T.C. Memo. 2016-112

UNITED STATES TAX COURT

MEDTRONIC, INC. AND CONSOLIDATED SUBSIDIARIES, Petitioner v. COMMISSIONER OF INTERNAL REVENUE, Respondent

Docket No. 6944-11. Filed June 9, 2016.

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Curt M. Rubin, Halvor N. Adams III, John E. Budde, Michael J. Calabrese, Paul L. Darcy, Laurie B. Downs, Frances Honecker Holmes, Rebecca J. Kalmus, G. Roger Markley, Jeannette D. Pappas, and H. Barton Thomas, Jr., for respondent.

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MEMORANDUM FINDINGS OF FACT AND OPINION

KERRIGAN, Judge: Respondent determined deficiencies as amended by answer in petitioner's Federal income tax of $548,180,115 for 2005 and $810,301,695 for 2006. Unless otherwise indicated, all section references are to the Internal Revenue Code in effect during the years at issue, and all Rule references are to the Tax Court Rules of Practice and Procedure. We round all monetary amounts to the nearest dollar.

The issues for consideration are: (1) whether income related to intercompany licenses for the intangible property required to manufacture medical device pulse generators (devices) and physical therapy delivery devices (leads) should be reallocated under section 482 to Medtronic US from its Puerto Rican subsidiary, Medtronic Puerto Rico Operations Co. (MPROC), for tax years 2005

[*6] and 2006 (devices and leads transfer pricing issue);[1] (2) whether Medtronic Europe, S.a.r.L. (Medtronic Europe) made arm's-length payments to Medtronic US or accrued royalties in excess of arm's length to manufacture devices sold to Medtronic USA, Inc. (Med USA), pursuant to a supply agreement effective as of May 1, 2002, among Medtronic US, MPROC, and Medtronic Europe (Swiss supply agreement issue); and (3) alternatively, if the Court does not find respondent's adjustments for 2005 and 2006 to be reasonable, whether Medtronic US, Med Rel, Inc., or Medtronic Puerto Rico, Inc.,[2] transferred intangible property compensable under section 367(d) to MPROC when Medtronic US restructured its Puerto Rican operations in 2002 (section 367(d) issue).

On January 22, 2015, the Court issued a protective order to prevent disclosure of petitioner's proprietary and confidential information. The facts and opinion have been adapted accordingly, and any information set forth herein is not

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[1]In 2005 and 2006 Medtronic US miscalculated the amount of royalties owed by MPROC using an incorrect amount for intercompany sales of devices and leads. Resolution of the devices and leads transfer pricing issue will determine the correct amount of royalty income that Medtronic US should recognize on these transactions.

Additionally, the parties have agreed to keep an issue involving the sec. 965 dividends received deductions for 2005 and 2006 in abeyance until the devices and leads transfer pricing issue has been resolved.

[2]Medtronic Puerto Rico, Inc., was MPROC's predecessor.

[*7] proprietary or confidential. Medtronic US is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota. During 2005 and 2006 Medtronic US was the parent corporation of a group of consolidated corporations and multinational affiliated subsidiaries (collectively, petitioner).

FINDINGS OF FACT

I. Overview of Medtronic

Since the early 1960s petitioner has been a leading medical technology company with operations and sales worldwide. By 2005 petitioner operated in more than 120 countries and had approximately 33,000 employees worldwide. During 2005 and 2006 petitioner operated through multiple business units; this case, however, involves only the Cardiac Rhythm Disease Management (CRDM) and Neurological (Neuro) business units. During the years at issue CRDM had more employees and substantially more revenue than Neuro. Both business units had devices and leads that are at issue in this case. The device operations across both business units were larger and earned more revenues than the leads operations. Medtronic maintained its operations in Puerto Rico through MPROC.

A. Class III Medical Devices

In order for certain medical devices to be legally marketed in the United States, they must be approved by the Food and Drug Administration (FDA). The

[*8] FDA requires all manufacturers of medical devices distributed in the United States to register their facilities, list their medical devices, and follow certain requirements. The FDA classifies medical devices according to the risks that they pose to consumers. The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act classified medical devices that were on the market at the time into one of three classes: class I, class II, and class III. Medical Device Amendments of 1976, Pub. L. No. 94-295, sec. 513, 90 Stat. at 540-541. Class I medical devices are subject to the fewest regulatory control, and class III medical devices are subject to the most stringent controls. Class III medical devices must comply with certain controls and go through a premarket approval (PMA) process. The PMA process is lengthy and can often take 5 to 10 years. Class III medical devices are higher risk and more novel than are those of classes I and II.

Class III medical devices generally cannot be classified as class I or class II because there is insufficient information that existing controls are sufficient to provide reasonable assurance of safety and effectiveness and they 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". Id. subsec. (a)(1)(C). Class III medical devices require more scrutiny than those of class I or class II. Class III medical devices include those which are life-

[*9] supporting or life sustaining. Examples are implanted cerebellar stimulators, heart valves, and certain dental implants. Examples of class I medical devices are elastic bandages and examination gloves. Examples of class II medical devices are powered wheel chairs and infusion pumps.

Class III medical devices must typically be approved by FDA before they are marketed through the PMA process. The PMA process is rigorous, costly, and time consuming. It requires a demonstration that the new medical device is safe and effective. That demonstration is performed by collecting data, including human clinical data, for the medical device.

The class III medical devices primarily at issue in this case are devices and leads. The devices and leads are developed, manufactured, marketed, and sold through Medtronic's CRDM and Neuro business segments, which are described in greater detail below.

B. Industry Background

During the years at issue the medical device industry was highly competitive. Success depended on several factors such as product innovation, sales proficiency and service, and product quality. Truly innovative products could significantly change a company's market share.

[*10] Product quality, however, was the driving factor for success in the industry. Without it, neither the innovativeness of a company's products nor the effectiveness of a company's service professionals would ultimately matter. There are several examples in the industry, discussed in greater detail below, of companies that have been adversely affected, acquired by competitors, or driven out of business because of actual or perceived product quality problems. Thus, there was a significant focus on quality, which included quality product designs and quality manufacture of components and finished products.

1. Customers

The customers in the medical device industry are generally surgeons, electrophysiologists, interventional cardiologists, cardiovascular surgeons, heart failure specialists, spinal surgeons, orthopedic surgeons, neurosurgeons, and others who make decisions about what type of devices to purchase, implant, and provide to patients. A key to a company's reputation and its relationship with physicians is how the company handles product flaws once they are known. Physicians expect that companies will notify them about problems along with the probability of occurrence so that they can decide how to best treat their patients. A company's failure to timely communicate to its customers can seriously harm its reputation.

[*11] 2. Competitors

The companies that competed successfully in the implantable medical device industry met the needs of their customers and differentiated themselves from their competitors by continuing to deepen the extent to which they met those needs. These companies progressively grew their customer base through deepening customer satisfaction and expanding their market share through product diversification. Product quality, however, remained the foundation that determined the extent to which companies met each of these goals.

CRDM's primary competitors were Guidant Corp. (Guidant), Boston Scientific Corp. (Boston Scientific) (after acquiring Guidant), and St. Jude Medical, Inc. (St. Jude). From the late 1990s through 2005 and 2006 the CRDM market was dominated by Medtronic, and then Guidant and St. Jude, with only minor other players.

Neuro's primary competitors were Johnson & Johnson, Boston Scientific, Advanced Neuromodulation Systems, Inc. (Advanced Neuro), St. Jude (after its acquisition of Advanced Neuro), and Stryker Corp. Medtronic had the largest share of the U.S. market for neuro spinal cord stimulators and had no competitors in the United States for neuro deep brain stimulators.

[*12] C. Self-Insurance

The threat of class action lawsuits or multidistrict proceedings are frequent consequences of product recalls in the medical device industry. The type of insurance coverage that Medtronic needed to insure itself fully against its product liability risk, namely "catastrophic insurance" on the order of billions of dollars, was not available in the marketplace during the years at issue. Since 2002 Medtronic has been unable to obtain product liability insurance to insure against losses at commercially acceptable premium amounts. Thus, Medtronic self-insured against product liability risk, effective May 1, 2002, as well as during 2005 and 2006. The decision to self-insure increased the level of scrutiny placed on quality. Once Medtronic made the decision to self-insure against product liability risk and no longer had any other kind of insurance to pay for losses associated with product quality, it was even more important that the finished product function properly.

One aspect of Medtronic's business and legal groups' responsibilities involved identifying and resolving customer complaints regarding product problems as early as possible. Because Medtronic was self-insured during 2005 and 2006, its claim management process was intended to minimize the risk of product liability litigation.

[*13] II. Entities and Roles

A. Medtronic US

Medtronic US is the headquarters of the worldwide CRDM and Neuro businesses. Medtronic US performs functions such as accounting, tax, finance, treasury, legal and regulatory affairs, information systems, science and technology, and general administration on behalf of itself and its affiliates.

In 2005 and 2006 Medtronic US owned Medtronic International Technology, Inc. (MITI), a U.S. corporation. MITI owned Medtronic Holding Switzerland GmbH (Swiss Holding), a Swiss entity. Swiss Holding owned MPROC, Medtronic Europe, and Medtronic Vascular Galway Ltd. (Medtronic Galway), which were all disregarded entities for U.S. Federal income tax purposes. For U.S. tax purposes Swiss Holding conducts manufacturing in Switzerland, Puerto Rico, and Ireland through manufacturing "branches."

1. Research and Development

Medtronic US was responsible for research related to core products, which focused on refinements to products already on the market. Medtronic US was also responsible for research related to new therapies, which focused on new indications and new products. As part of Medtronic US' research function, engineers and scientists performed feasibility work to determine whether an idea

[*14] was viable for development. Medtronic US sometimes collaborated with academics and third-party companies to perform research. Not all research activities performed by Medtronic US led to commercial products.

Medtronic US developed products in several ways. Not all products were created by engineers at the bench. Product development ideas often came from physicians' "bedside", i.e., as they were working.

2. Quality

Quality was always the first topic discussed at Medtronic's executive committee meetings and quarterly reviews. Quality was of the utmost importance in the devices and leads industry because the completed product would be implanted in a human body. The failure of an implanted device or lead can result in severe problems for the patient, and unfortunately even death.

Medtronic was concerned with what it referred to as a "doomsday scenario", in which a physician implanted a device and, because of poor quality, the patient died. The goal of the device and lead products was to enhance or save lives.

Medtronic US' corporate quality responsibilities included interpreting the regulations promulgated by the FDA and international regulatory agencies to ensure that Medtronic was in compliance with those regulations and to ensure that Medtronic's quality systems were aligned across its business units with the use of

[*15] the applicable multisite "umbrella procedures". Medtronic US had quality manuals and policies for each of its business units, including CRDM and Neuro. CRDM and Neuro both had quality officers in the United States. Each manufacturing site, however, spent time developing and revising its own respective quality policy and quality system manuals, as well as managing its quality system within its site.

Medtronic US was the first in the industry to issue "product performance reports", which aggregate longevity and reliability data for both devices and leads, as well as information concerning recalls or advisories for the use of physicians. Many physicians scrutinized these product performance reports, which Medtronic US first introduced in 1983 following a significant product recall, to ensure that the products they implanted were reliable and of the highest quality. Physicians would make their purchasing decisions accordingly.

3. Clinical

Medtronic US was responsible for clinical studies, which it designed, oversaw, and used to support PMA submissions. Medtronic US also used contract clinical research organizations to design and execute clinical trials.

Certain of Medtronic's clinical trials benefited the entire industry because companies could use the studies to support the safety and efficacy of their own

[*16] products, just as Medtronic might also have benefited from its competitors' clinical trials.

4. Regulatory

Medtronic US was obligated to adhere to the highly stringent regulatory requirements imposed on class III finished medical devices by the FDA and international regulatory agencies and bore the significant costs related to these regulatory requirements.

Medtronic US had global regulatory responsibilities generally relating to three areas: safety and efficacy of new products before commercialization; oversight and management of clinical studies of products that did not yet have regulatory approval; and oversight and management of clinical studies in order to expand indications for products already on the market. Additionally, Medtronic US compiled information from the various functional groups for regulatory submissions to the FDA and international regulatory agencies and reviewed marketing materials to ensure that they aligned with regulatory approvals.

Medtronic US' regulatory responsibilities included handling complaints and medical device reports, totaling more than 10,000 per year during the years at issue. Many of the complaints and reports related to products that MPROC manufactured.

[*17] As part of its postmarket compliance function Medtronic US submitted annual reports and PMA supplements, such as "30-day notices", to the FDA that described any changes that might affect the safety and effectiveness of products. Medtronic US reviewed any changes that might affect safety and effectiveness of the products it marketed and manufactured, in addition to maintaining device listings and reviewing labeling information and promotional materials.

5. Component Manufacturing

Medtronic US also performed product research and development related to devices and leads. It manufactured components through its vertically integrated component manufacturing branches, Medtronic Energy & Component Center (MECC), Medtronic Microelectronics Center (MMC), and Arizona Device Manufacturing (ADM). MECC and MMC were responsible for meeting the demand for component parts required by MPROC and Medtronic Europe. MMC also supplied products to unrelated parties.

a. MECC

MECC is in Minnesota. During 2005 and 2006 MECC was responsible for producing and selling, among other things, components, including batteries, capacitors, and feedthroughs for devices and leads produced and sold by MPROC. MECC also produced components for other Medtronic business units in addition

[*18] to CRDM and Neuro. MECC had responsibility for hiring, firing, recruiting and training certain of its employees. MECC sold components only to entities that Medtronic owned. MECC had its own quality manuals.

MECC operated high-volume manufacturing lines for batteries, capacitors, feedthroughs, and connectors. MECC manufactured low-power batteries used in pacemakers, and high-power batteries and capacitors used in implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices. MECC manufactured connectors (also called headers) and feedthroughs used in devices.

Feedthroughs, which are the interconnects for the electronics inside the device to the lead, were among the most important components. They are complex, especially for ICDs, because there are up to six wires and a lot of metallurgy related to them.

MECC also produced electrode tips used in leads, including pacing and ICD leads. Electrode tips were critical components, and each lead product had a unique electrode tip. Their design and composition required technology. Improvements in these products require advanced technology.

MECC was Medtronic's "Center of Excellence" for batteries and capacitors. MECC assisted other units of Medtronic with problems within its expertise.

[*19] MECC employees participated on CRDM and Neuro development teams and were on a product review committee.

b. MMC

MMC is in Arizona. During 2005 and 2006 MMC was a supplier of component parts, including hybrid integrated circuits (hybrids), to MPROC and Medtronic Europe. MMC was responsible for producing and selling components, including, among other things, hybrid integrated circuits used in Medtronic devices, which were sold by MPROC.

MMC designed and manufactured some integrated circuits in house and purchased certain other integrated circuits, in addition to certain silicon wafers, from third-party suppliers. MMC's hybrid technology and manufacturing equipment was not unique in the electronics industry. Thus, it competed against many third-party suppliers who could manufacture identical, similar, or more advanced component parts for devices. MMC also supplied products to unrelated parties. MMC had its own quality manuals.

MMC also developed the testing systems used at MPROC to do interim and final assembly testing of devices. MMC typically created a new tester for every new device, which was an expensive and very complex process.

[*20] FDA regulations required that MMC have traceability to determine where a problem originated. Medtronic had an integrated information technology function for all of its manufacturing facilities. MMC used the PROMIS Network, which was a traceability system that stored electronically all the information about which suppliers and components were used, the processing time, who processed the parts, and the test data.

c. ADM

Arizona Device Manufacturing (ADM) was in Arizona. During 2005 and 2006 ADM was in its final years as a supplier of component parts including shield assemblies, to MPROC and Medtronic Europe. ADM also served as a middleman between the engineering functions and high-volume manufacturing for devices. ADM had its own quality manuals.

B. Med USA

Med USA is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota. Med USA was a member of Medtronic US' consolidated group. During 2005 and 2006 MPROC sold devices and leads to Med USA for sale into the United States and other jurisdictions. Med USA's CRDM and Neuro sales organizations were responsible for: building relationships with and selling products to customers including physicians; growing their respective markets by

[*21] educating physicians and patients; delivering products to customers for use in surgery; and providing assistance to physicians and patients before, during, and after surgery. Med USA's sales representatives were not medical professionals; rather, they played a support role in surgery by providing technical support for devices and leads to implanting physicians as needed.

During the years at issue the CRDM sales organization consisted of approximately 2,000 sales representatives, and the Neuro sales organization consisted of approximately 200 to 300 sales representatives. Sales staff received base pay and commissions.

C. MPROC

MPROC was incorporated on August 16, 2001, under the laws of the Cayman Islands and is duly authorized to do business in Puerto Rico. MPROC was responsible for, among other things, manufacturing and selling devices (device operations) and leads (leads operations). MPROC manufactured class II and class III medical devices, as defined and determined by the FDA.

MPROC also had a sales branch, known as the Puerto Rico Sales Office, located in San Juan, Puerto Rico, which sold devices and leads in Central America, South America, Puerto Rico, and the Caribbean.

[*22] 1. Background

Medtronic has maintained operations in Puerto Rico since 1974, with the opening of the leads operations in Villalba, Puerto Rico. In 1999 the leads operations expanded to a second facility in which it manufactured CRDM leads and dedicated its older facility solely to the manufacturing of Neuro leads. In 1978 Medtronic opened its first device manufacturing facility in Humacao, Puerto Rico. In 2004 MPROC moved its device manufacturing to a new, expanded facility in Juncos, Puerto Rico. Before August 1, 2001, Med Rel, Inc., and Medtronic Puerto Rico, Inc. (jointly, section 936 possession corporations), were first-tier U.S. subsidiaries of Medtronic US operating as possession corporations pursuant to elections under section 936. Medtronic Puerto Rico, Inc., was incorporated on October 23, 1973, within the U.S. Med Rel, Inc., was incorporated on November 1, 1977, within the United States.

The section 936 possession corporations had access to U.S. intangibles for the purposes of manufacturing and selling Medtronic's medical devices. The section 936 possessions corporations did not independently own U.S. intangibles.

2. Puerto Rico Restructuring

In 2001, in response to Congress' announcement of a phaseout of section 936 benefits, Medtronic US reorganized its Puerto Rico operations into a branch

[*23] of Swiss Holding, a controlled foreign corporation. To accomplish the restructuring, the section 936 possession corporations each made capital contributions in August 2001 to the newly formed MPROC in return for stock. The goal was for MPROC to be one entity and to have the functions centralized. Medtronic also realized there would be tax savings from remaining in Puerto Rico.

On September 30, 2001, Medtronic US made a contribution of capital of all the stock of the section 936 possession corporations to MITI. The section 936 possession corporations each contributed substantially all of their operational assets, including employees, machinery, equipment, land, contracts, and associated liabilities to MPROC in exchange for MPROC stock in a section 351 nonrecognition transaction.

On or around January 25, 2002, Medtronic created a foreign holding company structure to manage the cash earned by Medtronic's foreign manufacturing operations. Swiss Holding was created, under MITI, to own each of Medtronic's major foreign manufacturing locations, including Medtronic Europe, Medtronic Galway, and MPROC. As part of the same transaction Medtronic opted to "check the box" with respect to each of Medtronic Europe, Medtronic Galway, and MPROC so that, although they were corporations from the

[*24] corporate law perspective of the countries in which they were organized, they were "branches" of Swiss Holding for U.S. tax purposes.

During 2005 and 2006 MPROC operated through two local branches: Med Rel Branch (Med Rel) and Medtronic Puerto Rico International (MPRI). Med Rel operated in Humacao, Puerto Rico, and moved to a new facility in Juncos, Puerto Rico, in 2004. MPRI operated two facilities in Villalba, Puerto Rico.

MPROC filed for, and received, a grant of industrial tax exemption from the Office of Industrial Tax Exemption of the Secretary of State of Puerto Rico (grant). The grant, as amended, provided that income from "pioneer products" was not subject to Puerto Rico income taxes; dividends from such income were not subject to income and withholding taxes if MPROC met the conditions in the amended grant; and all income from other products was subject to an income tax at a rate of 2%-7% depending on employment numbers.

During 2005 and 2006 MPROC met the condition in the amended grant and paid no Puerto Rican income tax from CRDM and Neuro pioneer products at issue in this case and no withholding or income taxes on the dividends received from those products. MPROC paid 2% income tax on all other products.

[*25] 3. Operations During 2005 and 2006

MPROC's device and leads operations were FDA-registered facilities that manufactured class III finished medical devices. These facilities were subject to regular premarket and postmarket inspection by the FDA, as well as by international regulatory agencies, and were solely responsible for manufacturing the products ultimately implanted in patients.

MPROC was responsible for its quality compliance, operational excellence, business profitability, innovation, and establishment of annual and three-year strategic goals and objectives. MPROC was responsible for preparing and maintaining internal and management financial reports, monthly financial statements, monthly financial forecasts, annual operating plans, and its general ledger. MPROC also conducted cost accounting and budgeting activities, developed financial and business proposals for capital expenditures, and managed certain treasury and tax functions, including facility insurance, forecasting, cash, tax compliance, and financing ongoing operations.

MPROC was responsible for its information technology systems. Its employees developed software systems that improved the quality of its device and leads operations. These systems were implemented in other Medtronic manufacturing sites, including Medtronic US and Medtronic Europe. The leads

[*26] operations maintained a Therapies and Procedure Training Center which offered onsite training and was used by physicians from South America, the Caribbean, and, in certain instances the United States.

MPROC had a vice president of operations responsible for its management. This individual was in touch with operations in Minnesota, but he ran the MPROC facility. He did not need permission from Medtronic US to make hiring and firing decisions. He made numerous key hires to help grow and unify MPROC. He was able to purchase capital equipment with a price up to $450,000 without approval. In addition, he could approve certain changes in the manufacturing process without approval. If a change was significant, the design team would be notified. Certain design changes would also need approval by the FDA. His role included providing followup to the FDA after a site visit in Puerto Rico. For example, he signed a response and sent it to the FDA after a visit. The response provided detailed information to the FDA about testing issues discovered during the site visit.

MPROC had an advisory council comprising the vice presidents of operations from the various business units that operated in Puerto Rico, plus the Puerto Rico general manager. The goal of the council was to bring the MPROC business units together to communicate about how to best use the businesses in

[*27] Puerto Rico in order to maximize quality, cost, and training. For example, the MPROC council facilitated improvement on Lean Sigma, which was an objective aimed at improving quality while reducing waste in manufacturing.

4. Plants

MPROC operated through two branches, Med Rel and MPRI. Before MPROC, Medtronic US' sites in Puerto Rico were basically independent of each other. MPROC served as an umbrella entity over the sites and reduced redundancy by consolidating and managing the human resources, finance, information technology, and supply chain functions so that the manufacturing sites could concentrate on manufacturing.

5. Employees

During 2005 and 2006 MPROC employed almost 2,300 people across its three sites, with approximately 500 in the device operations and 1,500 in the leads operations. About 70%-75% of those employees worked on the manufacturing lines. Turnover of MPROC's employees was very low. Temporary employees were hired sometimes to address workflow problems.

MPROC employees were not all line employees. There were also numerous engineers, including some who focused on product development. These engineers were involved with project implementation, technology harvesting, and process

[*28] development. They had input in the design review to make sure that a design was possible for manufacturing. Design review frequently resulted in numerous changes and refinements. Design review took place before a design freeze, which occurs when there is agreement on the design. These engineers also worked on new manufacturing technology to ensure that products would be of the highest quality.

MPROC was responsible for its own talent acquisition and management, compensation and benefits, organizational development, hiring, firing, training, disciplinary proceedings, employee relations, and promotion decisions for virtually all positions, including the device operations and the leads operations managers. MPROC's human resources function was also responsible for integrating the employees across all three sites. Operators at MPROC had to receive extensive training to become certified on the various manufacturing processes related to the devices and leads that MPROC manufactured. Certification could take up to three months, depending on the complexity of the particular process.

The process for making devices and leads was very detailed. It required skilled workers. MPROC would fire an employee if a defect could be traced back to the employee's work, even if it was the first mistake. MPROC tested and

[*29] sterilized finished devices and leads. MPROC had the responsibility for inspecting and handling the finished devices or leads and ensuring that each and every component was combined so that the device could provide the patient therapy, repeatedly and reliably. As Medtronic's senior vice president of medicine and technology convincingly testified: "You can have all the essentially great parts you want, but the critical stuff is in the systems engineering. Those things put it together and manufacture it reliably at scale. It's crucial. You don't do that you have no product."

MPROC was involved in every aspect of the manufacturing process. The manufacturing processes for both devices and leads was very detailed and took a week or longer. The products were made in an FDA-regulated "cleanroom" environment. Some processes could not be done automatically but required skilled workers to complete them by hand.

MPROC was not only concerned with being able to produce products at a high volume; it was also concerned that each product be of the highest quality and suitable to place inside a patient. It was difficult to manufacture sensitive medical equipment at a high volume and maintain quality. MPROC employees would participate in core teams where they would partner with Medtronic US through each development phase of new products to ensure that newly developed products

[*30] were manufacturable at commercial scale. The bottom line was that if a finished product could not be made, it could not be sold.

6. FDA Approval Process

FDA regulations require all class III finished medical devices, including the devices and leads manufactured by MPROC, to receive a PMA before they may be marketed in the United States. To obtain a PMA, Medtronic US is required to submit to the FDA an application for the class III finished medical device that includes: full reports of all clinical studies and investigations of the device's safety and effectiveness that have been published or are known to Medtronic US; the proposed labeling for the device; a full statement of the device's components, ingredients, and properties and of the principles of operation; a full description of the methods used in, and facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of the device; and samples of device components. MPROC provided input for the manufacturing sections of regulatory submissions. MPROC received the manufacturing section of the PMA submission packet that had already been drafted, and then reviewed it for accuracy and provided input. For postmarket submissions, MPROC noted, investigated, and corrected deviations from the manufacturing processes that the FDA had approved.

[*31] MPROC and its manufacturing facilities at Juncos and Villalba, Puerto Rico, were subject to regular inspection by the FDA and international regulatory agencies. All three sites were registered sites with the FDA. MPROC personnel were responsible for managing and supervising each of these regulatory inspections, for producing any documents requested during the regulatory inspections, and for providing any written responses to questions arising from the inspections. At the beginning of an inspection, the FDA issues Form 482, Notice of Inspection, to the most responsible individuals at each manufacturing site to ensure that the agency is getting the best information it can from a regulatory perspective. During each inspection of MPROC, FDA Forms 482 were issued to MPROC personnel.

7. Quality

Quality control was a critical aspect of the device and leads operations' success. The device and leads operations had their own quality control teams that developed, implemented, and monitored their quality control systems to ensure that the devices and leads were manufactured to and satisfied all necessary regulatory and quality standards and specifications. The device and leads operations were solely responsible for developing the required validation, inspection, and qualification steps and ensuring that the final manufactured

[*32] devices and leads met these established specifications. MPROC's quality personnel established manufacturing processes and instructions, incorporating visual inspections, quality checks related to tolerances, and sterilization. The quality assurance system had controls in place to prevent operators from performing manufacturing processes without having been properly and fully certified to do so. MPROC had the responsibility of determining whether a device or lead met the applicable regulatory standards and whether it was ready for implantation in the human body.

MPROC was responsible for its own quality organization. MPROC had its own quality committee consisting of quality managers from the different facilities in Puerto Rico. MPROC's vice president of operations created the quality committee in order to foster best practices and standardize processes.

MPROC wrote its own quality manual and had its own quality council. The quality manual included processes to ensure compliance with FDA standards and the European Medical Device Directive. Medtronic's vice president of quality and regulatory did not review or oversee the publication of this manual. The Medtronic corporate office also did not have a role in creating this manual. The MPROC quality committee was responsible for overseeing FDA site visits.

[*33] To comply with the requirements of 21 C.F.R. sec. 820 of the FDA's Quality System Regulation, MPROC's quality systems were both extremely broad in scope and detailed. Its systems covered numerous aspects of product quality, including incoming inspection, sterilization, corrective and preventative action (CAPA), and complaint handling, as well as the environmental, health and safety function, process excellence, the product traceability process, nonconformance evaluations, internal audits, product hold orders, management reviews, and the management of material review requests.

The CAPA program was especially important. Each of MPROC's sites independently maintained a CAPA board, which managed the CAPAs and decided whether to open or close a case on the basis of a quality complaint. If a CAPA was opened, the goal was to investigate, understand, and resolve the problem. Only the finished goods manufacturers, such as MPROC or Medtronic Europe, would instigate a CAPA. The components manufacturers, such and MMC or MECC, would become involved only if, through the CAPA investigation, MPROC discovered a problem at the components manufacturing level. If the components manufacturers became involved, MPROC would still manage the CAPA and the interaction with the supplier.

[*34] The CAPA program ensured continuous improvement to the quality and effectiveness of MPROC's products as well as its manufacturing operations. By understanding the cause of any reworked, defective, or rejected devices or leads, or any problems that might arise with respect to a manufacturing process, similar or related problems could be avoided in the future. MPROC was responsible for conducting all investigations of CAPA events and complaints for product issues that originate at MPROC.

MPROC plants participated in "Quality Days". These events were coordinated within CRDM. Patients would be invited to the plant where their medical devices were made. These days were often viewed as a celebration of achievement.

D. Medtronic Europe

Medtronic Europe was incorporated on September 25, 1995, establishing operations in Tolochenaz, Switzerland, in the Canton of Vaud. Medtronic Europe manufactured devices primarily for sale outside the United States market. Medtronic Europe did not manufacture leads. The manufacturing operations of Medtronic Europe were limited compared to MPROC's, and it could not produce a volume of devices similar to MPROC's.

[*35] III. Intercompany Agreements

Medtronic US and Med USA entered into various agreements and amendments with MPROC that were effective during 2005 and 2006.

A. Devices and Leads Licenses

Medtronic US and MPROC entered into license agreements, effective as of September 30, 2001, for the intangible property used in manufacturing devices (devices license, as amended over the years) and leads (leads license, as amended over the years) (jointly, devices and leads licenses). The devices license was for products in the following businesses: bradycardia pacing, tachyarrhythmia (tachy) management, and neurological stimulation. The leads license was for products that induce medical therapy delivery devices, which include electrode leads for implantable pulse generators and implantable cardioverter defibrillators, and neurostimulation electrode leads. Under the devices and leads licenses, MPROC obtained the exclusive right to use, develop, and enjoy the intangible property used in manufacturing devices for sale to customers in the United States and its territories and possessions, and leads for sale to customers worldwide. The intangible property comprised Medtronic US-developed inventions, secret processes, technical information, and technical expertise relating to the design of the devices and leads and all associated legal rights, including patents, trade

[*36] secrets, know-how, copyrights, and product regulatory approvals. The devices and leads licences also defined "improvements" as "any finding, discoveries, inventions, additions, modifications, formulations, or changes" made during the terms of the respective licenses by either Medtronic US or MPROC. MPROC agreed as part of these licenses to meet the quality control standards established jointly by Medtronic US and MPROC.

The device and leads licenses specifically include requirements about quality. Both agreements state:

> Section 2.4 Quality
>
> a. Product sold by Licensee shall meet the quality control standards and specifications established jointly by Licensor and Licensee, including any requirements of any applicable regulatory agencies.
>
> b. In the event that quality control of Licensee falls below the agreed upon standards and specifications, Licensor shall give Licensee written notice of such failures, and Licensee shall, at its expense and within a reasonable period set out in the notice, take such corrective action as is necessary to restore quality to the appropriate level.

In accordance with the devices and leads licenses, MPROC agreed to pay what Medtronic US and MPROC determined to be an arm's-length royalty of 29% to Medtronic US on its U.S. net intercompany sales of devices and 15% to Medtronic US on its net intercompany sales of leads.

[*37] The initial terms of the device and leads licenses were through April 30, 2003, and were renewed effective May 1, 2003 and 2004. The amendments effective May 1, 2003 and 2004, renewed the licenses through April 30, 2004 and 2005, respectively.

On May 22, 2007, Medtronic US and MPROC entered into amended and restated license agreements effective May 1, 2005. The amendments were made to reflect agreements reached in a memorandum of understanding (MOU) between Medtronic and respondent, which will be discussed in detail in a later section. The remaining terms of the devices and leads licenses remained in place. The amended agreements included a profit split methodology that changed the royalty rates. MPROC would pay a 44% royalty rate to Medtronic US on its net intercompany sales of devices and a 26% royalty to Medtronic US on its net intercompany sales of leads.

B. Components Supply Agreement

Medtronic US and MPROC entered into the components supply agreement, effective September 30, 2001. The components supply agreement was in effect during 2005 and 2006. Pursuant to the components supply agreement, MPROC agreed to purchase certain components from Medtronic US, including from MMC and MECC, for use in manufacturing devices and leads. "Components" include

[*38] hybrids, batteries, feedthrus, capacitors, connector modules, and electrode tips. Pursuant to the components supply agreement, Medtronic US' product liability risk from the components made by MMC and MECC was limited to the purchase price of the components it sold to MPROC. It stated that "[Medtronic US] shall have limited responsibility for any claim for damages or breach of warranty with respect to Components or Materials sold to [MPROC]. * * * Such responsibility shall be limited to the price paid by [MPROC] for the Component or Material."

C. Distribution Agreement

MPROC and Med USA entered into an undated distribution agreement with a stated effective date of September 30, 2001. The distribution agreement was in effect during 2005 and 2006. Under the distribution agreement MPROC appointed Med USA as a distributor in the United States for the devices that MPROC manufactured and as a distributor in the United States, Central America, South America, and Japan for the leads that MPROC manufactured. Pursuant to the distribution agreement Med USA was protected from any product liability risk potentially arising from products manufactured and sold by MPROC.

[*39] D. Trademark License

Medtronic US and MPROC entered into a trademark and trade name license (trademark license) effective September 30, 2001, which granted MPROC the right to use Medtronic US trademarks and trade names: (1) for devices in the United States, its territories and possessions and (2) for leads in the entire world. MPROC was to pay Medtronic US a royalty of 8% of MPROC's net intercompany sales of leads. MPROC agreed to pay Medtronic US a 5% royalty of product sales by MPROC to unrelated parties. The trademark license was in effect during 2005 and 2006.

IV. Swiss Supply Agreement

Medtronic US, MPROC, and Medtronic Europe entered into the Swiss supply agreement, effective as of May 1, 2002, which was in effect during 2005 and 2006. Under the Swiss supply agreement Medtronic Europe agreed to use its manufacturing operations in Tolochenaz, Switzerland, to assist MPROC by manufacturing and supplying the United States with devices when necessary to meet excess demand in the United States. The Swiss supply agreement provided that Medtronic Europe would pay Medtronic US directly an amount equal to the royalty that MPROC would have paid to Medtronic US if MPROC had manufactured the product and had made the sale itself. Medtronic Europe also

[*40] agreed to pay Medtronic US directly an amount equal to the MPROC trademark royalty that MPROC would have paid to Medtronic US if MPROC had made the sale itself.

V. CRDM and Neuro Business Units

A. CRDM

During 2005 and 2006 Medtronic's CRDM unit was the world's leading seller of cardiac rhythm stimulation devices. Medtronic's CRDM business focused on managing the entire spectrum of cardiac rhythm disorders to improve long-term patient care through products that restore and regulate a patient's heart rhythm and improve the heart's pumping function. Its products were devices, leads, and the associated delivery systems for the devices.

CRDM had a vice president for operations and quality who was responsible for implantable manufacturing operations, supply chain, quality, and regulatory compliance. During 2006 CRDM separated regulatory and quality from operations and quality and created a vice president of CRDM quality and regulatory. CRDM implemented quality guidelines.

1. Manufacturing

In general cardio devices have three primary components: implantable pulse generators (IPGs), leads, and programmers. IPGs are battery-powered

[*41] computer-based devices that continually monitor the heart, analyze cardiac signals, and apply therapeutic actions based on their programming algorithms. Leads are flexible sets of wire that connect the IPGs to the heart. Leads connect at one end to the heart and at the other end to the IPG. Programmers are external devices that communicate through the skin to the IPG to obtain information from the IPG regarding its activities. Programmers were manufactured by an outside vendor and are not relevant to this case.

a. Devices

CRDM device products consisted primarily of: bradycardia pacemakers, also known as IPGs; tachy devices, also known as ICDs; and CRT devices. IPGs treat abnormally slow heart rates. ICDs treat abnormally fast heart rates. ICDs also have capacitors as a component. CRTs treat insufficient blood flow and uncoordinated pumping of the heart's chambers.

During 2005 and 2006 the device operations at MPROC built more than 40 different models of devices and approximately 250,000 to 280,000 devices per year; it was the primary or sole manufacturer of most models of devices sold in the United States. Devices comprised approximately 750 individual components, which were purchased from third parties as well as from MMC and MECC. CRDM had its own quality manuals.

[*42] The device operations made complex pieces of electronic machinery that are extremely difficult to manufacture. The process was labor and capital intensive and time consuming and required numerous quality checks. Manufacturing a device was a multistep process in which a hybrid, a battery, a capacitor, a connector, and other components were constructed within a metal shield. There were approximately 40 total steps in the manufacturing of a device. Depending on the complexity of the particular device, manufacturing could take 7 to 14 days to build a single device.

While the device operations used automated processes to manufacture devices, they relied on employees to verify those automated processes, to perform multiple quality inspections throughout each manufacturing stage, to complete significant portions of the processes manually, and to oversee and troubleshoot all manufacturing processes generally. Highly trained and skilled operators oversaw all manufacturing processes. MPROC had to use extreme care to interconnect the various components of the device, ensure that the device was hermetically sealed, and sterilize the device. With regard to the interconnect welding step of the device manufacturing process, for example, operators had to painstakingly inspect the welding that took place at each and every preceding step of the device manufacturing process for any discoloration or damage. On account of the

[*43] stringent quality standards that class III finished medical devices must meet, the device operations maintained a detailed traceability system of each step of the manufacturing process in the event that it needed to trace a quality problem to its source in the manufacturing process.

MPROC was responsible for the sterilization of finished devices--a critical process because none of the components were sterilized. Harmful microorganisms had to be killed before a device could be implanted in a patient.

b. Leads

CRDM products included leads, highly complex "wiring" systems that connect devices to the human body and deliver therapies. Leads are the devices that transmit therapies from a device to the heart via electrical signals and information about the heart's activity from the heart to the device. Leads are thin wires insulated with silicone or polyurethane and implanted into the right atrium, right ventricle, or left ventricle of the heart.

Because CRDM leads are implanted in a patient's heart, removing the lead because of a product quality problem can be an extremely difficult procedure. After implant, fibrous tissue forms around the lead, around the nearby blood vessels, and within the heart. Leads were not designed to be extracted from the human body. When a product quality problem occurs, the physician and the

[*44] patient must determine whether to leave the lead in the patient's body or, if the severity of the problem requires it, or the patient demands it, to remove the lead through an "extraction" procedure. In the case of CRDM leads, an extraction was the most risky procedure an electrophysiologist could perform on a patient. On average, there was a 1% chance that during an extraction the procedure would tear a major vessel or make a hole in the patient's heart, either of which can be fatal.

c. Processes and Improvements

Even after a new product had been approved by the FDA and introduced into the marketplace, MPROC continued to suggest and implement improvements to the manufacturing process and product design in order to improve product quality. MPROC was responsible for determining what manufacturing process improvements were needed to make to the products it manufactured. MPROC was also responsible for determining whether changes that it made to the manufacturing process required reporting to the FDA and other regulatory agencies and, if so, for reporting those changes to Medtronic US for submission to the regulatory agencies. While FDA and other such regulatory approval may be required before MPROC may implement a change, Medtronic US did not need to approve the change and lacked the manufacturing expertise to do so. Medtronic

[*45] US' role was limited to a review of the process improvement, and to compiling the regulatory submission, if necessary.

Examples of MPROC's manufacturing process improvement activities during 2005 and 2006 included: implementing a laser ribbon bonder; resolving manufacturing problems that caused damage to a molded component that included a steroid drug on a particular lead; and eliminating wrinkling in leads. For example, MPROC developed the second generation of the laser ribbon bonder, a machine that connects components within devices through the use of laser welding and indium ribbon. MPROC's engineers also developed a method to translate the manufacturing process from the first generation of the machine, which used older, less accurate technology, to the newly developed machine, eliminating the need for design assurance testing and thereby reducing considerably expenses. While MPROC patented certain process innovations, many of its projects are protected by Medtronic as trade secrets.

d. Components

MPROC was responsible for managing its supplier relationships. MPROC worked to ensure that its suppliers were in compliance with FDA regulations. MPROC's device operations inspected incoming raw materials, components, and other supplies purchased from its suppliers, including MECC, MMC, and third

[*46] parties, on behalf of itself, the leads operations, and Medtronic Europe. This inspection function was an integral part of MPROC's product quality control process. MPROC worked with MMC, MECC, and third-party supplies to address quality problems related to components.

MPROC was responsible for managing its manufacturing resources and deciding how to fill each purchase ordered. MPROC managed its own production schedules and forecasts to determine their raw materials and supplies. There was no guaranty that Med USA would purchase all of MPROC's products.

2. Research and Product Development

Core teams were in charge of Medtronic US' product development, which included several phases: business analysis, commitment, development, evaluation, and market release. A Medtronic US core team, made up of specialists in development, regulatory, clinical, manufacturing, quality, finance, human resources, product planning and marketing, and supported by an extended team, was responsible for the development of a new product, from the initial concept to delivery to the patient. Design for Reliability and Manufacturability (DRM) was a foundational concept for product quality and represented the interaction during product development between the manufacturing engineers at MPROC and product design engineers at Medtronic US. The interaction ensured that products

[*47] could be designed and manufactured at commercial scale repeatedly, reliably, and at the highest levels of quality. Manufacturing products at a high-volume, commercial scale in the implantable medical device industry was particularly difficult and challenging. Thus, MPROC's DRM input was critical to ensuring that any new product could be commercially manufactured with maximum reliability and quality. Even if a product could be manufactured during the development phase, there was no guaranty that it could be manufactured reliably at commercial scale in a high-volume manufacturing environment. This "scale-up" of devices and leads to commercial levels took place at MPROC.

MPROC employees made key contributions during the business analysis phase of product development. MPROC determined the technologies available to manufacture the proposed product. These employees also helped develop new technologies and performed assessments of cost and manufacturability.

Once a business analysis was completed and product development progressed, the core team committed to developing the new product into a commercially manufacturable product. MPROC employees helped develop the manufacturing and implementation plan, including a timeline for all of the activities required to bring the new product to market.

[*48] Once the development phase of a product began, MPROC employees were responsible for developing repeatable, reproducible, and reliable manufacturing processes with regard to each new product and developing appropriate tools and fixtures. These employees provided guidance on product specifications and helped develop process operations descriptions.

For example, MPROC helped develop an MRI-safe lead. This was an important development because it allowed for an MRI to be taken safely of a patient who had a lead inserted. MPROC's engineers determined that a coiled conductor was not reliably manufacturable at a high volume. They subsequently developed a successful new conductor.

After a new product was developed, it was evaluated and tested. MPROC helped with the evaluation phase by providing support for clinical trials. MPROC wanted to ensure that the product developed in the development phase would be effective over time. MPROC would run yield tests on the products to make sure that they could be produced at a certain rate. The tests would be acceptable only if they came back with a 100% success rate.

3. Marketing

Medtronic's CRDM marketing function was responsible for product planning, i.e., the marketing group determined the unmet needs in the market for

[*49] CRDM therapies through market research, advisory groups, focus groups, and engagement with the sales force in the field. The sales force received daily feedback from physicians. Product innovation was important to Medtronic's mission. Marketing had a lot of input into determining the pricing for Medtronic's new products, which depended on the degree of innovation, reimbursement rates, and the average selling price of existing technologies. Marketing helped estimate revenue for new products and provided input on technological risk, competitive features risk, and speed-to-market risk. Marketing also provided segmentations, such as those explaining the differences between commodity buyers, who are more focused on price, and technology buyers, who are more interested in additional features, and cardiologists versus electrophysiologists. Marketing also evaluated how Medtronic's products stacked up against the competition's.

When there was a recall, or "field action", marketing was involved in developing and was an approver of the field communication plan that conveyed the information to the sales force and the physicians. The vice president of marketing was personally involved in developing the materials used to brief the doctors on the recalls.

[*50] At the beginning of 2005 marketing had at least 255 employees, all of whom were based in the United States. By the end of 2006, marketing had at least 293 employees, all of whom were based in the United States.

4. Sales

Sales representatives performed CRDM sales through the distribution agreement with Med USA. Sales representatives underwent both initial sales and technical training for about 18 months. Training involved study at home and at Minnesota facilities. CRDM instructors and outside physicians participated in the training at the Minnesota facilities by observing and working in the field with experienced representatives during implants, taking qualifying tests, working with a partner in the field before certification as "implant ready", and getting continuing education about new features and new products, which required more certifications before getting permission to sell. Sales representatives and clinical specialists reviewed a patient's problems with a physician in order to support the physician with the choice of a device, then supported the physician during the implant and ensured that the device was working properly by taking electrical measurements, and then provided postoperative followup support. CRDM clinical specialists had similar roles as sales representatives in working directly with physicians but did not have sales responsibility.

[*51] CRDM devices and leads came with extensive manuals, which sales representatives were required to be familiar with in order to answer any physician questions. Sales representatives were expected to know CRDM products, including product data and features. They were familiar with CRDM materials that compared the capabilities of the CRDM devices and were able to explain the differences to physicians. Sales representatives were also expected to know and explain to physicians how the features of CRDM products compared to those of competitors. Sales representatives were not responsible for ensuring that the CRDM products worked before they were sterilized and put into the final packaging.

B. Neuro

Medtronic's Neuro business included implantable neurostimulation devices (neuro devices) and leads that delivered electrical stimulation from neuro devices to the spinal cord, nervous system, or brain. The devices and leads delivered drugs or electrical stimulation to the spinal cord, brain, or other parts of the nervous system to treat pain, movement and other disorders, including Parkinson's disease, essential tremor, chronic pain, and spasticity. Neuro devices included: battery-operated generators; leads that connect the generators to the spinal cord,

[*52] brain, or the nervous system; and programmers to communicate with the generators or recharge the batteries.

Neuro's products were often used to treat chronic back and leg pain, complex regional pain, and neuropathy through spinal cord stimulation therapy. In spinal cord stimulation therapy, neuro leads were attached to specific parts of the spinal cord. The therapy functioned by blocking pain messages to the brain with electrical impulses to the epidural space near the spinal cord.

Neuro's products used in deep brain stimulation safely and effectively managed some of the most disabling movement disorders, such as Parkinson's disease, essential tremor, and dystonia. Leads were placed in targeted areas of the brain, and the amount of electrical stimulation was adjusted to meet the patient's needs. Neurosurgeons, neurologists, pain management specialists, and orthopedic spine surgeons used these products.

1. Manufacturing

The manufacturing process for Neuro's devices and leads was similar to the process for CRDM. Changes in the processes were due to different specifications of the products.

[*53] a. Devices

Neuro's devices were made in the Juncos facility in Puerto Rico. The process was very similar to the process for CRDM's devices. The specifications and applications of Neuro's devices were different from those of CRDM's devices.

b. Leads

The production of leads was extremely complicated and labor intensive. The Villalba facility was the only Medtronic facility manufacturing leads in high volume. Leads manufacturing was an almost completely manual process, performed within tight tolerances, and required skilled labor to join raw materials using lasers and adhesives. It could take up to several weeks to manufacture a single lead, and there could be over 100 steps in the manufacturing process. Each manufacturing step, after the first, began with a review of the quality of the work performed in the prior step. The manufacturing process for even the subassembly of a single portion of a lead, such as the outer assembly of the lead, comprised approximately 20 steps. In addition to interim quality reviews, there were as many as 50 quality tests throughout the leads manufacturing process, depending on the complexity of the particular lead. The leads operations maintained a detailed

[*54] traceability system of each step of the manufacturing process in the event that it needed to trace a quality problem back to its source.

The leads operations were responsible for specifying, purchasing, validating, and installing the equipment needed to manufacture leads. Neuro leads did not use any components from MMC or MECC. Some equipment used in manufacturing leads was custom designed to specifications established by the leads operations and built specifically for the leads operations. New equipment was subject to testing and required not only Medtronic but FDA and other regulatory agency approval before it could be used in the manufacturing process.

The leads needed to be sterilized upon completion in order to kill harmful microorganisms before the leads were implanted in a patient.

c. Components

MPROC was responsible for specifying, purchasing, and installing the equipment necessary to manufacture leads. Some of this equipment was designed by MPROC and often required FDA approval.

2. Research and Product Development

Neuro's product development efforts included developing new products and improving existing products. Product Development and Technology (PD&T) handled product development and research within Neuro. PD&T had over 100

[*55] employees, almost all in Minneapolis. For a new Neuro product, product feature, or technology, Neuro research evaluated whether the desired outcome for a physician and a patient could be obtained and then developed a product platform. PD&T had engineers and others who worked on software and circuits and participated on Neuro development teams. PD&T worked with core operations on operational strategies for product development and manufacturing. Neuro also did design verification in engineering laboratories in Minnesota. An organization within PD&T handled technology projects, i.e. research and exploratory activities on unproven ideas before formal product development.

3. Sales

Neuro sales representatives were hired on the basis of their level of compassion, experience, and communication skills. Training for Neuro sales representatives was extensive and included various stages, such as ongoing continuing education and evaluations of up-to-date knowledge of current technology. Multistage training was crucial for supporting physicians during implants. The representatives had to be aware of clinical studies and product specifications. Neuro sales representatives, who typically had seen more implants than most physicians, were the clinical and technical experts with Neuro's technology.

[*56] Physicians consulted with the sales representatives about implants. Sales representatives and physicians worked together to ensure that the device parts fit together and were positioned properly. An implant did not take place without the effective participation of a Neuro sales representative. These representatives needed the courage to speak up during an implant if it was not being done correctly. Neuro sales representatives participated in the postimplant programming of a device and educated the patient on how to use the technology. The quality of credible advice given by a trusted Neuro sales representative to physicians was essential to maintaining Neuro's brand and the physician's reputation for using safe and effective devices.

Sales representatives were not responsible for ensuring that Neuro products worked before they were sterilized and put into the final packaging.

VI. Pacesetter Agreement

In the late 1980s and early 1990s Medtronic US and Siemens Pacesetter, Inc. (Pacesetter), were engaged in patent litigation related to Medtronic US' patents for many of its cardiac rhythm stimulation devices, including patents underlying its pacemakers' rate-responsive technology that monitors and adapts to changes in cardiac rhythm. As part of the patent litigation, Medtronic US had won a successful court ruling that its patents were valid and being infringed on by

[*57] Pacesetter. Pacesetter was facing an injunction barring it from selling its own rate-responsive pacemakers. In the fall of 1991 through spring of 1992 Medtronic US and Pacesetter reached a resolution of the lawsuits and negotiated the Pacesetter agreement and the settlement agreement. After a tentative deal had been reached on May 26, 1992, Medtronic US' senior vice president and general counsel presented the proposed terms to Medtronic's board of directors, recommending that Medtronic accept the deal. Medtronic US projected that it would receive from Pacesetter total royalty payments of $200 to $300 million over the life of the agreement. Medtronic US and Pacesetter finalized the terms of their agreement in August 1992, and Medtronic's board of directors approved it on August 26, 1992.

At the time Medtronic US and Pacesetter negotiated the Pacesetter agreement, Siemens AG (Siemens), Pacesetter's parent company, had worldwide revenue of approximately $50 billion, including medical revenue (pharmaceutical, capital equipment, and medical device revenue) of approximately $5 billion. Siemens competed against Medtronic as one of the largest medical device companies in the world, manufacturing and selling cardiac pacing products as well as other medical device products. Siemens operated its cardiac pacemaker business through Pacesetter. In its 1993 fiscal year Pacesetter controlled

[*58] approximately 20% of the IPG market (the second largest market share at the time) and had revenues attributable to the sale of pacing devices of approximately $314 million. Moreover, Pacesetter was expected to become a more significant player in the tachy business by acquiring or developing its own tachy technology.

As part of the Pacesetter agreement, and to "buy peace", the parties agreed to cross-license their pacemaker and patent portfolios. Medtronic US attributed no value to the Pacesetter patents it received as part of the cross-license. Pacesetter agreed to pay Medtronic US $50 million up front and $25 million in royalty prepayments upon execution of the Pacesetter agreement. Thereafter, Pacesetter agreed to pay Medtronic US a 7% royalty on the sale in the United States of all cardiac stimulation devices or components (as defined by the Pacesetter agreement) and a 3.5% royalty on all sales outside the United States.

The initial term of the Pacesetter agreement was for 10 years, beginning in August 1992. The parties agreed to extend the term of the agreement if it was transferred to another party. In September 1994 St. Jude acquired Pacesetter from Siemens, and St. Jude became the assignee of Pacesetter's rights under the Pacesetter agreement. Accordingly, the term of the agreement was extended beyond the initial 10-year term, and St. Jude continued to pay royalties to

[*59] Medtronic US under the Pacesetter agreement through Medtronic US' 2005 fiscal year.

Pursuant to the agreed-upon 7% royalty rate, Medtronic US received approximately $506 million in royalty payments over the life of the Pacesetter agreement. The amount Medtronic US received exceeded its initial expectations of the total royalty payments it would receive from the Pacesetter agreement. The 7% royalty rate achieved in the Pacesetter agreement was the "most lucrative" deal Medtronic US had ever achieved and remains one of the highest royalty rates in the pacemaker and defibrillator industry to date.

VII. Product Recalls

Companies in the implantable medical device industry that encounter significant product quality problems face a number of direct and indirect expenses as a result. These costs include: the inherent risk to patients; a negative effect on the company's reputation; loss of market share; a decrease in the affected company's stock price; a shrinkage of the overall size of the market; legal settlement costs; direct product costs, such as writing off the affected inventory; distracted sales representatives; potential defection of sales representatives to competitors and related costs to keep sales representatives; other remediation costs relating to the product recall; and the distraction of management from long-term

[*60] company goals. Reflecting the risk that product reliability poses, the history of the implantable medical device industry is littered with companies that were adversely affected, acquired by competitors, or driven out of business altogether because of actual or perceived significant product quality problems.

The recall of Medtronic's Xytron pacemaker in the 1970s was, for example, a significant product quality problem that caused Medtronic's IPG market share percentage to fall from the mid-70s to the high-30s.

The experience of another company, Telectronics, is a further example of significant product quality problems that had devastating effects on companies in the implantable medical device industry. In 1994 Telectronics encountered a quality problem related to its Accufix-J lead, which, in certain instances, literally punctured the heart and caused patient deaths. Telectronics' recall of its Accufix-J lead caused its U.S. sales to fall by over 50% between 1994 and 1995 and its market share to fall by almost 50% over that same period. In May 1995 the FDA issued a consent decree to Telectronics that remained in effect until June 1996, requesting that Telectronics halt the shipment of all of its IPGs and associated leads to U.S. customers. Telectronics was no longer a viable company and was eventually acquired by St. Jude.

[*61] In 2005 Medtronic issued a recall of certain of its Marquis family of ICD and CRT devices because of a problem that sometimes led to the battery's draining too quickly. This caused a concern that the Marquis ICD or CRT might fail to deliver appropriate therapy when the patient needed it, a failure which could be fatal. The Marquis recall forced Medtronic to divert significant research, development, and other resources to address the underlying problem. Physicians paid careful attention to Medtronic's response to the Marquis problem to ensure that it had been resolved and would not be "carried forward into other products that * * * [they] were implanting." The Marquis recall was the first significant recall in the implantable medical device industry in almost a decade. The only reason that Medtronic did not lose market share as a result of the Marquis problem was that its competitor, Guidant, sustained a rash of recalls of its own as a result of product quality problems during the same time period. Medtronic nevertheless faced significant class-action litigation on account of the Marquis recall and sustained substantial out-of-pocket product liability expenses per year during 2005 and 2006 (in addition to legal costs) related to that litigation. Medtronic ultimately settled the Marquis class-action litigation. MPROC bore these out-of-pocket costs for the Marquis devices it made.

[*62] Shortly after the Marquis recall in 2005, Guidant, the clear-cut second-leading implantable medical device manufacturer, issued a series of recalls related to its Prizm family of ICDs. Guidant recalled over 60,000 ICDs following the failure of these ICDs to deliver therapy appropriately to patients. Following these recalls Guidant's ICD and CRT market share declined from 38% to 25%, and Guidant experienced a reduction of approximately 21% of its originally anticipated sale price to Johnson & Johnson. While Boston Scientific ultimately acquired Guidant, Boston Scientific's market share then languished between 22% and 28% through 2010. Boston Scientific also recorded goodwill impairment charges of over $2 billion associated with its U.S. cardiac rhythm business unit, and was forced to pay more than $550 million to settle the various civil and criminal claims related to Guidant's 2005 ICD recalls.

In 2007 Medtronic recalled its Sprint Fidelis ICD leads following the discovery of a product quality problem that caused affected Fidelis leads to inappropriately "shock" the heart. (ICDs monitor the heart for irregular heartbeats and, if an irregular heartbeat is detected, shock the heart through the delivery of electrical therapy via the lead to restore normal heart rhythm.) The inappropriate shocks from the Fidelis leads were akin to "being kicked in the chest by a horse." Patients could be shocked hundreds of times as a result of the underlying product

[*63] quality problem. One patient, for example, was shocked 42 times consecutively during a camping trip and had to have his Fidelis lead "immediately explanted". Some patients died as a result of the inappropriate shocks. Approximately 200,000 patients had been implanted with Fidelis leads at the time of the recall. The product quality problem underlying the Fidelis leads posed immense challenges to the physicians who had implanted the leads, as they were forced not only to address the needs of their affected patients but also to explant many of the affected Fidelis leads. Medtronic voluntarily suspended distribution of the Fidelis leads.

The Fidelis recall had a profound effect on Medtronic, severely harming Medtronic's reputation with physicians. It caused Medtronic to reduce its sales force significantly on account of the contraction in the overall ICD market due to the collective product quality problems of Medtronic and Guidant. The Fidelis recall further contributed to a marked decrease in the number of initial implants in the ICD and CRT market, which had not yet recovered more than five years later. The Fidelis recall also cost Medtronic vast sums of money attributable to increased replacement implants. The Fidelis recall caused Medtronic to lose billions in market capitalization in the days following the recall. While Medtronic had over a 50% market share in the CRT space just before the Fidelis problem transpired,

[*64] following Fidelis, that percentage fell by approximately six percentage points. Afterwards, physician-customers routinely split their purchases roughly evenly among the three major medical device manufacturers, resulting in a loss of sales for Medtronic.

MPROC suspected that there might be quality problems related to the Fidelis leads when it began production, because it experienced much lower yields in manufacturing Fidelis initially, which can be symptomatic of potential product quality problems. Once high-volume production had commenced, MPROC's manufacturing engineers continued to suggest design and manufacturing refinements that, although incorporated, were not enough to stave off the recall. The Fidelis quality problems involved both design and manufacturing.

Following the Fidelis recall, MPROC played a significant role in ramping up production of the predecessor Sprint Quattro lead to ensure that patient needs were met. Before the recall, Fidelis leads constituted approximately 80%-90% of the total volume of high-voltage leads that the leads operations manufactured, while Sprint Quattro leads represented the remaining 10%-20%. The leads operations were responsible for both developing and implementing the recovery plan that substituted Sprint Quattro lead manufacturing for the former Fidelis leads over the course of three months, ultimately meeting worldwide demand and

[*65] achieving the recovery plan's goals. MPROC bore responsibility for stopping production of all Fidelis leads and issuing a product hold order to ensure that no additional Fidelis leads were shipped out to the distribution sites.

Because of the recalls in the industry in the mid-2000s, physicians began to increasingly divide their use of devices among the various companies. This was referred to as the "splitter mentality". Physicians did not want all their patients to have the same device in case there was a recall.

The goal of Medtronic US' claim management process was to minimize the frequency and severity of litigation. The CRDM and business legal groups tried to resolve claims by patients represented by counsel. This approach led to settling more claims up front, and fewer claims went to litigation.

VIII. Audits and Notice of Determination

A. MOU

In an audit of petitioner's 2002 tax return, respondent analyzed the devices and leads intercompany transactions and the transfer prices among MPROC, Medtronic US, and Med USA, as well as the 2002 restructuring of Medtronic's operations in Puerto Rico. At the conclusion of the examination, respondent accepted the comparable uncontrolled transactions (CUT) identified by petitioner

[*66] and its adviser, Ernst and Young, LLP (EY), but adjusted the transactions to increase their "profit potential".

EY determined what petitioner considered to be an arm's-length royalty rate for the devices and leads licenses as well as for the trademark licenses. EY relied on the CUT method to determine royalty rates of 29% on intercompany sales of devices and 15% on intercompany sales of leads. EY determined that a royalty rate of 8% for the trademarks was arm's length.

Respondent was concerned that too much profit was being shifted to MPROC. He made adjustments based on a report of IRS industry economist Jeff Goodman titled "Economic Analysis of Intercompany Transactions between Medtronic Inc. and Medtronic Puerto Rico Operations Company". Goodman's report concluded that the CUT was not the best method for the intangibles licensed to MPROC. In the light of respondent's view, petitioner agreed to make changes to its original CUT.

The Puerto Rico MOU reflected an agreement at the end of the audit which was royalty rates of 44% for devices and 26% for leads to be paid by MPROC on its intercompany sales. The Puerto Rico MOU also included a profit split methodology that calculated the combined profit from manufacturing and distribution (system profit) that Medtronic US, MPROC, and Med USA were to

[*67] earn on sales of products manufactured and sold by MPROC. The purpose of the profit split methodology was to test the results of the transactions among the related parties and ensure that MPROC's profits were within a range agreed upon with the Commissioner. Specifically, the agreed system profit for MPROC was 38% for devices and 45% for leads, with the acceptable range extending to 3% on either side of the target--35%-41% for devices and 42%-48% for leads. Medtronic and respondent agreed in the Puerto Rico MOU that they would apply the Puerto Rico MOU to 2002 and all future years and that Medtronic would apply the "agreed royalty rates on its as filed tax returns, and the Internal Revenue Service would respect those royalty rates, as long as there are no significant changes in any underlying facts".

During respondent's examination of petitioner's 2002 tax return, he also valued certain assets and liabilities contributing to the going concern business value of Medtronic's then U.S. subsidiaries, the section 936 possession corporations. Respondent issued an engineering and valuation report prepared by an Internal Revenue Service engineer, Victor Venske, titled "Fair Market Value of Going Concern Business Assets of Med Rel and MPRI Branch Operations of Medtronic, Inc. located in Puerto Rico", dated June 24, 2005 (Venske report). In reliance on the Venske report, respondent concluded that workforce-in-place,

[*68] goodwill, and going concern value were contributed to MPROC and had a fair market value of $22,891,774. Respondent asserted that the assets that he determined were received by MPROC should be amortized over their 20-year life pursuant to section 367(d) and should be included proportionately in Medtronic US' income annually.

Medtronic accepted respondent's section 367(d) adjustments and, in accordance with the Venske report, included an additional $667,677 for 2002 for seven months of amortization and $1,144,589 annually in income for 2003 through 2006.

Following the completion of respondent's 2002 examination, petitioner applied the royalty rates established by the Commissioner, and tested the system profit of Medtronic US, Med USA, and MPROC, in reliance on and in accordance with the methodology set forth in the Puerto Rico MOU. He examined petitioner's 2003 and 2004 tax returns and agreed to the application of the Puerto Rico MOU. He did not identify any material changes in facts or law concerning the parties' operations.

B. 2005 and 2006 Tax Returns

Petitioner filed timely its 2005 and 2006 tax returns using the Puerto Rico MOU. To implement the Puerto Rico MOU, petitioner first applied the original

[*69] CUT royalty rates of 29% for intercompany sales of devices and 15% for intercompany sales of leads. Medtronic determined that the appropriate arm's-length royalty payments for devices and leads were $478,880,173 in 2005 and $712,761,701 in 2006. Petitioner then applied the increased royalty rates (44% for devices on intercompany sales and 26% for leads on intercompany sales) and the profit split methodology in reliance on respondent's determinations set forth in the Puerto Rico MOU. After applying the profit split methodology petitioner reported additional royalty income on its Schedules M-3 attached to its 2005 and 2006 tax returns. Medtronic US' total royalty income from the device and leads licenses as reported in petitioner's income tax returns was increased to $663,450,013 for 2005 and to $1,109,939,529 for 2006, a total of $581,747,668 greater than what petitioner had originally determined to be an arm's-length amount.

C. Audits for 2005 and 2006 Tax Returns

1. First Audit

Respondent's first examination of petitioner's 2005 and 2006 tax returns began in approximately May 2007. During the course of the examination, respondent proposed an initial $84 million adjustment as a result of revised calculations under the Puerto Rico MOU. In March 2009, after completing his initial examination, respondent proposed to increase the amounts of MPROC's

[*70] royalty payments to Medtronic US by another $455 million for 2005 and 2006. Petitioner protested respondent's proposed adjustments for 2005 and 2006 to the Internal Revenue Service Appeals Office in May 2009. In his response to petitioner's protest at Appeals, respondent maintained that he was continuing to follow the Puerto Rico MOU methodology and that his intent was to respect the revised intercompany royalty rates of 44% and 26%.

2. Second Audit

In March 2010 Appeals, at respondent's request, returned the case to the Internal Revenue Service's examination function, which reexamined Medtronic's 2005 and 2006 tax returns.

3. Notice of Deficiency

On December 23, 2010, respondent issued petitioner a notice of deficiency determining deficiencies in tax totaling $198,232,199 and $759,383,578 for 2005 and 2006, respectively.[3] Respondent calculated these deficiencies in reliance on the Heimert report, explained in greater detail below, which used the comparable profits method (CPM). On July 10, 2014, respondent amended his answer to exclude royalty amounts paid by MPROC for non-U.S. sales, asserting that his

[3]These amounts include amounts attributable to issues that the parties have settled.

[*71] adjustments under section 482 were understated by $51,650,809 for 2005 and $59,560,314 for 2006. Thus, the amounts of the proposed deficiencies related to the devices and leads transfer pricing issue are approximately $548,180,115 for 2005 and $810,301,695 for 2006.[4]

In the notice, respondent asserted several issues giving rise to the deficiencies. The parties were able to settle several of these issues.[5] The issues that remain are: the devices and leads transfer pricing issue, the Swiss supply agreement issue, and the section 367(d) issue.

OPINION

I. Overview of Parties' Positions

We must determine whether the four intercompany agreements among MPROC and Medtronic US and Med USA were at arm's length during 2005 and 2006. We must also determine whether respondent's allocation is arbitrary, capricious, or unreasonable. If we find that respondent's allocation was not arbitrary, capricious, or unreasonable, in whole or in part, then we must

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[4]Since petitioner had increased its income to reflect the royalty rates agreed upon for a prior tax year's informal resolution, the adjustment does not include the amount by which petitioner had increased its taxable income in reliance on the MOU. Petitioner is now seeking a refund by returning to its book reporting position.

[5]The parties filed a stipulation of settled issues on January 16, 2014.

[*72] alternatively determine whether Medtronic US, Med Rel, Inc., or Medtronic Puerto Rico, Inc., transferred intangible property compensable under section 367(d) to MPROC when Medtronic US restructured its operations in Puerto Rico in 2002.

Both parties presented experts to support their respective positions. For experts, we focus on the degree to which their opinions are supported by the evidence. Accordingly, our opinion is not based on comparing their qualifications, and so we do not list or discuss their qualifications, as listing them would unnecessarily lengthen the opinion. We do not use titles because we do not wish to imply a greater deference to academic experts than to industry experts. We do not discuss the opinion of any expert which does not pertain to our factual conclusions.

A. Petitioner's Position

Petitioner contends that the MOU royalty rates on the intercompany sales of devices and leads from MPROC to Medtronic US were greater than arm's length. In 2005 the MOU royalty rate was 37.6% for devices and 25.5% for leads after the profit split calculation. In 2006 the MOU royalty rate was 44% for devices and 26% for leads after the profit split calculation. Petitioner contends that, using the CUT method, the proper arm's-length royalty rates were 29% for devices and 15%

[*73] for leads. Petitioner presented expert testimony that supported these rates. Because of its downward adjustment of royalty rates, petitioner argues that it is entitled to overpayments pursuant to section 6512(b) of $184,569,840 for 2005 and $397,117,827 for 2006.

Petitioner also contends that respondent's allocations in the notice of deficiency using the CPM are much greater than arm's length and are therefore arbitrary, capricious, and unreasonable. Specifically, petitioner argues that respondent's value chain approach fails to respect and view separately the intercompany transactions between MPROC, Medtronic US, and Med USA. Petitioner also contends that respondent did not adequately consider that product quality determines success in the implantable medical device industry and that MPROC is ultimately responsible as the manufacturer of class III finished medical devices.

B. Respondent's Position

Respondent's position is that the CPM is the best method to determine the arm's-length royalty rates on the intercompany sales of devices and leads and that making the accompanying section 482 adjustments did not result in an abuse of discretion. Respondent contends that Medtronic US and Med USA performed all

[*74] but one of the economically significant functions for CRDM and Neuro.[6] Respondent contends that the only economically significant function that MPROC performed was assembling finished products, with Medtronic US providing significant oversight and help.

Respondent contends that petitioner's use of the CUT method does not meet the standard of section 482 and the accompanying regulations. Respondent rejects petitioner's argument that quality is the most important determinant of success in the medical device industry. Respondent contends that petitioner's experts' uncontrolled license arrangements are not comparable to the Medtronic US-MPROC royalty agreement.

II. Covered Transactions

MPROC and Medtronic US entered into four separate intercompany agreements: (1) the components supply agreement, (2) the distribution agreement, (3) the trademark license, and (4) the devices and leads licenses (collectively, covered transactions.)

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[6]In post trial briefs respondent referred to Medtronic, Inc. and its U.S. subsidiaries, which include activity taking place in the United States, as MED US. We will not use the term MED US since it is not a legal entity. Medtronic US and Med USA are separate legal entities with separate relationships with MPROC.

[*75] Pursuant to section 482, all four of the intercompany agreements must be at arm's length. Petitioner separately priced each of the four covered agreements between and among Medtronic US, MPROC, and Med USA. Respondent, on the other hand, performed a functional analysis that looked at all four covered agreements together.

The first agreement covers the sale of components. Although respondent did not concede that it was made at arm's length and included the agreement in the transfer pricing analysis performed by respondent's expert in conjunction with the notice of deficiency, respondent's expert concluded that the agreement was within arm's-length range for 2005 and above arm's-length range for 2006.

The second agreement covers the distribution of devices and leads manufactured by MPROC and sold by Med USA. Although respondent did not concede that this agreement was made at arm's length and included the agreement in the transfer pricing analysis, respondent's expert in conjunction with the notice of deficiency concluded that the sales of finished goods were within the arm's-length range for both 2005 and 2006.

The third agreement covers the ability of MPROC to use trademarks and trade names owned by Medtronic US. The parties dispute how to analyze this agreement. Respondent's analysis did not separate the trademark license from the

[*76] devices and leads licenses. Petitioner's analysis treats the trademark license as separate from the other three and concludes that 8% is a proper royalty rate.

The fourth agreement covers the licensing of intangible property used by MPROC in manufacturing devices and leads. This agreement is central to the dispute. It will be our main focus as we look at the facts and circumstances to determine whether respondent's result was reasonable.

III. Applicable Statute and Regulations

Section 482 was enacted to prevent tax evasion and to ensure that taxpayers clearly reflect income relating to transactions between controlled entities. Veritas Software Corp. & Subs. v. Commissioner, 133 T.C. 297, 316 (2009). This section gives the Commissioner broad authority to allocate gross income, deductions, credits, or allowances between two related corporations if the allocations are necessary either to prevent evasion of tax or to reflect clearly the income of the corporations. See Seagate Tech., Inc. & Consol. Subs. v. Commissioner, 102 T.C. 149, 163 (1994).

To determine true taxable income, the standard to be applied in every case is that of a taxpayer dealing at arm's length with an uncontrolled taxpayer. Sec. 1.482-1(b)(1), Income Tax Regs. The arm's-length result of a controlled transaction must be determined under the method that, under the facts and

[*77] circumstances, provides the most reliable measure of an arm's-length result. Id. para. (c)(1).

The Commissioner will evaluate the results of a transaction as actually structured by the taxpayer unless it lacks economic substance. Id. para. (f)(2)(ii)(A). The Commissioner, however, may consider the alternatives available to the taxpayer in determining whether the terms of the controlled transaction would be acceptable to an uncontrolled taxpayer faced with the same alternatives and operating under similar circumstances. Id. In this type of situation the Commissioner may adjust the consideration charged in the controlled transaction according to the cost or profit of an alternative, but the Commissioner will not restructure the transaction as if the taxpayer had used the alternative. See id.

The regulations provide four methods to determine the arm's-length amount to be charged in a controlled transfer of intangible property: the CUT, the CPM, the profits split method, and unspecified methods as described in section 1.482-4(d), Income Tax Regs. See id. sec. 1.482-4(a).

There is no strict priority of methods, and no method will invariably be considered more reliable than others. Id. sec. 1.482-1(c)(1). In determining which of two or more available methods provides the most reliable measure of an arm's-length result, the two primary factors to take into account are the degree of

[*78] comparability between the controlled transaction (or taxpayer) and any uncontrolled comparables, and the quality of data and assumptions used in the analysis. Sec. 1.482-1(c)(2), Income Tax Regs.

A. CPM

The CPM evaluates whether the amount charged in a controlled transaction is arm's length according to objective measures of profitability (profit level indicators) derived from transactions of uncontrolled taxpayers that engage in similar business activities under similar circumstances. Id. sec. 1.482-5(a). Profit level indicators are ratios that measure relationships between profits and costs incurred or resources employed. Id. para. (b)(4). The appropriate profit level indicator depends upon a number of factors, including the nature of the activities of the tested party, the reliability of available data with respect to uncontrolled comparables, and the extent to which the profit level indicator is likely to produce a reliable measurement of the income that the tested party would have earned had it dealt with controlled taxpayers at arm's length taking into account all facts and circumstances. See id.

B. CUT Method

The CUT method evaluates whether the amount charged for a controlled transfer of intangible property was arm's length by reference to the amount

[*79] charged in a comparable uncontrolled transaction. Id. sec. 1.482-4(c). If an uncontrolled transaction involves the transfer of the same intangible under the same or substantially the same circumstances as the controlled transaction, the results derived generally will be the most direct and reliable measure of the arm's-length result for the controlled transfer of an intangible. Id. subpara. (2)(ii).

The application of the CUT method requires that the controlled and uncontrolled transactions involve the same intangible property or comparable intangible property as defined in the regulations. Id. subdiv. (iii)(A). In order for intangibles to be considered comparable, both intangibles must: (i) be used in connection with similar products or processes within the same general industry or market and (ii) have similar profit potential. Id. subdiv. (iii)(B).

The profit potential of an intangible is most reliably measured by directly calculating the net present value of the benefits to be realized (on the basis of prospective profits to be realized or costs to be saved) through the use of subsequent transfers of the intangible, considering the capital investment and startup expenses required, the risks to be assumed, and other relevant considerations. Id. subdiv. (iii)(B)(ii).

[*80] C. Profit Split Method

The profit split method evaluates whether the allocation of the combined operating profit or loss attributable to one or more controlled transactions is arm's length by reference to the relative value of each controlled taxpayer's contribution to that combined operating profit or loss. Sec. 1.482-6(a), Income Tax Regs. Allocation under the profits split method must be made in accordance with either the comparable profit split method or the residual profit split method. Id. para. (c)(1).

The residual profit split method allocates the combined operating profit or loss from the relevant business activity between the controlled taxpayers via a two-step process: (1) allocate income to routine contributions, and (2) allocate residual profit. Id. subpara. (3)(i)(A) and (B). Routine contributions ordinarily include contributions of tangible property, services, and intangible property that are generally owned by uncontrolled taxpayers engaged in similar activities. A functional analysis is required to identify these contributions according to the functions performed, risks assumed, and resources employed by each of the controlled taxpayers. Id. subdiv. (i)(A). In cases where there is intangible property, there will normally be an unallocated residual profit after the allocation of income, and this residual profit is generally divided among the controlled

[*81] taxpayers according to the relative value of their contributions of intangible property to the relevant business activity. Id. subdiv. (i)(B).

D. Aggregation

Generally, transactions will be aggregated only when they involve related products or services as defined in section 1.6038A-3(c)(7)(vii), Income Tax Regs. Id. sec. 1.482-1(f)(2)(i)(A).[7] Related products or services are defined as groupings of products and types of services that reflect reasonable accounting, marketing, or other business practices within the industries in which the related party group operates. Id. sec. 1.6038A-3(c)(7)(vii).

E. Commensurate With Income

In 1986 Congress amended section 482 by adding: "In the case of any transfer (or license) of intangible property (within the meaning of section 936(h)(3)(B)), the income with respect to such transfer or license shall be commensurate with the income attributable to the intangible." Tax Reform Act of 1986, Pub. L. No. 99-514, sec. 1231(e)(1), 100 Stat. at 2562-2563.

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[7]This regulation is no longer in effect and was replaced with sec. 1.482-1T(f)(2)(i), Temporary Income Tax Regs., 80 Fed. Reg. 55541 (Sept. 16, 2015). which applies for taxable years ending on or after September 14, 2015. This Court held that the sec. 1.482-1(f)(2)(i)(A), Income Tax Regs. permits aggregation of transactions involving services, tangible property, and intangible property. Guidant LLC v. Commissioner 146 T.C. _ , _ (slip op. at 38) (Feb. 29, 2016).

[*82] The House report that accompanied the House version of the 1986 amendment to section 482 explains the reason for change, in relevant part, as follows:

> There is a strong incentive for taxpayers to transfer intangibles to related foreign corporations or possessions corporations in a low tax jurisdiction, particularly when the intangible has a high value relative to manufacturing or assembly costs. * * *
>
> * * * * * * *
>
> Many observers have questioned the effectiveness of the "arm's length" approach of the regulations under section 482. A recurrent problem is the absence of comparable arm's length transactions between unrelated parties, and the inconsistent results of attempting to impose an arm's length concept in the absence of comparables.
>
> * * * * * * *
>
> The problems are particularly acute in the case of transfers of high-profit potential intangibles. Taxpayers may transfer such intangibles to foreign related corporations or to possession corporations at an early stage, for a relatively low royalty, and take the position that it was not possible at the time of the transfers to predict the subsequent success of the product. Even in the case of a proven high-profit intangible, taxpayers frequently take the position that intercompany royalty rates may appropriately be set on the basis of industry norms for transfers of much less profitable items.
>
> * * * * * * *
>
> Transfers between related parties do not involve the same risks as transfers to unrelated parties. There is thus a powerful incentive to establish a relatively low royalty without the adequate provisions for

[*83] adjustment as the revenues of the intangible vary. There are extreme difficulties in determining whether the arm's length transfers between unrelated parties are comparable. The committee thus concludes that it is appropriate to require that the payment made on a transfer of intangibles to a related foreign corporation or possessions corporation be commensurate with the income attributable to the intangible. * * *

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Where taxpayers transfer intangibles with a high profit potential, the compensation for the intangibles should be greater than industry averages or norms. * * *

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In requiring that payments be commensurate with the income stream, the bill does not intend to mandate the use of the "contract manufacturer" or "cost-plus" methods of allocating income or any other particular method. As under present law, all the facts and circumstances are to be considered in determining what pricing methods are appropriate in cases involving intangible property, including the extent to which the transferee bears real risks with respect to its ability to make a profit from the intangible or, instead, sells products produced with the intangible largely to related parties (which may involve little sales risk or activity) and has a market essentially dependent, on, or assured by, such related parties' marketing efforts. However, the profit or income stream generated by or associated with intangible property is to be given primary weight.

H.R. Rept. No. 99-426, at 423-426 (1985), 1986-3 C.B. (Vol. 2) 1, 423-426.

The conference report that accompanied the 1986 amendment to section 482 states, in relevant part, as follows:

[*84] The conferees are also aware that many important and difficult issues under section 482 are left unresolved by this legislation. The conferees believe that a comprehensive study of intercompany pricing rules by the Internal Revenue Service should be conducted and that careful consideration should be given to whether the existing regulations could be modified in any respect.

H.R. Conf. Rept. No. 99-841 (Vol. II), at II-638 (1986), 1986-3 C.B. (Vol. 4) 1, 638.

The Department of the Treasury and the Internal Revenue Service did conduct a comprehensive study that was published in 1988. See Notice 88-123, 1988-2 C.B. 458 (1988 White Paper). The 1988 White Paper concluded that the arm's-length standard is the norm for making transfer pricing adjustments. Id., 1988-2 C.B. at 475. The 1988 White Paper concluded that Congress intended no departure from the arm's-length standard. Id. The 1988 White Paper explained the following:

> Looking at the income related to the intangible and splitting it according to relative economic contributions is consistent with what unrelated parties do. The general goal of the commensurate with income standard is, therefore, to ensure that each party earns the income or return from the intangible that an unrelated party would earn in an arm's length transfer of the intangible.

Id., 1988-2 C.B. at 472.

Treasury has repeatedly confirmed that Congress intended for the commensurate with income standard to work consistently with the arm's-length

[*85] standard. See, e.g., Treasury Department Technical Explanation of the 2001 U.S.-U.K. Income Tax Convention, art. 9, Tax Treaties (CCH) para. 10,911 at 201,307 ("It is understood that the 'commensurate with income' standard for determining appropriate transfer prices for intangibles, added to Code section 482 by the Tax Reform Act of 1986, was designed to operate consistently with the arm's-length standard."); Treasury Department Technical Explanation of the 2006 Model Income Tax Convention, art. 9, Tax Treaties (CCH) para. 215, at 10,640-10,641 (same); see also Altera Corp. v. Commissioner, 145 T.C. 91 (2015).

F. Taxpayer's Burden

When the Commissioner has determined deficiencies based on section 482, the taxpayer bears the burden of showing that the allocations are arbitrary, capricious, or unreasonable. See Sundstrand Corp. & Subs. v. Commissioner, 96 T.C. 226, 353-354 (1991) (citing G.D. Searle & Co. v. Commissioner, 88 T.C. 252, 359 (1987), and Eli Lilly & Co. v. Commissioner, 84 T.C. 996, 1131 (1985), aff'd on this issue, rev'd in part and remanded, 856 F.2d 855 (7th Cir. 1988)). The Commissioner's section 482 determination must be sustained absent a showing of abuse of discretion. See Bausch & Lomb, Inc. v. Commissioner, 92 T.C. 525, 582 (1989), aff'd, 933 F.2d 1084 (2d Cir. 1991).

[*86] Respondent's determination as set forth in the notice of deficiency is presumptively correct. See Sundstrand Corp. & Subs. v. Commissioner, 96 T.C. at 353. On July 10, 2014, respondent amended the answer to exclude royalty amounts paid by MPROC for non-U.S. sales, which meant that the notice adjustments for section 482 were understated by $51,650,809 for 2005 and $59,560,314 for 2006. We look to both the notice of deficiency and the revision as set forth in the amended answer to see whether respondent's section 482 allocation is arbitrary, capricious, or unreasonable.[8]

"Whether respondent has exceeded his discretion is a question of fact. * * * In reviewing the reasonableness of respondent's determination, the Court focuses on the reasonableness of the result, not on the details of the methodology used." Id. at 353-354; see also Am. Terrazzo Strip Co. v. Commissioner, 56 T.C. 961, 971 (1971).

If we hold that the adjustments set forth in the notice of deficiency are arbitrary, capricious, or unreasonable, then petitioner must next show that the

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[8]Pursuant to Rule 142(a) the burden of proof is on respondent for increases in deficiencies. Therefore, respondent has the burden of proof for the increased deficiencies asserted in the amended answer. See Olive v. Commissioner, 139 T.C. 19 (2012), aff'd, 792 F.3d 1146 (9th Cir. 2015). Our resolution of whether respondent abused his discretion in reallocating royalty payments under sec. 482 is based on a preponderance of the evidence, and not on the burden of proof.

[*87] allocations it proposes satisfy the arm's-length standard. Eli Lilly & Co. v. Commissioner, 856 F.2d at 860 (and the cases cited thereat). Where the evidence shows that neither side is correct, we must consequently determine the proper allocation. See Veritas Software Corp. & Subs. v. Commissioner, 133 T.C. at 318.

IV. Abuse of Discretion

We first consider whether there was an abuse of discretion when respondent reallocated the royalty payments under section 482. Petitioner sets forth two arguments for its contention that respondent abused his discretion. First, petitioner claims respondent abandoned a prior position. Second, petitioner claims that respondent's adjustments were unreasonable because they gave inadequate consideration to the importance of quality at MPROC.

A. Abandonment of Notice Position

In prior transfer pricing cases we have found respondent's actions to be arbitrary and capricious where respondent has abandoned the position in the notice of deficiency and argued a different position at trial. See id. at 319-320; Compaq Computer Corp. v. Commissioner, T.C. Memo. 1999-220, slip op. at 28 ("In most instances where respondent abandons his notice position at trial, courts conclude that allocation in the notice under section 482 are arbitrary and capricious."); see also Nat'l Semiconductor Corp. v. Commissioner, T.C. Memo. 1994-195.

[*88] Petitioner contends that respondent has had divergent views of the transactions at issue and of what constitutes an arm's-length transaction. Respondent has changed the position included in the MOU to the position reflected in the amended answer. Petitioner contends that there were no material changes in the facts or law between the time of the MOU and the issuance of the notice of deficiency.

Respondent contends that the notice of deficiency and the position at trial are consistent. Petitioner counters that respondent abandoned a previous position that was an informal resolution based on the audit for tax year 2002. The Commissioner is not bound by positions taken for a previous year. Dinkins v. Commissioner, 378 F.2d 825, 829 (8th Cir. 1967), aff'd, 45 T.C. 593 (1966).

Respondent based the notice of deficiency and the arguments made at trial on the same CPM analysis made by A. Michael Heimert. We conclude that respondent did not abandon the position taken in the notice of deficiency, but this does not end our analysis of whether there was an abuse of discretion.

B. Respondent's Section 482 Allocations

1. Respondent's Position

Respondent contends that there was no abuse of discretion in making adjustments in the notice of deficiency as revised in the amended answer.

[*89] Respondent does not contend that the covered transactions lacked economic substance. Rather, respondent contends that the CPM is the best method to determine the true taxable income of MPROC. As part of the CPM respondent used a value chain analysis, which segments a company's operations into functional activities, allowing qualitative assessment of each participant's economic contributions to the profits of the consolidated enterprise.

Respondent contends that Medtronic US and Med USA performed most of the functions of the CRDM and Neuro value chain, and bore the risks related to the functions they performed. These functions related to the overall CRDM and Neuro businesses. Respondent's view is that MPROC performed only the final manufacturing steps, which were completed according to processes approved by Medtronic US.

In the notice of deficiency respondent made adjustments based on the Heimert report, which contended that MPROC's profits were vastly overstated. The principal focus of Heimert's analysis was to determine the arm's-length returns for MPROC operations versus those of Medtronic US and Med USA. His analysis considered each party's functions, assets, and risks that were related to the CRDM and Neuro businesses for the U.S. market. For example, if petitioner earned $100 of profit in the CRDM or Neuro value chain, Heimert evaluated how

[*90] much of the $100 MPROC should have earned versus Medtronic US and Med USA. Heimert testified at trial and submitted an expert report which was generally consistent with the economic analysis in his original report.

2. Heimert's Economic Analysis

The purpose of Heimert's analysis is to determine the arm's-length returns and associated profits for MPROC's operations versus Medtronic US and Med USA. Heimert used the CPM and concluded that this method provides MPROC with a return for its finished-product manufacturing that is consistent with the returns earned by comparable manufacturers in the medical device industry. He also concluded that the CPM establishes the return to Medtronic US for its contributions to the U.S. CRDM and Neuro value chain by subtracting the operating profits attributed to MPROC from the overall value chain operating profits and allowing the remainder to accrue to Medtronic US.

Heimert performed an economic analysis of the functions performed, assets used, and risks assumed by MPROC, Medtronic US, and Med USA. His approach segmented Medtronic's operations into functional activities with a qualitative assessment of each controlled party's contributions. The only function assigned to MPROC was finished product manufacturing. His analysis assumed that all intangibles that MPROC needed to perform finished manufacturing, other than

[*91] assembled workforce and incremental process intangibles that MPROC may have developed since entering into the intercompany licenses in 2002, were licensed from Medtronic US.[9]

Heimert's analysis was based on his findings that MPROC performed one important function--finished manufacturing--among many important functions within the highly integrated value chain. This approach treated MPROC as equivalent to many other third-party medical device manufacturers who do not create nonroutine assets and who do not bear additional risks that would require the assignment of additional profits.

Respondent contends that Heimert considered the realistic alternatives available to petitioner and MPROC in selecting the best method. See sec. 1.482-1(d)(3)(iv)(H), Income Tax Regs. Respondent argues that MPROC's realistic alternative was to use its manufacturing capabilities to produce other products. According to respondent, if MPROC had not had the intercompany licenses, then its realistic alternative would have required that it contract with a third party to access similar intangibles and a sales force to sell its products. Respondent argues that MPROC was replaceable and that Medtronic US' realistic alternative was to

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[9]Heimert grouped the devices and leads licenses and the trademark license together under the umbrella term "technology royalty". He did not treat them separately.

[*92] outsource manufacturing to another Medtronic entity, to a third party, or to one of its U.S. plants, or to build a new plant.

Heimert's report determined that MPROC performed functions less complex than those performed by Medtronic US and did not contribute intangibles to the covered transactions that would differentiate it from other manufacturers in the medical device industry. For these reasons he applied the CPM with MPROC as the tested party to determine an arm's-length return and assigned the remainder of the profits to Medtronic US and Med USA.

Heimert's economic analysis consisted of four steps to determine arm's-length allocations for the covered transactions.

In the first step Heimert calculated the value chain operating profit.

In the second step Heimert applied the CPM to Medtronic US' sale of components to MPROC for the production of finished devices and leads. This analysis resulted in the amount of profits that Medtronic US would earn for its contributions as a routine manufacturer of device and lead components. Heimert used Medtronic US as the tested party with respect to its sale of components to MPROC. He selected 14 companies in the medical device industry. Although the products were not identical, Heimert contends that manufacturers of these types of products would be expected to employ resources and face risks similar to the

[*93] resources employed and risks faced by Medtronic US and MPROC in their capacity as manufacturers of CRDM and Neuro products. Heimert concluded that Medtronic US had operating profit from the routine aspects of the sale of components within arm's-length range for 2005. He concluded that profit from the routine aspects of the sale of components was above the arm's-length range for 2006 and adjusted it from $86.8 million to the median range of comparable companies of $59.2 million.

In the third step Heimert applied the CPM to MPROC's sale of finished devices and leads to Med USA in the U.S. markets. This analysis determined both the transfer price from MPROC to Med USA and the amount of operating profits that Med USA would earn for its routine contributions to the U.S. CRDM and Neuro value chain as a seller and distributor of finished devices and leads to its customers. After applying the CPM, Heimert concluded that petitioner's transfer price for purchase and resale of devices and leads for 2005 and 2006 was arm's length.

In the fourth and final step Heimert applied the CPM to the devices and leads licenses and the trademark license together to reach the technology royalty rate. Heimert concluded that MPROC was reporting profits above the arm's-length range, and he made an adjustment to achieve an arm's-length result. This

[*94] step determined the profits that the tested party would have earned if its profitability were the same as that of uncontrolled comparable companies performing similar functions under similar conditions. Heimert selected MPROC as the tested party because he believed that it performed less complex functions than Medtronic US and it did not own or contribute intangibles that differentiated it from other manufacturers in the medical device industry.

For comparables, he used the same 14 companies that he used in step 2 for the sale of components by Medtronic US to MPROC. He contends that all 14 companies are responsible for the quality of their products, and that they face types of risks similar to MPROC's. Heimert used a variety of products, and it is difficult to compare their relative risks. For calculating the profits split Heimert used the return on operating assets (ROA), which compares operating profits to operating assets.

As part of his analysis Heimert estimated that MPROC incurred only 8.7% and 11.7% of the value-added costs in the U.S. CRDM and Neuro value chain for 2005 and 2006, respectively, but earned 60.7% and 64.7% of the operating profits in those years, respectively. Under Heimert's analysis MPROC's reported ROA results are far greater than those of Medtronic US, Medtronic US' competitors, and all companies in the medical device industry, which include those with a full

[*95] suite of activities and intangible assets. MPROC's returns are four to five times greater than those of Medtronic US and its competitors' 5- to 10-year averages.

His conclusions showed that the profits which petitioner attributed to MPROC for 2005 and 2006 were significantly above the arm's-length range. MPROC's reported results for 2005 and 2006 far exceeded the median calculated by Heimert. He calculated the arm's-length results for the intercompany transactions by breaking out the arm's-length value chain of operating profits between MPROC, the routine aspects of U.S. distribution, component manufacturing, and the return for all of Medtronic US' and Med USA's nonroutine intangibles, including any additional contributions by the component manufacturers and distribution beyond the routine or benchmarked returns for distribution and manufacturing activities. He converted these arm's-length results into a royalty payment to Medtronic US for the intangibles. He concluded that there were 49.4% and 58.9% royalties on Medtronic US end sales for 2005 and 2006, respectively. Pursuant to his analysis of arm's-length operating profits, MPROC earned 8.1% and 5.6% of the operating profits for 2005 and 2006, respectively. Under these calculations for 2005, 91.9% of the operating profits were attributable to both Medtronic US and Med USA. For 2006, 94.4% of the

[*96] operating profits were attributable to both Medtronic US and Med USA. Heimert concluded that MPROC was reporting profits above the arm's-length range. Heimert made adjustments to the arm's-length royalty rate that Medtronic US received from MPROC to generate the arm's-length Medtronic US intangible profits that were consistent with his conclusions.

To perform his analysis Heimert had to reach conclusions about the operations of Medtronic US and MPROC. He believed that MPROC's contributions did not rise to the level of nonroutine intangibles that would differentiate it from similar manufacturers in the medical device industry. He sought to identify comparable companies to benchmark the routine portion of Medtronic US' component manufacturing and sales. His position is that nonroutine aspects of Medtronic US' component manufacturing and sales were compensated through the royalty payment.

Respondent contends that the Heimert report demonstrates the interplay of the four separate intercompany transactions and that there were multiple ways to price each of the four transactions and arrive at the same arm's-length result. Respondent believes the ultimate question is whether the amount of operating profit that was allocated to each participant was appropriate given their relative contributions to the U.S. CRDM and Neuro value chain. Respondent contends

[*97] that the pricing of the individual transactions cannot be viewed in isolation but must be viewed in the context of the overall U.S. value chain because the transactions are far too fundamentally interrelated to price independently.

3. Concerns With Heimert's Economic Analysis

Respondent contends that only one witness, Heimert, has provided the Court with an analysis of the best method, as required under the section 482 regulations. The best method rule requires that the arm's-length allocation of a controlled transaction must be determined under the method that, under the facts and circumstances, provides the most reliable measure of an arm's-length result. Sec. 1.482-1(c)(1), Income Tax Regs. Under Heimert's value chain approach, petitioner's operations are segmented into functional activities with a qualitative assessment of each controlled party's contributions. The section 482 regulations do not include a description of a value chain approach. We must examine the facts and circumstances and determine whether respondent's application of the CPM is arbitrary, capricious, or unreasonable.

a. Quality

Heimert assigned only one function to MPROC, and that was finished product manufacturing. In order to place a value on finished manufacturing he had to examine the role of quality.

[*98] The parties disagree about the role of quality.

i. Petitioner's Position

Petitioner stresses that quality is critical in the medical device industry and, in particular, to MPROC. Numerous witnesses testified on petitioner's behalf about the importance of quality. From the testimony of the chief executive officer to the testimony of MPROC employees, quality was stressed as being the most important factor.

ii. Respondent's Position

Respondent and Heimert downplay the role of quality. First, respondent contends that quality is not the main driver of success in the implantable medical device industry. Second, respondent contends that MPROC's focus on quality was not unique and that petitioner as a whole company was concerned with quality. Third, respondent contends that MPROC's role is not appreciably more significant than that of a components manufacturer. And fourth, respondent contends that MPROC is not that unique or important a facility because petitioner could easily maintain operations were something to happen to MPROC.

I. Quality: Driver of Success

Respondent contends that quality is not the primary driver of success and profits at petitioner or in the industry. Rather, respondent argues that petitioner's

[*99] growth was driven by its increased product offerings and by the size of its sales force. Respondent contends that it is petitioner's new product pipeline, successful clinical trials, and well-trained sales force that create sales and differentiate it from its competitors. Respondent believes that if quality drove success, petitioner "would focus its efforts on perfecting products to the exclusion of inventing new products".

Petitioner's chief executive officer during 2005 and 2006 testified that product quality is the "single greatest factor in terms of market share". Petitioner contends that "product quality is the 'sine qua non' of success within the implantable device industry" and that no company would survive without it.

A cardiac electrophysiologist testified on behalf of petitioner. He testified that pacemakers are a life-saving device and that it is critical that the device work properly throughout the duration of its life because removing the leads is extremely difficult, or even fatal. Because of this difficulty in removing or replacing the leads, he testified that he uses what he believes to be the best product. He further testified that if he became suspicious of a device he would stop using it. He testified that he used to use products from more than one company, but once Guidant had problems with reliability, he used its products

[*100] substantially less. His testimony emphasized that quality is important for the entire life of the device.

A regional sales director for Med USA's Neuro department also testified on behalf of petitioner. He testified about the Neuro devices and leads, and how they are used for deep brain stimulation. He referred to the neurological implantation industry as a "one shot" industry. He testified that when physicians insert an implant they "will often say we have to be really careful because it's a marriage"--for life. The devices and leads for Neuro are not matter of life and death like CRDM devices and leads, but the leads used in Neuro are devised to improve the quality of a patient's life and compromised leads are unable to provide appropriate therapy.

Respondent further contends that no company in the industry has been destroyed or driven out of existence because of a quality issue. Respondent contends that petitioner's "exaggerated claims of the importance and impact of quality fly in the face of the fact that Medtronic has had product recalls over many years, and despite that it continues to control and lead the marketplace".

Over the years both petitioner and other companies have had recalls that have diminished their respective market shares. Petitioner has had three notable recalls. First, in the 1970s petitioner had to recall its Xytron pacemaker because of

[*101] a quality problem. This recall caused petitioner's market share percentage to fall from the mid-70s to the high 30s. Second, in 2005 petitioner had to recall some of its Marquis devices. Petitioner did not lose its market share, likely because its competitor, Guidant, also sustained a rash of recalls due to product quality problems during the same time period. Regardless, petitioner still faced significant class-action litigation and settlement expenses because of the recall. Third, in 2007 petitioner had to recall its Sprint Fidelis ICD leads because of a quality problem that would cause the leads to inappropriately shock patients' hearts. This recall had a severe impact on petitioner and the industry, causing petitioner to lose a significant amount of market share, as well as severely damaged consumer confidence.

There are also several examples of other companies in the industry that have been harmed by recalls. In 2005 Guidant had to recall part of its Prizm family of devices. Not only did Guidant's market share drop substantially because of the recall, but its anticipated sale price was significantly reduced as a result. The damage did not end there. Guidant's eventual acquirer, Boston Scientific, was forced pay out over $550 million to settle the various lawsuits that arose out of the recall.

[*102] Respondent does not place enough emphasis on the importance of quality in the industry. The final product is the key to success. Product quality is the foundation for which implantable medical devices can be successful. A recall could make it very difficult for a company to continue to compete in the industry at the same level. A company can have a strong sales force and a creative marketing department, but these will not make a difference if the underlying product is unsafe and ineffective.

II. Importance of Quality

Respondent contends that quality was important to petitioner in its entirety, and not just to MPROC specifically. Respondent contends that quality was established at petitioner's headquarters in the United States and implemented by the disparate business units, including those at MPROC. Respondent points to the fact that quality was always on the executive committee meetings agenda and that CRDM and Neuro both had quality officers in the United States. Respondent argues that MPROC's role in quality was not unique and cannot explain MPROC's profits. Accordingly, Heimert's comparables spread out the quality risk throughout the entire value chain, in contrast to petitioner's focus on risk associated with final assembly at MPROC.

[*103] Petitioner argues that MPROC's role in quality was unique because it bore the greatest economic risk. Petitioner contends that MPROC "like the ancient Roman Hero, Horatio, represents the last line of defense before a potential product quality issue". As discussed above, a product quality problem could not only harm petitioner within the industry, but could fatally harm the user. Even though a salesperson reviews the product before insertion, a problem should be detected at an earlier point. The finished product had to be of the highest quality, and that quality assurance was MPROC's responsibility. MPROC was exposed to being sued if there was a defect in the manufactured device.[10]

MPROC was an FDA registered site that had to be in compliance with FDA standards. Since MPROC made class III implantable medical devices, there were inherent risks and compliance requirements. MPROC had a role in complying with the FDA and worked with petitioner as a whole to eliminate risk. MPROC's quality systems were in place in order to comply with its FDA requirements.

One of these quality systems was a robust CAPA program. This program would investigate whether there was a problem and how to resolve the issue. CAPAs were created in response to complaints. Each of MPROC's sites

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[10]The parties dispute the level of risk attributed to MPROC, but there is no dispute that MPROC bears some of the risk. We need not decide the party responsible under Federal products liability law.

[*104] maintained a CAPA board which would manage the CAPAs and decide whether to open or close a case on the basis of a quality complaint. The CAPA program ensured continuous improvement to the quality and effectiveness of MPROC's products and its manufacturing operations. Other quality systems included: incoming inspection; sterilization; the environmental, health, and safety function; process excellence; the product traceability process; nonconformance evaluations; internal audits; product hold orders; management reviews; and the management of material review requests.

MPROC also had a unique advisory council that was assembled to facilitate communication among the business units to maximize quality, cost, and training. A main focus of the advisory council was quality. The council comprised the vice presidents of operations from the various business units that operated in Puerto Rico, plus the Puerto Rico general manager.

MPROC also had quality control teams for each of its operations. These teams had significant responsibility, and were very involved in the entire manufacturing process. The quality control teams at each of the operations were solely responsible for developing the validation, inspection, and qualification steps necessary to ensure that the final manufactured devices and leads met the established specifications.

[*105] The devices and leads licenses included specific wording which addressed quality. The quality control standards and specifications were to be established jointly by MPROC and Medtronic US. Neuro, CRDM, and MPROC all had their own quality manuals. The MPROC manual was consistent with the other manuals, but had specific guidelines for MPROC. Under the terms of the licenses MPROC was required to take corrective actions as necessary to restore quality to the appropriate level in the event of quality control failure.

The fact that quality was important to the entire company does not mean MPROC's role in quality should be diminished. With these types of implantable devices, it is reasonable that the executives would be focused on quality. Executives' focus on quality, however, does not lessen the impact that MPROC had on quality. If MPROC did not meet high quality standards, it would not matter that the rest of the company was meeting the standards. MPROC was making devices and leads that were implanted in a human body and was responsible for ensuring that the manufactured devices and leads were of the highest quality. This process is very different from manufacturing electronic equipment such as a cell phone. If a cell phone malfunctions, the consumer could be inconvenienced; if a device or lead malfunctions, the consumer could die.

[*106] III. Role of MPROC

Respondent belittles MPROC's role in both petitioner's CRDM and Neuro business units. First, respondent contends that MPROC is similar to a manufacturer of components; and second, respondent contends that MPROC was replaceable.

Respondent asserts that MPROC's role as a manufacturer was comparable to that of a components manufacturer, such as MECC and MMC. Respondent therefore argues that quality control was the responsibility of the entire value chain, including the components manufacturers, and that accordingly, MPROC did not have a special role in quality.

Petitioner contends that since MPROC was responsible for assembling the final product, the importance of quality was vital. MPROC took all of the components and supplies received from MMC, MECC, and third-party suppliers and incorporated them into class III finished medical devices capable of improving or saving lives. MPROC had the responsibility of making sure that every component was combined to provide repeated and reliable patient therapy all the time.

MPROC not only assembled the product; it leveraged its systems engineering expertise to make the manufacturing process design improvements to

[*107] class III finished medical devices, enabling a safe product to be made. For example, MPROC focused on Lean Sigma manufacturing in order to eliminate waste when moving from a low production level to a high production level. MPROC engineers worked to ensure that finished products could be produced at a certain rate. There was no room for error. For run yield testing to be successful, it had to be 100%, i.e., each device had to be perfect.

MPROC differed from the makers of components. Components manufacturers are not manufacturers with FDA-registered facilities because they do not make finished products that are implanted in a human body. MPROC on the other hand was an FDA-registered facility responsible for putting together sophisticated medical devices that would remain in the human body for years. All the components might be made perfectly, but there could be problems if they are not put together perfectly.

Respondent contends that MPROC was easily replaceable because it performed standard manufacturing activities expected of any manufacturer in the medical device industry. Respondent argues that petitioner would not have been able to open a Swiss facility if MPROC's role was unique.

Even though MPROC's role was unique, there is a possibility that it could have been replicated, as respondent suggests, but not without substantial time and

[*108] costs. MPROC workers were highly trained, and its workforce could not be replaced overnight. The Swiss facility only made devices and could not make enough devices for both Europe and the United States. Petitioner was so concerned about quality, it never considered outsourcing the activities of MPROC. It did not want to rely on external partners for such a vital role.

Respondent also contends that MPROC was a finished device manufacturer that performed only finished assembly operations. MPROC owned rights to the licensed intangibles, purchased its own materials, and bore real market risks. Med USA did not guarantee that it would purchase MPROC's devices and leads. MPROC was not guaranteed a fixed return on its investments. Its profits were related to its ability to manufacture quality devices and leads which met industry standards.

MPROC contributed throughout the design process and had a role in product development. MPROC was an integral part of petitioner. It not only made the finished product; it made sure that the finished product was safe and could be implanted in a human body. MPROC's role was not only to make a safe product but to make a product that would stand the test of time.

[*109] b. Comparables

Heimert used 14 comparable companies to determine MPROC's return for manufacturing. Petitioner's expert Robert S. Pindyck criticized Heimert's comparables. His report explained that not all companies used as comparables manufacture devices similar to MPROC's. Many of the products made by the comparable companies do not require the same level of FDA scrutiny as implantable class III medical devices. Distinct products could have differing risk profiles, which may result in different level of profits attributable to the manufacturer. For example, one of the companies that Heimert identified as comparable manufactures orthopedic devices that include nonsurgical and minimally invasive surgical products. The risk associated with these products would likely be less than the risk associated with MPROC's products--a nonsurgical product can be easily replaced, whereas it is extremely difficult, or even fatal, to replace the lead of a pacemaker.

Pindyck pointed out that even the companies that do manufacture products similar to MPROC's do not manufacture them on the same scale. Pindyck's point calls into question their comparability because, for example, a manufacturer with $75 million in revenue may make business decisions very different from those of a

[*110] manufacturer with $1 billion in revenue. A smaller company may be likely to take on less risk.

Pindyck also discussed how many of the companies identified as comparables by Heimert performed sales functions, research and development functions, and clinical functions. MPROC did not perform these functions. Pindyk was concerned that using comparables that had nonmanufacturing functions threw in "a lot of noise".

The 14 comparable companies were diversified manufacturers in the medical device industry. Only one, Greatbatch, Inc., sold batteries of hybrids as part of its business activities and was in the pacemaker industry. The other 13 included companies that made diagnostic products, medical supplies, surgical devices, orthopedic devices, systems for intravenous therapy, and disposable products. These companies perform functions, have capabilities, and own assets that differ from MPROC's.

The degree of comparability between an uncontrolled taxpayer and the tested party is determined by applying the provisions of section 1.482-1(d)(2), Income Tax Regs. Sec. 1.482-5(c)(2)(i), Income Tax Regs. While a specific comparability factor may be of particular importance, each method requires an analysis of all the factors including functions and economic conditions. Id. sec.

[*111] 1.482-1(d)(1). A functional analysis compares and identifies the economically significant activities undertaken. Id. subpara. (3)(i). Functions that need to be accounted for include the following: research and development; product design and engineering; manufacturing, production, and process engineering; product fabrication, extraction, and assembly; purchasing and materials management; marketing and distribution functions; transportation and warehousing; and managerial, legal, accounting, and finance services. Id. The degree of comparability requires a comparison of significant economic conditions, including the level of the market, the economic condition of an industry, and the relative size of the market. Id. subdiv. (iv). Heimert stated in his report that "these companies also perform functions and have capabilities beyond those of MPROC, and they own any assets generated from, and bear any risk associated with those additional functions and capabilities." Heimert contends that because his comparable companies own all of the intangibles and bear all of the risks throughout the entire value chain, his application of the CPM may overstate the returns to MPROC. The Court disagrees and concludes that his comparable companies are not consistent with the regulations.

Further, these same 14 companies were used as comparables in step 2 of Heimert's analysis, which looked at Medtronic US' sale of components to

[*112] MPROC. Medtronic US was the tested party in step 2. It is disturbing that Heimert used the same 14 companies as comparables for different purposes. The same comparables were used for two different tested parties. A components manufacturer has a role different from that of a final product manufacturer. A components manufacturer is not an FDA-registered facility. The uses of the same comparables for different purposes make us question the reliability of the comparisons.

c. ROA

Heimert's analysis looks at the ROA to determine whether the transaction is at arm's length. When using the CPM method, the arm's-length range will be considered using comparable operating profits derived from a single profit level indicator. Sec. 1.482-5(b)(3), Income Tax Regs. Profit level indicators are ratios that measure relationships between profits and costs incurred or resources employed. Id. subpara. (4). Heimert used ROA as the profit level indicator to determine the arm's-length return to MPROC for two primary reasons. The first was that the ROA is most reliable when a company's operating assets play a critical role in its ability to generate operating profits. Second, the level of functional comparability required between the controlled and uncontrolled

[*113] transactions is reduced when using the ROA as compared to ratios that measure relationships between profit and costs or sales revenue.

The reliability of this profit level indicator increases as operating assets play a greater role in generating operating profits for both the tested party and the uncontrolled comparable. Id. subdiv. (i). Difficulty in properly valuing operating assets will diminish the reliability of this profit level indicator. Id.

Pindyck was critical of this valuation and testified that it is not easy to value the assets of a company such as MPROC. For example, he discussed what would happen if a natural disaster destroyed the MPROC facilities. He described this type of event as devastating and explained that it would take two or more years to rebuild operations to the prior level. He indicated that this type of catastrophe would result in Medtronic's losing market share.

Pindyck's focus was on step of 4 of Heimert's analysis. He specifically criticized the 14 companies Heimert identified as comparable to MPROC for determining profitability. He explains that Heimert's ROA estimates are calculated using aggregated financials corresponding to nonmanufacturing functions not performed by MPROC and representing manufacturing across other product types not manufactured by MPROC.

[*114] Pindyck believes the Heimert analysis does not correctly calculate the ROA because Heimert looked at the value of the buildings, equipment, and inventory. Heimert, however, did not look at the value of MPROC as an operation. Pindyck testified that MPROC is more valuable than just buildings and equipment, and the entire operation needs to be considered. Pindyck concludes that the ROA is not the best approach.

Heimert's approach ignores valuable intangible assets that were obtained through the devices and leads licenses because these assets are not recorded on petitioner's balance sheet. We agree that his approach is misleading because it ignores the value of the licensed intangibles.

d. Aggregation

The functions at issue in the covered transactions are able to exist independently. The regulations do not require that the transactions be aggregated. See sec. 1.482-1(f)(2)(i)(A), (iv), Income Tax Regs. The section 482 regulations provide examples of the CPM. See id. sec. 1.482-5(e). In Example 4, a U.S. company engages in a variety of activities using unique and invaluable intangibles and the products manufactured in its foreign subsidiary. See id. The example explains that in a separate analysis it is determined that the price charged by the foreign subsidiary to the U.S. company is an arm's-length price under section

[*115] 1.482-3(b), Income Tax Regs. See id. In this example the transactions do not involve related-party transactions requiring aggregation.

The transactions in Example 4 are similar to the covered transactions at issue here. Like the Example 4 transactions, the covered transactions are accounted for and priced separately in the market. Transactions may be aggregated if an aggregated approach produces the "most reliable means of determining the arm's length consideration for the controlled transactions." Veritas Software Corp. & Subs. v. Commissioner, 133 T.C. at 321; sec. 1.482-1(f)(2)(i)(A), Income Tax Regs.

Petitioner contends that the transactions should not be aggregated and that aggregation treats MPROC more like a contract manufacturer, failing to take into account its full role. Respondent contends that aggregating the transactions was required.

Section 1.482-1(f)(2)(i), Income Tax Regs., states that the combined transactions may be aggregated in certain circumstances. The regulations let the Commissioner aggregate separate transactions involving tangibles, intangibles, or services when doing so provides the best means of determining the true taxable income of a controlled taxpayer. Guidant LLC v. Commissioner 146 T.C. _ , _ (slip op. at 38) (Feb. 29, 2016); see, e.g., sec. 1.482-1(b)(2)(ii), (f)(2)(i), Income

[*116] Tax Regs. Thus, whether respondent abused his discretion by aggregating transactions involving intangibles, tangible goods, and provision of services is a question of fact. Guidant LLC v. Commissioner, 146 T.C. at _ (slip op. at 39-40).

In the instant case aggregating the transactions did not result in a reasonable determination of true taxable income. The Heimert aggregations resulted in assigning a value to MPROC's functions and allocating a system profit to MPROC. The resulting system profits allocated to MPROC were not reasonable because Heimert allocated an unreasonably small percentage of the profits to MPROC. Therefore, aggregation was not the most reliable means of determining arm's-length consideration for the controlled transactions. See sec. 1.482-1(f)(2)(i), Income Tax Regs.

4. Analysis

Respondent contends that the Heimert analysis is the best method, and thus should be used as required under section 1.482-1(c), Income Tax Regs. The best method rule, however, requires the facts and circumstances to be considered for determining the arm's-length result. See id. Specifically, we considered the licensing agreement of intangibles for devices and leads between MPROC and Medtronic US.

[*117] The Heimert analysis was dismissive of the importance of MPROC's role in quality. It also considerably downplayed the role of MPROC.

MPROC did more than assemble components. MPROC had the responsibility of taking all the third-party suppliers' components and incorporating them into class III medical devices. MPROC uses its systems engineering expertise to design improvements and improve quality. MPROC has a highly skilled workforce. MPROC tests and sterilizes the devices and leads. These products are not inspected again until they are about to be implanted in a patient. If a flaw is found at that point, there is a substantial chance that a physician may not want to use petitioner's devices and leads again. All class III medical devices are required to meet the same standards, but petitioner believes that quality is a key to its success.

The Heimert analysis and respondent's resulting position do not give the appropriate weight to the role of MPROC. Respondent's adjusted royalty rate attributes only 6%-8% of the profits to MPROC. This attribution is not reasonable. It is difficult to place an exact value on what MPROC contributed to the manufacturing of devices and leads, but it is certainly more than the 8%-12% value attributed by Heimert. Our focus is on the reasonableness of the result and

[*118] not on the details of the methodology employed. See Bausch & Lomb, Inc. v. Commissioner, 92 T.C. at 582.

We hold that petitioner has met its burden of showing that respondent's allocations were arbitrary, capricious, or unreasonable.

C. Commensurate With Income

Not only does respondent contend Heimert's method is the best method; respondent also contends that Heimert's method is commensurate with income and that petitioner's method is not. Respondent contends that petitioner transferred its "crown jewels" to MPROC. Respondent further contends that the facts in this case mirror the concerns expressed in the 1986 legislative change to section 482.

Congress was concerned that taxpayers relied on vastly different products for comparing intangibles, and the House committee stated that "[t]here are extreme difficulties in determining whether the arm's length transfers between unrelated parties are comparable." See H.R. Rept. No. 99-426, supra at 425, 1986-3 C.B. (Vol. 2) at 425. Petitioner had made transfers of similar intangibles to competitors, and the values of the intangibles were known. Similar transfers of intangibles occurred under the Pacesetter agreement.

Respondent contends that "[t]he White Paper, the Department of Treasury's comprehensive study on section 482, recognizes in cases where there is a transfer

[*119] of high-profit intangibles or the 'crown jewels' of the company, the arm's length super-royalty may be a rate that does not exist." Heimert used a value chain analysis which resulted in a super royalty. Petitioner's expert Louis P. Berneman testified that in the medical device industry, generally, "97% of the licenses are for royalty rates of 15% or less." Heimert concluded the royalty rates for the licensing of intangibles needed to be adjusted to 49.4% for 2005 and 58.9% for 2006 for the transactions to be arm's length.

Respondent contends that his method is the best and commensurate with income. The commensurate with income standard does not specify a specific method or a certain range of profits. Heimert's analysis concludes that 6%-8% of the system profits should be allocated to MPROC in order for the transactions to be arm's length. His conclusion shifts too much profit to Medtronic US. Petitioner contends that respondent continues "to press for a marginalizing transactional-based method" and relies on "results-oriented profits based approaches whenever he seeks to increase income subject to U.S. taxation".

The section 482 regulations do not flesh out a particular test or standard to determine whether a transaction is commensurate with income. The commensurate with income standard does not replace the arm's-length standard. See Altera Corp. v. Commissioner, 145 T.C. at _ (slip op. at 49-50); Xilinx Inc. v.

[*120] Commissioner, 125 T.C. 37, 57 (2005), aff'd, 598 F.3d 1191 (9th Cir. 2010). We conclude that respondent's use of the CPM is not required under the section 482 commensurate with income standard and respondent's arguments regarding that standard do not change the Court's view that respondent's allocations were unreasonable.

V. Petitioner's Method

Petitioner must prove that its allocations meet the arm's-length standard; and if petitioner fails, the Court must determine the proper allocations. See Eli Lilly & Co. v. Commissioner, 856 F.2d at 860 (and the cases cited thereat). Petitioner made two primary allocations: (1) for the devices and leads licenses royalties of 29% and 15%, respectively, and (2) for the trademark license royalties of 8%.

A. Devices and Leads Licenses Allocations

Petitioner contends that MPROC paid Medtronic US arm's-length royalties for the intangible property licensed pursuant to the devices and leads licenses. Petitioner contends that its licensing structure with MPROC was comparable to that of a full-fledged entrepreneurial licensee responsible for its own success. Using the CUT method, petitioner contends that royalties of 29% of net device

[*121] intercompany sales and 15% of net leads intercompany sales under the devices and leads licenses are arm's length.

Petitioner contends that the Pacesetter agreement is the best comparable transaction. As part of the Pacesetter agreement, petitioner and Pacesetter agreed to cross-license their pacemaker and ICD patent portfolios. The Pacesetter agreement covered some of the same intangibles that were licensed to MPROC. Pacesetter agreed to pay Medtronic US $50 million up front and $25 million in royalty prepayments upon execution of the agreement. Pacesetter agreed to pay Medtronic a 7% royalty on the retail sale in the United States of all cardiac stimulation devices or components.[11] The initial term of the agreement was for 10 years, but it was extended through petitioner's 2005 fiscal year.

Berneman testified in support of the royalty rates for the rights granted by Medtronic US to MPROC under the devices and leads licenses being arm's length. He believes the arm's-length royalty rate for the devices and leads licenses is 0.5%-20%.

Berneman explained that "[a]n intellectual property license is a grant of rights to make, use, and/or sell products and services that--but for the license--would infringe the exclusionary rights granted to the holders and owners of

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[11]The Pacesetter agreement included leads as part of cardiac devices.

[*122] intellectual property, such as patents, know-how, trade secrets, trademarks, and copyrights." Berneman reviewed almost 1,300 license agreements. He applied screening criteria such that a materially similar license must: (1) include a grant of rights to patents and/or associated know-how to manufacture, market, and/or sell a medical device product and/or a grant of rights to a licensor's trademark or tradename; (2) include exclusive rights for the licensee; (3) not contain redacted material terms (e.g., royalty rates); (4) involve only commercial entities; (5) include at least the United States in its applicable territory; (6) not be a sublicense; (7) relate to a fully developed, market-ready, and FDA-approved medical device; and (8) pertain to cardiovascular or neurological medical devices similar to petitioner's devices and leads. Berneman identified five agreements and included two additional agreements that did not include the exclusivity requirement. One of these additional agreements was the Pacesetter agreement. The Pacesetter agreement was a nonexclusive cross license.

Berneman testified that the Pacesetter agreement was the best comparable transaction, even though he concluded that the intercompany licenses for devices and leads granted much broader rights than did the Pacesetter agreement. He testified that the Pacesetter agreement was the best comparable because it "deals

[*123] with the same patents, the same market, the same product, in the same time frame, for the same customers, and offers the same profit potential." Berneman testified that "market and product stage and development are proxies for profit potential".

He testified that the Pacesetter agreement did not include rights to future developments, whereas the devices and leads licenses specifically included improvements defined as "any finding, discoveries, inventions, additions, modifications, formulations, or changes" made during the terms of the respective licenses by either Medtronic US or MPROC. Because the Pacesetter agreement did not include future developments, he applied an upward adjustment to the Pacesetter agreement of 2%-3% to account for the additional know-how that would have been granted in a comparable license.[12] He later testified that the Pacesetter agreement included a process for future patents, but he did not change his adjustment of 2%-3%. Berneman neither clarified nor explained the difference in the devices and leads licenses regarding the improvements and future products language in the Pacesetter agreement.

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[12]Berneman did his calculations using retail price numbers; he later made calculations to wholesale price numbers, which are used by the parties.

[*124] During his testimony Berneman explained adjustments made to the Pacesetter agreement. These adjustments were not described in his expert report. He doubled the royalty rate of 7% -14% to address exclusivity. Then he added 2%-3% as described above for know-how, giving a rate of 16%-17%. He explained that there would be an upward pressure on the royalty rate because Medtronic is obligated in the license agreement to continue to provide regulatory affairs assistance. He further explained that there would also be downward pressures. The first downward pressure is petitioner had total leverage in the Pacesetter agreement because Pacesetter's products had been found to have infringed and were subject to being enjoined. The second downward pressure is the license to MPROC is not exclusive because Medtronic had already granted licenses to major market competitors for some of the patents. Berneman concluded the royalty rate for the Pacesetter agreement as a comparable is 16%-17% (retail).

Unlike the Pacesetter agreement the agreements in this case include both Neuro and CRDM devices and leads. The devices and leads for the CRDM and Neuro businesses are similar but have differences. For the devices license, the products included medical device pulse generators in the following businesses: bradycardia pacing, tachy management, and neurological stimulation. For the

[*125] leads license, the products included medical delivery therapy devices, which represent electrode leads for implantable pulse generators and for implantable cardioverter defibrillators, and neurostimulation electrode leads in the following businesses: bradycardia pacing, tachy management, and neurological stimulation. The devices and leads are tailored for specific applications. The devices and leads perform different functions and have different requirements depending on whether they are CRDM or Neuro. CRDM and Neuro products serve distinct medical purposes. The Pacesetter agreement was only for CRDM devices. Berneman did not explain the differences in the patents in either the Pacesetter agreement or the devices and leads licenses. Berneman did not discuss or make any adjustments for the additional patents.

Not only did Berneman make no adjustments or distinguish that the devices and leads are for both CRDM and Neuro products; he did not analyze devices and leads separately; rather, he looked at them collectively. He determined that the royalty range for technology licenses is between 0.5% and 20% of sales and that the device royalty rate of 29% (19.7% retail) and the leads royalty rate of 15% (10.2% retail) were consistent with arm's-length behavior.[13] Berneman's range is

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[13]The Berneman comparables used retail prices and he converted the devices and leads rates to retail rates in order to make a comparison.

[*126] very broad, and we are not convinced that his analysis looks closely at the technology and products covered by the devices and leads licenses.

The Berneman report focused on seven comparable agreements. It appears that six were related to CRDM products. Berneman did not make adjustments based on technology, and he did not explain why such adjustments were not necessary. Some of the comparables, including the Pacesetter agreement, included a lump sum agreement. Berneman did not make upward adjustments to the royalty rates of any of his comparables to account for lump-sum payments.

Berneman's broad range of 0.5%-20% is unconvincing and vague. For example, in one of Berneman's comparable transactions, petitioner entered into an agreement for technology for both implantable and nonimplantable medical applications, including CRDM and Neuro. The royalty rates ranged from 2% of the net internal transfer price to 3% of actual selling prices. The report included no adjustments to this comparable even though it seems to be significantly lower than where an arm's-length rate would be for the devices and leads licenses. We do not consider this to be a comparable transaction because a royalty rate of 2%-3% is not even in the ballpark of what the rate should be for the devices and leads licenses. Berneman testified that not all licensing agreements within the range would be arm's length and that he looked for comparables that "addressed the

[*127] same drivers of value". His report and his testimony, however, failed to state what an appropriate range would be for the each of the devices and leads licenses. Only adjustments were made to the Pacesetter agreement, and Berneman made those adjustments during his testimony. His report and his testimony failed to explain how his conclusions specifically apply to the devices and leads licenses.

Berneman testified that he made a 2%-3% adjustment to the Pacesetter agreement for know-how because the Pacesetter agreement excluded future technology. Berneman provided no further explanation for how the know-how adjustment was calculated. The devices and leads licenses define know-how as all technical information presently available that relates to the product or improvements and information useful for the development, manufacture, or effectiveness of the product. Pacesetter, which later became St. Jude, made and sold products covered by the Pacesetter agreement. The evidence does not support an ongoing relationship between petitioner and Pacesetter whereas the evidence supports an ongoing relationship between Medtronic US and MPROC. Throughout the trial, we heard about the close relationship between Medtronic US and MPROC. Each party benefited from the know-how of the other. Medtronic US was constantly making improvements to products, and MPROC was ensuring the quality of the product and improving the manufacturing. There was give and

[*128] take between the engineers of Medtronic US and MPROC. MPROC had a relationship with Medtronic US that resulted in MPROC's receiving valuable know-how. Berneman failed to make a sufficient adjustment for know-how.

Under section 1.482-4(c)(2)(ii), Income Tax Regs., if an uncontrolled transaction involves the same transfer of the same intangible under the same, or substantially the same, circumstances as the controlled transaction, the result derived from applying the CUT method will generally be the most direct and reliable measure of arm's length. The Pacesetter agreement included some of the same intangibles, but the devices and leads licenses included additional intangibles. The Berneman report did not show which intangibles from the Pacesetter agreement were included in the devices and leads licenses. From a review of the agreements, we determine that no Neuro devices or leads were included in the Pacesetter agreement. We also note that the Pacesetter agreement came about because of litigation.

If an uncontrolled transaction of the same intangibles cannot be found, a comparable intangible can be used. Id. subdiv. (i). The CUT method requires that in order for intangible property involved in an uncontrolled transaction to be considered comparable to the property involved in the controlled transaction, certain factors must be considered, including profit potential. Id. subdiv.

[*129] (iii)(B)(1). Profit potential is most reliably measured by a net present value calculation of the benefits to be realized (based on prospective profits to be realized or costs to be saved) through the use or transfer of the intangible. Id. subdiv. (iii)(B)(ii). Berneman's analysis unacceptably lacks an examination of the profit potential of his comparable transactions, including the Pacesetter agreement as defined by regulations. Rather, Berneman concludes that market and product are proxies for profit potential. He did not explain how these proxies work, or provide detail of which markets and products were considered in his comparables. Merely looking at whether the product has CRDM or Neuro applications or whether the product is market ready is insufficient to determine whether there is a similar profit potential as defined by the regulations.

We find that the royalty rates petitioner proposed are not arm's length because, along with all of the concerns addressed above, appropriate adjustments were not made to the CUT method to account for variations in profit potential. See id. Therefore, petitioner has not met its burden.

B. Trademark License Allocations

Petitioner's expert Berneman concluded that a royalty rate of 8% (wholesale) for the trademark license exceeded arm's-length range. He looked at 75 agreements, including 57 to which petitioner was a party. These agreements

[*130] had a combined royalty rate for technology and trademark rights ranging from 0% to 15% of net sales. Using the same criteria as for the other licenses, Berneman selected 44 agreements that established separate and distinguishable payment terms for the grant of rights to a trademark or trade name. Each agreement contained trademark royalty rates ranging from 0% to 5% (retail) of net sales. The actual royalty rate contained in the trademark licence agreement is 5.3% of sales (retail), which exceeds the arm's-length ranges.

Therefore, we conclude that this agreement meets the requirements of section 482.

VI. Proper Allocation

A. Respondent's Failure To Provide an Adjustment to Petitioner's Methodology

Respondent took an all-or-nothing approach by advocating a result based on the CPM using value chain method and by refusing to suggest adjustments to petitioner's CUT method for the devices and leads licenses. Respondent consistently criticized petitioner's transfer pricing method and contended that respondent's method was the best. Because of respondent's approach, and because we have concluded that neither party's transfer pricing analysis was

[*131] reasonable, we are left with little help from the parties to determine the proper method.

In other transfer pricing cases, the Court was required to determine the proper transfer pricing method. See Perkin-Elmer Corp. & Subs. v. Commissioner, T.C. Memo. 1993-414 (the Court was forced to find a middle ground without sufficient help from the parties). Sometimes it has been necessary that we use imperfect comparables as a "base from which to determine the arm's length consideration for the intangible property". Sundstrand Corp. & Subs. v. Commissioner, 96 T.C. at 393; see Veritas Software Corp. & Subs. v. Commissioner, 133 T.C. at 335. Section 1.482-1(e)(2)(ii), Income Tax Regs., provides:

> Uncontrolled comparables must be selected based upon the comparability criteria relevant to the method applied and must be sufficiently similar to the controlled transaction that they provide a reliable measure of an arm's length result. If material differences exist between the controlled and uncontrolled transactions, adjustments must be made to the results of the uncontrolled transaction if the effect of such difference on price or profits can be ascertained with sufficient accuracy to improve the reliability of the results. * * *

The CUT is a proper method to determine taxable income in connection with a transfer of intangible property. See id. sec. 1.482-4(a). There are factors to determine comparability. These factors include: be used in connection with

[*132] similar products or processes and having similar profit potential. See id. paras. (a), (c)(2)(iii)(B)(1). The comparable circumstances also need to be considered, such as the terms of the transfer, the stage of development, the right to seek updates, the length of the license, and economic and product liability risks to be assumed by the transferee. See id. subdiv. (iii)(B)(2). Respondent contends that the Pacesetter agreement does not reflect a CUT to which adjustments should be made. Respondent states in his answering brief that "such exercise would be fruitless given that Pacesetter is not comparable in any sense". Respondent also criticized petitioner's method for making separate calculations. Respondent's expert, however, agreed that two of the covered transactions were arm's length despite petitioner's decision to calculate them separately. Respondent only concluded that the intangible property transactions were not arm's length. We do not think it is necessary to revise all four transactions to reach an arm's-length result when only one of the four transactions is not arm's length. We do not agree with respondent that his approach is the best method and that adjustments could not be made to the one troubling area of petitioner's methodology--the royalty rates for the licensing of intangibles for devices and leads. We conclude that appropriate adjustments should be made to petitioner's CUT.

[*133] B. Adjustments to Petitioner's CUT for Devices and Leads Licenses

Petitioner contends that the amount charged in the Pacesetter agreement is an appropriate CUT. The Pacesetter agreement includes some of the same patents which Medtronic US licensed to MPROC. Berneman's report indicates that he thought the requirements of section 1.482-4, Income Tax Regs., were consistent with his screening criteria or do not materially affect his determination of arm's-length royalty rates. Specifically, the Pacesetter agreement relates to some of the same products and has similar profit potential. Berneman testified that the Pacesetter agreement was the best comparable because it "deals with the same patents, the same market, the same product, in the same time frame for the same customers, and the same profit potential." We agree that the Pacesetter agreement is an appropriate CUT because it involved some of the same intangibles and had comparable circumstances. If the same intangibles are involved, it is usually the most direct and reliable measure of an arm's-length transfer of an intangible. See sec. 1.482-4(c)(2)(ii), Income Tax Regs. However, the devices and leads licenses include more intangibles than the Pacesetter agreement. As we discussed previously, the Pacesetter agreement included only CRDM products.

We have concluded that transactions not identical to controlled transactions may be sufficiently similar to provide a reliable measure of an arm's-length result.

[*134] See Compaq Computer Corp. v. Commissioner, slip op. at 33. Imperfect comparables "serve as a base from which to determine the arm's length consideration for the intangible property involved in this case". Sundstrand Corp. & Subs. v. Commissioner, 96 T.C. at 393; see Veritas Software Corp. & Subs. v. Commissioner, 133 T.C. at 335.

1. Starting Royalty Rate

Petitioner contends that the 7% royalty rate in the Pacesetter agreement is comparable. Petitioner's expert witness, Berneman, made adjustments to this rate. He applied a 7% increase for exclusivity and 2%-3% increase for know-how. He did not explain in detail the know-how increase, but he testified that it accounts for the grants of rights to future know-how contained in the devices and leads licenses. In the light of his adjustments, we start at 17%.[14] We conclude that these adjustments are reasonable and provide an appropriate starting point to calculate the royalty rate for the devices licenses.

[14]These percentages are based on retail sales because retail sales were used in the Berneman report.

[*135] 2. Adjustments

a. Know-How

MPROC maintained an extremely close relationship with Medtronic US. There was a back and forth between MPROC and Medtronic US with a focus on a single goal, making a high-quality product. MPROC had access to the know-how of Medtronic. Pacesetter and its successor, St. Jude, did not have an ongoing relationship with Medtronic. Berneman made an adjustment, which he referred to as know-how, but this adjustment was related to future technology. Berneman made no adjustments for the know-how that Medtronic shared with MPROC. Berneman doubled the Pacesetter royalty rate to account for the exclusivity of the devices and leads licenses. We conclude that the relationship between Medtronic and MPROC provides know-how that is equivalent to the exclusivity in the devices and leads licenses. Accordingly, we increase the Pacesetter royalty rate by 7%.

b. Profit Potential

We agree with respondent's criticism of petitioner's CUT that profit potential should have been taken into consideration. The products included in the devices licenses were profitable, and their profit potential was not part of the Berneman analysis. Profit potential looks at the benefits to be realized on the

[*136] basis prospective profits. See sec. 1.482-4(c)(2)(iii)(B)(ii), Income Tax Regs. In order to account for profit potential, we make an upward adjustment of 3.5%, which is half the value of the Pacesetter agreement. We think that certain of the products included in the devices licenses are very profitable and have led to petitioner's success. Similarly, the products covered by the Pacesetter agreement have been very profitable, but petitioner was the market leader during the years at issue. While we think that it is important to make an adjustment for profit potential, we think that exclusivity and know-how have a greater impact on the value of the licenses. Without exclusivity the licenses would have significantly less value. MPROC was able to make a product of superior quality because of know-how received from Medtronic US. For this reason we halve the amount of the adjustment for exclusivity and know-how to adjust for profit potential.

c. Scope of Products

We have previously discussed our concerns with the Berneman report, which failed to make an adjustment for the additional products included in the devices licenses. We have noted that the Pacesetter agreement includes only CRDM technology and the devices licenses include both CRDM and Neuro products. We realize that Berneman used other comparables that included different technology. However, Berneman failed to make adjustments to any of

[*137] these other comparables. His report failed to make an adequate comparison to the devices licenses. An adjustment is needed to take into account the additional products in the Neuro division and additional CRDM products. Neuro was not as large or as profitable as CRDM. We conclude that a 2.5% upward adjustment, which is slightly more than one-third of the Pacesetter royalty rate, is a proper adjustment.

3. Calculation of Revised Royalty Rate

The adjustments described above can be calculated as follows:

Adjustment	Percentage (in retail)
Starting royalty rate	17
Know-how	7
Profit potential	3.5
Scope of product	2.5
Total	30

Our adjustments to the Pacesetter agreement arrive at a revised royalty rate of 30%; converted to reflect wholesale sales it is 44%.[15] Therefore, an appropriate arm's-length rate for devices would be 44%.

[15]The conversion to wholesale used the same calculation Berneman used in his report.

[*138] In his report Berneman failed to distinguish devices and leads, and he did not have a separate rate. Petitioner contends that 15% is an appropriate royalty rate for the leads licenses, which is approximately half of the 29% royalty rate that petitioner contends is appropriate for the devices licenses. During the years at issue the device operations were substantially more profitable than the leads operations. We conclude that a reasonable royalty rate for the leads licenses would be 22%, half of the 44% that we determined for the devices licenses.

With the aforementioned adjustments, the CUT method is the best method for determining the arm's-length rate. We note that our adjustments result in rates that are close to the rates that the parties previously negotiated in the MOU. This is coincidental. The adjustments were not made to mimic the MOU but rather to reflect the facts and expert testimony.

VII. Swiss Supply Agreement

Medtronic Europe is a wholly owned, second-tier subsidiary of Medtronic US. Medtronic US, MPROC, and Medtronic Europe entered into a supply agreement in which Medtronic Europe agreed to assist MPROC by manufacturing and supplying the U.S. market with devices necessary to meet customer demand. Medtronic Europe agreed to pay Medtronic US directly an amount equal to the

[*139] royalties that MPROC would have paid if it had manufactured the devices and had made the sale to Med USA itself.

Respondent increased the amounts owed by Medtronic Europe to Medtronic US under the Swiss Supply Agreement. Petitioner contends that it is entitled to an overpayment pursuant to section 6512(b). This issue should be resolved in the same manner as the section 482 issue regarding devices. Therefore, the royalty rate for devices should be 44% for the Swiss Supply Agreement.

VIII. Transfer of Intangible Property

The notice of deficiency makes an alternative allocation under section 367(d) that may apply if we do not sustain respondent's section 482 allocations in their entirety. The notice of deficiency states alternatively "that significant value has been transferred to Medtronic Puerto Rico Operations Co. (MPROC), [and] then it is determined that such value transferred (exclusive of tangible assets transferred) is taxable under I.R.C. [section] 367(d)." The notice of deficiency further states that "Medtronic must include in taxable income amounts not to exceed $496,529,306 for the taxable year ended April 29, 2005, and $750,741,381 for the taxable years ended April 28, 2006." These amounts are the same as

[*140] those in the notice of deficiency for section 482 adjustments for CRDM and Neuro.[16]

Section 367(a) provides general rules for the taxation of outbound transfers of property by U.S. persons to foreign corporation transferees in transactions that would otherwise qualify as nonrecognition transfers, such as section 351 transfers. There are exceptions to this rule, and section 367(d) provides special rules for the taxation of outbound transfers of intangible property. Temporary regulations provide guidance on how the transferor should take into income an amount that represents an appropriate arm's-length charge for the use of the transferred property. See sec. 1.367(d)-1T(c)(1), Temporary Income Tax Regs., 51 Fed. Reg. 17954 (May 16, 1986). Section 367(d) applies "if a United States person transfers any intangible property (within the meaning of section 936(h)(3)(B)) to a foreign corporation in an exchange described in section 351 or 361". Sec. 367(d)(1).

Intangible property subject to section 367(d) is defined in section 936(h)(3)(B) as follows:

> (i) patent, invention, formula, process, design, pattern, or know-how;
>
> (ii) copyright, literary, musical, or artistic composition;

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[16]These amounts do not include the increases that were included in the amended answer.

[*141] (iii) trademark, trade name, or brand name;

(iv) franchise, license, or contract;

(v) method, program, system, procedure, campaign, survey, study, forecast, estimate, customer list, or technical data;

or

(vi) any similar item which has substantial value independent of the services of any individual.

Respondent contends that if we do not agree with the allocations under section 482 as set forth in the notice of deficiency, and as amended in the answer, then intangible property subject to section 367(d) "must have been" transferred to MPROC in 2002 when it was formed. This argument seems to be based on the premise that if we do not agree with respondent's section 482 allocation, we must agree that intangibles were transferred. Respondent argues that "it is a fact that the value of the newly formed MPROC did not appear out of thin air, but had to be the result of a massive infusion of intangible assets at its inception."

Respondent has not identified or alleged that any specific intangibles were transferred to MPROC by the section 936 possession corporations. Respondent's witness Venske, a member of the audit team for Medtronic's 2000-2002 tax years, stated that the team did not find that any section 936(h)(3)(B) intangibles were transferred to MPROC during the transaction. Rather, the gist of respondent's

[*142] argument seems to be that MPROC could not possibly be as profitable as it is unless intangibles were transferred to it. We are not persuaded by this argument.

During 2002 respondent raised the transfer of intangibles issue with regard to workforce in place and goodwill transferred from the section 936 possession corporations to MPROC on September 30, 2001. Petitioner agreed to resolve this issue, and this resolution was reflected on its tax returns for 2005 and 2006.[17]

Beginning in the mid-1970s, the section 936 possession corporations conducted their business operations entirely in Puerto Rico. Before the 2002 business restructuring, Medtronic Puerto Rico, Inc., actively manufactured leads at its plant in Villalba, Puerto Rico, and Med Rel, Inc., actively manufactured devices at its plant in Humacao, Puerto Rico. All of the tangible assets necessary to conduct the section 936 possession corporations' businesses were in Puerto Rico, and all of the equipment necessary to manufacture finished devices and leads was in Puerto Rico. As part of the 2002 business restructuring, the section 936 possession corporations contributed their operational assets to MPROC in exchange for MPROC stock in a section 351 transaction.

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[17]The adjustment made for 2002 does not prevent respondent from raising the sec. 367(d) issue here. See Greenberg's Express, Inc. v. Commissioner, 62 T.C. 324, 327 (1974).

[*143] Before the restructuring, the section 936 possession corporations had access to U.S. intangibles for the purpose of manufacturing and selling Medtronic's medical devices. After the restructuring MPROC entered into the devices and leads licences, which provided MPROC the access to the intangible property necessary to manufacture and sell devices and leads. Respondent states in his answering brief that "section 367(d) does not apply to the IP licensed by MPROC."

Petitioner contends that the section 936 possession corporations did not own any intangibles as defined pursuant to section 936(h) and therefore there was no intangible property to transfer to MPROC. Respondent did not specifically identify any intangibles or explain the specific value of any intangibles that should be covered by section 367(d) and what an appropriate arm's-length charge would be for the use of the intangibles. It is unclear which intangibles respondent believes are subject to section 367(d). It is clear that before restructuring the section 936 possession corporations made use of intangibles and these same intangibles were the subject of the devices and leads licenses.

On the record before us, we are not persuaded that intangibles were transferred that should be subject to section 367(d).

[*144] Any contentions we have not addressed are irrelevant, moot, or meritless.

An appropriate order will be issued.