Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

ORIGINAL

In the Matter of	)	
	)	
Biotronik, Inc.	)	
	)	File No. 0223-EX-PL-2002
Experimental Radio Station License	)	
(Call Sign WD2XAA)	)	
	)	

OPPOSITION TO PETITION FOR RECONSIDERATION

Biotronik, Inc. ("Biotronik"), by its attorneys, submits this opposition in response to the Petition for Reconsideration filed by Medtronic, Inc. ("Medtronic" and the "Medtronic Petition") against Biotronik's experimental authorization granted on October 21, 2002 (call sign WD2XAA) to conduct a clinical study of its Belos DR-T medical implant device, using 400 home monitoring systems.[1]

In its petition, Medtronic misunderstands and mischaracterizes the nature and scope of Biotronik's experimental authority and seeks to reargue its earlier petition for reconsideration regarding Biotronik's grant of equipment authorization for the Philos DR-T device.[2] For the reasons explained herein, Biotronik asks the Commission to dismiss or deny Medtronic's latest Petition for Reconsideration.

I. BACKGROUND

On October 21, 2002, Biotronik was granted a two-year experimental license to conduct a clinical study of its Belos DR-T medical implant device, using 400 home

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[1] *See* Petition for Reconsideration filed by Medtronic, Inc., File No. 0223-EX-PL-2002 (Jan. 2, 2002) ("Medtronic Petition").

[2] *See* Petition for Reconsideration of Medtronic, Inc., FCC ID. No. PG6BA0T (May 22, 2001).

monitoring systems.[3] The experimental license authorizes Biotronik to operate the home monitoring systems in accordance with Section 5.3(i) of the Commission rules.[4] Biotronik's experimental grant was placed on public notice on December 3, 2002.[5] Medtronic filed a petition for reconsideration of the grant on January 2, 2003, to which this opposition responds.

Distinct from its experimental authorization for the Belos DR-T (WD2XAA), Biotronik also holds an equipment authorization (FCC ID. No. PG6BA0T) for its Philos DR-T medical implant device, which has more limited functionality than the Belos DR-T device.[6] Medtronic filed a petition for reconsideration of the grant of this equipment authorization.[7] By letter order dated March 8, 2002, the Deputy Chief, Office of Engineering and Technology ("OET"), denied in part and granted in part Medtronic's petition, finding that: (1) OET properly had authorized the device to operate when it detects problems with a patient's heartbeat or when the patient reports discomfort or concern, but (2) the Philos device's "automatic signal" feature was not "within the letter of the Commission's [medical implant] Rules."[8]

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[3] *See* Experimental Radio Station Construction Permit and License, Biotronik, Inc., Call Sign WD2XAA, File No. 0223-EX-PL-2002 (granted Oct. 21, 2002). The experimental license application requested 400 units to be authorized, 300 of which will be used for the clinical study proposed in the application and an additional 100 units to be used for the purposes of research and development prototypes, validation units, and working demonstration systems. *See* Letter from Mark Johnson, Biotronik, Inc., to Experimental Licensing Branch, File No. 0223-EX-PL-2002 (Oct. 8, 2002).

[4] *See* 47 C.F.R. § 5.3(i) (permitting experimental licensees to conduct "[d]evelopment of radio technique, equipment, operational data or engineering data related to an existing or proposed radio service").

[5] *See* Experimental Actions, Public Notice, Rep. No. 352 (Dec. 3, 2002).

[6] *See* Grant of Equipment Authorization, Biotronik, Inc. (FCC ID. No. PG6BA0T) (originally granted April 23, 2001).

[7] *See* Petition for Reconsideration of Medtronic, Inc., FCC ID. No. PG6BA0T (May 22, 2001).

[8] Letter Order from Bruce A. Franca, Deputy Chief, Office of Engineering and Technology, FCC ID. No. PG6BA0T (Mar. 8, 2002) at 3 ("OET Letter Order").

Biotronik filed a petition for reconsideration of OET's Letter Order or, in the alternative, a request for waiver of the relevant Part 95 rules.[9] In its petition/waiver request, Biotronik demonstrated that the so-called "automatic signal" of the Philos DR-T device is in reality a scheduled transmission arranged and timed solely by the patient's physician and therefore qualifies as a medical implant event under the Commission's Medical Implant Communications Service (MICS) rules.[10] Biotronik's petition/waiver request has been pending for nine months.

In its latest petition for reconsideration, Medtronic blurs the line between Biotronik's experimental authorization for the Belos DR-T device and Biotronik's equipment authorization granted April 21, 2001, authorizing the Philos DR-T device. These two authorizations are distinct and involve unrelated devices. While Medtronic's Petition is styled a petition for reconsideration of the grant of the Belos DR-T experimental authorization, it addresses in scattershot fashion additional issues concerning Biotronik's equipment authorization for the Philos DR-T device. Nonetheless, Biotronik responds to all of the allegations contained in Medtronic's Petition because Medtronic has painted with a very broad brush and has questioned Biotronik's good faith in complying with the Commission's rules.[11]

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[9] *See* Petition for Reconsideration or Waiver of Biotronik, Inc., FCC ID. No. PG6BA0T (Apr. 8, 2002). Medtronic filed a Petition for Review of the OET Letter Order, which also remains pending. *See* Petition for Review of Medtronic, Inc., FCC ID. No. PG6BA0T (Apr. 8, 2002).

[10] *See* Petition for Reconsideration or Waiver of Biotronik, Inc., FCC ID. No. PG6BA0T (Apr. 8, 2002) at 3-5; *see also* 47 C.F.R. Pt. 95, Subpt. E, App. 1 (defining the term "medical implant event").

[11] Medtronic also has seemingly requested reconsideration of the Commission's grant of an earlier experimental license issued to Biotronik on April 12, 2002 to test 200 Belos VR-T devices. *See* Medtronic Petition at 5; *see also* Experimental Radio Station Construction Permit and License, Biotronik, Inc., Call Sign WC2XWI, File No. 0062-EX-PL-2002 (granted Apr. 12, 2002). Biotronik's earlier grant was placed on public notice on June 7, 2002. *See* Experimental Actions, Public Notice, Rep. No. 346 (June 7, 2002). Therefore, Medtronic's opportunity to file a timely petition for reconsideration of that grant expired nearly half a year ago. *See* 47 C.F.R. § 1.106(f) (petition for reconsideration must be filed within 30 days of the date of public notice of final Commission action). Moreover, Biotronik is already ten months into the experimental authority granted on April 12, 2002, and has invested substantial resources in reliance upon that grant. Accordingly, Biotronik asks the Commission to dismiss with prejudice, as

II. DISCUSSION

For the reasons set forth below, Biotronik requests that the Commission dismiss or deny Medtronic's Petition.

A. Biotronik Has Not Engaged In The Unauthorized Sale Or Marketing Of The Belos DR-T Medical Implant Device

At bottom Medtronic asserts that Biotronik is selling and marketing Belos DR-T devices pursuant to its experimental authorization in contravention of the Commission's rules.[12] This charge is false and, giving Medtronic the benefit of the doubt, seems to be based on Medtronic's misunderstanding of the nature and purpose of Biotronik's experimental authority.

The Belos DR-T device consists of two primary components: (1) an implantable cardioverter defibrillator (ICD) which is implanted in the patient's body, and (2) a home monitoring system which receives data from the ICD and transmits therapy-relevant information to the patient's physician via the cellular telephone network.[13] The Belos DR-T device is a more advanced and improved version of Biotronik's less sophisticated Belos DR model, which does not have the remote monitoring capabilities of the Belos DR-T and is not subject to FCC authorization.

Biotronik's purpose in obtaining the experimental authority for the Belos DR-T is to test only the functionality and clinical application of the home monitoring component of the device in interacting with the ICD. That is, the focus of the clinical study undertaken pursuant to Biotronik's October 21, 2002 experimental license is on the home monitoring system and not the medical implant device itself. While both components of

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untimely, any arguments made in Medtronic's petition that apply or may apply to Biotronik's April 12, 2002 experimental authorization to test 200 Belos VR-T devices.

[12] *See* Medtronic Petition at 6-7.

[13] A description of the Belos DR-T is available at http://www.biotronik.com/content/detail.php?id=2220.

the Belos DR-T have substantial value, patients involved in the clinical trial are not charged for the Home Monitoring transceiver system or the wireless communications technology authorized pursuant to Biotronik's experimental license.[14]

B. No Additional Conditions On Biotronik's Experimental License Are Warranted

Medtronic asks the Commission to reissue Biotronik's experimental authorization with a number of unnecessary conditions on the license.[15] As shown above, Medtronic's premise in seeking the conditions is false—there is no improper marketing of the Belos DR-T device. The conditions proposed by Medtronic, moreover, would have the effect of discouraging physicians and their patients from participating in the clinical trials involving the Belos DR-T device. While this might benefit a competitor such as Medtronic, it would not benefit the seriously ill people who are participating in the clinical trials.

First, Medtronic proposes the condition that Biotronik may not sell or lease any devices which are not authorized by the Commission, including the Belos DR-T defibrillator, the Belos VR-T, and the Philos DR-T pacemaker.[16] To the extent that Medtronic merely is repeating the Commission's rules,[17] this "condition" is unobjectionable, but superfluous. Medtronic goes astray, however, in asserting that the

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[14] Medtronic also asserts that it is unnecessary for Biotronik to use 300 hundred Belos DR-T devices in its clinical study, citing to past trials conducted by Biotronik of its BA03 pacemaker where it used only 15 units. *See* Medtronic Petition at 8 and fn. 20. Medtronic is comparing apples to oranges. Unlike the BA03 pacemaker units, which were strapped externally to patients' bodies in trial runs, the Belos DR-T will be implanted inside patients' bodies. Therefore, it is imperative for Biotronik to be sure that the technology works properly by testing a larger number of units. Moreover, Biotronik's trials of the BA03 pacemaker were informal. In contrast, testing of the Belos DR-T unit is intended to be a statistically valid clinical study which requires the use of larger numbers of units.

[15] *See* Medtronic Petition at 1-2.

[16] *See id.* at 1.

[17] *See* 47 C.F.R. § 2.803(a) (requiring Commission authorization prior to the sale of lease of a device that is subject to equipment certification).

experimental devices (the Belos DR-T and Belos VR-T) are being improperly marketed and that the authorized device (the Philos DR-T) is not really authorized.

Medtronic proposes a second condition that Biotronik must inform all medical health care professionals and implant patients who participate in its experimental study that Biotronik's implant devices are authorized for operation based on a "two-year experimental FCC license" and that "the operation of any non-compliant features, such as automatic periodic transmissions, must cease once the two-year period expires."[18] In other words, Medtronic wishes to impose the same condition on Biotronik's authorization that would apply if Biotronik were conducting limited market studies of the Belos DR-T device pursuant Section 5.3(j) of the Commission's rules.[19] Limited market study of the Belos DR-T, however, was not the purpose of Biotronik's experimental authority.

As its authorization clearly states, Biotronik sought experimental authority under Section 5.3(i), which permits the study and development of the Belos DR-T and the gathering of operational and engineering data.[20] Such experimental licenses do not require the same disclaimers imposed on licenses issued for purposes of limited market studies. Thus, Medtronic's proposed condition would frustrate the intended purpose of Biotronik's clinical study and would serve no other purpose than to deter physicians and patients from using the Belos DR-T device. Again, while such a condition would benefit a competitor such as Medtronic, it is not in the public interest.

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[18] Medtronic Petition at 1. Biotronik responds to Medtronic's erroneous suggestion that the Belos DR-T device utilizes "automatic periodic transmissions" in Section II.C of this opposition.

[19] *See* 47 C.F.R. § 5.3(j) (experimental licensees may conduct limited market studies); *see also* 47 C.F.R. § 5.93(b) (licensees granted for the purpose of limited market studies must inform anyone participating in the experiment that the service or device is granted under an experimental authorization and is strictly temporary).

[20] *See* 47 C.F.R. § 5.3(i).

In any event, the Commission's experimental rules allow for renewal of experimental licenses beyond the initial two-year term upon an adequate showing of need.[21] Therefore, there is no need to impose the two-year disclaimer on Biotronik's license as the company is permitted under the rules to request renewal of its experimental authority at a later date.[22] Alternatively, Biotronik may seek to obtain an equipment authorization for the Belos DR-T before its experimental authorization expires. In either case, there is no justification for imposing a two-year disclaimer on a device which currently complies with the Commission's rules and may have a useful life beyond Biotronik's initial two-year experimental authorization.

Finally, Medtronic proposes the condition that all Biotronik literature concerning the Belos DR-T, Belos VR-T, and the Philos DR-T devices contain a notice in accordance with Section 2.803 of the Commission's rules "that the products are not available for sale or lease until the requisite authorization has been granted by the FCC."[23] Here again, Medtronic is confusing the status of and the requirements for Biotronik's various devices. The Belos DR-T and Belos VR-T are subject to their respective experimental authorizations and are not being marketed, while the Philos DR-T is authorized and is being marketed. Therefore, in neither case is the Section 2.803 disclaimer applicable.

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[21] *See* 47 C.F.R. § 5.71(a).

[22] Medtronic also asks the Commission to make public Biotronik's entire experimental license application upon expiration of its two-year license term. *See* Medtronic Petition at fn. 25. Biotronik's application contains proprietary and confidential information that could be misused in the hands of a direct competitor like Medtronic. For this reason, to the extent necessary, Biotronik requests confidential treatment of the proprietary information submitted to the Commission in its experimental application beyond the two-year term of its license.

[23] Medtronic Petition at 2.

C. There Is No "Automatic Periodic Transmission Feature" In The Philos DR-T Device

Medtronic asserts that Biotronik has "proceeded to market equipment with an automatic periodic transmission feature" in contravention of OET's Letter Order dated March 8, 2002 concerning Biotronik's equipment authorization for the Philos DR-T device.[24]

As Biotronik demonstrated in response to Medtronic's earlier petition for reconsideration regarding the Philos DR-T equipment authorization,[25] all of the transmissions used in connection with the Philos DR-T qualify as "medical implant events" under the Commission's rules.[26] Scheduled transmissions occur only because a physician has determined that they are required. Accordingly, Biotronik sought reconsideration of the OET's ruling or, failing reconsideration, a waiver of the rule, as interpreted by the OET. In such circumstances, and given the medical importance of the scheduled transmission feature,[27] Biotronik should not be required to cease marketing the device while the Commission rules on its request.

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[24] *Id.* at 4.

[25] *See* Petition for Reconsideration or Waiver of Biotronik, Inc., FCC Id. No. PG6BA0T (Apr. 8, 2002) at 3-5.

[26] *See* 47 C.F.R. Pt. 95, Subpt. E, App. 1 (defining the term "medical implant event" as an event "recognized by a medical implant device, or a duly authorized health care professional, that requires the transmission of data from the medical implant transmitter in order to protect the safety or well-being of the person in whom the medical implant transmitter has been implanted").

[27] *See* Letters to Mr. Edmond Thomas, Chief, Office of Engineering Technology from Yakima Hear Center (Apr. 11, 2002); New Jersey Pacemaker and Defibrillator Evaluation Center, Inc. (Apr. 11, 2002); Stanford University Medical Center (Apr. 15, 2002); Covenant Health System (Apr. 15, 2002); Legacy Heart Institute (Apr. 17, 2002); University Hospital of Cleveland (Apr. 17, 2002); Providence Everett Medical Center (Apr. 19, 2002); and Cardiology of Georgia, P.C. (Apr. 25, 2002), all filed in support of Biotronik's pending Petition for Reconsideration or Waiver concerning OET's March 8, 2002 Letter Order.

III. CONCLUSION

For the foregoing reasons, Biotronik asks the Commission to dismiss or deny Medtronic's Petition for Reconsideration of the grant of Biotronik's October 21, 2002 experimental license.

Respectfully submitted,

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January 15, 2003

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Opposition to Petition for Reconsideration was sent by hand delivery this 15th day of January, 2003, to each of the following:

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