Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)	
	)	
Respironics, Inc. and Boston Scientific	)	
Corporation	)	ET Docket No. 05-331
	)	
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

Adopted: September 15, 2010 **Released: September 15, 2010**

By the Chief, Office of Engineering and Technology:

I. INTRODUCTION

1. By this Order, we grant a request by Boston Scientific Corporation ("Boston Scientific") to extend the existing waiver of Section 15.205 of our rules for its Contak Renewal TR, Cognis, and Teligen cardiac devices.[1] This will permit their continued use of the 90-110 kHz band while Boston Scientific finalizes the development and introduction of replacement devices that will not operate in that band. The present waivers are scheduled to expire on May 8, 2011, and the extension granted herein will permit the continued manufacture and marketing of these devices until December 31, 2011.

2. Because cardiac patients will be afforded with the continued availability of the salutary health benefits provided by these devices, and because the risk of harmful interference to other authorized operations in the band is extremely small, we conclude that good cause exists for extending the existing waiver and that the public interest will thereby be served.[2]

II. BACKGROUND

3. Boston Scientific manufactures several lines of implantable cardiac medical devices, including cardiac resynchronization therapy devices (the Contak Renewal TR devices), cardiac resynchronization devices with pacemakers (the Cognis devices), and cardioverter defibrillators (the Teligen devices). As presently designed, these devices rely on inductive coupling to initiate communication sessions that download data from, and modify the operational settings of, the implanted devices and to serve as a backup communications link.[3] Because this inductive coupling technique

[1] *See* "Request for Extension of Waiver" in ET Docket No. 05-331, filed by Boston Scientific Corporation on May 5, 2010.

[2] *See WAIT Radio v. FCC*, 459 F.2d 1203, 1207 (D.C. Cir. 1972).

[3] *See* "Petition for Waiver" in ET Docket No. 05-331, filed by Boston Scientific Corporation on June 6, 2006, ad pages 5 and 12. With the inductive coupling technique used by these devices, data transfer is initiated by placing an external "wand" reader over the patient's chest within centimeters of the implant. The wand and implant then communicate on other (unrestricted) frequencies by sending and receiving data that provide information stored in

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produces fundamental emissions in the 90-110 kHz restricted band, these devices do not comply with the restricted band provisions of Section 15.205 our rules.[4]

4. On June 6, 2006, Boston Scientific first requested a waiver of Section 15.205 of the Commission's rules for its Contak Renewal TR, and the precursors of the Cognis and Teligen devices described above, the PDM and PD2 families. The PDM and PD2 devices used inductive coupling at 90-110 kHz for their entire communications sessions, and at the time of the June 6, 2006 waiver request, Boston Scientific was well into the process of developing the Cognis and Teligen devices, which rely on inductive coupling in the 90-110 kHz only for the initiation phase of the communications, thus significantly reducing its encroachment on the restricted 90-110 kHz band, and had begun development of devices that would rely solely on transmissions in the 900 MHz band, as permitted by our rules. Boston Scientific argued that a waiver of Section 15.205 would permit it sufficient time to exit the 90-110 kHz band in an orderly manner while it developed the fully compliant devices.

5. On November 16, 2006, the Chief of the Office of Engineering and Technology (OET), by delegated authority, issued an Order (*Waiver Order*) granting a waiver of Section 15.205 of the Rules.[5] Pursuant to the *Waiver Order*, Boston Scientific was permitted to continue the manufacture and marketing of the Contak Renewal TR devices for three years from the release date of the *Waiver Order*; or, until six months after final regulatory approval of the Cognis and Teligen devices, whichever came first. With respect to the Cognis and Teligen devices, the *Waiver Order* permitted their manufacture and marketing for three years after the release date of the Order.[6] This time frame was intended to minimize the time for which the noncompliant devices would be used before the new, fully compliant products would enter the market.[7]

6. Subsequently, on July 11, 2007, in response to a petition for reconsideration filed by Boston Scientific,[8] the Chief of OET issued a further order (*Waiver Modification Order*) that modified the terms of the original *Waiver Order*. This modification permitted Boston Scientific to continue the manufacture and marketing of its next generation Cognis and Teligen series of devices for three years after FDA approval, rather than three years from the date of the Order.[9] FDA approval was received for these

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the device's memory to allow physicians to monitor a patent's cardiac events and the functioning of the implanted system. In the event the primary communications channel does not function properly, the initial coupling link at 90-110 kHz is also used to transfer this data.

[4] 47 C.F.R. §15.205. Under Section 15.205 of the Commission's rules for unlicensed radio devices, intentional radiators generally are not permitted to operate in certain sensitive or safety-related frequency bands that are designated as "restricted bands." The restricted bands listed in Section 15.205 are bands employed by radio services that function, as a nature of their operation or use, with extremely low signal levels. These systems may be passive, such as radio astronomy, or active, such as satellite down links.

[5] *See* "In the Matter of 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," 21 FCC Rcd 13450, Order, ET Docket No. 05-331, DA 06-2316 (2006) (*Waiver Order*). The Respironics waiver is not at issue herein.

[6] Boston Scientific had requested that the waiver endure for six years after Food and Drug Administration ("FDA") approval.

[7] *Waiver Order, supra,* at para. 13.

[8] *See* "Petition for Reconsideration" in ET Docket No. 05-331, filed by Boston Scientific on December 18, 2006.

[9] *See* "In the Matter of 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," 22 FCC Rcd 12881, Order, ET Docket No. 05-331, DA 07-3160 (2007) (*Waiver Modification Order*).

devices on May 8, 2008, so that the waiver for the Cognis and Teligen devices is currently set to expire on May 8, 2011.

7. On July 14, 2009 the Chief of OET issued a further waiver (*Contak TR Waiver Modification Order*) granting a March 6, 2009, Boston Scientific request to extend the expiration date of the waiver for the Contak TR to the same date as the new date for the Cognis and Teligen devices.[10]

8. Boston Scientific now requests a further extension of the waiver for all three of its current product lines, *i.e.*, the Contak Renewal TR, Cognis and Teligen devices, until the end of 2011. In support of this request, Boston Scientific states that, despite investing millions of dollars in the redesign of its products to comply with FCC regulations, it has experienced unanticipated delays as a result of unplanned but necessary further design enhancements. It submits that it is now in the final stages of development for the next generation, compliant products, but that the time remaining in its current waiver will is not adequate to complete reliability testing, FDA review and approval, and introduction of the new products into the medical community. Boston Scientific states that the requested extension of the waiver is needed to allow it to make an orderly transition of its products to new devices that will be fully compliant with our rules.. Boston Scientific notes, with emphasis, that when the Commission last considered the subject of two of these waivers, its decision contemplated, with approval, an extension of the waiver beyond the date which it is now requesting.[11]

III. DISCUSSION

9. We find that the particular circumstances that supported the grant of the previous *Waiver Order, supra,* the subsequent *Waiver Modification Order, supra,,* and the related *Contak TR Waiver Modification Order, supra,* also support our grant herein of a relatively short extension of the waivers for the Contak Renewal TR, Cognis, and Teligen devices as requested by Boston Scientific.

10. As we stated in the previous Orders involving these products, 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 purposes.[12] We acknowledge Boston Scientific's continued efforts to transition its production to fully compliant devices, and conclude that, in furtherance of achieving this desirable goal, it is reasonable and appropriate for us to accommodate the additional development delays that have occurred. The extension granted herein will 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, and the critical benefits provided by these devices continue to present a significant public interest basis for the requested relief. As we have previously determined, these cardiac devices present an extremely small risk of harmful interference to other authorized operations, such as

[10] "Request for Extension of Waiver" (March 6, 2009). Boston Scientific asked for and was granted an extension until the *earlier* of (i) May 8, 2011, or (ii) 90 days after the FDA approval date on for fully rules-compliant replacements for the Contak Renewal TR. "In the Matter of 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, ET Docket No. 05-331, DA 09-1527, released July 14, 2009. FDA approval was not granted by May 8, 2008, and consequently May 8, 2011 became the default date for expiration of the waivers.

[11] In the *Waiver Modification Order*, *supra*, the Commission extended the Cognis and Inteligen waivers to the earlier of three years from (a) the date on which the first design received FDA approval or (b) January 31, 2009. *Id.* at para. 14. In other words, the Commission was amenable at that time to the waiver for these devices extending until January 31, 2012, one month longer than the time that Boston Scientific now requests.

[12] *See Waiver Modification Order, supra,* at para. 10.; *Contak TR Waiver Modification Order, supra***,** at paras. 11, 12.

LORAN-C, in the 90-110 kHz band.[13] Given the remote likelihood of such interference, we find that grant of this waiver will not contravene the underlying purpose of Section 15.205 of the Rules. The likelihood of interference to other users continues to appear to be miminal,[14] and as noted by Boston Scientific, we have previously determined that a date even later than that requested here could be accommodated. This decision remains consistent with our earlier determination to minimize the time for which noncompliant devices would be used before used before new, fully compliant products would enter the market.[15]

11. Accordingly, consistent with our earlier actions with respect to this matter, we find good cause to extend the waiver of Section 15.205 of our rules for the Contak Renewal TR, Cognis, and Teligen devices.

IV. ORDERING CLAUSES

12. Accordingly, pursuant to Sections 4(i), 302, 303(e), 303(r) and 405 of the Communications Act of 1934, as amended (47 U.S.C. §§ 154(i), 302, 303(e), 303(r) and 405), and Section 1.106(a)(1) of the Commission's rules (47 C.F.R. § 1.106(a)(1)), IT IS ORDERED that the "Contak Renewal TR," "Cognis," and "Teligen" product lines of cardiac medical devices may continue to be manufactured and marketed by Boston Scienific until December 31, 2011.

13. It is FURTHER ORDERED that Boston Scientific MUST SHOW that it has obtained FDA approval, including date of such approval, as part of its submission for equipment certification of the FCC rules-compliant replacement for the subject devices.

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp, Chief
Office of Engineering and Technology

[13] As stipulated in the original *Waiver Order*, *supra,* and the *Contak TR Waiver Modification Order, supra*, the temporary waiver embodied by this Order only applies to the constraints on emissions in the restricted frequency bands as specified in Section 15.205 of the Commission's rules. This waiver does not provide relief of the requirements of Section 15.5(b). Specifically, this includes the requirement that interference to the subject Boston Scientific Corporation products that may be caused by the operation of a LORAN-C radio station must be accepted. *See Waiver Order, supra,* at para. 9; *Contak TR Waiver Modification Order, supra*, at n. 20.

[14] We note that the use of LORAN-C has diminished since we granted the initial waiver Orders, and it does not appear that it will increase prior to the expiration of the extension granted herein.

[15] *See,* para. 5, *supra*, n. 8, *supra*.