United States Tax Court

T.C. Memo. 2022-84

MEDTRONIC, INC. AND CONSOLIDATED SUBSIDIARIES, Petitioner v. COMMISSIONER OF INTERNAL REVENUE, Respondent¹

Docket No. 6944-11.

Filed August 18, 2022.

Andrew D. Allen, David J. Berke, Melinda Gammello, Thomas V. Linguanti, Rajiv Madan, and Jaclyn M. Roeing, for petitioner.

John Edward Budde, Paul L. Darcy, Laurie B. Downs, Elizabeth P. Flores, Jill A. Frisch, Jeannette D. Pappas, and H. Barton Thomas, for respondent.

SUPPLEMENTAL MEMORANDUM FINDINGS OF FACT AND OPINION

KERRIGAN, *Chief Judge*: This matter is before the Court on remand from the U.S. Court of Appeals for the Eighth Circuit for further consideration consistent with its opinion in *Medtronic II*, 900 F.3d 610. The Eighth Circuit remanded the case for further consideration in the light of the views set forth in its opinion. *See id.* at 615. The Eighth Circuit stated: "The [T]ax [C]ourt determined that the Pacesetter agreement was an appropriate [comparable uncontrolled transaction (CUT)] because it involved similar intangible property and had similar circumstances regarding licensing. We conclude that the [T]ax [C]ourt's

¹ This Opinion supplements our previous Opinion Medtronic, Inc. & Consol. Subs. v. Commissioner (Medtronic I), T.C. Memo. 2016-112, vacated and remanded, Medtronic, Inc. & Consol. Subs. v. Commissioner (Medtronic II), 900 F.3d 610 (8th Cir. 2018).

[*2] factual findings are insufficient to enable us to conduct an evaluation of that determination." *Id.* at 614.

The Eighth Circuit stated that we did not provide (1) sufficient detail as to whether the circumstances between Siemens Pacesetter, Inc. (Pacesetter), and Medtronic US were comparable to the licensing agreement between Medtronic US and Medtronic Puerto Rico (MPROC) and whether the Pacesetter agreement was one created in the ordinary course of business; (2) an analysis of the degree of comparability of the Pacesetter agreement's contractual terms and those of the MPROC's licensing agreement; (3) an evaluation of how the different treatment of intangibles affected the comparability of the Pacesetter agreement and the MPROC licensing agreement; and (4) the amount of risk and product liability expense that should be allocated between Medtronic US and MPROC. See id. at 614–15. The Eighth Circuit "deem[s] such findings to be essential to [its] review of the [T]ax [C]ourt's determination that the Pacesetter agreement was a CUT, as well as necessary to [its] determination whether the [T]ax [C]ourt applied the best transfer pricing method for calculating an arm's length result or whether it made proper adjustments under its chosen method." Id. at 615.

The parties agreed that the record did not need to be reopened with respect to the amount of risk and product liability expense that should be allocated between Medtronic US and MPROC because the record is already sufficient to make additional factual findings on that issue. Pursuant to the Court's May 3, 2019, Order, further trial was scheduled for expert testimony to address:

- (1) whether the Pacesetter agreement is a CUT;
- (2) whether this Court made appropriate adjustments to the Pacesetter agreement as a CUT;
- (3) whether the circumstances between Pacesetter and Medtronic US were comparable to the licensing agreement between Medtronic and [MPROC] and whether the Pacesetter agreement was an agreement created in the ordinary course of business;
- (4) an analysis of the degree of comparability of the Pacesetter agreement's contractual terms and those of the [MPROC] licensing agreement;

- [*3] (5) an evaluation of how the different intangibles affected the comparability of the Pacesetter agreement and the [MPROC] licensing agreement;
 - (6) an analysis that contrasts and compares the CUT method using the Pacesetter agreement with or without adjustments and the [comparable profits method (CPM)], including which method is the best method.

See Medtronic II, 900 F.3d at 614–15.

Respondent determined deficiencies as amended by Answer in petitioner's federal income tax of \$548,180,115 and \$810,301,695 for 2005 and 2006 (years in issue), respectively. Unless otherwise indicated, all statutory references are to the Internal Revenue Code, Title 26 U.S.C. (Code), in effect at all relevant times, all regulation references are to the Code of Federal Regulations, Title 26 (Treas. Reg.), in effect at all relevant times, and all Rule references are to the Tax Court Rules of Practice and Procedure. We round all monetary amounts to the nearest dollar.

We held in *Medtronic I* that the CUT method was the best method for determining the arm's-length rate. *Medtronic I*, at *138. We concluded that a reasonable wholesale royalty rate for the devices is 44%, a reasonable wholesale royalty rate for the leads is 22%, and the wholesale royalty rate for devices should be 44% for the Swiss supply agreement. *Id.* at *137–39.

The issues for our consideration are (1) whether the CUT method is the best method for determining the arm's-length rate, (2) what the proper royalty rates are for the devices and the leads, and (3) what the proper royalty rate is for devices sold pursuant to the Swiss supply agreement.

After analyzing the above issues, we conclude that petitioner has not met its burden to show that its allocation under the CUT method and its proposed unspecified method satisfy the arm's-length standard. We further conclude that respondent's modified CPM results in an abuse of discretion and that the wholesale royalty rate for devices and leads is 48.8%. Accordingly, the wholesale royalty rate for devices covered by the Swiss Supply Agreement is 48.8%.

[*4] FINDINGS OF FACT

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

Facts of this case were found in our original Opinion, *Medtronic I*, and are incorporated by this reference. We summarize, clarify, and add to the facts to address the holding in *Medtronic II*.

I. Overview of Petitioner

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 in 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. Medtronic Puerto Rico

MPROC has been manufacturing class III implantable medical devices for sale in the United States and around the world for nearly 50 years. For the past almost 20 years, it has been conducting its operations under licenses from its parent, Medtronic US.

MPROC manufactures devices and leads, both of which are lifesaving or life-sustaining class III medical devices, as defined and determined by the Food and Drug Administration (FDA). Medtronic US and MPROC entered into license agreements under which MPROC **[*5]** obtained the right to use, develop, and enjoy the intangible property for manufacturing devices for sale to customers in the United States and its territories and possessions and leads for sale to customers worldwide.

MPROC's device and leads operations were FDA-registered facilities subject to regular pre-market and post-market 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 involved in every aspect of the manufacturing processes for devices and leads. It was solely responsible for ensuring that the final manufactured devices and leads met the required specifications and for determining whether a device or lead met the applicable regulatory standards and whether it was ready for implantation in the human body. MPROC had the responsibility of inspecting and handling the finished devices or leads and ensuring that all components were properly combined so that the device could provide the patient therapy repeatedly and reliably.

The process to make devices and leads was very detailed. It required skilled workers. MPROC would fire an employee if a defect could be traced back to that employee's work, even if it was the employee's first mistake. MPROC tested and sterilized finished devices and leads. As Medtronic's senior vice president of medicine and technology testified convincingly: "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."

The manufacturing processes for both devices and leads takes a week or longer. The products are made in an FDA-regulated "cleanroom" environment. Some processes cannot be done automatically and require 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 made with the highest quality and be able to be placed 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 were manufacturable at commercial scale. The bottom line was that if a finished product cannot be made, it cannot be sold.

[*6] 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's consolidated group. During 2005 and 2006 MPROC sold devices and leads to Med USA for sale in 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; developing their respective markets by 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 in 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. Class III Medical Devices

In order for certain medical devices to be legally marketed in the United States, they must be FDA approved. The 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, § 2, 90 Stat. 539, 540 (codified as amended at 21 U.S.C. 360c). Class I medical devices are subject to the fewest regulatory controls, 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 five to ten years. Class III medical devices are higher risk and more novel than are those of classes I and II.

Medical devices are categorized as class III if there is insufficient information that existing controls applicable to classes I and II devices are sufficient to provide reasonable assurance of safety and effectiveness [*7] and the devices 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." 21 U.S.C. 360c(a)(1)(A)(ii)(II). Class III medical devices require more scrutiny than class I or class II devices. Class III medical devices include those which are life supporting or life sustaining, such as 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 wheelchairs and infusion pumps.

Class III medical devices must typically be FDA approved before they are marketed through the PMA process, which is rigorous, costly, and time consuming. The PMA 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.

- D. CRDM and Neuro Business Units
 - 1. 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.

a. Manufacturing

In general cardio devices have three primary components: implantable pulse generators (IPGs), leads, and programmers. IPGs are battery-powered 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 **[*8]** IPG regarding its activities. Programmers were manufactured by an outside vendor and are not relevant to this case.

b. *Devices*

CRDM device products consisted primarily of bradycardia pacemakers, also known as IPGs; tachyarrhythmia (tachy) devices, also known as implantable cardioverter defibrillators (ICDs); and cardiac resynchronization therapy (CRT) devices. IPGs treat abnormally slow heart rates. ICDs treat abnormally fast heart rates. ICDs also have capacitors as components. 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. The 40 different models of devices comprised approximately 750 individual components.

MPROC's 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 that involved approximately 40 steps. 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, MPROC relied on its employees to verify those automated processes, to perform multiple quality inspections throughout each manufacturing stage, to complete significant portions of the process manually, and to oversee and troubleshoot all manufacturing processes generally. Highly trained and skilled operators oversaw all manufacturing processes.

MPROC needed to use extreme care to interconnect the various components of a device, ensure that it was hermetically sealed, and sterilize it. 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. Because of the stringent quality standards that class III finished devices must meet, the device operations maintained a detailed traceability system of each step of the manufacturing process in the event that it **[*9]** needed to trace a quality issue to its source in the manufacturing process.

c. Leads

CRDM products included leads, which are 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 that are insulated with silicone or polyurethane and are implanted into the right atrium, right ventricle, or left ventricle of the heart.

Because CRDM leads are implanted in a patient's heart, removing a lead because of a product quality defect 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 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 riskiest 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 create a hole in the patient's heart, which can be fatal.

2. 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 disorders, 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, brain, or 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 **[*10]** are attached to specific parts of the spinal cord. The therapy functions 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 manage some of the most disabling movement disorders, such as Parkinson's disease, essential tremor, and dystonia. Leads are placed in targeted areas of the brain, and the amount of electrical stimulation is adjusted to meet the patient's needs. Neurosurgeons, neurologists, pain management specialists, and orthopedic spine surgeons commonly use these products.

a. *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.

b. *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, but the specifications and applications of Neuro's devices were different from those of CRDM's devices.

c. Leads

The production of leads was extremely complicated and labor intensive. Leads manufacturing was an almost completely manual process, performed within tight tolerances, requiring skilled labor to join raw material with 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 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 traceability system of each step of the manufacturing process in the event that it needed to trace a quality issue back to its source.

[*11] MPROC's leads operations were responsible for specifying, purchasing, validating, and installing the equipment that it needed to manufacture leads. Neuro leads did not use any components from the Medtronic Microelectronics Center or the Medtronic Energy & Component Center. 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 approval, not only from Medtronic, but also from the FDA and other regulatory agencies, before the equipment could be used in the manufacturing process.

E. Competitors

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. (Stryker). 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.

F. Self Insurance

The threats 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 in 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. [*12] Medtronic's business and legal groups were responsible for 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.

II. MPROC Agreement

Medtronic US and Med USA entered into various agreements and amendments with MPROC that were effective during 2005 and 2006. 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, tachy management, and neurological stimulation. The leads license was for products that include medical therapy delivery devices, which include electrode leads for implantable pulse generators and implantable cardioverter defibrillators, and neurostimulation electrode leads.

The MPROC agreement provided MPROC with an exclusive license to use Medtronic US's patents and Medtronic US's portfolio of technology implantables. The total number of patents made available to MPROC under the MPROC agreement exceeded 1,600 by May 2004 and topped 1,800 through April 2006.

Under the terms of the MPROC agreement, each party was required to disclose and share all know-how and product improvements with the other. If terminated, the MPROC agreement barred MPROC from using or disclosing any confidential know-how or other information received from Medtronic US for six years unless the information was public or was documented by MPROC before the agreement began. The 2005 MPROC agreement had a one-year term, and the 2006 MPROC agreement had a three-year term.

Under the devices and leads licenses, MPROC obtained the exclusive right to use, develop, and enjoy, not only Medtronic US's patents, but also the full array of intangible property necessary in manufacturing devices for sale to customers in the United States and its territories and possessions, and leads for sale to customers worldwide.

The devices and leads licenses both define intangible property for any product as:

[*13] Section 1.4. Intangible Property

"Intangible Property" shall mean Licensor developed inventions, secret processes, technical information, and technical expertise relating to the design of Product and all legal rights associated therewith, including without limitation, patents, trade secrets, know-how, copyrights and all Regulatory Approvals associated with Product.

As specified in the devices and leads agreements, intangible property included know-how, which the agreements both defined as:

Section 1.5. Know-How

"Know-How" shall mean any and all technical information presently available or generated during the term of this Agreement that relates to Product or Improvements and shall include, without limitation, all manufacturing data and any other information relating to Product or Improvements and useful for the development, manufacture, or effectiveness of Product.

Under the devices and leads agreements, improvements consist of:

Section 1.3. Improvements

"Improvements" shall mean any findings, discoveries, inventions, additions, modifications, formulations, or changes made by either Licensor or Licensee to product design during the term of this Agreement that relate to Product.

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, [*14] 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.

The MPROC licenses assigned all product liability risk for devices and leads to MPROC and stated that MPROC was "liable for all costs and damages arising from recalls and product defects." MPROC took two main approaches to managing product liability. First, MPROC made every effort to ensure that its finished devices and leads were consistently manufactured to the highest standards in order to minimize the potential for product failures. Second, in the event of a lapse in product quality, the terms of the MPROC licenses dictated that MPROC was solely responsible for restoring product quality to agreed-upon standards and bore all associated product liability costs.

In accordance with the devices and leads licenses, MPROC agreed to pay what Medtronic US and MPROC determined to be an arm'slength wholesale royalty of 29% to Medtronic US on MPROC's U.S. net intercompany sales of devices and 15% to Medtronic US on MPROC's net intercompany sales of leads. The initial terms of the device and leads licenses were through April 30, 2003. The MPROC agreements were renewable at both parties' option 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 US and the IRS. The amended agreements included a profit split methodology that changed the royalty rates. MPROC would pay a 44% wholesale royalty rate to Medtronic US on its net intercompany sales of devices and a 26% wholesale royalty rate to Medtronic US on its net intercompany sales of leads. Other provisions of the licenses remained in place.

III. Pacesetter Agreement

In the late 1980s and early 1990s Medtronic US and Pacesetter were engaged in patent litigation related to Medtronic US's patents for many of its cardiac rhythm stimulation devices, including patents underlying its "Activitrax" technology, which established rate[*15] responsive pacemakers that monitor and adapt to changes in cardiac rhythm. To prevail in the dispute Medtronic US had to establish that its relevant CRDM patents were valid and that Pacesetter had infringed on one or more of them. Medtronic US was successful, and in late 1991 and early 1992, the district court ruled that (1) Medtronic US's Activitrax patent was valid; (2) Pacesetter was infringing on it; and (3) Pacesetter was permanently enjoined from selling three of its five rate-responsive CRDM products.

A. Background on CRDM Patents

The development of ICDs started around 1968. Dr. Mirowski was a pioneer in the field. His work resulted in implantable pacemakers. Dr. Mirowski's work transformed the industry from high voltage external pacemakers to sophisticated implantable devices that use multiple leads. He licensed two issued patents and a patent application to Medrad, Inc. (Medrad), referred to as the Mirowski license, effective on January 30, 1973. The inventions covered by the Mirowski license were not proven until years after 1973. In addition to a running royalty rate, Dr. Mirowski received an unknown amount of equity in Medrad.

The Mirowski license is regarded as an important license in the CRDM industry. This license was important for gaining market access. It was exclusively licensed to Eli Lilly and its subsidiary Cardia Pacemakers, Inc. (CPI). Eli Lilly and CPI desired to maximize the economic value of the Mirowski license.

The Mirowski license included patents for an elective intra-atrial cardioverter, a semi-implantable defibrillator, and an implantable defibrillator. Eli Lilly and CPI entered into numerous license agreements and the royalty rate remained 3% for approximately 30 years. In 1991 Medtronic entered into a cross-license agreement with Eli Lilly and CPI that gave Medtronic access to the Mirowski patent portfolio in exchange for access to Medtronic's Activitrax patent. Medtronic licensed its patents to competitors, both before and after the Pacesetter agreement.

B. Pacesetter Litigation Settlement

From fall 1991 through spring 1992 Medtronic US and Pacesetter reached a resolution of the lawsuits and negotiated the Pacesetter agreement and the settlement agreement. During that negotiation period, Medtronic US's management analyzed potential settlement terms and presented that analysis to Medtronic US's board of directors. [*16] After a tentative deal had been reached on May 26, 1992, Medtronic US's senior vice president and general counsel presented the proposed terms to Medtronic US's board of directors, recommending that Medtronic US 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 and that the value of the settlement in net present value (NPV) terms was expected to be \$157 million. The NPV was increased to \$200 million in a final analysis. According to petitioner, \$17 million of litigation costs would be avoided by reaching a settlement.

Medtronic US and Pacesetter finalized the terms of their agreement in August 1992, and Medtronic US's board of directors approved it on August 26, 1992. The Pacesetter agreement settled nine lawsuits and resulted in the dismissal of all litigation with prejudice.

The terms of the Pacesetter agreement were negotiated between competitors. Through the 1990s and 2000s the CRDM industry was dominated by three to five major companies, including Medtronic US, Pacesetter, and later, St. Jude. 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 US 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 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. Pacesetter was expected to become a more significant player in the tachy business by acquiring or developing its own tachy technology.

On March 3, 1992, Medtronic US prepared a comparative analysis of the potential value of continuing to litigate its patent infringement claims relative to settling on terms that would be acceptable to Medtronic US. After settlement discussions had been initiated, in late April 1992, Pacesetter filed a countersuit alleging Medtronic US's infringement of two of its patents by Medtronic US's pacemakers, Elite and Legend. That was the first time Pacesetter had claimed Medtronic US infringed on its patents. [*17] Medtronic US and Pacesetter finalized the terms of their agreement in August 1992. The financial terms of the finalized license were more favorable to Medtronic US than those originally presented in May 1992. In addition the finalized terms included a "Future Patent Provision," which was added as Pacesetter's other suits and counterclaims had previously related to unfair competition and antitrust claims and Medtronic US's claims of infringement. Medtronic US's board of directors approved the settlement on August 26, 1992.

Those final settlement terms were incorporated into the Pacesetter agreement, which included two documents: a patent license agreement and a settlement agreement. As part of the Pacesetter agreement, the parties agreed to cross-license their existing CRDM patent portfolios. The CRDM patent portfolio that Medtronic US licensed to Pacesetter was closely comparable to the MPROC licenses between Medtronic US and MPROC. Pacesetter and Medtronic US also settled all other pending litigation between the parties.

As the result of the Pacesetter agreement, Pacesetter was licensed 342 of Medtronic US's patents. MPROC, by comparison, received licenses for upwards of 1,800 of Medtronic US's patents. As of May 2004 approximately 9% of the patents licensed by Medtronic US to MPROC were also licensed to Pacesetter in 1992. As of April 2006 approximately 6.2% of the patents licensed to MPROC were also licensed to Pacesetter in 1992.

C. Pacesetter Agreement Terms

The Pacesetter settlement comprised two documents: a patent license and a settlement agreement that resolved patent, antitrust, and unfair competition litigation with Pacesetter. The two documents "comprise[d] one agreement and the entire agreement of the parties." The Pacesetter agreement provided Pacesetter with a nonexclusive license to certain Medtronic US patents.

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. The Pacesetter agreement thus functioned as a one-way license from Medtronic US to Pacesetter. Upon execution of the Pacesetter agreement, Pacesetter agreed to pay Medtronic US \$50 million up front to compensate Medtronic US for Pacesetter's past infringement and a \$25 million royalty prepayment credited against **[*18]** a 1.8% "portfolio access fee" added to the base rates. Both the \$50 million and \$25 million payments were characterized by Medtronic US as portfolio access royalty payments. Thereafter, Pacesetter agreed to pay Medtronic US a 7% royalty on CRDM devices and leads sales in the United States and Japan, and a 3.5% royalty on all other international sales. Medtronic US did not pay Pacesetter for the license of Pacesetter's patents.

As part of the Pacesetter agreement the parties also settled on a maximum rate clause whereby each party could compel a license to any of the other's CRDM patents developed during the agreement's term for an aggregate rate of no more than 15%. This meant that Siemens, Pacesetter's parent company, was entitled to license all of Medtronic US's CRDM patents for an aggregate rate not higher than 15%, which included the 7% royalty that Pacesetter was already paying for current patents.

The maximum rate clause was limited by the key patent clause, a narrow exception under which each party could designate up to three patents per year as "key." The designation as a key patent provided a roughly three-year period during which the other party could not compel a license for the patent. During the terms of the Pacesetter agreement Medtronic US did not designate any of its patents as key patents.

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.

D. St. Jude's Acquisition of Pacesetter

The initial term of the Pacesetter agreement was ten years, beginning in August 1992. The parties agreed that if Pacesetter were sold the term would reset, extending the term to 10 years post sale (but not more than 15 years total). The Pacesetter agreement thus contemplated the possibility of an extension through 2007. In September 1994 St. Jude acquired Pacesetter from Siemens. Upon acquisition of Pacesetter, St. Jude assumed all of Siemens's rights and obligations under the Pacesetter agreement. St. Jude did not modify the [*19] terms of the Pacesetter agreement and accepted it in whole, including the royalty rate. Per the Pacesetter agreement, the original term reset, resulting in a two-year extension. Accordingly, St. Jude paid royalties to Medtronic US through September 2004 (i.e., into Medtronic US's 2005 tax year, which began in May 2004).

The Pacesetter agreement was assigned to St. Jude in its entirety, including the maximum rate clause. Survival of the maximum rate clause is evidenced by several agreements entered into by St. Jude during the term of the Pacesetter agreement; these agreements refer to the Pacesetter agreement as being "in full force and effect." In 1996 St. Jude acquired Ventritex, a CRDM competitor, and the agreement stated that the Medtronic US agreement was "in full force and effect and will not by its terms terminate by reason of the [m]erger." Additionally a 2002 amendment to the Pacesetter agreement confirmed the survival of the maximum rate clause.

Siemens could have elected to buy out its remaining royalty agreements, instead of selling to St. Jude. The Pacesetter agreement included terms, in the event of a sale by Siemens, that Siemens may elect to not transfer its rights under the Pacesetter agreement. The Pacesetter agreement included terms that provided a formula to calculate a payment for buying the remaining royalty obligations.

IV. Product Recalls

Companies in the implantable medical device industry that encounter significant product quality issues 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 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 issues. [*20] 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, which could be fatal. The Marquis recall forced Medtronic US to divert significant research and development (R&D) and other resources to address the underlying issue. Physicians paid careful attention to Medtronic US's response to the Marquis issue to ensure that the problem 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 US did not lose market share as a result of the Marquis issue was that its competitor, Guidant, sustained a rash of recalls of its own as a result of product quality issues during the same period. Medtronic US 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 US ultimately settled the Marquis class action litigation. MPROC bore these out-of-pocket costs for the Marquis devices it made.

V. Swiss Supply Agreement

Medtronic US, MPROC, and Medtronic Europe entered into the Swiss supply agreement, effective 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 devices when necessary to meet excess demand. 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 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.

VI. Notice of Deficiency

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 [*21] restructuring of Medtronic US's operations in Puerto Rico. At the conclusion of the examination, respondent accepted the CUT method identified by petitioner and its adviser, Ernst & Young, LLP, but adjusted the transactions to increase their "profit potential." 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 an MOU between Medtronic US and the IRS. 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.

Petitioner filed timely its 2005 and 2006 tax returns using the MOU. Respondent's first examination of petitioner's 2005 and 2006 tax returns began in approximately May 2007. 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.² Respondent calculated these deficiencies in reliance on a report prepared by respondent's expert A. Michael Heimert, explained in greater detail below, which used the CPM. On July 10, 2014, respondent amended his Answer to exclude royalty amounts paid by MPROC for non-U.S. sales, asserting that his 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 2006.³

OPINION

I. Overview of Parties' Positions

Both parties presented experts to support their respective positions. We focus on the degree to which experts' opinions are

 $^{^{\}rm 2}$ These amounts include amounts attributable to issues that the parties have settled.

³ 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.

[*22] supported by the evidence. We do not discuss the opinion of any expert which does not pertain to our factual conclusions.⁴

A. Petitioner's Position

Petitioner asserts that the Pacesetter agreement can be reliably used to establish the royalty rate for the intangibles licensed to MPROC. It also contends that the Pacesetter agreement is appropriate for use as a CUT in this case. In its posttrial briefs and at a posttrial hearing petitioner proposed an unspecified method. *See infra* Section IV.E.⁵

B. Respondent's Position

Respondent's position is that the CPM is the best method in this case and that the Pacesetter agreement is not a CUT under the regulatory standards. Respondent rejects petitioner's proposed unspecified method and argues that it is based upon the same flawed methodology used in petitioner's CUT method. Respondent further argues that petitioner proposes to correct deficiencies in its CUT by making adjustments once again to the Pacesetter agreement which produced "the deficiencies in the first place," referring to respondent's arguments in *Medtronic I* that the Pacesetter agreement was not comparable to the MPROC licenses.

II. 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). The Commissioner will evaluate the results of a transaction as actually structured by the taxpayer unless it lacks economic substance. Treas. Reg. § 1.482-1(f)(2)(ii)(A). The Commissioner, however, may consider the alternatives available to the taxpayer in determining whether the terms of the controlled transaction

⁴ See Appendix for experts who testified during the further trial.

⁵ A remote hearing was held on December 2, 2021, to address issues raised in the parties' opening posttrial briefs.

[*23] 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.*

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. Id. para. (b)(1). As in effect during 2005 through 2006, the regulations provide four methods to determine the arm'slength amount to be charged in a controlled transfer of intangible property: the CUT method, the CPM, the profit split method, and unspecified methods as described in Treasury Regulation § 1.482-4(d). See id. § 1.482-4(a).⁶ The best method rule provides that the arm'slength result of a controlled transaction must be determined using the method that, under the facts and circumstances, provides the most reliable measure of an arm's-length result. Id. § 1.482-1(c)(1). There is no strict priority of methods, and no method will invariably be considered more reliable than another. *Id.* 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 comparability between the controlled transaction (or taxpayer) and any uncontrolled comparables, and the quality of data and assumptions used in the analysis. Id. subpara. (2).

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.* § 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

⁶ The regulations provide an additional method, the cost plus method, for cases involving the manufacture, assembly, or other production of goods sold solely to related parties. *See* Treas. Reg. § 1.482-3(d)(1).

[*24] that the tested party would have earned had it dealt with controlled taxpayers at arm's length, taking into account all facts and circumstances. *Id. See generally Coca-Cola Co. & Subs. v. Commissioner*, 155 T.C. 145, 210–13, 221–37 (2020).

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 charged in a comparable uncontrolled transaction. Treas. Reg. § 1.482-4(c)(1). 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)(1).

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 or subsequent transfer of the intangible, considering the capital investment and startup expenses required, the risks to be assumed, and other relevant considerations. *Id.* subdiv. (iii)(B)(1)(*ii*).

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. *Id.* § 1.482-6(a). Allocation under the profit 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 comparable profit split method is derived from the combined operating profit of uncontrolled taxpayers whose transactions and activities are similar to

[*25] those of the controlled taxpayers in the relevant business. *Id.* subpara. (2).

D. Unspecified Method

Methods not specified in paragraphs (a)(1), (2), and (3) of Treasury Regulation § 1.482-4 may be used to evaluate whether the amount charged in a controlled transaction is arm's length. Any method used must be applied in accordance with the provisions of Treasury Regulation § 1.482-1. Treas. Reg. § 1.482-4(d)(1). Consistent with the specified methods, an unspecified method should take into account the general principle that uncontrolled taxpayers evaluate the terms of a transaction by considering the realistic alternatives to that transaction, and only enter into a particular transaction if none of the alternatives is preferable to it. *Id*. An unspecified method should provide information on the prices or profits that the controlled taxpayer could have realized by choosing a realistic alternative to the controlled transaction. *Id*. As with any method, an unspecified method will not be applied unless it provides the most reliable measure of an arm's-length result under the principles of the best method rule. *Id*.

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, § 1231(e)(1), 100 Stat. 2085, 2562–63.

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 [*26] 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.

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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 adequate provisions for 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....

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

[*27] 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. Rep. No. 99-426, at 423–26 (1985), *reprinted in* 1986-3 C.B. (Vol. 2) 1, 423–26 (footnote omitted).

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

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. Rep. No. 99-841 (Vol. II), at II-638 (1986) (Conf. Rep.), *reprinted in* 1986-3 C.B. (Vol. 4) 1, 638.

The Treasury Department and the Internal Revenue Service conducted a comprehensive study that was published in 1988. See I.R.S. 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. at 475. The 1988 White Paper concluded that Congress intended no departure from the arm's-length standard. Id. The 1988 White Paper explained:

Looking at the income related to the intangible and splitting it according to relative economic contributions is

[*28] 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. at 472.

The Treasury Department has repeatedly confirmed that Congress intended for the commensurate with income standard to work consistently with the arm's-length standard. *See, e.g.*, Treasury Department Technical Explanation of the 2001 U.K.-U.S. 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 10,640–41 (same).

III. Issues Remaining for Consideration

On the basis of the Eighth Circuit's mandate, the Court must make additional factual findings in order to determine the arm's-length allocation of income between Medtronic US and MPROC. In agreeing to reopen the record in its May 3, 2019, Order, this Court expressly identified the issues to be considered pursuant to the Eighth Circuit's mandate:

(1) whether the Pacesetter agreement is a CUT;

(2) whether this Court made appropriate adjustments to the Pacesetter agreement as a CUT;

(3) whether the circumstances between Pacesetter and Medtronic US were comparable to the licensing agreement between Medtronic and [MPROC] and whether the Pacesetter agreement was an agreement created in the ordinary course of business;

(4) an analysis of the degree of comparability of the Pacesetter agreement's contractual terms and those of the [MPROC] licensing agreement; [*29] (5) an evaluation of how the different intangibles affected the comparability of the Pacesetter agreement and the [MPROC] licensing agreement;

(6) an analysis that contrasts and compares the CUT method using the Pacesetter agreement with or without adjustments and the CPM, including which method is the best method.

This Court is to decide the amount of risk and product liability expense that should be allocated between Medtronic US and MPROC.

A. Whether the Pacesetter Agreement Is a CUT

In *Medtronic I* the Court made adjustments to the Pacesetter agreement in an effort to reach a result that would provide an arm'slength standard. The result in *Medtronic I* was not the first time this Court approved the CUT method to measure arm's-length prices for intercompany transfers of intangibles. *See Veritas Software*, 133 T.C. 297. A comparable with different royalty rate may 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. 226, 393 (1991).

The degree of comparability between controlled and uncontrolled transactions is determined by applying the comparability provisions of Treasury Regulation § 1.482-1(d); however, specified factors are particularly relevant to the CUT method. Treas. Reg. § 1.482-4(c)(2)(iii). Pursuant to Treasury Regulation § 1.482-1(d)(1), the five general comparability factors are (1) functions, (2) contractual terms, (3) risks, (4) economic conditions, and (5) property or services. The application of the CUT method specifies that the controlled and uncontrolled transactions need not be identical but must be sufficiently similar that they provide an arm's-length result. Id. subpara. (2). If there are material differences between the controlled and uncontrolled transactions, adjustments must be made if they can be made with sufficient accuracy to improve the reliability of the results. *Id.* If adjustments for material differences cannot be made, the reliability of the analysis will be reduced. Id.

For intangible property to be considered comparable, the intangibles must be used in connection with similar products or processes within the same general industry or market and have similar profit potential. *Id.* § 1.482-4(c)(2)(iii)(B)(1). In evaluating the

[*30] comparability of the circumstances of the controlled and uncontrolled transactions the following factors "may be particularly relevant": (1) the terms of the transfer; (2) the stage of development of the intangible; (3) rights to receive updates, revisions, or modifications of the intangible; (4) the uniqueness of the property; (5) the duration of the license; (6) any economic and product liability risks; (7) the existence and extent of any collateral transactions or ongoing business relationships; (8) the functions to be performed by the transferor and transferee; and (9) the accuracy of the data and the reliability of assumptions used. *Id.* subdivs. (iii)(B)(2), (iv). These factors are often referred to as the circumstantial comparability factors.

The Pacesetter agreement is not identical to the MPROC licenses. In the light of the Eighth Circuit's remand, we must analyze the general comparability factors to determine whether the Pacesetter agreement and the MPROC licenses are similar enough to meet the comparability requirements of the regulations.

Of the five general comparability factors, we conclude that the functions, economic conditions, and property or services are not comparable. Therefore, the Pacesetter agreement is not a CUT.

1. Functions

Determining the degree of comparability requires an analysis that looks at the functions of the two transactions such as R&D; product design and engineering; manufacturing; product fabrication; purchasing and materials management; marketing and distribution functions; transportation and warehousing; and managerial, legal, accounting, and other personnel management services. *Id.* § 1.482-1(d)(3)(i). A functional analysis is not a pricing method and by itself does not determine an arm's-length result. *Id.*

Respondent argues that the transactions are not comparable because different functions were performed. As a licensor under the MPROC agreement, Medtronic US performed R&D with respect to MPROC products that was 8.2% and 9% of revenues respectively for 2005 and 2006. Additionally, Medtronic US spent 4.3% of revenues and 5% of revenues respectively for 2005 and 2006 on business management activities for CRDM and Neuro. However, in the Pacesetter agreement, Medtronic US as licensor did not perform R&D to develop Pacesetter products, nor did it perform any other activities to help Pacesetter market its products. Pacesetter performed these services as a licensee. [*31] MPROC's function was that of a finished manufacturing of class III medical devices, and this differs from Pacesetter because Pacesetter also performed R&D, component manufacturing, and distribution. Therefore, we conclude MPROC and Pacesetter did not perform the same functions.

2. Economic Conditions

The Pacesetter agreement has a "horizontal" relationship because the agreement is between competitors. The MPROC license has a "vertical" relationship because the agreement is between a corporation and a controlled subsidiary. Respondent contends that the agreements cannot be comparable because of the different types of relationships.

The section 482 arm's-length standard is premised on the principle that a controlled transaction is compared to an uncontrolled transaction. See Treas. Reg. § 1.482-1(b). The regulations do not require that both transactions compared have vertical or horizontal relationships. The regulations provide examples in which a controlled transaction is compared with transactions between a third party and a competitor. See id. § 1.482-4(c)(4) (examples 1 and 3). We disagree with respondent's position that the Pacesetter agreement and the MPROC licenses cannot be comparable because a transaction with a vertical relationship and one with a horizontal relationship are being compared.

Even though we disagree with respondent's position regarding the relationships between transactions being compared, we still have concerns. In this case we can find only one transaction—the Pacesetter agreement—that comes close to being a CUT; however, we have concerns about the profit potential. The CUT method does not address adequately our concerns about the profit potential. Furthermore, we are concerned that there is only one comparable transaction with which to compare the MPROC licenses.

Respondent contends that the profit potential of the Pacesetter agreement and that of the MPROC licenses are not similar. We concluded in *Medtronic I* that petitioner's expert Louis Berneman's analysis did not include a comparison of profit potential consistent with the regulations' requirement that the profit potential be similar. *See Medtronic I*, at *129. Respondent's expert Heimert's analysis shows there was a difference between MPROC's product profit margin of 54% and Pacesetter's product profit margin of 29%. His analysis also shows that revenues for Pacesetter products were \$233 and \$361 million **[*32]** versus \$2.68 and \$3.54 billion for Medtronic products for 2005 and 2006, respectively. Because of the difference in profit potential, we conclude that the economic conditions are not comparable.

3. *Property or Services*

The Pacesetter and the MPROC licenses include comparable products; however, the Pacesetter agreement does not include Neuro products. This is not enough to make the products not comparable. To determine whether the products are comparable, we need to look at the property and the services provided. The intangible property licenses under the MPROC agreement include secret processes, technical information, technical expertise relating to the design of devices and leads, and all legal rights including know-how. The total number of patents available to MPROC under the licenses reached 1,800 in 2006, whereas the Pacesetter agreement licensed 342 patents. Accordingly, we conclude that the products licensed are not similar.

Furthermore, the determination of whether the products and services are considered comparable is similar to the determination of whether the functions are comparable. For the same reasons that we conclude the functions are not comparable, we conclude the products and services are not comparable.

Three of the five general comparability factors are not met, and this raises concerns about the CUT as proposed by petitioner. Taking into consideration economic conditions, property or services, and functions, we conclude that the Pacesetter agreement and the MPROC licenses do not meet the general comparability factor requirements. Since we conclude that the general comparability factors are not met, we do not need to analyze the circumstantial comparability factors to determine whether the Pacesetter agreement is a CUT.

B. Whether the Tax Court Made Appropriate Adjustments to the Pacesetter Agreement as a CUT

Petitioner contends that appropriate adjustments may be made to the Pacesetter agreement and that the Pacesetter agreement with appropriate adjustments remains a CUT. Petitioner's expert Jonathan Putnam made adjustments to the CUT and proposed two approaches. One approach started with a 7% royalty rate, and the other approach started with a 15% royalty rate. For both approaches Putnam calculated a low and high wholesale royalty rate. These adjustments differ from the Court's adjustments in *Medtronic I*. The major difference is the **[*33]** Court made an adjustment for leads by decreasing the rate for devices by 50%, instead of having the same royalty rate for both devices and leads. *See Medtronic I*, at *138.

Respondent's position is that there are no appropriate adjustments that can be made to the CUT. Respondent further contends that the Court's adjustments were not in compliance with the regulations and that making adjustments compounds the chances of error.

In the light of the Eighth Circuit's mandate we have reviewed our adjustments in *Medtronic I* and conclude that adjustments can be made to the Pacesetter agreement; however, too many adjustments result in the Pacesetter agreement as a CUT not being the best method pursuant to the section 482 regulations. During the further trial we heard from ten experts and have reached the conclusion that the outcome in *Medtronic I* should be changed. *See infra* Section IV.D.

C. Whether the Circumstances Between Pacesetter and Medtronic US Were Comparable to the Licensing Agreement Between Medtronic US and MPROC and Whether the Pacesetter Agreement Was an Agreement Created in the Ordinary Course of Business

Treasury Regulation § 1.482-1(d)(4)(iii)(A)(1) provides that transactions "ordinarily will not constitute reliable measures of an arm's length result" if they are "not made in the ordinary course of business." Treasury Regulation § 1.482-1(d)(4)(iii)(B) (example 1) provides an example of a transaction not in the ordinary course of business. In this example a U.S. manufacturer sells its products to an unrelated distributor. This manufacturer is forced into bankruptcy and sells all its inventory at a liquidation price. Since this sale was due to bankruptcy, it is not treated as a sale in the ordinary course of business.

The Pacesetter agreement occurred in the context of resolving litigation. The Pacesetter litigation clarified Pacesetter's and Medtronic US's rights and obligations over Medtronic US patents.

Petitioner's experts Richard Cohen, Fred McCoy, and Christopher Spadea testified that patent litigation and settlement licenses were and are common in the CRDM industry. Litigation can help the parties become informed as to their respective legal rights and obligations. It can resolve, rather than cast doubt on, a patent's value. Putnam testified that "litigation actually helps us draw better inferences about **[*34]** the value of the IP." He explained that if there is concern about the role of litigation, the 15% provision in the Pacesetter agreement should be looked to because it is unrelated to the patents that were being litigated in 1992. The 15% provision in the Pacesetter agreement is the maximum royalty rate and is for patents identified as key patents.

Often, in the absence of a lawsuit, royalty negotiations are based upon the outcome that the parties would expect in litigation. A patent license provides an arm's-length transaction between two private parties that places a monetary value on the patent. Jonathan S. Masur, *The Use and Misuse of Patent Licenses*, 110 Nw. U. L. Rev. 115, 120 (2015).

The Pacesetter agreement included a broad cross-license that included patents in addition to those subject to the dispute between Medtronic US and Pacesetter. St. Jude's acquisition of Pacesetter reinforces that the Pacesetter agreement was created in the ordinary course of business. When St. Jude acquired Pacesetter in 1994, it had to determine whether to accept and to continue the terms of the Pacesetter agreement. The decision to continue the agreement was made in a commercial setting.

The value of discontinuing the case for Medtronic US was small compared to the income from a royalty rate. Petitioner expected that continuing litigation with Pacesetter would cost an additional \$17 million. The expected cashflow of the license to Pacesetter was over \$205 million. Putnam contends that if the cost of litigation is small in relation to the total payment, then avoided litigation costs would constitute only a small fraction of the payment made to the licensor.

Putnam further testified that parties resolving a patent infringement lawsuit, and parties who are deciding whether to enter into a commercial license over patent rights, share several key considerations. He explained that there is not an established bright-line rule as to when the parties begin considering litigation in the context of their negotiations. He stated: "[A]ll licenses are negotiated 'in the shadow' of litigation, because all licenses only pay royalties when circumstances 'compel' them to do so." His view is that the licensee's profit-motivated evaluation of that compulsion exists whether actual litigation exists or not and that these evaluations are therefore ordinary. He explained that litigation costs are not distortionary because both parties avoid litigation costs. [*35] Petitioner's expert Cohen testified about the evolution of crosslicenses in the cardio device industry. He explained that the experience in the industry was that patents were potent weapons that could enable the patent holder to delay a company from introducing an important feature or product critical to commercial success of that company. He compared the patent process in the cardio device industry to navigating a minefield. According to his testimony, the process became a minefield because the devices were complex with many features. He explained that each of the major competitors was at risk that there would be a major innovation and that any one of them might be blocked from introducing products incorporating this innovation.

His assessment is that the major competitors realized eventually that they would be better off cross-licensing their patent portfolios and focusing on developing the markets. He contends that by cross-licensing broad patent portfolios, the major competitors could eliminate the costs of attempting to engineer around each other's patents and the costs of litigation. Cohen explained that companies in the cardio device industry developed patents to protect their individual innovations, and these patent portfolios interfered with the ability of each of the companies in the space to introduce products that incorporated all the medically important and attractive features without the risk of being sued. He reached the conclusion that cross-license agreements following litigation or threatened litigation became part of the ordinary course of business in the cardio device industry.

We conclude that the Pacesetter agreement was reached in the ordinary course of business; however, this conclusion is not enough to conclude that the Pacesetter agreement was a CUT for the purpose section 482.

D. An Analysis of the Degree of Comparability of the Pacesetter Agreement's Contractual Terms and Those of the MPROC Licensing Agreement

There are enough differences between the Pacesetter agreement and MPROC licenses to conclude that the Pacesetter agreement was not a CUT; however, there are enough similarities that the Pacesetter agreement can be used as a starting point for determining a proper royalty rate. The terms of the payments are comparable. *See* Treas. Reg. § 1.482-4(c)(2)(iii). Both agreements had running royalty rates based on sales of devices and leads. *See id.* § 1.482-1(d)(3)(ii)(A)(1). [*36] Petitioner's expert Putnam testified that the base royalty rate paid by Pacesetter may be viewed as the net of two claims: Medtronic US's claim on Pacesetter's sales, less Pacesetter's claims on Medtronic US's sales. Pacesetter's claims on Medtronic US were minimal. According to the Pacesetter agreement, the parties agreed that Pacesetter's grant of patent rights was royalty free and fully paid up. He estimated that the value of Pacesetter's claims against Medtronic US at the time of the Pacesetter agreement was to be 0.5% to 1% of Pacesetter's sales. Medtronic US did not benefit substantially from the cross-licensing provisions.

The lump-sum payment of \$50 million for past infringement does not undermine comparability. Putnam testified that the \$50 million payment does not contaminate the inferences to be drawn from the Pacesetter agreement based on his analysis, which shows that past sales had about the same royalty rate of the going forward rate of 7%. The \$25 million prepaid credit against a portion of the future running royalty rate can be accounted for by a 1.8% upward adjustment as suggested by Putnam.

In 1994 St. Jude bought Pacesetter, and this resulted in an extension of the Pacesetter agreement. When St. Jude acquired Pacesetter, it evaluated the Pacesetter agreement and came to the same conclusion that the royalty rate was appropriate. St. Jude did not seek to modify the Pacesetter agreement. There is no evidence that St. Jude tried to change the Pacesetter agreement post acquisition.

Petitioner contends that there was no paradigm shift in the time between the Pacesetter agreement and the MPROC licenses. The 7% royalty rate was among the highest rates in the industry. McCoy testified that the rate of 7% and the initial rate of 8.8% were high for the industry. He is not aware of any royalty rate in the CRDM industry which is higher.

Petitioner's expert Cohen concluded that between 1992 and 2004, there was no "technological paradigm shift" in the CRDM industry. He explained in his report that the Mirowski patent was issued in 1990 and was the foundation patent for CRT devices. He concluded that advancements were made in 2002 and these advances simply involved additional pacing functionality. His analysis supports that there was no paradigm shift because there was no sustained increase in market growth.
[*37] Petitioner's expert Glenn Hubbard testified that the gross margins of Medtronic US, Boston Scientific, Guidant, and St. Jude did not show any dramatic change from 1992 to 2006. He referenced a 2005 Morgan Stanley report which estimated that Medtronic US's 2004 gross profit margin of 75.2% would increase to 76.8% by 2010. Hubbard concluded no adjustments to royalty rates specified in the Pacesetter agreement are needed to account for broad changes in the medical device industry during 2005 and 2006.

The Pacesetter agreement Included a maximum rate of 15%, which was for key patents. This shows that Medtronic US was offering its CRDM portfolio to St. Jude for no more than 15% through 2004, and this was about the same time the MPROC licenses were negotiated. Medtronic US never designated any patents as key patents. This inaction supports that there was not a paradigm shift.

Even though there is a level of comparability between the Pacesetter agreement and the MPROC licenses, it is not enough to conclude that the CUT is the best method for the reasons previously discussed. The comparability of contractual terms is just one of many factors that needs to be considered.

E. An Evaluation of How the Different Intangibles Affected the Comparability of the Pacesetter Agreement and the MPROC Licensing Agreement

Generally, intangible property is considered comparable if it is used in connection with similar products. Treas. Reg. § 1.482-4(c)(2)(iii)(B)(1)(i). We have concluded previously that the intangibles are not comparable enough to meet the general comparability factors. *See supra* Section III.A.

F. An Analysis That Contrasts and Compares the CUT Method Using the Pacesetter Agreement with or Without Adjustments and the CPM, Including Which Method Is the Best

Under the CUT method, controlled and uncontrolled transactions must involve the same or comparable intangible property, and differences in contractual terms and economic conditions should be considered. See Treas. Reg. § 1.482-4(c)(2)(iii). The regulations provide contractual and economic factors to assess the comparability of circumstances between a controlled and an uncontrolled transaction for the CUT method. See *id.* subdiv. (iii)(B)(2). These factors were **[*38]** discussed *supra* Section III.A., and we concluded that the general comparability factors were not met and the circumstantial comparability factors need not be considered.

In the Court's previous Opinion we found that the royalty rates petitioner proposed are not arm's length because appropriate adjustments were not made to the CUT method to account for variations in profit potential. See Medtronic I, at *129. We concluded that "Berneman's analysis unacceptably lacks an examination of the profit potential of his comparable transactions, including the Pacesetter agreement as defined by regulations." Id. We have not changed our view regarding the Berneman analysis and still find that it is necessary to make adjustments to the Pacesetter agreement.

Respondent contends that the Pacesetter agreement was not a CUT because the patent licenses were not comparable and the Pacesetter agreement was not entered into in the ordinary course of business. Respondent further contends that using the Pacesetter agreement as a CUT results in MPROC's receiving the "lion's share" of profits earned from the sales of CRDM and Neuro products. This line of argument raises the question of why MPROC's profitability dwarfs that of Medtronic US, the owner of the "crown-jewel" intangibles.

Respondent compares the MPROC licenses to the arrangement Coca-Cola had with its affiliates. A CPM analysis was appropriate for the nature of the assets and the activities performed by the controlled taxpayers in Coca-Cola Co., 155 T.C. at 217–18. The nature of the assets owned and the activities performed by MPROC are not comparable. In *Coca-Cola Co.* the manufacturing process entailed forms of extraction, filtration, mixing, blending, aging, and precision filing. The affiliates performed routine quality control pursuant to detailed specifications from the U.S. parent. Id. at 159–60. With one exception, the affiliates had no employees of their own specifically dedicated to quality assurance. Id. at 160. The taxpayer's experts agreed that the affiliates' manufacturing activity was a routine activity that could be benchmarked to the activities of contract manufacturers, meriting compensation no greater than cost plus 8.5%. Id. The manufacturing of sweetened beverages under these circumstances does not compare to the manufacturing of life-saving devices for which quality is of the utmost importance. We previously concluded that the role of MPROC was more than that of a routine manufacturer of finished products. Medtronic I, at *106–08.

[*39] Respondent maintains the same position from *Medtronic I* that the CPM is the best method to price the MPROC licenses. In *Medtronic I* we concluded that an allocation of 6%–8% was not reasonable. *Id.* at *117. Respondent is asking the Court to reconsider its position and conclude that Heimert's original CPM is the best method. The Court is not going to reverse its opinion that petitioner met its burden of showing that respondent's allocations were arbitrary and capricious. *See id.* at *118.

Petitioner's expert Hubbard testified about the challenges of conducting a CPM with regard to the MPROC licenses and the importance of the tested party. Heimert used MPROC as the tested party. Hubbard explained that the tested party is critical because residual profits are attributed to the nontested party. He explained further that choosing one tested party or the other can yield substantially different results, and thus substantially different estimates of royalty rates. He concludes that when the tested party predominantly performs one business function, as did MPROC, it is important to select comparables that predominantly perform the same business function. According to Hubbard, it is preferable to choose as the tested party the entity whose functions, activities, and risks can be benchmarked most reliably to comparable companies.

Hubbard testified that neither Medtronic US nor MPROC is an obvious candidate to serve as the tested party because neither Medtronic US nor MPROC has functional roles and risks that can be easily benchmarked. Additionally, he was critical of Heimert's selection of MPROC as the tested party. Hubbard concluded that the Heimert CPM is incomplete because it fails to give proper consideration to the fact that MPROC performed nonroutine functions such as ensuring product quality and assuming the risk for product liability.

The CPM benchmarks the arm's-length level of operating profits earned by the tested party with reference to the level of operating profits earned by comparable companies. *See* Treas. Reg. § 1.482-5(b)(1). According to Hubbard, from an economic perspective certain product characteristics should be considered in assessing the comparability of companies. His report indicated that the FDA estimates that about 10% of medical devices receive the class III designation. He concludes that the risks and returns are much lower for class I devices than they are for class III devices. Class II devices, such as powered wheelchairs, pose a higher risk to patients but differ from class III devices, which sustain or support life. Hubbard explained that a company that largely [*40] produces elastic bandages is unlikely to be comparable to a company that largely produces implantable pacemakers, even though both companies "produced medical devices."

Hubbard concludes that a CPM analysis will be unreliable when there are material differences in factors that affect profitability, such as varying cost structures, differences in business experience, and differences in management efficiency. In his report he conducted a search to find comparables to MPROC but did not find any. He reached this conclusion by searching FDA databases for class III companies. With the exception of Greatbatch Medical (Greatbatch), none of Heimert's comparables produced exclusively class III devices.

Hubbard further testified that there is a distinction between medical devices that are short lived and those that are long lived. Implantable devices are considered short lived because each is provided only once to a single patient. According to Hubbard, short lived medical devices tend to have high operating margins, as they significantly improve patient health and are subject to high rates of reimbursement for healthcare providers. In contrast he explained that long lived products, such as hospital beds or syringes, often have lower profit margins.

Hubbard concluded that there were no appropriate comparables if MPROC were the tested party. We also raised concerns about Heimert's comparables in *Medtronic I*. See *Medtronic I*, at *109–12. In the light of the Eighth Circuit's mandate we have reexamined the CPM method and reach the same conclusion that we did in *Medtronic I* that the use of Heimert's original CPM was an abuse of discretion. *Id.* at *118. The Court's CUT in *Medtronic I* requires too many adjustments, and the CPM results in an unrealistic profit split and too high a royalty rate. Therefore, we conclude neither method is the best method.

G. Allocation of Product Liability Expenses

Pursuant to the MPROC licenses all the product liability risk was allocated to, and borne by, MPROC. Similarly, under the Pacesetter agreement all risk was borne by Pacesetter. Respondent contends that product liability risk did not rest exclusively with MPROC under the intercompany agreements. The MPROC license states that MPROC is "liable for all costs and damages arising from recalls and product defects." [*41] Pursuant to the regulations "the consequent allocation of risks . . . that are agreed to in writing before the transactions are entered into will be respected if such terms are consistent with the economic substance of the underlying transactions." Treas. Reg. § 1.482-1(d)(3)(ii)(B)(1). The regulations specify that risks include product liability risks. *Id.* subdiv. (iii)(A)(5). MPROC's assumption of the product liability risk was consistent with the economic substance because MPROC had the financial capacity to bear the burden of the product liability risk. MPROC had managerial and operational control over the manufacturing operations for the finished devices and leads.

Respondent contends that a \$25 million adjustment can be made to the CPM to adjust for the assumption that MPROC bore all product liability costs for CRDM and Neuro products. According to respondent's expert from the prior trial Paul Braithwaite the ultimate claimed costs for injuries and related legal expenses were \$25.2 million and \$26.2 million for 2005 and 2006, respectively. In contrast petitioner's expert from the prior trial Paul Dowden testified that the value of the product liability insurance Medtronic US received from MPROC during 2005 and 2006 was between \$220 million and \$235 million for each year.

MPROC had two responsibilities for managing product liability. First, MPROC needed to minimize the potential for product failures by making every effort to ensure that its finished devices and leads were manufactured to the highest standards. Second, MPROC was responsible for restoring product quality and bearing all associated product liability costs.

Petitioner's expert Hubbard testified that, in theory, MPROC had uncapped exposure to product liability risk; however, in practice, MPROC's liability would be capped by the aggregate value of all its assets that could be made available to cover the product liability related claims and costs. He discussed the value of prior recalls. MPROC had product liability costs of \$117 million of the \$205 million total costs from the Marquis device recall and \$271 million of the \$324 million total costs of the Sprint Fidelis defibrillator lead recall. He explained that certain costs were allocated to other Medtronic entities in compliance with the MOU entered into between petitioner and respondent.

Respondent has proposed a product liability adjustment of \$25 million per year as part of the proposed modified CPM. This adjustment is not in line with the costs associated with prior recalls. We are not

[*42] convinced by the evidence that respondent's adjustment is enough to account for MPROC's role regarding product liability claims.

IV. Best Method

A. Introduction

In *Medtronic I* we reviewed respondent's section 482 reallocations for abuse of discretion. On remand the Eighth Circuit did not overrule this holding, nor did the Eighth Circuit hold that this Court's choice of transfer pricing was incorrect. Rather, the Eighth Circuit found that the analysis in this case required more detailed comparison and explanation as to comparability of circumstances, contractual terms, intangibles, and risk and product liability expense, without mention as to the appropriateness of any particular method.

At trial both parties mostly maintained their original positions regarding which transfer pricing method is the best method as it relates to the royalty rates for devices and leads. In the light of the Eighth Circuit's mandate we now analyze the testimony provided by expert witnesses from both parties.

B. Analysis of Respondent's Position

Respondent maintains the position that the CPM is the best method and continues to rely upon the analysis of Heimert. In his analysis for the further trial Heimert kept MPROC as the tested party and the same 14 companies to benchmark the return to MPROC. His analysis concludes that the technology wholesale royalty rates are 64.3% and 68.4% for 2005 and 2006, respectively.⁷

During trial Heimert testified that the 14 comparables could be reduced to the comparables that made implantables. At the conclusion of the further trial, he made alterations to his CPM. Instead of using 14 comparables, calculations were made using 5 of the 6 comparables that manufactured implantables. Greatbatch was excluded because of its manufacture of components rather than devices. Heimert testified that he was not able to find any companies that performed a role similar to MPROC which was the manufacturer of devices and leads, class III products.

 $^{^7}$ These rates do not account for the 8% trademark wholes ale royalty rate which was addressed in *Medtronic I*.

[*43] The only other adjustment Heimert made was for product liability. Respondent, assuming arguendo that MPROC bore all product liability risk, made adjustments to account for product liability. These adjustments are \$25.2 million and \$26.2 million for 2005 and 2006, respectively.

Respondent's calculations reducing the number of comparables and making an adjustment for product liability result in wholesale royalty rates of 59.6% for 2005 and 64% for 2006. We refer to this calculation as respondent's modified CPM. The modified CPM would result in total system profits for MPROC of 14% in 2005 and 12% in 2006. Respondent did not suggest an unspecified method and is opposed to using an unspecified method.⁸

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., 96 T.C. at 353 (first citing G.D. Searle & Co. v. Commissioner, 88 T.C. 252, 358 (1987); and then citing 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). "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." Sundstrand Corp., 96 T.C. at 353–54; see also Am. Terrazzo Strip Co. v. Commissioner, 56 T.C. 961, 971 (1971).

The modified CPM results in retail royalty rates of 40.7% and 48.8% for 2005 and 2006, respectively, and wholesale royalty rates of 59.6% and 64% for 2005 and 2006, respectively, whereas the CPM without modifications resulted in wholesale royalty rates of 64.3% and 68.4% for 2005 and 2006, respectively. The modified CPM results in MPROC's earning 14% of the profits in 2005 and 12% of the profits in 2006. The CPM without modifications results in MPROC's earning 8.1%

⁸ In respondent's supplemental brief, respondent included a chart that shows various wholesale royalty rates, including a Pacesetter comparable profit split method resulting in a wholesale royalty rate 62.4%. Respondent provided no analysis for this method.

[*44] of the profits in 2005 and 5.6% of the profits in 2006. See Medtronic I, at *95.

The problems that *Medtronic I* addressed regarding Heimert's CPM remain the same. Even reducing the comparables from 14 to 5, they still have fundamentally different asset bases and involve different functions and risks from those of a class III medical device manufacturer. Heimert limits the comparables to Bard, Inc. (Bard), Orthofix International NV (Orthofix), Stryker, Wright Medical Group, Inc. (Wright Medical Group), and Zimmer Holdings, Inc. (Zimmer). Four of these companies manufactured orthopedic devices, including reconstructive orthopedic devices. The other company made a broad range of vascular and urology products. None of the five made similar cardio or neuro devices. Additionally, none of the five companies performed only the function of finished device manufacturing. All five performed some combination of the following functions: R&D, component manufacturing, finished medical device manufacturing, and distribution.

Petitioner's expert Hubbard expressed concern regarding Heimert's subset of five companies because all of the companies also made class I and/or class II devices, not just class III devices as petitioner did. According to Hubbard, limiting the comparables to implantables resulted in blended profitability measures across the several functions of Heimert's comparables when only one of those functions, the manufacturing of medical devices, is relevant for the CPM in this matter. Even with reducing the number of comparables, the remaining companies are still not good enough comparables to result in the CPM's being the best method.

Hubbard explained that MPROC focused exclusively on manufacturing finished medical devices, specifically class III medical devices. He opined that to be able to use the CPM, comparables should "conduct similar functions and bear similar risks." He contends that if Heimert's comparables focused exclusively on class III finished medical device manufacturing, then his CPM would appropriately treat MPROC as the "pure-play manufacturer of class III medical devices that it was." Even if Heimert's comparables are reduced to five companies that make implantable devices, there are still flaws with the comparables.

Hubbard explained that a company's products are among the factors that influence the company's profitability. He disagreed with Heimert's position that narrowing the set of comparables to the **[*45]** implantables does not affect the overall range of return on assets (ROAs). Hubbard's calculations show that the median ROA for the six implantables (including Greatbatch) is 40.4% from 2003 to 2005 and the median ROA for 14 comparables is 28.1%. From 2004 to 2006 the median ROA for the six implantables is 40.5%; whereas, the median for the 14 comparables is 26%.

The regulations provide that when determining which method provides the most reliable measure of an arm's-length result, the two primary factors to take into account are (1) the degree of comparability between the controlled transaction (taxpayer) and any uncontrolled comparables and (2) the quality of the data and assumptions used in the analysis. Treas. Reg. § 1.482-1(c)(2). Heimert's CPM analysis falls short regarding the comparables and assumptions used. See Medtronic I, at *109–14.

Hubbard explained that even though the five companies making implantables have higher ROAs, his view has not changed regarding the CPM. He contends that the five comparables that Heimert classifies as makers of implantables do not represent a profit level indicator of pureplay implantable medical device manufacturers. Two of the five were engaged in R&D, component manufacturing, and distribution, in addition to finished medical device manufacturing. The other three were involved in R&D and distribution, aside from finished medical device manufacturing. All five companies made class I and/or class II devices in addition to class III devices. Both Hubbard and Heimert agree that data limitations prevent extracting information pertaining to only class III finished medical devices from the aggregate financial data.

Hubbard contends that the comparability with respect to size of the comparable company does matter. He criticizes Heimert's analysis for the range in the size of companies and asserts that there is no justification for Heimert to include companies with lower or higher levels of revenue or operating assets than MPROC in his comparables. When analyzing comparable companies, Hubbard looked at the size of the companies and used revenues as a proxy. He was unable to identify companies similar in size to MPROC. Only one of Heimert's five comparables (Bard) had revenues comparable to MPROC's revenues of approximately \$2 billion in 2005.⁹ Stryker and Zimmer had over double MPROC's revenues whereas Wright Medical Group and Orthofix had less than half of MPROC's 2005 revenue. Additionally, Hubbard's

⁹ MPROC's revenue for 2005 based on Hubbard's calculations.

[*46] criticism of the selection of MPROC as the tested party still applies to respondent's CPM.

Respondent contends that the CPM is the best method and commensurate with income. The commensurate with income standard does not specify a specific method or a certain range of profits. The modified CPM results in an allocation of 86.9% of the profits to Medtronic US and Med USA and 13.1% to MPROC.¹⁰ Heimert's original CPM analysis concludes that 6%–8% of the system profits should be allocated in order for the transactions to be arm's length. *See id.* at *119.

MPROC was an FDA-registered facility responsible for putting together sophisticated medical devices that would remain in the human body for years. *See id.* at *107. All the components for the devices and leads could be made perfectly, but there could be problems if they are not put together perfectly. *Id.*

Hubbard concluded that MPROC played a pivotal role in ensuring the quality of finished CRDM and Neuro devices and leads. He explained that the quality of such class III medical devices was "paramount" because their failure could prove fatal to patients. MPROC employed a highly trained workforce that was ultimately responsible for inspecting finished devices and leads, ensuring that the finished devices functioned property. Hubbard concluded that quality is more important for a manufacturer solely of class III devices than for the companies Heimert selected as comparables.

The modified CPM is a minor change to the CPM. The modifications are not enough to overcome the flaws. The adjustment for product liability is inadequate. See supra Section III.G. Therefore, the modified CPM is not the best method and there is an abuse of discretion by respondent which is due to the use of flawed comparables. Petitioner has shown that respondent has implemented his methodology in an unreasonable manner, e.g., by employing erroneous assumptions, incorrect data, or analysis that is internally inconsistent. See Coca-Cola Co., 155 T.C. at 203; see also Veritas Software, 133 T.C. at 323–27 (finding allocations based on a discounted cashflow methodology unreasonable where the Commissioner "employed the wrong useful life, the wrong discount rate, and an unrealistic growth rate"); Altama Delta Corp. v. Commissioner, 104 T.C. 424, 466 (1995) (finding allocations unreasonable where the Commissioner implemented his cost-plus

¹⁰ This calculation is an average for 2005 and 2006.

[*47] method by marking up operating profit margins instead of gross profit margins); Seagate Tech., Inc., 102 T.C. at 192 (rejecting expert's pricing of component parts upon finding that his methodology "d[id] not meet the description of the cost-plus method" in the regulations); Achiro v. Commissioner, 77 T.C. 881, 900 (1981) (rejecting the Commissioner's allocation where he made no "reasonable attempt[] to reflect arm's-length transactions among the related entities"). In this case the use of comparables that did not make solely class III medical devices, as were the devices finished manufactured by MPROC, resulted in an abuse of discretion by respondent.

C. Analysis of Petitioner's Position

Petitioner relies on the testimony of its expert Putnam to determine royalty rates. Petitioner maintains its position that the CUT is the best method and that the Pacesetter agreement is a valid CUT.

Putnam offered two approaches adjusting the royalty rate, and for both approaches he estimated low and high rates. The first approach using retail royalty rates starts with a 7% rate, the rate of the Pacesetter agreement. The resulting wholesale royalty rates under this approach are 22.3% and 33.4% for cardio and 17.9% and 27.5% for Neuro. The second approach starts with 15% retail royalty rate which is equivalent to the maximum rate in the Pacesetter agreement. The wholesale royalty rates under this approach are 29.4% and 33.8% for cardio and 25% and 27.9% for Neuro.

Putnam made an adjustment to the Pacesetter agreement to account for profit potential. This adjustment is to account for the differences between Pacesetter in the 1992 to 1994 timeframe and petitioner's CRDM business in the 2003 to 2005 timeframe. His conclusion is that a retail rate adjustment of 0.9%–4.9% is needed. His report states: "That adjustment is not linked to any particular source; any such linkage would be inherently imprecise, because the two companies' financial statements do not reliably reveal the cause of these differences."

Putnam's suggested adjusted retail royalty rate increase of 0.9%-4.9% is a broad range. In *Medtronic I* we concluded that a retail royalty adjustment of 3.5% is necessary to account for the difference in profit potential. Evidence presented during the further trial did not convince us that this adjustment should be lower than 3.5%. *See Medtronic I*, at *136. Furthermore, we conclude that an adjustment of this [*48] magnitude results in the transaction's not having the same profit potential as defined in Treasury Regulation § 1.482-4(c)(2)(iii)(B)(1)(ii). According to respondent's expert Brian Becker, Putnam's royalty rate would result in MPROC's being six times as profitable as Pacesetter.

Petitioner must show the allocations that it proposes satisfy the arm's-length standard. See Eli Lilly & Co. v. Commissioner, 856 F.2d at 869 (and the cases cited thereat). We continue to have concerns about petitioner's use of the CUT method, including the version put forth by Putnam. His low CUT (calculated at the low end of the range) resulted in a blended wholesale royalty rate of 21.8%, which is significantly lower than the blended wholesale royalty rate of 38% concluded in *Medtronic I*. The adjustments to the Pacesetter agreement did not result in a reliable CUT. As in *Medtronic I*, we are concerned about profit potential and that an adjustment of 3% is not adequate for knowhow. See Medtronic I, at *127–29. Petitioner has not shown that its allocation meets the arm's-length standard required by section 482.

In response to the Court's questions at the conclusion of the further trial and the posttrial hearing, petitioner changed its focus to its proposed unspecified method. In its Posttrial Answering Brief petitioner contends that its unspecified method "bridges the gap" because it addresses the Court's questions about the profitability of its CRDM and Neuro businesses relative to Pacesetter.

Petitioner recommends two versions of an unspecified method that combines aspects of the CUT with the Pacesetter agreement as a comparable and of the CPM. It rejects an unspecified method averaging the CUT and the CPM. Petitioner contends further that after considering alternatives there is "no gap to bridge" beyond its unspecified method. For this reason we will not analyze in further detail Putnam's two proposed royalty rates using the CUT method with adjustments made to the Pacesetter agreement.

D. Unspecified Method

The 1968 section 482 regulations promulgated three methods, in order of preference: the comparable uncontrolled price method, the resale price method, and the cost plus method. See Treas. Reg. § 1.482-2(e)(1)(ii) (1969). These regulations provide for another method if none of these three specified methods could "reasonably be applied under the facts and circumstances of a particular case." Sundstrand Corp., 96 T.C. at 358. Courts have approved the use of unspecified

[*49] methods and referred to these methods as appropriate methods within the context of the regulations. See Eli Lilly & Co., 84 T.C. at 1147–51; Mornes, Inc. v. Commissioner, T.C. Memo. 1982-27, aff'd, 696 F.2d 1000 (8th Cir. 1982); E.I. Du Pont De Nemours & Co. v. United Sates, 221 Ct. Cl. 333, 350–54 (1979).

After Congress amended section 482 to include the commensurate with income provision, changes were made to the regulations. See Tax Reform Act of 1986 § 1231(e)(1). In 1994 Treasury promulgated new regulations that superseded the 1968 regulations. See Treas. Reg. § 1.482-1(j)(4); T.D. 8552, 1994-2 C.B. 93. These regulations replaced the hierarchical approach of the 1968 regulations with the "best method rule" and provide four permissible methods for determining the arm's-length result for controlled transfer of intangible property: the CUT method; the CPM; the profit split method; and an "unspecified method" subject to constraints set forth in the regulations. Treas. Reg. §§ 1.482-1(c)(1), 1.482-4(a); see also Coca-Cola Co., 155 T.C. at 211–12. There is no strict priority of methods, and no method is considered to be more reliable than another. Treas. Reg. § 1.482-1(c)(1).

If neither party has proposed a method that constitutes "the best method," the Court must determine from the record the proper allocation of income. *Sundstrand Corp.*, 96 T.C. at 354. After hearing expert witnesses during further trial and reviewing the parties' positions, we conclude that there are some benefits to the CUT, and the Pacesetter agreement is an appropriate comparable as a starting point. We are concerned that there is only one comparable, that adjustments need to be made, and that if too many adjustments are made, the Pacesetter agreement might cease to be useful even as a starting point.

We reviewed the adjustments made in *Medtronic I* and conclude that improvement can be made to the adjustments and that fewer adjustments can be made. Even with making adjustments we further conclude that, to be consistent with the Eighth Circuit's mandate, the CUT is not the best method.

Petitioner originally made an allocation for the devices and lead licenses based on retail royalty rates of 29% and 15%, respectively. See *Medtronic I*, at *120. We concluded that these royalty rates were not arm's-length transactions. See id. at *120–29. In *Medtronic I* we concluded that the wholesale royalty rate for devices was 44% and the rate for leads was 22%. See id. at *137–38. We made the following adjustments:

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

See id. at *137.

After considering the testimony of petitioner's expert witnesses McCoy, Cohen, Putnam, and Hubbard, and respondent's expert witnesses Heimert and Peter Crosby, we conclude the royalty rate should be the same for devices and leads. We still have the same view of Heimert's original CPM as we did in *Medtronic I. See id.* at *88–119. Heimert's CPM is still not the best method, and neither is respondent's adjusted CPM the best method because of the lack of class III comparables.

Petitioner proposed an unspecified method that combines elements of the CUT and the CPM. It provides two versions of this method, each consisting of three steps. The first two steps are the same for both versions, and the third step is modified by changing the ratio by which residual profit is allocated between Medtronic US and MPROC.

The first version includes a 35% allocation of residual profits to Medtronic US and a 65% allocation to MPROC (35/65 allocation), resulting in a wholesale royalty rate of 35.7%, and the second version includes a 50% allocation of residual profits to Medtronic US and a 50% allocation to MPROC (50/50 allocation), resulting in a wholesale royalty rate of 40%. We are concerned that the first version results in a wholesale royalty rate lower that the blended wholesale royalty rate of 38% and the second version is only 2 percentage points higher than 38%.

Relying upon the expert testimony from the further trial, we conclude that the royalty rate in *Medtronic I* is too low. We are still concerned that petitioner's position does not take into consideration

[*51] adequately the difference in profit potential between MPROC and the Pacesetter agreement.

Respondent's expert Heimert testified that it was important for products to have "some level of close product similarity" and that "it is always a matter of degree." He further testified: "[W]e want to try to get as close a comparability as we can." Specifically, regarding the CPM he testified: "[W]hat we're sort of looking at is a blender amalgamation of returns from many different companies in employing a CPM . . . to smooth out some of these differences." He further testified that some comparables are stronger in one area while other comparables are weaker in some areas.

During his testimony Heimert suggested using 5 comparables instead of 14 as he did in his original report. We are concerned that the remaining five companies are not comparable enough to makers of devices and leads. He testified that some of the implantables that are used as comparables are orthopedic parts that do not have "batteries, capacitors, or a heavy degree of software in them" and that would not be "necessarily equivalent." His testimony also indicated that potential risk to a patient should be considered.

Limiting the comparable companies to five is an improvement; however, the remaining five comparables are not identified as solely class III products. None of the comparable companies makes similar cardio or neuro devices. Limiting the comparables increases the percentage of profits allocated from Medtronic US from 8% to 12%. We conclude that a 12% allocation is unreasonable for the same reasons that we did in *Medtronic I. See Medtronic I*, at *116–18.

Heimert raised concerns that limiting the comparison to only one comparable, such as Pacesetter, on the basis of function puts aside other differences such as distribution. He further testified that by adjusting the ROA the royalty rate changes. A higher ROA results in a lower royalty rate, and vice versa, a lower ROA results in a higher royalty rate.

Heimert testified that a possible way to adjust the profits would be to restrict the set of comparables. He also testified that an adjustment for product liability would increase the ROA. Even though he believes that the Pacesetter agreement was not a reliable CUT, another solution would be to look at adjustments made to the Pacesetter agreement. **[*52]** The CUT method and the CPM both provide information that helps determine whether a method is the best method. The CUT method focuses on price, whereas the CPM focuses on profit benchmark. Respondent's concerns with the CUT method are that there is not a sufficient level of comparability with the Pacesetter agreement. Petitioner argues that respondent's CPM uses companies that differ fundamentally from MPROC; therefore, it fails to take into account the central importance of MPROC.

Becker's report includes a table which shows that MPROC was offered a license that required MPROC to perform far less work than Pacesetter. He explained that Pacesetter had 71% of the operating costs, whereas MPROC had 14.8% of the operating costs, which includes cost of components. He further explained that the profit potentials were different, with MPROC's having a profit potential of 63.6% and the Pacesetter agreement's having a profit potential of 29%. He testified that the royalty rates suggested by Putnam and the Court's Opinion in *Medtronic I* were "on the right track." His testimony addressed how to bridge the gap. He testified that "there's a lot of criticism on both sides" and "at the end of the day, the full package of adjustments has to make some sense." Becker further testified the following:

And if he [referring to Putnam] came in and said, oh, I did all these adjustments and I came up with 40% or even 35% or even 45%, I would basically say, yeah, I don't like Dr. Putnam's logic. They—I don't like the logic of it, but ultimately his answer is fine. I don't really have much to say. But that's not what happened here. So I think with an eye towards that, there adjustment that, as I recall, you have made, Dr. Putnam has made, Dr. Berneman has made. And some of those are not really based on true data. Some of them are more assumptions and estimates. But if you kind of look at the maximum of some of those, it may get you closer to this answer that you say, okay, here's all the potential adjustments, we take the highest of this and the highest of that and see if it get us to a number that's at all reasonable, and then you have, A, your Pacesetter CUT but you also have your CPM as the check and you sort of recover both ways.

Our task is to bridge the gap and find the right adjustments that make sense for this specific case. The Court asked about possible methods including averaging the CUT and the CPM. Respondent chose **[*53]** neither to comment on this suggestion nor to make any additional suggestions, except for a comment in respondent's Final Supplemental Posttrial Brief.¹¹

E. Petitioner's Proposed Unspecified Method

Petitioner's proposed unspecified method combines aspects of both the CUT and the CPM. The first step is to apply a modified version of petitioner's CUT method and the arm's-length wholesale royalty rate of 8% for the trademark license to allocate profits to Medtronic US's R&D activities. Step two applies a modified version of respondent's CPM to allocate profit to MPROC's activities.

After completing the first two steps and allocating a portion of profit for tax years 2005 and 2006, a portion of device and lead system profit remains unallocated. The third step allocates the remaining profit between Medtronic US and MPROC. This step differs from the CUT method and the CPM.

For step one, petitioner uses the Pacesetter royalty rate to establish a royalty rate to allocate profits to Medtronic US for its R&D activities and allocates the remaining profits to MPROC. Petitioner respondent's price MPROC's finished uses CPM to device manufacturing activities using Heimert's ROA to allocate the corresponding profit to MPROC and allocate the remaining profits to Medtronic US and Med USA on the basis of the arm's-length prices for component manufacturing and distribution. The return to MPROC is reduced for profits allocated to Medtronic US and Med USA. In short petitioner proposes to use both the CUT method and the CPM as starting points to price MPROC's and Medtronic US's activities, then at step three divides the remaining profit between the two entities using commercial and economic evidence.

Petitioner contends that a key aspect of its unspecified method is to address the higher profitability of its devices and leads compared to the lower profitability of Pacesetter in 1992. The first two steps of the unspecified method do not address profitability. Petitioner describes the third step as a proxy for Medtronic US's relatively higher profitability.

¹¹ Respondent's Final Supplemental Posttrial Brief includes a chart of wholesale royalty rates, which include a rate using the comparable profit split method based on the adjusted Pacesetter agreement.

[*54] 1. Step One

Petitioner starts with Putnam's proposed adjustments to the Pacesetter agreement. In his expert report Putnam provides two approaches: one using the Pacesetter agreement retail royalty rate of 7% and the other using the maximum 15% retail royalty rate included in the Pacesetter agreement. For calculating step one, the 7% retail royalty rate is used because the maximum 15% retail rate includes an adjustment for profitability. According to petitioner this is unnecessary because step three makes an adjustment for profitability.

Putnam includes low and high ranges in his expert report. For the purposes of the unspecified method, the high-end range is used. The total retail royalty rate is 17.3%.

Base rate	7.0%
Portfolio access fee	1.8
Cross license	1.0
Know-how	3.0
CRDM/Neuro avg. sub-license	4.54
Total royalty rate ¹²	17.3%

The modified CUT royalty plus the retail rate of 5.4% for the trade license (wholesale royalty rate of 8%) results in an allocation of \$674,352,148 in profits to Medtronic US for 2005 and 2006 for its R&D activities.

Unspecified method	Medtronic US profit for TY 2005–06	MPROC profit for TY 2005–06
Device and lead system profit to allocate	\$3,333,823	3,544
Step 1: Modified CUT + trademark license allocates returns to Medtronic US	674,352,148	_

¹² All rates in chart are retail royalty rates.

[*55] 2. Step Two

Petitioner makes modifications to Heimert's CPM analysis to address its concern about the book values used for MPROC's operating assets. The unspecified method makes an upward adjustment to MPROC's operating assets. Petitioner contends that asset intensity allows for a more reliable comparison of asset values and that MPROC's asset intensity is too low as compared to the 14 comparables in Heimert's analysis. Asset intensity is equal to operating asset value divided by revenue. Petitioner contends asset intensity is an important metric for comparing MPROC's book asset values to those of other companies.

The median asset intensity for the five companies that Heimert identified in his testimony is 52%, and the asset intensity percentage for MPROC is 13.3%. Petitioner contends that MPROC's asset intensity is too low because of the book value of MPROC's operating assets. It argues that its adjustments to asset intensity are supported by the regulations.

One of the examples provided in the regulations of the CPM method allows for adjustments for asset intensity. See Treas. Reg. § 1.482-5(e) (example 5(ii)). The example allows for each uncontrolled comparable's assets to be reduced by the amount relative to sales by which they exceed the tested party's accounts receivable. See *id*. The regulations explain that it may be necessary to take into account recent acquisitions, leased assets, intangibles, currency fluctuations, and other items that may not be explicitly recorded in the financial statements of the tested party or uncontrolled comparable. *Id*. para. (d)(6).

Petitioner further contends that the value of operating assets that MPROC carries on its balance sheet has depreciated over time, and the book value does not reflect fair market value of the assets. It adjusted MPROC's asset intensity to 52.3%. The results of the adjustment are in the table below.

Year	MPROC average operating assets in Dr. Heimert's CPM	Adjusted average operating assets with 52.3% asset intensity
2005	\$393,029,644	\$1,401,712,258
2006	424,192,500	1,853,316,656

[*56] After making an adjustment for asset intensity, the unspecified method allocates to MPROC profits based on a 41.3% ROA, the average of ROAs for Heimert's five companies as applied to MPROC's adjusted asset base. This results in the allocation of \$1,344,326,942 in profit to MPROC for 2005 and 2006 based on the modified CPM. The returns for components and distribution are subtracted from MPROC's returns. The table below demonstrates these calculations.

Unspecified method		Medtronic US profit for TY 2005–06	Med USA profit for TY 2005–06	MPROC profit for TY 2005–06
Device and lead system profit to allocate		\$3,333,823,544		
Step 1: modified CUT + trademark license allocates returns to Medtronic US		\$674,352,148	_	_
Step 2(a): modified CPM allocates returns to MPROC		_	_	\$1,344,326,942
Step 2(b): MPROC payments for components and distribution	Components	138,805,027		-138,805,027
	Distribution	_	\$425,697,389	-425,697,389

3. Step Three

This final step allocates the remaining overall system profit not allocated in steps one and two, which is explained in the table below.

[*57]

Unspecified method		Medtronic US profit for TY 2005–06	Med USA profit for TY 2005–06	MPROC profit for TY 2005–06
Device and lead system profit to allocate		\$3,333,823,544		
Step 1: modified CUT + trademark license allocates returns to Medtronic US		674,352,148	-	_
Step 2(a): modified CPM allocates returns to MPROC		_	_	\$1,344,326,942
Step 2(b): MPROC payments for	Components	138,805,027		-138,805,027
and distribution	Distribution	_	\$425,697,389	-425,697,389
Remaining profit to be allocated			\$1,315,144,454	

Petitioner has two versions of its unspecified method. For both versions steps one and two are the same. Step three allocates the remaining profits to MPROC and Medtronic US. Petitioner's first version allocates 65% of the remaining profit to MPROC and 35% to Medtronic US (65/35 allocations), resulting in 51% of the overall system profit being allocated to Medtronic US and Med USA and 49% to MPROC.

[*58]

Unspecified method with 65/35 residual allocation		Medtronic US profit for TY 2005–06	Med USA profit for TY 2005–06	MPROC profit for TY 2005–06
Device and lead system profit to allocate		\$3,333,823,544		
Step 1: modified CUT + trademark license allocates returns to Medtronic US		\$674,352,148	_	_
Step 2(a): modified CPM allocates returns to MPROC		_	_	\$1,344,326,942
Step 2(b): MPROC	Components	138,805,027		-138,805,027
payments for components and distribution	Distribution		\$425,697,389	-425,697,389
Step 3: allocate remaining profit based on evidence in the record with 65/35 allocation		460,300,559	_	854,843,395
Total system profit allocated		\$1,699,1	155,123	\$1,634,667,921

Petitioner's second version is a 50–50 allocation of the remaining system profit between Medtronic US and MPROC. This version allocates approximately 57% of the system profit to Medtronic US and Med USA and 43% to MPROC.

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[*59]

Unspecified method with 50/50 residual allocation		Medtronic US profit for TY 2005–06	<i>Med USA profit</i> for TY 2005–06	MPROC profit for TY 2005–06
Device and lead system profit to allocate		\$3,333,823,544		
Step 1: modified CUT + trademark license allocates returns to Medtronic US		\$674,352,148		_
Step 2(b): MPROC payments for components and distribution	Components	138,805,027		-138,805,027
	Distribution	_	\$425,697,389	-425,697,389
Step 3: allocate remaining profit based on evidence in the record with 50/50 allocation		657,572,227		657,572,227
Total system profit allocated		\$1,896,	426,791	\$1,437,396,753

Version one results in a wholesale royalty rate of 35.7% whereas version two results in a wholesale royalty rate of 40%.

[*60]

Royalty rates for the unspecified method	Unspecified method 65/35 allocation	Unspecified method 50/50 allocation
Total profit allocated to Medtronic US + Med USA	\$1,699,155,123	\$1,896,426,791
Expenses	\$835,807,413	\$835,807,413
Less distribution return	-\$425,697,389	-\$425,697,389
Less component manufacturing return	-\$138,805,027	-\$138,805,027
Gross royalty payment to Medtronic US	\$1,970,460,120	\$2,167,731,788
Total intercompany sales	\$4,511,601,171	\$4,511,601,171
Total intercompany rate (TM + IP)	43.7%	48.0%
Less trademark intercompany royalty rate	-8.0%	-8.0%
IP intercompany royalty rate	35.7%	40.0%
Intercompany conversion rate	68%	68%
IP royalty rate	24.3%	27.2%

F. Analysis of Petitioner's Proposed Unspecified Method

The regulations require that the same realistic alternatives analysis be performed for both specified and unspecified methods. See Treas. Reg. § 1.482-4(d)(1). We concluded in *Medtronic I* that MPROC's role was "unique" and could be replaced with only "substantial time and costs." *Medtronic I*, at *107–08. MPROC had substantial negotiating leverage to seek a significant portion of the system profits. Respondent relies upon the Court's conclusion in *Coca-Cola Co.*, 155 T.C. at 254. This case is distinguishable from *Coca-Cola* because the supply points in that case "were contract manufacturers that performed routine functions" and were "easily replaceable." *Id.* By contrast in *Medtronic I* we concluded that MPROC did not perform routine functions. *See Medtronic I*, at *106–12. **[*61]** Respondent errs in relying on the regulations to support a different conclusion. In the example a U.S. company, USbond, licenses intellectual property (IP) to its foreign subsidiary, Eurobond. Treas. Reg. § 1.482-4(d)(2). Eurobond uses that IP to manufacture and sell an industrial adhesive in Europe. *Id*. The royalty rate that USbond charges Eurobond is \$100 per ton, and Eurobond charges \$550 per ton to unrelated buyers. *Id*. In this example the \$100 royalty rate is not arm's length because USbond could produce and sell the product itself for a profit. *Id*.

Respondent contends that Medtronic US can be compared to USbond and that Medtronic US could have stopped using MPROC and instead manufactured the devices and leads. We have already ruled out this alternative as being nonviable. *See Medtronic I*, at *106–08. We remain with our original conclusion that MPROC could not be easily replaced.

In *Medtronic I* respondent made the same argument that MPROC was easily replaceable because it performed standard manufacturing activities expected of any manufacturer in the medical device industry. As an example respondent points to petitioner's Swiss facility. The Swiss facility only made devices and could not make enough devices to supply both Europe and the United States. Petitioner never considered outsourcing the activities performed by MPROC because of concerns about quality. Respondent has not provided evidence that disproves our initial conclusion that MPROC could not be replaced without substantial time and costs. *See id*.

As the royalty rate decreases, the profits to Medtronic US decrease. The overall profit split refers to a split of profit when considering the revenues and costs from all of the intercompany transactions involved in Medtronic US's CRDM and Neuro businesses: component manufacturing, distribution, finished manufacturing, and R&D (technology and trademark IP). The R&D/MPROC profit refers to the split of profits between MPROC's functions and Medtronic US's R&D (technology and trademark IP). This profit split subset does not include the allocation of profits with respect to manufacturing and distribution.

The allocation of the remaining profits in step three is a way to adjust the royalty rates without having to make further adjustments to the CUT. We examine each step of petitioner's proposed unspecified method.

[*62] 1. Step One

Petitioner's expert witness Hubbard testified that by using Putnam's high-end range, 62%–64% of the profit goes to MPROC and 36%–38% goes to Medtronic US. He thought these profits splits were reasonable. Petitioner relies upon Hubbard's testimony to support its proposed unspecified method.

Respondent contends that a 17.3% retail royalty rate should not be used in step one of petitioner's proposed unspecified method. Respondent's position is that the rate is too low and does not adjust for all the differences between the MPROC licenses and the Pacesetter agreement. Petitioner contends that the 17.3% rate intentionally excludes any adjustment for differences in profitability to isolate and address differences in profitability in step three. We agree with petitioner that profits should not be addressed in step one because they are instead addressed in step three.

Petitioner further argues that the adjustments to royalty rates made in step one are not items that would materially alter the relative split between Medtronic US and MPROC. Petitioner makes the following arguments regarding each of the adjustments to the Pacesetter retail royalty rate. First, the portfolio access fee of 1.8% is accounted for in the early years of the Pacesetter agreement. Second, the 1% cross-license adjustment does not affect higher profitability. Third, know-how is properly accounted for with a 3% adjustment. Fourth, the CRDM/Neuro sublicense adjustment of 4.5% is for a mechanical passthrough of 4.5% of fixed royalties that does not affect the profit split in step three.

In *Medtronic I* we made an adjustment of 7% for know-how. *See Medtronic I*, at *137. Putnam reduced that adjustment 4%. We are not convinced that petitioner's adjustment is high enough.

Respondent argues that the intellectual property under the MPROC licenses is the "crown jewels." We agree that these were important patents in the cardio and Neuro industries; however, we do not agree with respondent that these patents are crown jewels. Petitioner had licenses with competitors for similar products. Pacesetter, St. Jude, Guidant, and CPI/Eli Lilly all had access to these patents and were not as profitable as Medtronic US. No patents were identified as key patents under the Pacesetter agreement.

[*63] 2. Step Two

We agree with petitioner that an adjustment to asset intensity is necessary because Heimert's comparable companies perform functions, have capabilities, and own assets that differ from MPROC's. *See id.* at *110. By increasing MPROC's asset intensity to make it more comparable to the selected five companies, the comparison of MPROC and the five companies is easier to make; but the evidence does not support petitioner's proposed adjustment which increased asset intensity from 13.3% to 52.3%.

Respondent contends that petitioner's inflating MPROC's operating assets results in a lower allocation to Medtronic US. By increasing asset intensity to 52.3%, petitioner adjusts MPROC's operation assets by over \$1 billion for each year. We disagree with petitioner that depreciation and acquisitions justify this increase. We agree with respondent's concerns that MPROC's revenues are inflated because they include sales attributable to contributions by Medtronic US and MPROC.

Respondent argues that MPROC should have a lower asset intensity than the comparables because MPROC performs fewer activities. Pacesetter's asset intensity of 45.6% is higher than MPROC's, which is expected because of the different functions that they performed. Heimert's five comparables used in the modified CPM have asset intensities between 40% and 80%. We agree that the comparables perform more activities than MPROC, but this does not alleviate our concern about the comparability of Heimert's five comparables.

3. Step Three

Respondent criticizes petitioner's proposed unspecified method for using a 17.3% royalty rate in step one and a 7% royalty rate in step three. According to respondent, petitioner uses the 7% Pacesetter royalty rate for determining the residual profit split. Petitioner disagrees with respondent.

Petitioner contends that in step three it relies upon the Pacesetter agreement to split Pacesetter's profits under the Pacesetter agreement, which had a 7% retail royalty rate. According to petitioner, step three does not use the 7% royalty rate as respondent contends. Rather, petitioner uses the 7% royalty rate as part of the evidence to determine how Medtronic US and Pacesetter split profits as licensor and licensee of technology used in class III implantable medical devices. For step [*64] three petitioner wanted to look at how commercial parties with comparable negotiating levels split a given pool of profit.

Petitioner contends that step three does not require a different profit split from that under the Pacesetter agreement because MPROC also licensed other nonpatent rights such as know-how, which is compensated by an adjustment in step one. According to petitioner, step three looks at how arm's-length parties would split the remaining profit after allocations in steps one and two. Petitioner looked at the portion of Pacesetter's profit that Medtronic US expected to receive as a licensor.

According to Robert Pindyck, an expert for petitioner in the prior trial, 22%–23% of the profits went to Medtronic US and 77%–78% of the profits went to Pacesetter. Petitioner contends that step three is focused on the Medtronic US/Pacesetter profit split for insight into how Medtronic US and MPROC, acting at arm's length, would divide the additional profit remaining after steps one and two. In other words petitioner believes that step three should be determined by looking at how arm's-length commercial actors split the profits arising from the license of technology used in class III implantable medical devices. According to petitioner step three relies upon this profit split rather than the royalty rate.

Respondent is critical of step three and believes it has the same problems as the CUT. Respondent has the same concerns that it had in *Medtronic I* and argues that the Pacesetter agreement and the MPROC licenses do not have the same degree of comparability as required by the regulations. *See* Treas. Reg. § 1.482-1(d)(3)(ii)(A).

G. Conclusion

Respondent contends that petitioner's proposed unspecified method is not commensurate with income as required under section 482 and Treasury Regulation § 1.482-4(a). Respondent's position is that Putnam's CUT "flunks the similar profit potential requirement," resulting in Medtronic US's royalty income from the licensed intangible not being commensurate with income. We agree with respondent that under petitioner's proposed unspecified method Medtronic US's royalty rate is not commensurate with income.

[*65] H. Adjustments to Achieve Royalty Rate

Respondent contends that petitioner's proposed unspecified method "bridges no gaps" between respondent's CPM and petitioner's CUT method. Petitioner provides a method which enables the Court to move in the right direction. Respondent provides no suggestion for realistically bridging the gap. Even though we are rejecting petitioner's unspecified method as proposed, we will rely upon petitioner's methodology as setting forth a framework for determining the royalty rate for devices and leads.

As we have discussed, petitioner's proposed unspecified method is not perfect. Adjustments need to be made to account for the inadequacy of the CUT method. The major concerns with the CUT method are that there (1) is only one comparable, (2) are too many adjustments, and (3) are inadequate adjustments for profit potential. Petitioner makes an attempt to address these concerns, but its proposed unspecified method falls short, and the results do not bridge the gap adequately.

We can start by determining whether a separate rate is needed for devices and leads and whether it should be adjusted every year. We previously reached the conclusion that there can be a single royalty rate which does not need to be adjusted every year.

We agree with petitioner that Putnam's high-end range of a 17% retail royalty can be a starting point. There are not too many adjustments made to reach the 17% rate because we are not relying on petitioner's proposed method as a CUT method. The adjustments increase the starting retail royalty rate of 7% by 10 percentage points, and 4.5 are from sublicenses in which the royalty rate is being passed through. We differ with the amount of adjustment for know-how. In *Medtronic I*, at *135, we acknowledged that MPROC had access to the know-how of Medtronic US. Pacesetter and its successor St. Jude did not have an ongoing relationship with Medtronic US. *Id*.

During the prior trial petitioner's expert 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 timeframe for the same customers, and the same profit potential." *Id.* at *133. The Pacesetter agreement is not ideal, but it is an appropriate starting point. **[*66]** Petitioner's unspecified method can be used to address prices and profits. No adjustments need to be made to the first two steps. Putnam's royalty rate is not perfect, but further adjustments would be too speculative. The second step made too high an adjustment for MPROC's asset intensity. From the expert testimony, we have difficulty pinpointing what adjustments should be made.

The third step can be adjusted. As petitioner demonstrates with its two versions of the proposed unspecified method, the allocation of the profits between Medtronic US and MPROC can be adjusted and affect the royalty rate. By allocating more of the remaining profits in step three to Medtronic US, a higher royalty rate can be achieved. Step three is calculated using yearly data so the royalty rate does not need to be adjusted yearly.

After taking into account both parties' experts' testimonies, we concluded that neither party put forth the best method. Our solution may not be perfect, but it reflects a detailed analysis in the context of the Eighth Circuit's mandate and takes into consideration the level of technology that is needed to make safely the devices and leads. It is not an attempt to create a new method which is simply a hybrid of the CUT method and the CPM. If respondent had provided a way to make further modifications to the CPM, we would have considered that approach.

The only adjustment that we are making is in step three by changing the allocation of the remaining profits to Medtronic US and MPROC. In *Medtronic II* the Eighth Circuit raised concerns that the Court did not evaluate how the different treatment of intangibles affects comparability. By making an adjustment, we account for know-how and other items that may be directly or indirectly related to the patents licensed to MPROC. *See Medtronic II*, 900 F.3d at 615.

Even though we do not make an adjustment to step two, we believe that petitioner made too high an adjustment to MPROC's ROA. This adjustment resulted in a greater allocation of profit in step two to MPROC than to Medtronic US. By making a greater allocation of the remaining profits in step three to Medtronic US than to MPROC, we can address our concerns pertaining to step two.

Our adjustment to the third step increases the allocation of remaining profits to Medtronic US. It results in an allocation of 80% to Medtronic US and 20% to MPROC (80–20 allocation). This adjustment is a way of accounting for the imperfections of the CUT method, such as

[*67] "know-how," having only one comparable, and differences in profit potential, and imperfections of the CPM, such as the inadequacy of the comparables and an unrealistic profit allocation to MPROC. Additionally, the adjustment takes into account petitioner's unsupported increase in asset intensity in step two.

Changing the allocation to 80–20 results in a wholesale royalty rate of 48.8%.

Unspecified method with 80/20 residual allocation		Medtronic US profit for TY 2005–06	Med USA profit for TY 2005–06	MPROC profit for TY 2005–06	
Device and lead system profit to allocate		\$3,333,823,544			
Step 1: modified CUT + trademark license allocates returns to Medtronic US		\$674,352,148	_	_	
Step 2(a): modified CPM allocates returns to MPROC		_	_	\$1,344,326,942	
Step 2(b): MPROC	Components	138,805,027		-138,805,027	
payments for components and distribution	Distribution	_	\$425,697,389	-425,697,389	
Step 3: allocate remaining profit based on evidence in the record with 80–20 allocation		1,052,115,563	_	263,028,891	
Total system profit allocated		\$2,290,9	970,127	\$1,042,853,417	

[*68]

Royalty rates for the unspecified method	Unspecified method—80/20 allocation
Total profit allocated to Medtronic US + Med USA	\$2,290,970,1277
Expenses	\$835,807,413
Less distribution return	-\$425,697,389
Less component manufacturing return	-\$138,805,027
Gross royalty payment to Medtronic US	\$2,562,275,124
Total intercompany sales	\$4,511,601,171
Total intercompany rate (TM + IP)	56.8%
Less trademark intercompany royalty rate	-8.0%
IP intercompany royalty rate	48.8%
Intercompany conversion rate	68%
IP royalty rate	33.2%
Overall profit	t split
Medtronic US	68.72%
MPROC	31.28%
R&D profit	split
Medtronic US	62.34%
MPROC	37.66%

Increasing the wholesale royalty rate to 48.8% results in an overall profit split of 68.72% to Medtronic US/Med USA and 31.28% profit split to MPROC and a R&D profits split of 62.34% to Medtronic US and 37.66% to MPROC. The resulting profit split reflects the importance of the patents as well as the role played by MPROC. The profit split is more reasonable than the profit split of 56.8% to Medtronic US/Med USA and 43.2% to MPROC resulting from petitioner's unspecified method with a 50–50 allocation. According to respondent's

[*69] expert Becker, MPROC had incurred costs of 14.8% of retail prices. The evidence does not support a profit split which allocates 43.2% of the profits to MPROC when it has only 14.8% of the operating cost.

The table below shows our resulting wholesale royalty rate of 48.8% in comparison with the wholesale royalty rates under other methods, along with the resulting allocation of profits.

MPROC	Medtronic US		MPROC	Medtronic US/Med USA		Wholesale royalty rate	[*70]
81.6%	18.4%		67.8%	32.2%	Overall profit split	21.8%	Putnam CUT (low)
76.4%	23.6%		63.5%	36.5%		25.0%	Berneman CUT
76.1%	23.9%	R&D/MPROC profit split	63.2%	36.8%		25.2%	MDT petition
63.2%	36.8%		52.5%	47.5%		33.1%	Putnam CUT (high)
59.0%	41.0%		49.0%	51.0%		35.7%	Unspecified (35–65)
55.2%	44.8%		45.9%	54.1%		38.0%	Tax Court (Medtronic I)
53.4%	46.6%		44.4%	55.6%		39.1%	MOU
52.0%	48.0%		43.2%	56.8%		40.0%	Unspecified (50–50)
37.6%	62.4%		31.3%	68.7%		48.8%	Unspecified (80–20)
15.8%	84.2%		13.1%	86.9%		62.2%	Modified CPM
15.5%	84.5%		12.9%	87.1%		62.4%	Pacesetter CPSM
8.5%	91.5%		7.0%	93.0%		66.7%	Heimert CPM

[*71] We conclude that wholesale royalty rate is 48.8% for both leads and devices, and the royalty rate is the same for both years in issue.

According to the regulations an unspecified method will not be applied unless it provides the most reliable measure of an arm's-length result under the principles of the best method rule. Treas. Reg. § 1.482-4(d). Under the best method rule, the arm's-length result of a controlled transaction must be determined under the method that, under the facts and circumstances, provides the most reliable method of getting an arm's-length result. *Id.* § 1.482-1(c)(1). We have concluded previously that petitioner's CUT method, petitioner's proposed unspecified method, the Court's adjusted CUT method in *Medtronic I*, respondent's CPM, and respondent's modified CPM do not result in an arm's-length royalty rate and are not the best method. Only petitioner suggested a new method, its proposed unspecified method; however, for reasons previously explained, that method needed adjustment for the result to be arm's length.

In transfer pricing cases it is not unique for the Court to be required to determine the proper transfer pricing method. See Perkin-Elmer Corp. & Subs. v. Commissioner, T.C. Memo. 1993-414 (requiring the Court to find a middle ground without sufficient help from the parties). During further trial and posttrial briefs we received suggestions from the parties and their expert witnesses. Our adjustments are premised upon the regulations and expert witness testimonies.

As respondent's expert witness Becker suggested, our adjustments start with a maximum rate. Petitioner's proposed unspecified method starts with a rate of 17.3%, which we do not adjust. Including an aspect of the CUT method enables R&D activity to be priced. Including an aspect of the CPM in the unspecified method enables finished device manufacturing to be priced.

Our adjustments consider that the MPROC licenses are valuable and earn higher profits than the licenses covered by the Pacesetter agreement. We also looked at the ROA in the Heimert analysis and from the evidence cannot determine what the proper ROA should be. The criticisms each party had of the other's methods were factored into our adjustment. Respondent's expert Becker testified that you may not like the logic of a method but ultimately the answer is fine. Because neither petitioner's proposed CUT method nor respondent's modified CPM was the best method, our goal was to find the right answer. The facts in this **[*72]** case are unique because of the complexity of the devices and leads, and we believe that our adjustment is necessary for us to bridge the gap between the parties' methods.

A wholesale royalty rate of 48.8% for both devices significantly bridges the gap between the parties. Petitioner's expert witness Putnam proposed a CUT which resulted in a blended wholesale royalty rate of 21.8%; whereas respondent's expert Heimert's original CPM analysis resulted in a blended wholesale royalty rate of 67.7%. In *Medtronic I* we concluded that the blended wholesale royalty rate was 38%, and after further trial, we conclude that the wholesale royalty rate is 48.8%, which we believe is the right answer.

V. 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 (Swiss Supply Agreement) in which Medtronic Europe agreed to assist MPROC by manufacturing and supplying the U.S. markets with devices necessary to meet customer demand. Medtronic Europe agreed to pay Medtronic US directly an amount equal to the royalties that MPROC would have paid if it had manufactured the devices itself and made the sale to Med USA itself.

Respondent increased the amount owed by Medtronic Europe to Medtronic US under the Swiss Supply Agreement. We concluded in *Medtronic I*, at *139, that the issue should be resolved in the same manner as the section 482 issue regarding devices; therefore, the wholesale royalty is 48.8% for devices covered by the Swiss Supply Agreement.

Any contentions we have not addressed are irrelevant, moot, or meritless.

To reflect the foregoing,

Decision will be entered under Rule 155.
APPENDIX

Petitioner's Expert Witnesses

1. Richard Cohen

[*73]

Dr. Cohen is the Whitaker Professor in Biomedical Engineering at the Massachusetts Institute of Technology's (MIT) Institute of Medical Engineering and the Harvard-MIT Health Sciences and Technology Program. He received his M.D. degree from Harvard Medical School and Ph.D. degree in physics from MIT. The Court recognized Dr. Cohen as an expert in the medical device industry.

2. <u>Glenn Hubbard</u>

Dr. Hubbard is the Russell L. Carson Professor in Economics and Finance in the Graduate School of Business of Columbia University. He is also a professor of economics in the Department of Economics of the Faculty of Arts and Sciences at Columbia University. From 2007 to 2017 he was an adviser to the president of the Federal Reserve Bank of New York. From 2001 to 2003, he served as Chairman of the President's Council of Economic Advisers. He received B.A. and B.S. degrees in economics from the University of Central Florida and A.M. and Ph.D. degrees in economics from Harvard University. The Court recognized Dr. Hubbard as an expert in financial economics.

3. <u>Fred McCoy</u>

Mr. McCoy is president and chief executive officer (CEO) of NeuroTronik Limited. He received his B.S. degree in business administration from the University of North Carolina and his M.B.A. degree from the Kellogg School of Management at Northwestern University. The Court recognized Mr. McCoy as an expert in the medical device industry.

4. Jonathan Putnam

Dr. Putnam is the founder and principal of Competition Dynamics, Inc., a litigation and management consulting firm. He has taught at the University of Toronto, Boston University, Columbia University, Yale University, and Vassar College. He received B.A., M.A., and Ph.D. degrees in economics from Yale University. The Court recognized Dr. Putnam as an expert in the economics of intellectual property.

[*74] 5. Christopher Spadea

Mr. Spadea is a senior consultant with Ankura Consulting Group, LLC, in the intellectual property practice. He is a certified licensing professional. He received a B.S.B.A. degree in finance from the University of Delaware. The Court recognized Mr. Spadea as an expert in licensing and intellectual property valuation.

Respondent's Expert Witnesses

1. Brian Becker

Dr. Becker is president of Precision Economics, LLC. He has taught at John Hopkins University, Marymount University, and George Washington University. He received a B.A. degree in applied mathematics and economics from Johns Hopkins University and M.A. and Ph.D. degrees in applied economics from the Wharton School of the University of Pennsylvania. The Court recognized Dr. Becker as an expert in economics with specialization in transfer pricing.

2. Iain Cockburn

Dr. Cockburn is chair of the Strategy and Innovation Department of the Questrom School Business of Boston University. He has also taught at the University of British Columbia and has been a visiting scholar in the Department of Economics at Harvard University. He received a B.S. degree in economics from Queen Mary College, University of London, and A.M. and Ph.D. degrees in economics from Harvard University. The Court recognized Dr. Cockburn as an expert in the economics of innovation and intellectual property.

3. <u>Peter Crosby</u>

Mr. Crosby has been the CEO of six medical device companies in four countries. He is CEO and managing partner of Biomedical Business Resources, LLC. He received a B.A. degree in electrical engineering and an M.A. degree in biomedical engineering from the University of Melbourne, Australia. The Court recognized Mr. Crosby as an expert in the medical device industry.

[*75] 4. <u>A. Michael Heimert</u>

Dr. Heimert is a senior adviser to Duff & Phelps, providing transfer pricing advisory services. He was a professor at Benedictine University. He received a B.S. degree in business economics from Marquette University and M.A. and Ph.D. degrees in economics from the University of Wisconsin–Milwaukee. The Court recognized Dr. Heimert as an expert in economics and transfer pricing.

5. Christine Meyer

Dr. Meyer is an economist and managing director and the chair of the intellectual property practice at National Economic Research Associates, Inc. She taught statistics and economics at Bentley College and Colgate University. She received a B.A. degree with a concentration in economics from the U.S. Military Academy and a Ph.D. degree in economics from MIT. The Court recognized Dr. Meyer as an expert in applied microeconomics and in the economic analysis of licenses, patents, and other intellectual property.