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September 25, 2008

VIA ECFS

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

**Re: ET Docket Nos. 06-135, 05-213, 03-92, & RM-11271
Ex Parte Presentation**

Dear Mr. Knapp:

Medtronic Inc. responds to the *ex parte* presentation submitted in these proceedings by ON Semiconductor Corporation (“ON Semi”) on September 18, 2008, asking the FCC to authorize a 300 kHz channel in the 405-406 MHz band for wireless hearing aids. For the reasons Medtronic set forth in its February 25, 2008 *ex parte* presentation and for the additional reasons provided below, the ON Semi proposal should be rejected.

While hearing aid improvement is a laudable goal, permitting ON Semi’s proposed operations in the upper 405-406 MHz wing-band portion of the MedRadio band would effect a *de facto* 300 kHz reallocation for wireless hearing aids. Successful sharing of the wing bands, like that of the MICS band, will depend on use of LBT/AFA with an exception to allow low-power, low-duty-cycle (0.1%) devices. ON Semi seeks a 300 kHz swath of the MedRadio band for devices that will operate at maximum power (*i.e.*, -16 dBm) with a 100% duty cycle – effectively precluding use of that 300 kHz band by any other devices.

Even at -36 dBm, however, ON Semi’s proposal flies in the face of the widely-supported rules that the FCC proposed for the 401-402 and 405-406 MHz wing bands, which – consistent with the ETSI standard developed and approved via industry consensus in Task Group 30 and Medtronic’s July 2005 Petition for Rulemaking – are limited to non-voice communications.¹ To limit interference, the

¹ See ETSI Standard EN 302 537-1 at 11 ¶ 3.1 (MEDS service permits non-voice communications only).

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proposed rules allow transmissions without LBT/AFA techniques at -36 dBm and a 0.1% duty cycle. The proposed 0.1% duty cycle limitation² is a far cry from the 100% duty cycle that ON Semi is proposing. Moreover, while initially positing operation full time at -36 dBm, On Semi asserts that “additional functionalities, such as audio zoom capabilities, would require ... a -16 dBm limit” for its devices.³

The interference analysis in ON Semi’s filing is patently flawed. In contrast to its claims, if the communications range is one meter, the interference range is far greater – in excess of 5 meters.⁴ Not only would ON Semi’s proposal severely limit the spectrum available for other medical users in the band, but it also would make it difficult for wireless hearing aid users to avoid interfering with each other. ON Semi would then look for more 300 kHz channels in other MedRadio spectrum.

As for the audio streaming and binaural hearing capability posed by ON Semi, there are a plethora of options available for such an application, including Bluetooth and assistive listening devices currently authorized under Parts 15 and 95. Oticon and Phonak, both leading manufacturer of hearing aids, have implemented solutions for the above using a combination of inductive techniques and Bluetooth technology. Inductive techniques are ideal for the very short range between dual hearing aids because there is little (if any) body absorption of the inductive field.

Also, contrary to ON Semi’s assertions, the ETSI work on wireless hearing aids is to proceed without a New Work Item (“NWI”) focused on the 401-406 MHz band. The NWI for wireless hearing aids was approved by the ETSI Committee on EMC & Radio Spectrum Matters (“ERM”) without any reference to the 401-406 MHz band.⁵ Indeed, a reference to this band was removed from the NWI after a formal

² See *Investigation of the Spectrum Requirements for Advanced Medical Technologies*, Notice Of Proposed Rulemaking, Notice Of Inquiry And Order, FCC 06-103 ¶ 25 (July 18, 2006).

³ ON Semi Ex Parte Presentation (Sept. 18, 2008) n. 3.

⁴ Medtronic expects a communications range of up to 10 meters for MEDS devices at -16 dBm in the 401-402 and 405-406 MHz bands. In such a case, the interference range from ON Semi’s devices could be 50 meters. ON Semi’s belief that a one meter service radius equates to a one meter interference range runs counter to good engineering practice.

⁵ See ETSI Details of ‘DTR/ERM-TG17WG3-009’ Work Item (July 10, 2008).

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objection to its inclusion was sustained. As presently constituted, the NWI is a request to investigate the RF spectrum to find a suitable home for the application where their system will not cause interference. This is exactly what the FCC contemplated when it asked industry to develop proposals for the future to be addressed via a second NPRM.

Medtronic understands that the only European country in which a wireless hearing aid is known to have been formally approved in the 402-405 MHz band is Germany.⁶ A German hearing aid manufacturer reportedly received the approval. An objection to this action was lodged with the Telecommunications Conformity Assessment and Market Surveillance Committee (“TCAM”), which concluded that such hearing aid devices operating in the MICS band are not compliant with the RTTE Directive and should be withdrawn from the market.⁷

In sum, regardless of the merits of wireless hearing aids, operation of such devices in the 405-406 MHz wing band would substantially impact use of the MedRadio band by medical implant devices and body-worn sensors integral to therapeutic and diagnostic equipment. The ON Semi proposal should be rejected.

Respectfully,

David E. Hilliard

David E. Hilliard
John W. Kuzin

⁶ While a European proponent may persuade a notified body to approve such a device – as the experience in Germany shows – such an action would not occur without objection. Indeed, the *notified body* approach is somewhat analogous to a U.S. Telecommunications Certification Body granting a waiver, something the Commission has refused to permit.

⁷ The TCAM (Telecommunications Conformity Assessment and Market Surveillance Committee) is the standing Committee assisting the Commission in the management of Directive 99/5/EC. This Interest Group was set-up to facilitate the exchange of documents between Member States and the Commission.



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