

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

In the Matter of	)	
	)	
BOSTON SCIENTIFIC CORPORATION	)	ET Docket No. 05-331
	)	
Petition for Waiver of	)	
Section 15.205 of the Commission's Rules	)	

**PETITION FOR RECONSIDERATION**

Pursuant to Section 1.106 of the Commission's rules, 47 C.F.R. § 1.106, Boston Scientific Corporation ("BSC") hereby petitions for reconsideration of the Waiver Order released on November 16, 2006 in the above-captioned matter as it applies to BSC's next generation of medical implants, the Cognis/Teligen 100 series.<sup>1</sup> Specifically, BSC requests that the waiver period for these devices begin at the time of FDA approval and extend for six years. Adjustment of the Cognis/Teligen 100 series waiver period is appropriate because 1) the devices have no adverse impact to licensed users of the band, 2) implantable cardiac devices are complex to design and test and, therefore, there can be no assurance that the re-design process can reliably be completed in three years, and 3) the devices are subject to a lengthy FDA approval cycle, which may extend beyond the Commission's waiver.

In its Waiver Order, the Commission properly found that "there is good cause" to grant BSC a temporary waiver of Section 15.205 of the Commission's rules, 47 C.F.R. § 15.205, because such waiver "will afford medical patients . . . important health benefits . . . for which

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<sup>1</sup> *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*, DA 06-2316, Order, ET Docket No. 05-331 (rel. Nov. 16, 2006) ("Waiver Order"). BSC is currently evaluating the Ingenio family of devices, which were included with the Cognis and Teligen families in the Waiver Petition and whether a waiver will be needed for these devices.

there currently are no reasonable alternatives.”<sup>2</sup> The Commission accordingly granted varying waiver periods for the different BSC families of implantable devices.<sup>3</sup> But one of those waiver periods — the three-year waiver for the Cognis/Teligen 100 series — begins well before the first device in the family will have even received Food & Drug Administration (“FDA”) approval and will end within only a few months of the devices being brought to market, rendering the waiver for the Cognis/Teligen 100 series all but meaningless.

This is the unfortunate result of a recent slippage in the product development cycle and FDA submission schedule for the Cognis/Teligen 100 devices, events that were largely unforeseeable and beyond BSC’s control at the time of waiver request. Thus, the health and safety of potentially tens of thousands of cardiac patients who are the intended candidates for the Cognis/Teligen 100 series family of devices will be impacted if they are unable to receive treatment by these advanced implant devices.<sup>4</sup> To properly account for the significant time and resource commitment required to re-design and test a new telemetry function for an implant, as well as the delays associated with the re-preparation for FDA approval, BSC urges the Commission to reconsider its Order and allow for a six-year waiver period for the Cognis/Teligen 100 series, beginning on the date of initial FDA approval.

**I. Unique circumstances in the implantable device market justify a six year waiver term for the Frontier I family.**

Design cycles for implantable medical devices necessarily are very long due to the complexity of the product’s design, extensive testing to verify design reliability and the FDA

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<sup>2</sup> *Id.* ¶ 1.

<sup>3</sup> *Id.* ¶ 14. The PDM and PD2 families were given two year waivers and the Contak Renewal and Cognis/Teligen families were given three year waivers.

<sup>4</sup> BSC does not know whether other implant manufacturers will be in a position, over the next few years, to offer devices with similar advanced capabilities as the Cognis/Teligen 100 series. Given the long lead time to design, develop and obtain FDA approval, if such capabilities are not already featured in competitors’ next generation implants they will not be available to heart patients until long after the waiver period expires.

approval process. This timing is not driven by mere “business concerns.”<sup>5</sup> Rather, implantable medical devices present extreme design challenges because of the complex interactions among the various subsystems, all of which are packaged into a remarkably small device, which must meet extraordinary reliability standards because they are not easily accessible after being implanted in the human body. A new or replacement design for the Cognis/Teligen 100 series simply cannot be developed, tested, approved and brought to market between November 2006 and November 2009, the three-year period allowed by the Commission’s Waiver Order. Even if all these steps could be accomplished within the three year window there would still be insufficient time to train physicians and upgrade the installed programmer base<sup>6</sup> to make devices in the new family available to replace the 90-110 kHz devices which would be coming off the market almost immediately after they were being introduced. Thus, without some extension of the three year waiver, there is a serious risk that the Cognis/Teligen 100 series will not be commercially viable and, moreover, replacement devices with these next-generation features will not be available to “bridge the gap.”

This is particularly the case for an advance implant design like the Cognis/Teligen 100 series which has yet to even be submitted for FDA approval. The nearly seven-year design cycle has been extraordinarily long due to features that have been integrated into the new devices to make them smaller, longer lived and more reliable. As the inductive telemetry sub-system in the Cognis/Teligen 100 series is a foundation-level component of the platform design, any changes made at this late stage in development will propagate through many other subsystems. Thus, the inductive telemetry sub-system cannot be changed without retesting and redesigning

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<sup>5</sup> *Id.* ¶ 12.

<sup>6</sup> Introduction of implants using new inductive frequencies will require a software upgrade to enable all programmers to be capable of “reading” two sets of inductive signals, one for existing devices and one for the new devices. Physicians will require instruction on the efficient use of such programming devices.

many of the other subsystems in the implant. For example, the change of clock timing signals used to set the inductive subsystem frequency would have to be realigned with clocking signals in the RF subsystem and the safety core system to ensure that data streams and transfers would remain synchronized for all combinations of device operational modes and sub-modes.

Additionally, modified circuitry would require major revisions to custom integrated circuits that would impart additional component fabrication and testing times. Collectively, these subsystem changes will significantly lengthen the FDA approval process and delay the availability of these devices for clinical users and their patients.

Given the current approval processes, and consistent with industry standards, BSC plans to submit the first implant in the Cognis/Teligen 100 series for FDA approval in late 2007.<sup>7</sup>

Once a heart implant is submitted to the FDA, the review and approval cycle typically takes at least six months and can go considerably longer, particularly when novel features are involved.

While the exact timing of FDA approval is always difficult to predict, BSC currently expects the Cognis/Teligen 100 series to be approved by early 2008. Yet, it is possible that the timing could slip — for reasons wholly outside BSC’s control — and approval might not be received until immediately before, or even after, the expiration of the three year waiver period allotted for these devices.

It is this highly unpredictable nature of the design, testing and FDA approval processes for implantable cardiac devices that, BSC submits, necessitates a longer waiver period.<sup>8</sup> In many cases, these processes can take an unexpected number of years, extending the period for cost

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<sup>7</sup> The Waiver Petition projected that the first submission would be made in August 2006. However, BSC was unable to meet this target date due to the necessity of conducting additional testing prior to FDA submission.

<sup>8</sup> In 2004, the Commission granted a waiver to Dexcom, Inc. to permit periodic operation of its MICS device without the use of Listen-Before-Talk capability for a period of three years. (19 FCC Rcd 4208 (2004)). In that case, the three year period was quite significant because the device had already been approved and was in production. Thus, Dexcom received the full benefit of the three year waiver.

recovery and slowing down new product replacements. Thus, it is important that where there is no risk of harmful interference to other spectrum users – which is the case here -- the Commission should not take actions that will force manufacturers to re-start these processes prematurely, particularly when it involves a medical technology designed to improve the safety and efficacy of devices that save the lives.

Moreover, there is a clear public interest in giving patients access to several generations of products concurrently, providing choices for physicians and patients regarding costs and features. The Commission will do the public a great disservice by requiring BSC to cease distribution of the Cognis/Teligen 100 platform simply because other, albeit less advanced, implants are available on the market. Accordingly, BSC respectfully requests that the Commission reconsider BSC's original request for a six-year waiver term.

**II. The waiver should start upon FDA approval of the first Frontier I device.**

Finally, because the waiver period for the Cognis/Teligen 100 series set forth in the Waiver Order begins so far in advance of FDA approval — significantly reducing the value of a waiver that the Commission properly saw fit to grant — the Commission should at least reconsider the date on which the waiver period should begin. Otherwise, the Commission's finding that the waiver is necessary to deliver important health benefits to cardiac patients becomes undermined because the waiver would expire almost immediately following introduction of the Cognis/Teligen 100 series products to the market. To better align the term of the waiver with the timing of FDA approval, BSC requests that the term begin upon the date of FDA approval of the first implant in the Cognis/Teligen 100 family. The FDA approval date is an objective, publicly cognizable date and any delay in bringing products to market after that

date would be entirely within BSC's control. To ensure that the Commission is aware of that date and to facilitate implementation of the waiver period, BSC will agree to notify the Commission in writing within ten business days of its receipt of FDA approval.

For the foregoing reasons, as well as the reasons set forth in the Petition for Waiver, BSC respectfully requests that the Commission reconsider the duration and timing of the waiver for the Cognis/Teligen family of devices and grant a six year waiver period commencing upon FDA approval.

Respectfully submitted,

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