

Cite as Det. No. 03-0254, 23 WTD 280 (2004)

BEFORE THE APPEALS DIVISION
DEPARTMENT OF REVENUE
STATE OF WASHINGTON

In the Matter of the Petition For Correction of)	<u>D E T E R M I N A T I O N</u>
Assessment of)	
)	No. 03-0254
)	
...)	Registration No. ...
)	... /Audit No. ...
)	Docket No. ...
)	
)	

RULE 24003; RCW 82.04.4452, RCW 82.63.010: B&O TAX – RESEARCH AND DEVELOPMENT ("R&D") EXEMPTION – DEVELOPMENT OF NEW DRUGS. Payments which a pharmaceutical company gives a physician for treating patients and recording the results as part of new drug trials do not qualify for the B&O tax exemption allowed for R&D. Taxpayer's activities are neither the discovering technological information nor translating technological information into new or improved products, processes, techniques, formulas, inventions, or software.

Headnotes are provided as a convenience for the reader and are not in any way a part of the decision or in any way to be used in construing or interpreting this Determination.

Lewis, ALJ, - Taxpayer operates a medical clinic. Taxpayer receives payment either directly from pharmaceutical companies or a middleman (clinical research organizer-company) to conduct new drug investigational clinical trials. Taxpayer is paid to locate qualifying patients, administer the experimental new drug, and record the effects of the drug. The Audit Division of the Department of Revenue ("Department") assessed service-other B&O tax on the payments Taxpayer received for conducting the clinical trials.¹ Taxpayer maintained that the payments were not taxable medical fees, but rather were payments that qualified for the research and development ("R&D") tax credit.

¹ According to www.clinicaltrials.gov a clinical trial is:

a research study to answer specific questions about vaccines, new treatments or new ways of using know treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatment that work in people.

We [deny] Taxpayer's petition concluding that Taxpayer's activities [do not] qualify for the R&D B&O tax credit, . . .²

ISSUE:

Did the Department err in disallowing the R&D B&O tax credit taken on income derived from conducting clinical trials on experimental new drugs, based solely on the conclusion that such trials are not subject to the credit?

FINDING OF FACTS:

Taxpayer is a personal service corporation whose employees provide obstetric and gynecological care at a medical clinic in . . . , Washington. The Department's Audit Division audited Taxpayer's business records for the period January 1, 1999 through September 30, 2001. On August 26, 2002, the Department issued a \$. . . tax assessment representing the assessment of service-other business and occupation ("B&O") tax on underreported income received for conducting clinical drug trials.³

The United States Food and Drug Administration requires pharmaceutical companies to conduct clinical trials to provide evidence that new drugs are both effective and safe. The clinical trials are paid for by the pharmaceutical company and include payments to the patients, physician fees, clinical coordinator fees, lab fees, and advertising costs. The pharmaceutical company may either contract directly with the physician to conduct the study or with a middleman ("clinical coordinator") who locates and pays the physician on behalf of the pharmaceutical company.

Clinical drug trials require that qualifying individuals take the medication and that the administering physician monitor and record the effects of the drug.⁴ 21 C.F.R. 312. When the pharmaceutical company hires a clinical coordinator, the clinical coordinator may assist in the design of the drug test protocol, monitor the study, and prepare and evaluate the research reports.

The Audit Division examined Taxpayer's activities in performing clinical drug trials and concluded that the income it received did not qualify for the R&D B&O tax credit. The Audit Division concluded that Taxpayer did not conduct R&D. Rather, the Audit Division concluded that Taxpayer was providing medical services because its primary role was to administer drugs and maintain data regarding the drug's effect on the patient. The Audit Division viewed the administration and monitoring of drugs within a physician's normal duties and outside of clinical drug trials. Taxpayer disagreed. In a July 10, 2002 letter to the Audit Division, Taxpayer explained that as a clinical researcher the physician does much more than treat a patient.

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³ At the same time the Department issued another assessment adjusting use tax and associate physician fee income. The adjustments contained in the second assessment are not protested.

⁴ The pharmaceutical company hopes for the best results where the clinical studies show that the drug is both effective and without side-effects. The worst case is where the clinical trials disclose that the drug causes side-effects (not safe) and is not effective.

Taxpayer explained that involvement in a research protocol requires performance of the following duties:

- Participate in pre-study investigator meetings to evaluate the design of the study and to recommend protocol changes to the sponsor before the study is submitted to the Internal Review Board (“IRB”) for approval.
- Negotiate with the clinical research organization (“CRO”) regarding budgetary issues such as patient advertising and stipends and supplies.
- Responsible for training support personnel and evaluation of patients as being legitimate candidates for participation.
- Keep aware of data as it is collected and, when appropriate, report trends to the central study sponsor and the IRB.
- Certify that all of the data collected is correct.

While not required by the study, a physician may participate in writing and/or reviewing articles that cite the findings and recommendations of the study.

ANALYSIS:

Washington imposes a B&O tax on every person for the privilege of engaging in business in Washington. RCW 82.04.220. In general, persons providing professional medical services, such as chemists, dentists, physicians, and laboratory operators, report their income under the service – other B&O tax classification. RCW 82.04.290; WAC 458-20-224 (“Rule 224”). Taxpayer, a medical services provider, maintains that its participation in clinical drug studies is much more than simply providing medical services. Taxpayer maintains that it need not pay B&O tax on the payments it receives for conducting clinical drug studies, relying on the B&O tax credit provided for those that conduct qualified R&D projects. RCW 82.04.4452.

RCW 82.04.4452(1) allows a credit against B&O taxes for research and development spending that exceeds 0.92 percent of the person’s taxable amount during the same calendar year. “The credit is equal to the greater of the amount of qualified research and development expenditures of a person or eighty percent of amounts received by a person . . . in compensation for the conduct of qualified research and development, multiplied by the rate provided in . . . in RCW 82.04.290(2)” RCW 82.04.4452(2). Thus, the credit may be taken by either persons incurring qualified R&D expenditures or persons paid by others to do qualified R&D.

Thus the threshold question is whether Taxpayer is incurring qualified R&D expenditures or being paid by others to do qualified R&D. In either case, the taxpayer must be performing qualified R&D, because only qualified R&D projects qualify for the B&O tax credit.

RCW 82.04.4452(9)(b) provides that “qualified research and development” shall have the same meaning as in RCW 82.63.010.” RCW 82.63.010(14) provides:

"Qualified research and development" means research and development performed within this state in the fields of advanced computing, advanced materials, biotechnology, electronic device technology, and environmental technology.

RCW 82.63.010(4) defines “Biotechnology” as:

. . . the application of technologies, such as recombinant DNA techniques, biochemistry, molecular and cellular biology, genetics and genetic engineering, cell fusion techniques, and new bioprocesses, using living organisms, or parts of organisms, to produce or modify products, to improve plants or animals, to develop microorganisms for specific uses, to identify targets for small molecule pharmaceutical development, or to transform biological systems into useful processes and products or to develop microorganisms for specific uses.

RCW 82.63.010(16) defines "Research and development" as:

. . . activities performed to discover technological information, and technical and nonroutine activities concerned with translating technological information into new or improved products, processes, techniques, formulas, inventions, or software. The term includes exploration of a new use for an existing drug, device, or biological product if the new use requires separate licensing by the federal food and drug administration under chapter 21, C.F.R., as amended. The term does not include adaptation or duplication of existing products where the products are not substantially improved by application of the technology, nor does the term include surveys and studies, social science and humanities research, market research or testing, quality control, sale promotion and service, computer software developed for internal use, and research in areas such as improved style, taste, and seasonal design. (Emphasis added.).

Thus, under the RCW 82.63’s definitions of “research and development” and “Biotechnology”, the development of a new drug [may] qualify[y] for the R&D tax credit. Here, however, Taxpayer is not developing a new drug, nor is Taxpayer attempting to translate the technology into a new product. Rather, after the drug has been developed, Taxpayer finds qualified patients, administers an experimental medicine, and records patient data regarding the safety and efficacy of the new drug.

Recently adopted WAC 458-20-24003(6)(c) provides an example to help explain the distinction between qualifying and nonqualifying biotechnological R&D. Example (c) explains:

c) Company A is engaged in research and development in biotechnology and needs to perform standard blood tests as part of its development of a drug. It contracts with a lab, B, to perform the tests. The costs of the tests are qualified research and development expenditures for A, the company engaged in the research and development. Although the

tests themselves are routine, they are only a part of what A is doing in the course of developing the drug. B, the lab contracted to perform the testing, is not engaged in research and development with respect to the drug being developed. B is neither discovering technological information nor is it translating technological information into new or improved products, processes, techniques, formulas, inventions, or software. B is not entitled to a credit on account of the compensation it receives for conducting the tests.

Like the lab in the example, Taxpayer is neither discovering technological information nor is it translating technological information into new or improved products, processes, techniques, formulas, inventions, or software. Similarly, like B in the example, Taxpayer is not entitled to a credit on account of the compensation it receives for conducting the tests.

DECISION AND DISPOSITION:

Taxpayer's petition is denied.

Dated this 29th day of July, 2003.