Hand Deliver to Secretary:
236 Massachusetts Avenue, NE
Suite 110
Washington, DC 20002

Before the

Federal Communications Commission

Washington, DC 20554

In the Matter of
Experimental Radio License Grant to
Biotronik, Inc.

File No. 0223-EX-PL-2002

MEDTRONIC'S OPPOSITION TO MOTION FOR LEAVE TO FILE A RESPONSE TO REPLY

Biotronik's Motion for Leave to File a Response to Medtronic's Reply must be denied.[1] Biotronik's Response is unauthorized and procedurally improper. In addition, there is nothing in the filing that could not have been presented in opposition to Medtronic's Petition for Reconsideration. The only "new" information Biotronik offers in its Response are concessions brought about by Medtronic's Petition.[2]

Biotronik's Response further confirms the points outlined in Medtronic's Petition:

- Biotronik is marketing unauthorized devices in contravention of the Commission's rules; and
- Biotronik is using the experimental licensing program to market and sell unauthorized RF medical implant devices that operate with automatic, periodic transmissions.[3]

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[1] *See* Biotronik Motion for Leave to Respond, File No. 0223-EX-PL-2002, Feb. 11, 2003 ("Biotronik Motion") *and* Response to Medtronic Reply, File No. 0223-EX-PL-2002, Feb. 11, 2003 ("Biotronik Response").

[2] For example, Biotronik now acknowledges that at the end of the two-year experimental license period it must turn off the transmitter functionality within its implants or seek permanent Commission authorization for the equipment. *See* Biotronik Response at 4 n.12.

[3] *See* Biotronik Response at 2-9.

Biotronik's Response leads the Commission further down the plank towards regulatory decisions that will eviscerate longstanding FCC policies and rules governing experimental licenses and the marketing of unauthorized RF products. Biotronik's ongoing sleight-of-hand only strengthens the need for the conditions Medtronic outlined in its Petition for Reconsideration and Reply.

I. BIOTRONIK'S MOTION MUST BE DENIED AS IT IS PROCEDURALLY IMPROPER AND ONLY REPEATS EARLIER MISGUIDED ARGUMENTS.

Biotronik's Motion For Leave To Respond must be denied because Biotronik's Response is not authorized by the FCC's rules and because it adds nothing new to the record in this case.

A. The Commission Routinely Denies Attempts To File Unauthorized Pleadings Such As Requested By The Instant Motion.

The Commission's rules allow a party opposing a petition for reconsideration to file an opposition.[4] The rules allow the petitioner to file a reply.[5] Biotronik's latest filing is tantamount to a second Opposition that is not permitted under the Commission's rules. Biotronik is simply trying to recast the Commission's pleading rules so that it is provided with the "last word" on Medtronic's Petition for Reconsideration.

Indeed, the Commission has routinely denied such attempts to alter its well-established pleading rules. *See, e.g., Glendale Electronics, Inc., Regarding the License of SMR Station WNGQ365, Santiago Peak and Mount Lukens, California*, 2002 FCC LEXIS 5806, ¶ 8 n.25 (Nov. 5, 2002) (Commission's rules "do not provide for filing of a response to a reply to the opposition to [the petition]" and "we will not consider the arguments presented in [the] response."); *Investigation of Special Access Tariffs of Local Exchange Carriers*, 12 FCC Rcd 7026, ¶¶ 260-263 (Feb. 14, 1997) (denying MCI's motion for leave to file its surrebuttal because

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4 *See* 47 C.F.R. § 1.106(g)

5 *See* 47 C.F.R. § 1.106(h).

it "merely repeats arguments made in its second supplemental opposition"). *Cf. Amendment of Section 73.202(b) Table of Allotments FM Broadcast Stations (Melbourne, Florida),* 5 FCC Rcd 1031, ¶ 1 n.1 (Feb. 23, 1990) (denying motion for leave to file an unauthorized pleading). Accordingly, Biotronik's motion to file its unauthorized pleading must be summarily dismissed.

B. The Confusion That Biotronik's Unauthorized Motion Claims To Clarify Is Of Biotronik's Own Making.

Good cause does not exist for granting the instant motion. In fact, all of the allegations and argument in Biotronik's latest filing are responsive to the statements Medtronic raised in the Petition for Reconsideration.

Biotronik implores the Commission to accept its latest response because it "clarif[ies] confusing elements of the record."[6] However, the confusion that exists in the record is of Biotronik's own making. Several examples are outlined below.

1. Biotronik's "duly authorized" Philos DR-T device

Biotronik first asserted that it must be allowed to market the unauthorized Philos DR-T device because of "the medical importance of the scheduled transmission feature,"[7] and in its latest filing asserts unequivocally that Philos DR-T is "authorized."[8] In reality, the Commission has authorized none of Biotronik's home monitoring implants – including the Philos DR-T,

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[6] *See* Biotronik Motion at 1.

[7] *See* Biotronik Opposition at 8.

[8] *See* Biotronik Response at 1, 5 n.17, and 7. According to Biotronik, the Philos DR-T "is subject to a valid equipment authorization and therefore may be marketed ... without the Section 2.803(c) notice that Medtronic proposes." *See id.* at 5 n.17. Curiously, since the filing of Biotronik's Motion and Response, Biotronik has added a notice to its website literature stating that the Philos DR-T is "[n]ot available for sale in the U.S. market." *See* Biotronik Website Literature: Philos DR-T Dual-Chamber Pacemaker with Home Monitoring, *available at* <http://www.biotronik.com/content/detail.php?id=1783>, *last accessed* Feb. 19, 2003. This notice, which has been added to all Home Monitoring Product Descriptions (as of February 19, 2003), fails to comport with Section 2.803(c).

which OET found non-compliant with the MICS rules. Biotronik never complied with OET's Order "to submit a modification or a new application for equipment authorization [for the Philos DR-T], deleting the automatic transmission option,"[9] nor has Biotronik requested a stay of that Order. Biotronik's claim that it may market the unauthorized Philos DR-T unit in contravention of the FCC's Order because it filed a petition to reconsider the order is wrong.[10]

If any party who receives an adverse decision from the FCC were permitted to avoid complying with the decision until the Commission ruled on the party's petition for reconsideration, the FCC would be inundated with such petitions because its decisions would always be challenged.

2. Biotronik's "T-chip" argument

As a second example, Biotronik's Response introduces a "T-chip" argument in an effort to support its claim that the Commission's rules allow an integrated RF device to be "dissected" into two parts, "one requiring the Commission's authority and one not."[11] Nevertheless, Biotronik is still unable to cite to any FCC precedent or FCC rules that support its novel interpretation. Using this interpretation, Biotronik claims that it may sell its experimental Belos

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[9] *See* FCC Letter Order, Mar. 8, 2002, from Bruce A. Franca, OET, to David E. Hilliard, counsel for Medtronic, and Mark Johnson, Biotronik, at 3 ("OET Letter Order").

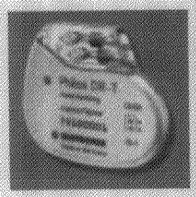
[10] To support this position, Biotronik only repeats the arguments it made in its petition for reconsideration and request for waiver of the OET Letter Order. *See* Biotronik Response at 7-8.

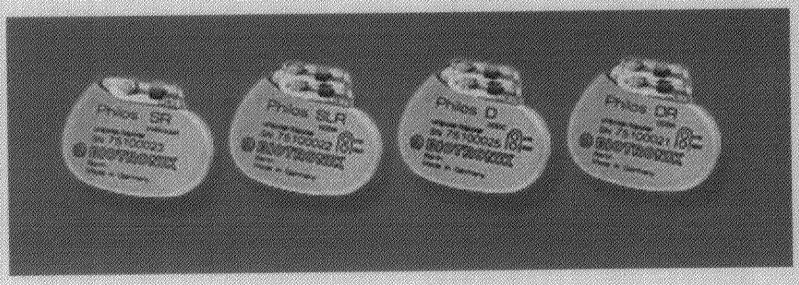
The Response uses misleadingly a statement from Medtronic's comments during the rulemaking to support Biotronik's own expansive definition of a "medical implant event." *See id.* The medical implant event exception to the listen before transmit requirement permits a health care professional to program the implant to transmit critical information immediately following a medical event such as the failure of a heart to beat within a given time period. Biotronik's interpretation of a medical event, however, includes all transmissions from the RF implant including automatic periodic transmissions with no connection to an actual medical event. This interpretation would gut the policies underlying the MICS rules, including frequency agility and channel sensing by MICS transceivers.

[11] *See* Biotronik Response at 3.

VR-T and DR-T units because Biotronik is able to sell related devices (*i.e.*, the Belos VR and DR units) that it asserts the FCC lacks authority over because these devices do not include the Home Monitoring RF transmitter.[12] This argument is not only without legal support, but it is also belied by the facts.

Biotronik asserts that its Home Monitoring implants include a "T-chip" that is not "integrated with [nor] essential to the usual functioning of the medical implant device."[13] This is wrong. These external photos from Biotronik's website show a fully integrated (and sealed) Philos DR-T device package alongside the four Philos units that do not include the RF circuitry.





In addition, the internal photos of the Philos DR-T that Biotronik submitted along with the application for equipment authorization show that the implant's RF circuit is tightly integrated with the other device components, shares a common circuit board and battery with these other components, and occupies about 20% of the real estate on the circuit board.[14] Clearly, the RF

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12 As noted above, *see supra* n.8, Biotronik has added a notice to all of its Home Monitoring implant product descriptions stating that devices are "[n]ot available for sale in the U.S. market." *See, e.g.*, Biotronik Website Literature: Belos DR-T Dual-Chamber ICD with Home Monitoring, *available at* <http://www.biotronik.com/content/detail.php?id=2220>, *last accessed* Feb. 19, 2003. Not only does this notice fail to comport with Section 2.803(c), but also it runs counter to Biotronik's statements in the record that it is selling the devices being implanted in the U.S. *See also* Redacted Letter from H. Goldberg, Counsel for Biotronik, to J. Burtle, Chief, FCC Experimental Licensing Branch, Feb. 11, 2003 ("Goldberg Letter").

13 *See* Biotronik Response at 2.

14 *See* Biotronik Philos DR-T Equipment Authorization Application, Exhibit H – Internal Photos, FCC ID# PG6BA0T (attached to this Opposition as Exhibit A). Biotronik has not disputed Medtronic's claim that the RF circuitry in each of Biotronik's Home Monitoring

circuit is not a single "T-chip."[15] It is made up of over twenty-five (25) separate circuit components (including an antenna).

Biotronik's "T-chip" (or "device dissection") argument is without merit.

3. Biotronik's marketing campaign

A third example of Biotronik's self-created confusion concerns its broad-based marketing campaign. Biotronik continues to assert that the Belos defibrillator units, which are subject to experimental license authorizations, are not being marketed, while the Philos DR-T pacemaker is being marketed because it is "duly authorized." The record before the Commission belies both statements.[16] Any physician or patient who reads Biotronik's press releases and website literature advertising the devices or reviews its trade press advertisements would conclude that all of Biotronik's Home Monitoring implants are available for sale.

Biotronik's assertion that the trade press advertisements for the full suite of its Home Monitoring RF implants "makes no representation that either of [the Belos defibrillator] devices is available for sale in the United States"[17] is proven false by the clear language in the ad. According to Biotronik's ad: "BIOTRONIK'S Home Monitoring system is currently available in the United States for both pacemakers and Implantable Cardioverter Defibrillators (ICDs)."[18] This unequivocal language includes all Belos defibrillators and the Philos DR-T pacemaker unit.

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implants is very similar. *See* Petition at 5 n.12. Thus, the RF circuitry in the Belos units is likely very similar to what is shown in Exhibit A to this Opposition.

[15] Biotronik implies that the "T-chip" can be removed from the device much like a youngster can exchange Nintendo® Game-Boy cartridges; however, the attached photos of the Philos DR-T establish otherwise. *See* Ex. A.

[16] The latter statement is addressed in Section I.B.1, *supra*.

[17] *See* Biotronik Response at 5.

[18] *See, e.g.,* Indications and Contraindications Notice to Biotronik Advertisement in PACE Journal, Dec. 2002, Vol. 25, No. 12 at xii (attached to this Opposition as Exhibit B). PACE (Pacing And Clinical Electrophysiology), which is published in Armonk, New York, is the

Similarly, Biotronik's press releases regarding the FDA's approval of its Belos defibrillator units announce the products' availability in the U.S. market. Remarkably, even the press release language Biotronik quotes in its Response states that the products "have now been approved for the U.S. market."[19] Another Biotronik "FDA" press release out of its U.S. headquarters announces to the medical community that the Belos units are available for sale:

> BIOTRONIK, Inc. announced today the **commercial release of the Belos DR-T** ... .
>
> **Physicians are now able to offer patients** ... with the most accurate AV discrimination feature **on the market today**. ...
>
> The Belos family **joins the existing market-released Tachos DR** with Atrial therapies in BIOTRONIK's growing line of rate-adaptive ICD products.[20]

Any physician or cardiac patient viewing these press releases, trade press ads, and Biotronik's other marketing literature is informed that all Home Monitoring devices are available for sale and would have no idea that the FCC has yet to approve – or even has the authority to approve – their operation.[21] Thus, Biotronik is impermissibly marketing and offering for sale all RF devices on the same basis.[22] Biotronik's apparent concession to "add a disclaimer" to its web

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Official Journal of (1) The North American Society of Pacing and Electrophysiology and (2) The International Cardiac Pacing and Electrophysiology Society. *See also* Petition at 2 n.3.

[19] *See* Biotronik Response at 5.

[20] *See* "BIOTRONIK's Innovative Belos Dual-Chamber ICD with Exclusive Wireless Remote Monitoring Receives FDA Approval," Jan. 6, 2003, *available at* <http://www.biotronik.com/content/detail.php?id=2204>, *last accessed* Feb. 19, 2003 (emphasis added). *See also* Petition at 6 n.15 *and* Reply at 4 n.17.

[21] And further that their operation is limited to the conditions attendant to an experimental license – conditions that are at odds with the normal operation and life expectancy of a medical implant.

[22] *See* Petition at 4 n.9 (citing Biotronik website literature for Philos DR-T and Belos VR-T). Since Medtronic filed the Petition, Biotronik added detailed website literature for the Belos DR-T and A+/T units. The descriptions of all four (4) RF implants advertise the automatic periodic transmit feature. *See generally* Biotronik Website Product Search, *available at* <http://www.biotronik.com/content/detail.php?id=179>, *last accessed* Feb. 19, 2003.

pages clarifying that its devices are not available for sale in the United States is not sufficient.[23] As Medtronic requested in its Petition and Reply, all Biotronik literature referencing (explicitly and/or implicitly) any of its unauthorized RF products, including trade magazine ads, press releases, and Internet website pages listing the products, must contain the notice required by Section 2.803(c) that the products are not available for sale or lease, until the requisite authorization has been granted by the FCC.[24]

II. BIOTRONIK IS ENGAGING IN A MARKETING STUDY YET IT INSISTS ON WITHHOLDING CRITICAL DECISIONMAKING INFORMATION FROM PHYSICIANS AND IMPLANT PATIENTS.

Because Biotronik is carrying out an extensive marketing campaign with its experimental authorizations involving countless physicians and patients, the Commission's marketing study rules must be applied to Biotronik's experimental license grant. Even the information Biotronik supplied in response to the FCC's letter request for additional information related to the instant application confirms that it is carrying out a marketing study. According to Biotronik:

> "[it] does not know the market value of the T chip technology and the home monitoring equipment and services used with the Belos DR-T, which is one reason for the clinical trial and experimental authorization. Consequently, Biotronik has not determined a price for these components ... ."[25]

Thus, Biotronik concedes that it is conducting a "market study," as its trial will help it determine the market value of its RF circuitry (or "T chip").[26] Biotronik is using as a shield the

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[23] *See* Biotronik Response at 5. The website disclaimer recently added by Biotronik only states: "Not available for sale in the U.S. market." This does not comport with the Commission's marketing rules under Section 2.803.

[24] *See* Petition at 2 *and* Reply at 9.

[25] *See* Goldberg Letter at 2.

[26] Biotronik's statement is suspect in light of Biotronik's position that the Philos DR-T is "duly authorized" and has been marketed for some time. Because the RF transmitter circuitry in the Belos units is very similar to that in the Philos units, one would think that Biotronik already knows the "market value" of the technology.

Commission's experimental license authorizations to market and sell the Belos VR-T and DR-T devices.[27]

Biotronik must comply with the Commission's limited market study rules in Section 5.93 of the Experimental Radio Service regulations. Absent explicit authority, these rules prohibit the sale of any experimental RF device and make the licensee "responsible for informing anyone participating in the experiment that the service or device is granted under an experimental authorization and is strictly temporary."[28] Here, the licensee, Biotronik, is conducting an experimental study using unapproved RF devices that are being marketed to members of the public who will use and rely on the devices. Indeed, Biotronik is implanting experimental RF devices into consenting cardiac patients.

Incredibly, Biotronik wants to conduct its experiment with patients and health care professionals who are not fully informed. Biotronik's stated desire to withhold the truth from cardiac patients and administering medical professionals is not informed consent for treatment nor can it be deemed to be in the "public interest."[29] These individuals need to appreciate fully the terms and conditions of Biotronik's study in order to make an informed decision. They must be advised that the Commission has authorized the RF implants under a two-year experimental

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[27] *See* Biotronik Opp. at 4-5.

[28] 47 C.F.R. § 5.93(a) and (b).

[29] Biotronik's claim that providing such critical information to cardiac patients and physicians is "not in the public interest" is shocking. Biotronik Opp. at 6 ("Medtronic's proposed condition [that Biotronik inform anyone participating in the experiment that the device is under an experimental authorization and operation is temporary] would serve no other purpose than to deter physicians and patients from using the Belos DR-T device. ... **[S]uch a condition ... is not in the public interest**.") (emphasis added); *see also* Biotronik Response at 6.

license, and that, by law, Biotronik is not permitted to sell, lease, or give away the devices.[30] Accordingly, the limited market rules must be applied.

Biotronik's experimental licensing scheme cannot be deemed to be in the public interest when it is: (1) withholding critical information from attending physicians and implant patients participating in the experiment, and (2) selling non-compliant RF devices using the experimental license program as a shield. Its admission that it is impermissibly selling unauthorized devices underscores the need for close FCC review of this application. Biotronik's gambit to "hide in plain sight" by devising unsupported rule interpretations and asserting that it is not engaged in a broad-based marketing campaign is belied by Biotronik's own public statements.

CONCLUSION

For the foregoing reasons, Medtronic respectfully requests that the Commission deny the instant motion and rule on the already existing record. The FCC should rescind the experimental license grant to Biotronik or, at a minimum, explicitly impose the conditions outlined in Medtronic's Petition for Reconsideration and Reply.

Respectfully submitted,

MEDTRONIC, INC.

By: David E. Hilliard

David E. Hilliard
John W. Kuzin
Wiley Rein & Fielding LLP
1776 K Street, NW
Washington, DC 20006
Its Attorneys

February 21, 2003

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[30] This prohibition on the sale, lease or give away of RF devices includes all of the integrated components in each device implanted pursuant to the experimental authorizations. *See* 47 C.F.R. § 5.93(a); *see also* 47 C.F.R. § 2.803.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on the date printed below, the foregoing MEDTRONIC'S OPPOSITION TO MOTION FOR LEAVE TO FILE A RESPONSE TO REPLY was delivered by First Class U.S. mail to the persons listed below.

Mr. Mark Johnson
Director, U.S. Marketing
Biotronik, Inc.
6024 SW Jean Road
Building B
Lake Oswego, OR 97035

Henry Goldberg, Esq.
Goldberg, Godles, Wiener & Wright
1229 19th Street, NW
Washington, DC 20036
Counsel for Biotronik, Inc.

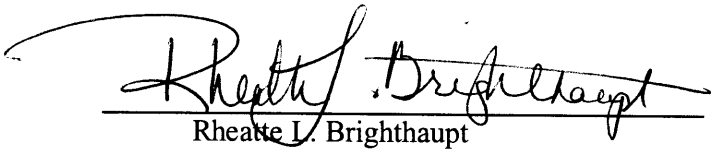
Mr. Bruce Franca*
Deputy Chief
Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Mr. Julius Knapp*
Deputy Chief
Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Mr. James Burtle*
Chief
Experimental Radio Branch
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

Mr. Bruce Romano, Esq.*
Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

February 21, 2003



Rheatte L. Brighthaupt

* Courtesy copy via electronic mail.