Bloomberg BNA

Tax Management
Transfer Pricing Report™

VOL. 25, NO. 7 AUGUST 11, 2016

Considering the Value of Manufacturing Trade Secrets, Confidential Know-How in 'Medtronic'

The author examines the U.S. Tax Court's recent decision for Medtronic Inc., noting that the court agreed with the company that its Puerto Rican manufacturing operations deserved significant compensation because they represented ''the last line of defense before a potential product quality issue.''

By Helen Y. Trac, Hogan Lovells

These days, licensing between affiliate members of a multinational corporate family is prevalent. While reaching agreement between friendly parties on licensing terms may be easier than it normally would be between arms-length parties from an economic perspective, these transactions are likely to come under intense scrutiny from the relevant tax authorities worldwide.

Understanding the value of not just the assets at issue in the license, but the intangible assets that each party to the license brings to the table, is essential not only for determining arm's-length licensing terms but also for defending those terms in court. Medtronic Inc. successfully convinced the U.S. Tax Court that the manufacturing trade secrets and know how held by its Puerto Rican subsidiary were incredibly valuable to not only the production, but also the development, of its Class III medical devices. Indeed, the intangible assets of Medtronic's subsidiary were so important the court attributed to it more than half of intercompany sales revenue in arriving at a fair market value royalty rate.

Judge Kathleen Kerrigan's 144-page opinion, issued June 9, decided the proper royalty rate of a 2002 intercompany license between Medtronic and its subsidiary, Medtronic Puerto Rico Operations Co. (MPROC).[1]

The license at issue covered Medtronic device pulse generators (devices) and physical therapy delivery devices (leads) in the company's Cardiac Rhythm Disease Management (CRDM) and Neurological (Neuro) business units. (The headquarters of these businesses will

Helen Y. Trac is an associate at Hogan Lovells in San Francisco and focuses her practice on intellectual property litigation.

[1] *Medtronic Inc. v. Commissioner*, T.C. Memo 2016-112. See 25 Transfer Pricing Report 143 (analysis), 214 (text).

 ISSN 1063-2069

be referred to as Medtronic U.S.) The opinion was adapted under a protective order issued by the court, to protect Medtronic's ''proprietary and confidential information,'' which included its trade secrets and other confidential commercial information not in the public domain.

The IRS argued that Medtronic U.S. owed additional tax of $1.3 billion for 2005-06 because the license for the devices and leads allocated too much profit to MPROC. The license gave MPROC the exclusive right to use, develop and enjoy the intangible property used in manufacturing devices for sale to customers in the U.S. and leads for sale to customers worldwide. The licensed intangible property comprised Medtronic U.S.-developed inventions, secret processes, technical information and technical expertise relating to the design of the devices and leads and all associated legal rights, including patents, trade secrets, know-how, copyrights and product regulatory approvals.

Under the license, MPROC paid Medtronic U.S. a 29 percent royalty rate on intercompany sales of devices and a 15 percent royalty rate on intercompany sales of leads. In addition, under a separate trademark license, MPROC paid Medtronic U.S. an 8 percent royalty rate for Medtronic U.S.'s trademarks. The IRS and its expert argued that in an arms-length transaction, MPROC should receive only 8.1 percent and 5.6 percent of the operating profits for 2005 and 2006, respectively, with the remaining 91.9 percent and 94.4 percent of the operating profits being attributed to Medtronic U.S.

Medtronic's Business

Medtronic U.S. is the headquarters of Medtronic's worldwide CRDM and Neuro businesses. It is responsible for the research and development of new products and refinements of existing products. MPROC manufactures Class III finished medical devices,[1] including the devices and leads at issue in this case. Its devices and leads operations take place in facilities registered with the U.S. Food and Drug Administration, subject to regular pre-market and post-market inspection by the FDA. During 2005 and 2006, MPROC sold devices and leads to Med USA, a member of Medtronic U.S.'s consolidated group, for sale into the U.S. and other jurisdictions. Class III medical devices are higher-risk and more novel than Class I and Class II devices, and therefore are subject to the most stringent controls. They must go through a pre-market approval process, which can often take between five and 10 years. Medtronic U.S. is responsible for the clinical studies, which it designed, oversaw and used to support pre-market approval submissions. It also bears the significant costs related to the FDA's stringent regulatory requirements for Class III medical devices.

[1] Medical devices are classified based on the level of regulatory control required. Class III devices require a higher level of control than do Class I and Class II devices.

The IRS argued that Medtronic U.S. and Med USA performed most of the functions of the CRDM and Neuro businesses and that MPROC performed only the final manufacturing step. Even those were completed according to processes approved by Medtronic U.S., the IRS noted. In arriving at a royalty rate, the IRS's expert assumed that all intangibles MPROC needed to perform finished manufacturing (other than assembled workforce and incremental process intangibles that MPROC may have developed since entering into the intercompany licenses in 2002) were licensed from Medtronic U.S.

Medtronic, meanwhile, argued that MPROC's manufacturing and quality control secret processes and know-how constituted a substantial part of the intangibles needed to create the devices and leads. MPROC further argued that it played a critical role of ensuring product quality—that is, ''like the ancient Roman Hero, Horatio,'' MPROC ''represents the last line of defense before a potential product quality issue.'' According to Medtronic, product quality ''is the 'sine qua non' of success within the implantable device industry'' and the single greatest factor in terms of market share. As an example, Medtronic cited a 1970s recall of a pacemaker that caused its market share percentage to fall from the mid-70s to the high 30s.

The Court agreed:

> [The IRS] does not place enough emphasis on the importance of quality in the industry. The final product is the key to success. Product quality is the foundation for which implantable medical devices can be successful.
>
> . . .
>
> MPROC was making devices and leads that were implanted in a human body and was responsible for ensuring that the manufactured devices and leads were of the highest quality. . . . if a device or lead malfunctions, the consumer could die.
>
> . . .
>
> [While] [i]t is difficult to place an exact value on what MPROC contributed to the manufacturing of devices and leads, but it is certainly more than the 8%-12%.

Kerrigan adjusted the calculation of royalties for the devices from the 29 percent proposed by Medtronic to 44 percent, and adjusted royalties for the leads from 15 percent to 22 percent. In determining those rates, the court emphasized MPROC's system engineering expertise and its integral role in the product lifecycle, stating: ''The bottom line [is] that if a finished product could not be made, it could not be sold.''

The court found that because it is 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 U.S. through each development phase of new products to ensure that newly developed products

were able to be manufactured at commercial scale. MPROC employed numerous engineers who were involved with product development, project implementation, technology harvesting and process development. They also developed new manufacturing technology and MPROC's own software systems to ensure product quality.

Value Ascribed to MPROC

The court also stressed that MPROC was involved in every aspect of the manufacturing process. During 2005 and 2006, MPROC employed almost 2,300 people, and between 70 percent and 75 percent of them worked on the manufacturing lines. The manufacturing processes for both devices and leads were very detailed and took a week or longer. Some steps had to be completed by hand by skilled workers.

Indeed, quality was so important that MPROC would fire an employee if a defect could be traced back to the employee's work, even if it was the first mistake. In addition, MPROC wrote its own quality manual and had its own quality council. MPROC's quality systems were both extremely broad in scope and detailed – covering numerous aspects of product quality, including incoming inspection, sterilization, corrective and preventative action and complaint handling. Because the finished devices and leads wouldn't be inspected again until they were about to be implanted in a patient, it was vital that they be perfect when they left MPROC.

In short, the court ascribed significant value to MPROC's secret processes, technical expertise, and confidential know-how that wasn't reflected on its books. In fact, the court explicitly recognized the value of both companies' confidential know-how: ''Each party benefited from the know-how of the other. Medtronic US was constantly making improvements to products, and MPROC was ensuring the quality of the product and improving the manufacturing.''

In addition, the court noted that, in intangible property transactions, ''[l]ooking at the income related to the intangible [property] and splitting it according to relative economic contributions is consistent with what unrelated parties do.'' By assigning the majority of the sales to MPROC, the court must therefore have concluded that the relative economic contribution of MPROC's manufacturing expertise, confidential know-how and secret processes exceeded the economic contribution of the intangibles licensed by Medtronic U.S. to MPROC in the license for devices and leads.

Role of Manufacturer

This decision is significant in that the court recognized the critical role of a manufacturer and the intangible assets that it brings to the table. The IRS stereotypically regarded all manufacturers as being ''low skill'' and interchangeable, rather than an integral part of the product lifecycle. The court recognized that where product quality is paramount and where its manufacturing process is cutting edge and complex, stellar manufacturing capabilities contribute just as much to success as a stellar product.