was redesignated as section 30. The Tax Reform Act of 1986 redesignated the credit as section 41. In the recodification of section 30 as section 41 under the Tax Reform Act of 1986, the definition of “qualified research” was amended to include requirements in addition to the requirement that the expenses qualify under section 174. However, the additional definitional requirements did not alter the qualifications necessary for an expenditure to be treated as an an expense under section 174. Accordingly, the

legislative history and case law under section 41 addressing such additional definitional requirements (such as the “discovery test” in section 41(d)(1)(B)) are not relevant to the current issue of whether the expenses qualify under section 174.

Please call if you have any further questions.

By: _____

HARVE M. LEWIS
Chief, Passthroughs & Special
Industries Branch
Field Service Division