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

In the Matter of	)	
	)	
Boston Scientific Corporation	)	ET Docket No. 05-331
	)	
Request 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: October 22, 2012 **Released: October 23, 2012**

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 Cognis cardiac device.[1] Granting Boston Scientific's request will permit this device to continue to use the 90-110 kHz frequency band while Boston Scientific completes its ongoing MultiSENSE clinical trial, begun in 2010, in which it is using the Cognis device to collect physiologic data related to patients' worsening heart failure.[2] The present waiver is scheduled to expire on November 17, 2012, and the extension granted herein will permit the continued manufacture and marketing of the subject devices until December 31, 2013, when the referenced clinical trial is expected to complete its enrollment.

2. This further extension is needed due to unanticipated delays enrolling a sufficient number of patients for a valid clinical trial. According to Boston Scientific, FDA protocol requires that the Cognis devices be implanted before patients are assessed for and permission is requested for participation in the trial.[3] In light of the health benefits provided by this device and the value of a successfully executed trial in enhancing patient care, and because the risk of harmful interference to other authorized operations in the band is extremely small, we conclude that good cause exists, and the public interest would be served by, extending the existing waiver.[4]

[1] *See* "Request for Limited Further Extension of Waiver" in ET Docket No. 05-331, filed by Boston Scientific Corporation on August 8, 2012 (Request).

[2] The MultiSENSE clinical trial is expected to provide data about patient events during worsening heart failure, demonstrate how sensor measurements vary during patient daily activities and during the development and recovery from events of worsening heart failure, and aid in the development of algorithms capable of detecting the onset of worsening hear failure prior to the over presentation of patient symptoms, using reference measurements. Request at 9.

[3] Request at 6.

[4] *See WAIT Radio v. FCC*, 418 F.2d 1153, 1159 (D.C. Cir. 1969).

II. BACKGROUND

3. Boston Scientific manufactures several lines of implantable cardiac medical devices, including cardiac resynchronization therapy devices, cardioverter defibrillators, and cardiac resynchronization devices with pacemakers (the Cognis device). As earlier designed, these devices relied 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.[5] Because the inductive coupling technique produced fundamental emissions in the 90-110 kHz restricted band, these devices would not comply with the restricted band provisions of Section 15.205 our rules.[6]

4. On June 6, 2006, Boston Scientific first requested a waiver of Section 15.205 of the Commission's rules for its several of its devices, including the Cognis device. These precursor 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 next generation devices that used inductive coupling only for the initiation phase of the communications, thus significantly reducing its encroachment on the restricted 90-110 kHz band. At that time Boston Scientific had also begun development of devices that would rely solely on transmissions in the 900 MHz band, as permitted by our rules. It 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. We granted that waiver on November 16, 2006,[7] and various modifications and extensions of the waiver on July 11, 2007,[8] July 14, 2009,[9] September 15, 2010,[10] and August 23, 2011.[11] We have

[5] *See* "Petition for Waiver" in ET Docket No. 05-331, filed by Boston Scientific Corporation on June 6, 2006, at pages 5 and 12. The inductive coupling technique used by these devices initiates a data transfer 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 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 can also be used to transfer this data.

[6] 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 downlinks.

[7] *See* 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, 21 FCC Rcd 13450 (Office of Engineering and Technology, 2006) (*Waiver Order*). The Respironics waiver is not at issue herein.

[8] *See* 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, 22 FCC Rcd 12881 (Office of Engineering and Technology, 2007) (*Waiver Modification Order*).

[9] "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 for fully rules-compliant replacements for the Contak Renewal TR. 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, 24 FCC Rcd 9089 (Office of Engineering and Technology, 2009). The FDA did not grant approval by May 8, 2008, and consequently May 8, 2011 became the default date for expiration of the waivers.

received no complaints of interference related to the waiver. As Boston Scientific has transitioned to fully compliant devices, the waiver has become moot with respect to all of the devices covered by it with the exception of the subject Cognis device, which is the only device considered here. Although the fully compliant replacement for the subject device (Progeny) is approved and available for use, the research software used for the MultiSENSE trial is compatible with the Cognis device, but not with the new product.

III. DISCUSSION

6. Section 1.3 of the Commission's rules allows waivers if the petitioner demonstrates good cause for such action.[12] Good cause, in turn, may be found and a waiver granted "where particular facts would make strict compliance inconsistent with the public interest."[13] To warrant such a public interest determination, the waiver cannot undermine the purposes of the rules, and there must be a stronger public interest benefit in granting the waiver than in applying the rule.[14]

7. We find that the circumstances presented by Boston Scientific support our grant herein of a relatively short (13 month) extension of the waiver for the Cognis device. We acknowledge Boston Scientific's successful efforts to transition its products to fully compliant devices within the timeframe provided by the last waiver extension.[15] However, Boston Scientific states that it needs a waiver extension to continue to manufacture and market its Cognis device in order to complete its on-going clinical trial.[16] Boston Scientific explains that unanticipated delays in enrollment for this trial have caused it to continue longer than expected, and that the trial results to date could be undermined if Boston Scientific is unable to complete the trial.[17] Thus, as was the case in the previous *Orders* involving these products, grant of this waiver is supported by a compelling public interest,[18] in that it will enable completion of clinical trials that will aid in the understanding of and refinement of the treatment of patients with heart failure.

8. We conclude further that granting this waiver extension will not undermine the purpose of Section 15.205. That rule prescribes certain technical parameters designed to prevent harmful

(...continued from previous page)

[10] 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, 25 FCC Rcd 13143 (Office of Engineering and Technology, 2010).

[11] Boston Scientific Corporation, Request 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, 26 FCC Rcd 11405 (Office of Engineering and Technology, 2011) (*2011 Waiver Extension*).

[12] 47 C.F.R. § 1.3; *WAIT Radio v. FCC*, *supra*.

[13] *Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164, 1166 (D.C. Cir. 1990); and *WAIT Radio,* 418 F.2d at 1159.

[14] *See, e.g., WAIT Radio*, *supra* at 1157 (stating that even though the overall objectives of a general rule have been adjudged to be in the public interest, it is possible that application of the rule to a specific case may not serve the public interest if an applicant's proposal does not undermine the public interest policy served by the rule); *Northeast Cellular*, 89 F.2d at 1166 (stating that in granting a waiver, an agency must explain why deviation from the general rule better serves the public interest than would strict adherence to the rule).

[15] Request at 11.

[16] Request at 6-7.

[17] Request at 7.

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

interference. As we have previously determined, the Cognis device presents an extremely small risk of harmful interference to other authorized operations.[19] 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. Because these devices are already operating pursuant to waiver, there are no significant costs associated with extending the waiver.

9. Accordingly, consistent with our earlier actions with respect to this matter, we find good cause to extend the waiver of Section 15.205 of the Commission's rules for the Cognis device as requested.

IV. ORDERING CLAUSES

10. Accordingly, pursuant to Sections 4(i), 302, 303(e), and 303(r) of the Communications Act of 1934, as amended (47 U.S.C. §§ 154(i), 302, 303(e), 303(r), and Section 1.3 of the Commission's rules (47 C.F.R. § 1.3), IT IS ORDERED that Boston Scientific may continue to manufacture and market the Cognis product line of cardiac medical devices until December 31, 2013, for the purpose of completion of the MultiSENSE clinical trial currently underway using this device.

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp, Chief
Office of Engineering and Technology

[19] As stipulated in the original *Waiver Order*, *supra,* and the subsequent modifications and extensions, 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) that the subject devices do not cause interference to and must accept interference from other authorized stations, radiators or equipment. *See Waiver Extension Order, supra* at n. 13. (As we noted in our last extension Order, LORAN-C operations (in the 90-110 kHz band) have been discontinued. See, http://www.navcen.uscg.gov/?pageName=loranMain. *2011 Waiver Extension*, *supra* at n. 11.)