

REDACTED FOR PUBLIC INSPECTION

**Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554**

In the Matter of)
)
Respironics, Inc. and Boston Scientific)
Corporation)
)
Requests for Waiver of Section 15.205 of the) ET Docket No. 05-331
Commission's Rules to Permit the Marketing)
and Operation of Certain Medical)
Communications Devices that Operate in the)
90-110 kHz Band)
)

REQUEST FOR FURTHER EXTENSION OF WAIVER

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INTRODUCTION AND SUMMARY

Boston Scientific Corporation (“Corporation”) manufactures and distributes certain life-enhancing, implantable medical devices that use an inductive telemetry system which generates extremely low levels of radio frequency (“RF”) emissions in the 90-110 kHz band to communicate with monitoring equipment at a physician’s office. Specifically, these are cardiac devices (such as pacemakers, defibrillators) that are chosen by physicians based on the specific needs and characteristics of the patient, and then implanted in the patient for an extended period of time. These RF frequencies are used only for limited purposes in the physician’s office, and only infrequently and for a limited period of time in each instance. Because the Commission’s rules provide priority to the LORAN radionavigation system in this band,¹ and because this band is not available for unlicensed uses under Section 15.205 of the Commission’s rules, Boston Scientific previously requested and received a waiver of the Commission’s rules to permit continued manufacture and sale of its legacy Cognis, Teligen, and Contak Renewal TR devices. As extended by the Commission, that waiver expires on December 31, 2011.

Despite diligent efforts to complete the final stages of development for its redesigned products that do not use the 90-110 kHz band, Boston Scientific has experienced unanticipated delays in the schedule for launching the replacement products. FDA approval for the replacements for the legacy Cognis and Teligen devices are not expected until late 2011 or early 2012. Likewise, due to unanticipated delays in completion of the development and launch of the replacement for the legacy Contak Renewal TR device, FDA approval is not expected until late 2011 or early 2012, but given the inherent uncertainties of the development and approval processes, could be as last as the middle of 2012. In addition, even after the new

¹ 47 C.F.R. § 2.106. The term LORAN refers to Long Range Aids to Navigation. LORAN-C operations ceased as of October 1, 2010.

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devices have successfully completed the FDA approval process, the devices must be introduced to the medical community. Recent changes in the health care system have significantly lengthened the timeline for making new devices available to patients. Overall, the uncertain nature of the medical device development, testing, and approval process have delayed FDA approval of the replacement products, and changes in health care provider policies over the past year are expected to lengthen the time associated with the introduction of the products into the medical community.

Boston Scientific now expects to be able to complete the FDA approval process and also phase out the current devices under the new health care provider policies by no later than June 30, 2013. An extension of the existing waiver until a suitable time after FDA approval for each replacement device would ensure that the life-enhancing treatment options offered by the existing devices continue to be available to the public until the replacement products can be brought to market in an orderly manner. Given that the Cognis and Teligen cardiac rhythm management devices are widely chosen by physicians as the optimal solution for their patient's needs, an orderly introduction of the replacement products into the medical community is essential. Moreover, the Contak Renewal TR device offers a unique treatment option that is critical to a certain segment of cardiac patients. The requested extension for each of these devices is no longer than necessary to achieve the necessary transition. Due to the limited and localized use of these frequencies in a medical facility, the limited extension that Boston Scientific requests is not anticipated to adversely affect any users of the 90-110 kHz band. Moreover, the LORAN-C systems that previously operated in the 90-110 kHz band which Boston Scientific understands was the basis for the restriction in 15.205(a), have now been decommissioned.

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REQUEST FOR FURTHER EXTENSION OF WAIVER

Boston Scientific Corporation ("Boston Scientific") hereby requests a further extension of the waiver of Section 15.205(a) of the Commission's rules, granted in the above-referenced proceeding, permitting the continued manufacture and sale of certain life-enhancing, implantable medical devices that operate in the 90-110 kHz band.² The current waiver expires on December 31, 2011. Boston Scientific seeks an extension for its Cognis, Teligen and Contak Renewal TR implantable cardiac devices until the earlier of twelve months after receipt of FDA approval of the respective replacement devices, or June 30, 2013. As set forth below, there is good cause for granting the requested waiver extension.

² *Respironics, Inc. and Boston Scientific Corporation, Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Communications Devices that Operate in the 90-110 kHz Band*, Order, 21 FCC Rcd 13450 (2006) ("Waiver Order"), *modified*, Order, 22 FCC Rcd 12881 (2007) ("Waiver Modification Order"), *modified*, Order, 24 FCC Rcd 9089 (2009) ("Contak Renewal TR Waiver Modification Order"), *modified*, Order, DA 10-1744 (rel. Sept. 15, 2010) ("2010 Waiver Modification Order").

I. BACKGROUND

Boston Scientific is a leading worldwide manufacturer of implantable cardiac devices, such as pacemakers (or pacers), defibrillators and cardiac resynchronization therapy (“CRT”) devices. These devices are implanted into patients with cardiovascular disease and deliver electrical stimuli to treat abnormal heart rhythms. The Teligen device is an implantable cardioverter defibrillator (“ICD”), which is designed to deliver a high voltage electrical impulse to treat a heart rhythm that is abnormally fast. The “Cognis” and “Contak Renewal TR” products are CRT devices. CRT devices are designed to resynchronize heart rhythms in patients suffering from heart failure. Most CRT devices, including the Cognis device, also include a defibrillation capability, which requires high voltage electronics, most notably high voltage capacitors.³ The Contak Renewal TR, however, is a unique, smaller CRT device that does not deliver defibrillation therapy.⁴

Each of these implantable devices uses inductive telemetry to communicate with heart monitoring and device programming equipment, allowing physicians to download information stored in the device’s memory to monitor a patient’s cardiac events and the functioning of the implanted system. Inductive telemetry operates using magnetic coupling between a coil in a hand-held “wand” and a coil in the implanted device. In the typical case, the physician initiates a communication session with the implanted device by placing the wand on the patient’s chest over the device to establish an inductive link between the wand and the

³ Such devices that include defibrillation are known as “CRT-D” devices.

⁴ The Contak Renewal TR device lacks high voltage circuitry, such as high-voltage capacitors, and is thus significantly smaller than the defibrillation-capable version. Contak Renewal TR and its replacement are referred to as “CRT-P” devices because they are pacers without defibrillation capability. Physicians may choose an implantable cardiac device that does not have defibrillation shock capabilities to treat certain cardiac conditions. Physicians follow the approved indications for each type of therapy as defined by the American Heart Association/Heart Rhythm Society guidelines.

implanted device. The wand must be within centimeters of the device to detect the extremely low-power inductive transmissions.

Certain devices still being manufactured and distributed by Boston Scientific, including the Cognis, Teligen and Contak Renewal TR devices at issue here, use an inductive telemetry system that emits extremely low levels of RF emissions in the 90-110 kHz band during physician communication sessions.⁵ The Commission's rules provide priority to the LORAN radionavigation system in this band, and this band is not available for unlicensed uses under Section 15.205. Boston Scientific therefore has requested, and the Commission has granted, waivers to ensure that the life-enhancing benefits offered by these cardiac devices remain available to patients who need them while the next-generation devices that do not emit in the 90-110 kHz band are made available. The next-generation replacement devices for the Cognis and Teligen devices are part of the "Progeny" technology platform.⁶ The Contak Renewal TR device will be replaced by the Cognis CRT-P, a device based on the "Ingenio" technology platform.⁷

On June 6, 2006, Boston Scientific first requested a waiver of the Commission's rules with respect to the operation, manufacture and sale of implantable cardiac devices that

⁵ The cardiac devices generate RF energy in the 90-110 kHz band at extremely low levels and for periods of only a few minutes over the course of a year. Typically, the Contak Renewal TR inductive system is operated for about twenty minutes about four times per year in a clinical setting; the Teligen and Cognis devices are typically operated for much shorter periods – just a few seconds per year – as the inductive communication system that operates in the 90-110 kHz band is typically used to initiate a wireless communication session. Furthermore, only the implanted device itself emits RF signals in this band. The external programming and monitoring equipment transmits on a frequency outside this band.

⁶ "Progeny" is Boston Scientific's name for the development program. The commercial devices will be known by other names.

⁷ Boston Scientific may rename the Cognis CRT-P device prior to commercialization, but for simplicity the device is referred to in this request as "Cognis CRT-P" or "replacement for Contak Renewal TR."

operate at 90-110 kHz. At the time, the Contak Renewal TR device was being manufactured and sold, and the Cognis and Teligen devices were about six years into a development cycle.

On November 16, 2006, the Commission issued an Order granting Boston Scientific a waiver to permit the manufacture and sale of (i) Contak Renewal TR devices until the earlier of (x) November 16, 2009, or (y) six months after the final regulatory approval of the replacement devices for Contak Renewal TR, and (ii) Cognis and Teligen devices until November 16, 2009.⁸ The Commission determined that “the short-term product shortage that would result from taking the current devices off the market without a phase-out period would likely be detrimental to the public, and specifically medical patients and their families who benefit from their use.”⁹ The Commission further concluded that there was a negligible chance that these products would interfere with LORAN-C operations at 90-110 kHz.¹⁰

When the Commission granted the waiver in 2006, the Cognis and Teligen products were still in development and were not expected to receive FDA approval until 2008. On December 18, 2006, Boston Scientific requested a modification of the waiver for the Cognis and Teligen devices to provide sufficient time to bring these products to market and to sell them until replacement products that do not employ the 90-110 kHz band could be developed and introduced. On July 11, 2007, the Commission modified the waiver to provide three years to market the Cognis and Teligen devices, commencing on the earlier of the date of FDA approval

⁸ Waiver Order ¶ 13. The Waiver Order also permitted the manufacture and sale of products on Boston Scientific’s Ingenio technology platform that used the 90-110 kHz band until November 16, 2009. Boston Scientific has successfully modified the design of the Ingenio products to eliminate use of the 90-110 kHz band. The Waiver Order also permitted the manufacture and sale of certain other implantable pacemakers and cardioverter defibrillators (known as “PDM” and “PD2”) that used the 90-110 kHz band. Boston Scientific has ceased marketing those products. The Commission specified that devices implanted in patients under the provisions of the waiver will be permitted to continue to operate indefinitely. *See id.* n.16.

⁹ *Id.* ¶ 11.

¹⁰ *Id.*

for the first device in the series, or January 31, 2009.¹¹ Boston Scientific received FDA approval on May 8, 2008.

Despite a significant investment in quality and research and development, and due to unexpected delays in the product development process, Boston Scientific was required to request extensions of the waiver for the Contak Renewal TR devices, as well as the Cognis and Teligen devices. On March 6, 2009, Boston Scientific requested that the Commission extend the waiver for the Contak Renewal TR device from November 16, 2009 until the earlier of (i) May 8, 2011, or (ii) 90 days after the date of FDA approval of the replacement device for the Contak Renewal TR. On July 14, 2009, the Commission granted Boston Scientific's request to align the expiration of the Contak Renewal TR waiver with that of the modified waivers for the Cognis and Teligen devices.¹² The need for the waiver extension for Contak Renewal TR was based in part on the major redesign of the Ingenio product line that Boston Scientific undertook to move the communications frequencies outside of the 90-110 kHz band, bringing the Ingenio devices into compliance with the Commission's rules and obviating the need for any waiver for the Ingenio devices.¹³

On May 5, 2010, Boston Scientific requested an extension of the waivers for the Cognis, Teligen and Contak Renewal TR devices until December 31, 2011 due to necessary but unplanned further design enhancements that arose during the final stages of development for the next generation devices. The Commission granted that extension on September 15, 2010, recognizing that these waivers "present an unusual and compelling public interest situation in which patients and their caregivers rely on the devices at issue for health- and life-critical

¹¹ Waiver Modification Order ¶ 14.

¹² See Contak Renewal TR Waiver Modification Order ¶ 13.

¹³ *Id.* ¶ 11.

purposes,” and that the extension granted would “ensure that the treatment benefits provided by these devices will continue to be available to patients until FCC-compliant replacements can be brought to market in an orderly manner.”¹⁴ In granting each of these waiver modifications, the Commission has recognized that “these cardiac devices present an extremely small risk of harmful interference to other authorized operations, such as LORAN-C, in the 90-110 kHz band.”¹⁵

II. BOSTON SCIENTIFIC HAS MADE SUBSTANTIAL PROGRESS DEVELOPING REPLACEMENT PRODUCTS

Boston Scientific has continued to make significant progress toward the completion and launch of the products that will replace the Cognis and Teligen devices, and the products that will replace the Contak Renewal TR devices. Although those replacement products are nearing completion, it has become clear that, contrary to Boston Scientific’s earlier expectations, the December 31, 2011 expiration of the existing waiver will provide insufficient time to accommodate the completion of product evaluation testing of the replacements for Contak Renewal TR, FDA review and approval of the all of the replacement products, and introduction of the replacement products into the medical community.

A. Product Development

¹⁴ 2010 Waiver Modification Order at ¶ 10.

¹⁵ *See, e.g., id.* ¶ 10.

¹⁶

B. FDA Status

Approval for Progeny is not expected until late 2011 or early 2012.

¹⁸ Obtaining FDA approval will clear the path for the Cognis and Teligen replacement devices to be brought to market, and as a result, the vast majority of Boston Scientific's cardiac rhythm management implants that are sold will operate outside of the 90-110 kHz band.

¹⁸ Regulatory review and approval is outside Boston Scientific's control and therefore somewhat difficult to predict.

Assuming no further delays,

Boston Scientific currently expects to receive FDA approval for Ingenio in late 2011 or early 2012, but given the inherent uncertainties of the development and regulatory approval processes, approval could be as late as the middle of 2012.

C. Phase-In of Replacement Devices

Following receipt of FDA approval, Boston Scientific must develop arrangements with hospitals and allow for the orderly introduction of the new products, and the phase-out of the existing products. Changes in the health care system over the past year have lengthened this process. To more closely monitor and reduce costs, most hospitals now require contracts for medical device purchases to be reviewed and approved by a technical assessment committee. Because these committees typically meet only periodically (in some cases on a quarterly basis), the actual commencement of distributing replacement devices will depend on when these committees convene. Therefore, the time allowed for phase-out of the Cognis, Teligen and Contak Renewal TR devices should account for this lengthened period.

In addition, time is needed to ensure that patients and physicians have the resources available to implement the new products. For example, the approximately 12,000 device programmers (medical equipment) located in clinics and hospitals around the U.S. must be updated with new software that is needed to interact with the replacement products. In addition, hands-on training will be necessary to instruct physicians regarding the use of a new lead connection standard that, subject to receipt of FDA approval, will work with the new devices. Neither the programmer updating nor the device training can begin before receipt of

FDA approval. Moreover, the training and other transition activities typically cannot be scheduled at year end, when many physicians and hospital staff are unavailable.

With respect to the Cognis product, the need for a further extension of the waiver is also necessary in light of an ongoing clinical study that Boston Scientific is conducting known as the Multisensor Chronic Evaluations in Ambulatory Heart Failure Patients (“MultiSENSE”) study. Based on the existing Cognis platform, the MultiSENSE study is expected to yield data that will allow Boston Scientific and its clinical partners to determine how ambulatory sensor measurement changes as heart failure worsens, potentially leading to the development of detection algorithms that provide advance notice of worsening heart failure and allow for earlier medical intervention. The waiver extension requested here will permit sufficient time to assure full enrollment in the study by qualifying patients with implanted Cognis devices. To ensure consistency in the study, and because the replacement products are not configured to provide the necessary data, the replacement products cannot be used for the study. Early intervention benefits both the patient, who enjoys better health, and the public, which does not bear the cost of hospitalization of the patient. A large fraction of heart failure patients receive Medicare benefits, which are paid with public tax dollars.

For these reasons, therefore, the December 31, 2011 expiration of the current waiver will not be sufficient to allow the life-enhancing benefits of these products to continue to be made available to the physicians who select these products as the best solution for the health needs of their cardiac patients. If the FCC waiver expires before all of the steps described above have been completed, there is a risk that some patients may not have access to the life-enhancing treatment options that these devices offer.

III. THE CIRCUMSTANCES IN THIS CASE JUSTIFY EXTENDING THE WAIVER

There is good cause to grant Boston Scientific's request for a further extension of the waiver period for the Cognis, Teligen and Contak Renewal TR devices, to extend the "bridge" to the replacement products that will not operate at 90-110 kHz, and accommodate the unforeseeable delays described above.¹⁹ The life-enhancing benefits that the devices offer with "an extremely small risk of harmful interference to other authorized operations" in the 90-110 kHz band provide more than good cause for extending the waiver beyond the current December 31, 2011 expiration, and "[g]iven the remote likelihood of such interference, . . . grant of this waiver will not contravene the underlying purpose of Section 15.205 of the Rules."²⁰

In the Order that initially granted relief to Boston Scientific, and throughout this proceeding, the Commission consistently has recognized the importance of Boston Scientific's cardiac devices to heart patients and noted that restricting the availability of these products would be harmful to the public interest.²¹ Each cardiac patient's unique condition is reviewed by a physician who ascertains whether the particular functions and attributes of a specific cardiac implant device are best suited for that patient. For example, one advantage of the current Cognis and Teligen devices (and their replacements) is their thin profile, which is especially desirable in small-bodied patients. The Contak Renewal TR device is unique because it is smaller than other CRT devices offered by Boston Scientific and has a unique pacemaker/cardiac resynchronization

¹⁹ See 47 C.F.R. § 1.3 ("Any provision of the rules may be waived by the Commission . . . if good cause therefore is shown."). A waiver of the Commission's rules is appropriate where, as here, special circumstances warrant a deviation from the rule and strict compliance with the rule is inconsistent with the public interest. *WAIT Radio v. FCC*, 418 F.2d 1153, 1159 (D.C. Cir. 1969); see also, *Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164, 1166 (D.C. Cir. 1990).

²⁰ 2010 Waiver Modification Order ¶ 10.

²¹ Waiver Order ¶ 11; see also Contak Renewal TR Waiver Modification Order ¶ 11 (noting that "these waivers present an unusual and compelling public interest situation in which patients and their caregivers rely upon the devices at issue for health- and life-critical purposes") (footnote omitted); 2010 Waiver Modification Order ¶ 10.

functionality.²² Without a grant of the requested extension, some cardiac patients would not have access to the thin-profile Cognis and Teligen devices or any Boston Scientific device with the unique pacemaker/cardiac resynchronization functionality offered in the Contak Renewal TR product.

Significantly, the risk of harmful interference to other users in this band is virtually nonexistent. As an initial matter, Boston Scientific is not aware of any interference complaints related to cardiac implant devices that operate at 90-110 kHz.²³ As described above, the short duration on the occasional emissions that occur in a controlled clinical environment reduces the chance of an interference problem. The Commission has consistently acknowledged that the risk of interference with LORAN-C operations in the restricted 90-110 kHz band is negligible.²⁴ LORAN-C operations have now ceased as of October 1, 2010.²⁵

Thus, there is ample cause to grant the requested extension. Based on the unanticipated delays in product development and in obtaining FDA approval, and the changes in

²² The Contak Renewal TR device that is being replaced by the Ingenio line is a more specialized product that accounts for a very small percentage of the current population of Boston Scientific's implanted devices.

²³ There have been no reported cases of interference. LORAN-C users include the U.S. Coast Guard and non-federal aviation and Private Land Mobile services, and LORAN-C receivers thus typically operate on mobile air, land and marine platforms. It is extremely unlikely that a cardiac device communicating in the restricted band with nearby external clinical equipment would interfere with any LORAN-C communications.

²⁴ Waiver Order ¶ 11; Contak Renewal TR Waiver Modification Order ¶ 11; 2010 Waiver Modification Order ¶ 10.

²⁵ Coast Guard, Terminate Long Range Aids to Navigation (Loran-C) Signal, Notice, Docket No. USCG-2009-0299, 75 Fed. Reg. 998 (Jan. 7, 2010).

On October 28, 2009, the President signed into law the 2010 Department of Homeland Security Appropriations Act, which, among other things, allowed for the termination of the LORAN-C system upon certification from the Coast Guard that the termination of the LORAN-C signal will not adversely impact the safety of maritime navigation, and upon certification from the Department of Homeland Security that the LORAN-C system infrastructure is not needed as a backup to the GPS system or to meet any other federal navigation requirement. Department of Homeland Security Appropriations Act, 2010, Public Law No. 111-83, 123 Stat. 2142, 111th Cong., 2^d Sess., § 559. *See also*, <http://www.navcen.uscg.gov/Loran/default.htm>

the health care system, Boston Scientific requests an extension of the waiver to allow it to manufacture and distribute the Cognis, Teligen and Contak Renewal TR devices until twelve months after receipt of FDA approval of the respective replacement devices, but no later than June 30, 2013.²⁶

This extension request is limited to the length of time required to complete development and testing of the Contak Renewal TR, obtain FDA approval for the replacement devices, and to allow for the orderly transition to replacement products that do not emit in the 90-110 kHz band, as well as a brief period to account for some uncertainty in each of these phases. Thus, the requested extension is no longer than necessary to achieve this transition to the replacement products. Therefore, the extension will provide for a life-enhancing “bridge” to replacement products that do not operate in the 90-110 kHz band, while creating at most a negligible interference potential to users of this band.

IV. CONCLUSION

For the foregoing reasons, Boston Scientific respectfully requests that the Commission grant an extension of the waiver for the Cognis, Teligen and Contak Renewal TR devices until the earlier of twelve months after receipt of FDA approval of the respective replacement devices, or June 30, 2013. The unanticipated delays in product development and the FDA approval process, and recent changes in health care provider policies, warrant the requested extension. Allowing Boston Scientific to manufacture and sell the Cognis, Teligen and Contak Renewal TR devices until a suitable time after FDA approval for each respective replacement

²⁶ The Commission has previously granted waiver extensions to Boston Scientific for these devices based on the compelling public interest of maximizing the reliability of Boston Scientific’s implantable heart devices, as is the case in this extension request.

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device would ensure that the life-enhancing treatment options offered by the existing devices continue to be available to cardiac patients until the replacement products can be brought to market in an orderly manner, while posing only a negligible risk of harmful interference to users of the 90-110 kHz band.

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