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Critical Tax Issues Facing the Pharmaceutical,
Biotech and Medical Devices Industries

# MANAGING AND RESOLVING R&D ISSUES

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# **AGENDA**

- > Assume working knowledge of section 41
- > Recent developments legislative, regulatory, cases, and administrative
- > Common IRS objections / potential pressure points
- ➤ The elephant in the room substantiation
- > Tips for managing and resolving R&D issues



# Recent Developments

### RECENT DEVELOPMENTS – LEGISLATIVE

- > The credit is currently expired.
- ➤ Pending legislative efforts:
  - The Expiring Provisions Improvement Reform and Efficiency (EXPIRE) Act extends the research credit in its current form through December 31, 2015.
  - The Tax Reform Act of 2014 makes credit permanent, reduces regular credit rate, eliminates supply QREs, and converts base amount to rolling 3-year average.
  - The American Research and Competiveness Act of 2014 makes the credit permanent, raises the ASC rate, and allows ASC election on amended returns.
- Most likely outcome is an extension sometime this year without significant changes to the credit.



# RECENT DEVELOPMENTS – REGULATORY

- > September 2013 proposed amendments to section 174 regulations
  - Experimental but fully functional prototypes are "pilot models."
  - The ultimate sale or use of prototype does not disqualify R&E costs.
  - Introduces shrink-back rule when uncertainty exists only as to a component.
  - Enduring uncertainties:
    - > When is uncertainty resolved in a fluid development process?
    - > What is the "pilot model" when a new component is integrated into a larger product?
    - > Is the shrink-back rule a sword for the IRS or a shield for taxpayers?



# RECENT DEVELOPMENTS – REGULATORY

- ➤ December 2014 proposed regulations to section 41 regulations
  - General rule = gross receipts from intragroup transactions are excluded from base amount computation.
  - Proposed amendments create an exception requiring inclusion of gross receipts from transactions between US and foreign controlled group members when followed by a transaction between a foreign group member a non-group member involving the same property or services and not giving rise to effectively connected income.
  - Can increase the base amount and reduce the regular credit.
  - Inconsistent with Procter & Gamble, 2010 WL 2925099 (S.D. Ohio July 6, 2010), and creates substantial administrative burdens to trace the sales cycle.
  - Several commentators have urged withdrawal.



# RECENT DEVELOPMENTS – CASES

- > FedEx Corp. v. United States, 2009 WL 2032905 (W.D. Tenn. August 27, 2003)
  - In August 2013, the Government withdrew its appeal of the district court's ruling rejecting Notice 2004-09 insofar as it required taxpayers electing to be governed by the T.D. 8930 internal use software rules to also follow the repudiated discovery test.
- ➤ Geosyntec Consultants, Inc. v. United States, 2013 WL 5238479 (S.D. Fl. April 17, 2013)
  - In April 2013, the district court ruled that an engineering firm's research under fixedprice contracts was not funded, but its research under capped cost-plus contracts was funded.
  - The capped cost-plus ruling is on appeal to the 11th Circuit.



# RECENT DEVELOPMENTS – CASES

- > Shami v. Commissioner
  - Tax Court (March 2012)
    - > Taxpayer failed to prove CEO and EVP salaries were QREs.
    - > Lab records non-probative and testimony incredible.
  - Fifth Circuit (January 2014)
    - > Cohan did not compel Tax Court to make an estimate where taxpayers had failed to provide a "reasonable basis."
    - > "[I]t is far from clear . . . that Shami directly supervised FSI employees actually conducting qualified research as opposed to merely acting as an upper-level manager."
    - > Issuance of a patent does not conclusively prove that a taxpayer engaged in qualified research.



# RECENT DEVELOPMENTS – ADMINISTRATIVE

- ➤ No longer a tiered issue controlled by Issue Management Team.
  - Control has been given back to the agent, who can obtain guidance from the Business Credits IPG.
  - Remains a compliance priority.
- > De-coordination of CIPs (i.e., IUS, utilities, self-constructed supplies, etc.)
  - To the extent that a CIP contains relevant guidance, it will be made available through internal IPG and IPN websites.
  - Whether to raise issues in agent's discretion.



# RECENT DEVELOPMENTS – ADMINISTRATIVE

- > Still coordinated within Appeals with four assigned Technical Specialists.
  - Review and concurrence no longer required.
- ➤ 2013 IRS NSAR 1102F VSPs are not R&E expenditures
- ➤ 2012 LB&I Directive QREs from Stages 1 (discovery and preclinical stage) and 2 (clinical trial stage) of pharmaceutical development process ("core R&D") will not be challenged with taxpayer certification.
  - Stage 3 (regulatory review stage) and Stage 4 (post approval stage) not covered by the directive.
  - Certification Statement
    - > Taxpayer should provide signed C/S to the examiner within 30 days of when IDR is issued with respect to QREs taken.
    - > Separate C/S for each taxable year; common parent of consolidated group must sign.
    - > Certifies (1) will provide documents, (2) QREs computed per section 41(b), (3) excluded activities not included, and (4) amount of QREs for Stages 1 and 2.
  - What has been your experience?



# Common IRS Objections / Potential Pressure **Points**

# **COMMON IRS OBJECTIONS – SECTION 174 TEST**

- > Lack of uncertainty concerning capability, method, or design of the product
  - No objective uncertainty based on known facts
  - Uncertainty eliminated; experimentation has ended
  - Uncertainty limited to a component of overall system
- ➤ Government-mandated R&D does not qualify
- > Construction and installation versus R&D costs
- > Costs are for depreciable property or components thereof



# COMMON IRS OBJECTIONS – PROCESS OF EXPERIMENTATION TEST

- ➤ Requires experimentation in the "scientific sense" of formulating and testing alternative hypotheses in a structured way
- ➤ Insufficient taxpayer evaluation and analysis
- > Activities are validation and troubleshooting
- ➤ Software maintenance, configuration, evaluation, debugging, modifications, upgrades, and code rewriting do not pass the test.



# COMMON IRS OBJECTIONS – EXCLUDED ACTIVITIES

- ➤ Research after commercial production taxpayer's functional and economic requirements already satisfied
- ➤ Duplication and adaptation reverse engineering, customization, etc.
- ➤ Internal-use software
  - Still applying discovery test for taxpayers electing T.D. 8930
  - High standards for innovativeness and technical/economic risk
- Funded research research under a contract is funded unless payments made explicitly contingent on success of the research (*Fairchild*).



# **COMMON IRS OBJECTIONS – QRES**

# Wages

- Direct support –activities not normally be done by a researcher ineligible; focus on employees in administrative, manufacturing, marketing, regulatory, legal, etc. functions
- Direct supervision above first-line managers categorically excluded
  - > Technical-degreed high-level executives often perform direct research and directly supervise research
    - a) Effective hierarchy of technical departments is often very flat and VPs of technical departments often heavily involved in actual research and direct supervision of research
    - b) Brainstorming and technical problem solving are themselves research, not supervision
    - c) Directly supervising first-line managers when the first-line managers are performing research is direct supervision
    - d) Executive questionnaire (see handout)



# **COMMON IRS OBJECTIONS - QRES**

# > Supplies

- Purchased primarily for non-research purposes; not directly related to performance of qualified services
- Overhead, G&A, depreciation allowances, leasing costs, license fees, etc.
- Depreciable property (e.g., prototypes)
- ➤ Contract research expenses
  - Nature of work per contract documentation (e.g., SOW)
  - Taxpayer must be at risk for success of research
  - Ineligible expenses e.g., offshore work, licenses, routine services, etc.
- ➤ Distinguishing contract research at risk and not at risk, on one hand, from contracts for qualified supplies, on the other (see handout)



# COMMON IRS OBJECTIONS – RESEARCH CREDIT COMPUTATION

- > Omission of controlled group members and common-control entities
- ➤ Omission of gross receipts from prior 4 years
- ➤ Inconsistent determination of QREs in credit versus base years
- > Failure to adjust fixed-base percentage for acquired businesses
- ➤ Validity of section 280C(c) election



# The Elephant In The Room – Substantiation

# SUBSTANTIATION – THE IRS'S PERSPECTIVE

- ➤ Because tax credits are matters of "legislative grace," taxpayers bear a heavy burden to prove entitlement.
- ➤ Taxpayers are required to establish a factual "nexus" between claimed QREs and specific business components.
  - Particularly difficult for taxpayers with cost center accounting and wide-ranging R&D activities.
- Contemporaneous project-based documents are much more reliable than oral testimony.
- > Retrospective look-back studies are inherently unreliable.
- Not required to accept estimates or extrapolations.



# SUBSTANTIATION – THE IRS'S PERSPECTIVE

# > Standard IDR requests

- "Identify and list each new or improved business component for which the QREs are being claimed."
- "For each business component identified in item a, provide the QRE wages by employee, the QRE supplies, and the contract QREs by contract, and reconcile the QREs by business component to the total QREs on your Form 6765."
- "Does the claim rely on any oral testimony or employee surveys to determine the QREs in the credit years?"
- "Does the claim rely on estimates or extrapolations to determine any portion of the QREs in the credit year?

# > Standard NOPA language

 "The taxpayer's reconstruction of claimed QREs is unreliable, incomplete, and wholly insufficient to establish that its claimed research expenditures qualify for the research credit."



# SUBSTANTIATION – LEGAL PRINCIPLES

- ➤ Taxpayers "must retain records in sufficiently usable form and detail to substantiate that the expenditures claimed are eligible for the credit." Reg. § 1.41-4(d).
- ➤ But the legal authorities also establish:
  - Eligibility not contingent on meeting unreasonable record keeping requirements.
  - Taxpayers should be accorded "reasonable flexibility" in the manner in which they substantiate their research credits.
  - No particular types of documents are required.
  - Claims may be supported by credible oral testimony.
  - Estimation is allowed (or required) where the taxpayers perform qualified research and provide a reasonable basis.



# Managing And Resolving R&D Issues

- > Claiming the credit is not easy.
- > Requires dedicated resources and systems for—
  - Identifying qualified research activities
  - Identifying and quantifying QREs
  - Computing the credit
  - Gathering the records and data to substantiate the credit
- > Considerable manpower, cooperation, resources, and time are required.
- ➤ The sophistication and focus of the methodology depends on your business, the value of the credit, and expected scrutiny.



- ➤ Original versus amended returns.
- ➤ All factors equal, the closer in time to the R&D the better.
- ➤ Leverage available tools:
  - Statistical sampling Rev. Proc. 2011-42
  - Project and time tracking software programs
  - Post hoc project tracking
    - > Project lists and allocations
    - > "Chunky peanut butter" approach
  - RCRAs Notice 2004-11
  - PFAs re appropriate methodology Rev. Proc. 2009-14
  - Informal agreements with your exam team



- > The best offense is a good defense.
- > Data gathering:
  - Taxpayers armed with contemporaneous documents are best positioned.
    - > No particular type required; documents created in normal course of your R&D are best.
      - Monthly reports
      - Capital authorizations
      - Lists of patents and patent applications (and similar technical certifications)
      - Project lists
  - Consider section 41(d) tests when gathering documents.



- Data gathering
  - Consider all available sources of information: public information, tracking systems, internal records, site visits, in-house experts, etc.
  - Leverage technical and accounting personnel.
    - > Explain QRE definition with emphasis on avoiding any preconceived notions of what "research" must be
    - > Establish a pipeline for future project information and changes in department activities
  - Memorialize interviews and surveys; recognize they'll be requested.
- > Data retention; may need to override normal policies



# MANAGING AND RESOLVING R&D ISSUES – AUDIT

- > Anticipate and prepare for audit issues.
- ➤ Maintain a good rapport with your exam team.
  - Be responsive.
  - Pick your battles, but don't be afraid to stand your ground.
- ➤ Consider statistical and judgment samples to streamline the audit.
- > Consider other ways to focus on the big-ticket issues.
- ➤ The facts are your friend.
- > Prepare your witnesses.
- ➤ Identify additional QREs and gross receipts
- > The consistency requirement is a 2-way street.



# MANAGING AND RESOLVING R&D ISSUES - APPEALS

- > The protest should be better than the NOPA.
  - Describe the company and its research in clear, understandable terms.
  - Show why the research satisfies I.R.C. § 41(d).
  - Attack the NOPA's contentions.
- ➤ Consider how best to leverage your in-house experts.
- > Objectively evaluate the merits and hazards of your position.
- ➤ Consider ADR alternatives: Fast Track, DO 4-24, etc.



# Questions?

# Thank You.