Coordinated Issue Biotech and Pharmaceutical Industries Legally Mandated R&E Expense (Effective Date: June 18, 2003)

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ISSUE

Whether research and experimentation that is undertaken to meet legal requirements imposed by more than one political entity with respect to improvement or marketing of specific pharmaceutical products or processes falls within the exclusive apportionment rule for legally mandated expenses provided in Treas. Reg. §1.861-17(a)(4).

CONCLUSION

Research and experimentation expenditures incurred to meet legal requirements imposed by more than one political entity with respect to improvement or marketing of specific pharmaceutical products or processes do not fall within the exclusive apportionment rule for legally mandated research and experimentation provided in Treas. Reg. §1.861-17(a)(4). Pursuant to Treas. Reg. §1.861-17(a)(1), expenditures that are not subject to the exclusive apportionment rule for legally mandated research and experimentation are generally considered to be definitely related to all income reasonably connected with the relevant broad product category (or categories) of the taxpayer and therefore allocable to all items of gross income as a class related to such product category (or categories).

FACTS

Introduction

The Food and Drug Administration (FDA) regulates the marketing of pharmaceutical products in the United States. Before a drug can be marketed in the United States, the manufacturer, or sponsor, must establish that the product is safe and effective. This is typically done through the filing of a New Drug Application (NDA) with the FDA that contains adequate data and information on the product's safety and "substantial evidence" of the product's effectiveness. The manufacturer establishes a product's safety and effectiveness through testing and research. The FDA publishes regulations on premarketing requirements and approval procedures that are binding on all sponsors.

These regulations focus on the standard of evidence needed for approval as derived from adequate and well-controlled clinical investigations. The FDA also publishes guidelines that are not legally binding on the sponsors but are designed to provide informal guidance on specific methods through which they might satisfy regulatory requirements.

The pharmaceutical product development process is generally composed of four stages: preclinical or discovery research, clinical development, regulatory approval, and postmarketing. In the preclinical or discovery research stage, a compound is tested on animals and non-human systems. The FDA established a set of standards, called Good Laboratory Practice for this stage of development to ensure quality of animal testing and the resultant data for an Investigation New Drug Application (IND) or NDA. After this stage is complete, an IND is filed to permit the compound to be tested in humans.

The second stage, clinical development, is normally conducted in three phases. In Phase I the first trials in humans are conducted for safety, tolerance and pharmacokinetics. In Phase II, testing is done to evaluate effectiveness, dosage and safety in selected populations of patients with the disease or condition to be treated, diagnosed or prevented. In Phase III, expanded clinical trials are conducted to gather additional evidence to verify dosage and effectiveness for specific indications and to better understand safety and adverse effects. These are large-scale trials typically involving thousands of patients to prove effectiveness against a specific disease or condition.

After Phase III trials have been completed, the regulatory approval stage begins. Sponsors file an NDA with the FDA to obtain authorization to market a new pharmaceutical product. The NDA consists of clinical and nonclinical data on the product's safety and effectiveness and a full description of the methods, facilities, and quality controls employed in manufacturing and packaging. The FDA requires data from one adequate and well controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) sufficient to establish substantial evidence of effectiveness. FDCA 505(d); 21 U.S.C. 314.126. These studies are generally referred to as pivotal studies. Until the FDA grants authorization, a drug sponsor cannot market the drug in the United States.

The final stage, post-marketing studies (also called Phase IV) occurs after the product has received FDA approval. These studies are performed to determine the incidence of adverse reactions, to determine the long-term effect of a drug, to study a patient population not previously studied, and to conduct marketing comparisons against other products and other uses.

The pharmaceutical industry is multinational, with most of the major companies marketing products throughout the world. According to Pharmaceutical Research and Manufacturers of America's (PhRMA) 2000 Industry Profile, approximately thirty-six percent of pharmaceutical research conducted worldwide is performed in the United States. The United States is the largest market for pharmaceuticals and accounts for one-third of global pharmaceutical sales. In addition, approximately 45 percent of the 152 major global drugs developed between 1975 and 1994 were of U.S. origin.

In recognition of the global market for pharmaceutical products, representatives from pharmaceutical companies and regulatory authorities from the United States, Europe, and Japan formed the International Conference on Harmonization (ICH) in 1990. The purpose of ICH is to make recommendations on ways to achieve harmonization in the interpretation and application of technical guidelines and requirements for drug development and approval in order to eliminate the duplication of testing in these three areas of the world.

The ICH developed a Common Technical Document, described as a "global dossier," that provides a harmonized format and content for new product applications for drug approvals in the three areas. A 1997 ICH Utilization Survey determined that the ICH guidelines affected and were used by a significant numbers of companies: 62 percent of companies in the European Union (EU), 77 percent of companies in Japan, and 85 percent of companies in the United States.

Under the auspices of the ICH, the FDA published guidance entitled "E5 Ethnic Factors in the Acceptability of Foreign Clinical Data" in 1997. This guidance recommends regulatory and developmental strategies to permit clinical data collected in one region to be used for support of drug and biologic registration in another region. The guidance is based on the premise that it is not necessary to repeat the entire clinical drug development process in another region. Europe and Japan have undertaken similar steps to accept clinical data collected in another region.

Meeting the Legally Mandated Standard

If a drug receives approval for sale first in the United States and second in one or more foreign jurisdictions, then to meet the legally mandated standard and allocate research and experimentation expenditures solely to gross income from sources within the United States, the taxpayer must establish that research and experimentation undertaken to meet U.S. requirements was not also used to obtain foreign approval. In contrast, if a drug receives approval in a foreign jurisdiction prior to

receiving approval in the United States, then to meet the legally mandated standard and allocate research and experimentation expenditures solely to gross income from sources within the United States, the taxpayer must establish that research and experimentation undertaken to meet U.S. requirements was not previously used to obtain foreign approval. Whether first approved in the United States or in a foreign jurisdiction, the results of the research and experimentation must not reasonably be expected to generate more than de minimis amounts of gross income outside the United States.

LAW AND ANALYSIS

Section 901 allows as a credit against the U.S. tax liability of a domestic corporation the amount of "any income, war profits, and excess profits paid or accrued during the taxable year to any foreign country" subject to the limitations of section 904. Section 904(a) limits the amount of foreign income taxes that a taxpayer may credit during any one year to the taxpayer's pre-credit U.S. tax on its foreign source taxable income (the foreign tax credit limitation). The foreign tax credit limitation is computed by multiplying the taxpayer's precredit U.S. income tax liability by the ratio of the taxpayer's foreign source taxable income to its worldwide taxable income. A taxpayer's foreign source taxable income (the numerator of the ratio) is determined by deducting from a taxpayer's foreign source gross income the expenses, losses, and deductions properly apportioned or allocated thereto, and a ratable part of any expenses, losses or other deductions which cannot definitely be allocated to some item or class of gross income. Sections 862(b) and 863(b).

In order to determine the expenses, losses, and deductions that reduce foreign source gross income, Treas. Reg. §1.861-8 generally requires taxpayers to allocate deductions to a class of gross income and, to the extent necessary to make the determination required by an operative Code section, to apportion deductions within the class between statutory and residual groupings of gross income. A class of gross income is the gross income to which a specific deduction is definitely related. A statutory grouping is the gross income from a specified source or activity that must be determined in order to arrive at taxable income from such source or activity under an operative Code section.

Treas. Reg. §1.861-17 provides general rules for allocating and apportioning research and experimentation expenditures that are deductible under section 174. Treas. Reg. §1.861-17 recognizes that research and experimentation is an inherently speculative activity and that the gross income derived from successful research and experimentation must bear the cost of unsuccessful research and experimentation.

Treas. Reg. §1.861-17(a) provides that research and experimentation expenditures that a taxpayer deducts under section 174 ordinarily shall be considered deductions that are definitely related to all income reasonably connected with the relevant broad product category (or categories) of the taxpayer and therefore allocable to all items of gross income as a class (including income from sales, royalties, and dividends) related to such product category (or categories). A taxpayer shall determine the relevant product categories by reference to the three-digit standard industrial classification code (SIC code).

Treas. Reg. §1.861-17(a)(4) provides that where research and experimentation is undertaken solely to meet legal requirements imposed by a political entity with respect to improvement or marketing of specific products or processes, and the results cannot reasonably be expected to generate amounts of gross income (beyond de minimis amounts) outside of a single geographical source, the deduction for such research and experimentation shall be considered definitely related and therefore allocable only to the grouping of gross income within that geographic source as a class. In order to meet this exception, the taxpayer must establish the following criteria as to specific products or processes:

- The expenses were incurred solely to meet legal requirements imposed by a political entity;
- The expenses were incurred with respect to improvement or marketing of specific products or processes; and,
- The research and experimentation results cannot reasonably be expected to generate amounts

of gross income, beyond de minimis amounts, outside of a single geographic source.

Example 1:

Facts:

P, a multinational corporation headquartered in the United States, is engaged in the business of manufacturing pharmaceuticals. P generates revenues from the sale of its products in both the U.S. and foreign markets. Its global strategy is to develop products that will alleviate or cure certain conditions for the worldwide patient population. P has research facilities in the U.S. and abroad.

In year 1, P completes clinical trials of Phases I , II, and III in the United States for Drug A and submits Drug A for FDA approval. In its application, the research results of all clinical trials are included. As a result, Drug A is approved by the FDA in year 1. In year 2, P submits Drug A for approval in two foreign countries. The two foreign countries require as part of their pharmaceutical approval process all of the research data and results that were submitted to the U.S. FDA. P submits the results of all such research and experimentation used in the FDA approval process. As a result, Drug A is approved by the two foreign countries in year 2. P expects upon approval to obtain more than de minimis amounts of gross income from sales of Drug A in each country. From year 2 on, P sells Drug A with approval in the United States and in the two foreign countries and generates substantial amounts of gross income in each country. On its U.S. income tax return for year 1, P claims all U.S.-based clinical trials as legally mandated expenses allocated exclusively to U.S. source income.

Result:

The clinical trial expenses do not qualify as legally mandated expenses because the research and experimentation was required to obtain regulatory approval for Drug A in all three countries and was therefore not required solely by one political entity.

Example 2:

Facts:

In year 1, P enters into a co-marketing agreement with an unrelated foreign company to sell Drug B in the United States (and only in the United States). Drug B was developed by the foreign company outside of the U.S. and has been sold in that foreign market for several years. The co-marketing agreement requires the P to perform all clinical tests necessary to obtain FDA approval for the sale of Drug B in the U.S. The co-marketing agreement also provides that P will be reimbursed by the foreign company for one-half of the costs of the required U.S. clinical trials. On its U.S. income tax return for year 1, P claims expenses for all U.S.-based clinical trials as legally mandated expenses allocated exclusively to U.S. source income.

Result:

The taxpayer incurred expenses for U.S.-based clinical trials that are required to obtain FDA approval. These research and experimentation expenses incurred by P qualify as legally mandated expenses because they were incurred solely to meet U.S. FDA requirements and, because the co-marketing agreement is limited to the United States, one may not reasonably expect the research and experimentation to generate gross income (beyond de minimis amounts) outside the U.S. However, the taxpayer may only deduct those expenses for which it was not reimbursed. Code sections 174 and 864.

Accordingly, only the research and experimentation expenses that are deductible under Code section 174 are subject to allocation and apportionment under the legally mandated rule.

Because determination of whether research and experimentation is legally mandated is fact intensive, documentation is critical in the development of this issue. Estimates or internal interviews of company personnel may not be sufficient in and of themselves to qualify the expense for the

legally mandated exception. Projects, products or processes need to be identified. Foreign clinical data sections of foreign applications need to be provided. Research budgets, company drug review processes, strategic marketing plans, sales projections, annual reports, and FDA correspondence files need to be reviewed. Access to such data will expedite the resolution of this issue, which will ultimately benefit both the taxpayer and the Service.

Pharmaceutical manufacturers typically must obtain regulatory approval for each product in each foreign jurisdiction in which they sell the product. The regulatory approval process frequently permits the research data amassed in order to obtain approval in one country to be used to obtain regulatory approval in other countries. To allocate research and experimentation expenditures solely to U.S. source gross income under the legally mandated research and experimentation rule of Treas. Reg. §1.861-17(a)(4), a taxpayer must establish that the research and experimentation expenditures in relation to the improvement or marketing of the specific products or processes (1) were not required and used to obtain foreign approvals and (2) are not reasonably expected to generate gross income beyond de minimis amounts outside of the U.S. Failure to meet any of these requirements means that the research and experimen-tation expenses will not qualify as legally mandated expenses under Treas. Reg. §1.861-8(e)(3) for tax years ending before or on December 31, 1995, and Treas. Reg. §1.861-17(a)(4) for tax years beginning after December 31, 1995.

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