ZARLINK SEMICONDUCTOR

ZARLINK Semiconductor (U.S.) Inc.
15822 Bernardo Center Drive, Suite B
San Diego, CA 92127
Tel: (858) 675-3400
Fax: (858) 675-3450
Internet : www.zarlink.com

January 6, 2009

Marlene H. Dortch, Secretary
Federal Communications Commission
Office of the Secretary
445 12th Street, SW
Washington, DC 20554

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

Dear Ms. Dortch:

Zarlink Semiconductor Inc. ("Zarlink") strongly opposes the request by ON Semiconductor Corporation ("ON Semi") for the Commission to authorize a 300 kHz channel in the 405-406 MHz band for wireless hearing aids.[1] For the following reasons, if the Commission nevertheless decides to consider ON Semi's request it should do so only after it develops a full record through a notice of proposed rulemaking:

1. The Devices that ON Semi's Proposal Would Detrimentally Impact Have Tremendous Life-Sustaining or Life-Altering Benefits.

2. The Number of Devices that Would be Detrimentally Impacted by ON Semi's Proposal Will Be Growing Geometrically Over the Next Several Years, Further Exacerbating the Harm.

3. ON Semi's Proposal Would Cause a Significant Reduction in the Life-Span of Medical Implants, to the Tremendous Detriment of Patients and the Health Care Industry.

4. ON Semi's Proposal Would Cause Interference to MEDS-Band Radios, Thereby Undermining their Functionality and Placing Patient Care at Risk.

5. ON Semi's Proposal is a Moving Target.

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[1] This *ex parte* filing supplements Zarlink's October 27, 2008 submission in this proceeding. For the sake of brevity, several of the arguments and issues raised therein are not repeated in this filing.

6. ON Semi's Proposal Would Cause Device Manufacturers who are in Late Stage Development of Medical Implant Devices to be Saddled with Tremendous Losses.

7. The Commission Should, as it did with MICS and Wireless Medical Telemetry Service, Limit MEDS to Non-Voice Applications.

8. Other Spectrum is Available for Wireless Hearing Aids.

Brief Summary

There are currently hundreds of thousands of life-sustaining or life-altering medical implant devices that utilize MICS-band radios, and it is anticipated that in the next several years there will be millions more of these cutting-edge devices that will utilize either MICS-band radios or MEDS-band radios. If the ON Semi Proposal is adopted, the tremendous medical benefits of these devices will be greatly undermined. If the proposal is adopted, (i) these implant devices will have much shorter life-spans, thereby forcing patients to more frequently undergo medical implant device replacement surgery, which entails significant clinical risks and costs; and (ii) these devices will be subject to a far greater risk of interference, thereby undermining their benefits and compromising their recipients' health care needs.

In addition, if the ON Semi proposal is adopted (the most recent version of which was filed by ON Semi just a couple of weeks ago), Zarlink and its customers, who have at all times followed the Commission rules and relied on those rules, will be forced to spend untold millions of dollars to redesign their products in an effort to somewhat reduce (but by no means eliminate, because that is not practicable) the detrimental impact of ON Semi's proposal on medical implant devices currently under development, which will seriously undermine the deployment of this tremendously beneficial technology. Therefore, the Commission should, just as it did in the MICS and Wireless Medical Telemetry Service proceedings, refuse to permit the use of voice applications here.

Finally, it is not necessary for wireless hearing aid manufacturers to use the MEDS spectrum for their products. Zarlink, for example, provides components for wireless hearing aids operating at 902-928 MHz, and ON Semi (or for that matter any other wireless hearing aid manufacturer) could do the same.

1. The Devices that ON Semi's Proposal Would Detrimentally Impact Have Tremendous Life-Sustaining or Life-Altering Benefits

There are hundreds of thousands of medical devices currently implanted that utilize MICS-band radios that fully comply with all applicable laws and regulations, and most of these devices are implanted in persons residing in the United States. These devices generally provide life-sustaining or life-altering cutting-edge benefits to their recipients. They greatly improve the quality of medical care for these patients. They allow physicians to be alerted to emergency events more quickly, and obtain much larger volumes of pertinent information about the patient's condition and the device status far quicker than the devices they are intended to replace, and therefore permit patients to receive the medical care they need much more rapidly. They often allow patients to live at home, where they ordinarily have much better results, rather than in a health care facility. In addition, many of these devices significantly lower health care costs.

There are a wide variety of medical implant devices that currently use or are being designed to use the MICS-band radios. Examples of these devices include the following:

- ICDs (Implantable Cardiac Defibrillators), which detect abnormal and often lethal fast cardiac rhythms, and stimulate or shock the patient's heart back to normal rhythm. This is the implanted equivalent of the large "crash cart" defibrillator found in medical facilities, and increasingly now seen in airports and other public locations.
- IPG (Implantable Pulse Generator), or Cardiac Pacemaker, which detect abnormally slow cardiac rhythms that debilitate patients with breathlessness, fainting, and the general inability to function adequately. IPGs provide stimulation to hold the patient's pulse at a high enough rate for them to function adequately.
- Neural-stimulators, which operate to provide electrical simulation to a patient's nervous system. There are a multitude of devices emerging in this category, including but not limited to:
    - DBS (Deep Brain Stimulation) for the treatment of tremor and degrade motor functions associated with Parkinson's Disease, Dystonia, Epilepsy and a variety of other neurological conditions.
    - Pain stimulators for the treatment of chronic pain, which are often prescribed for the treatment of chronic pain resulting from lower back injury. They provide stimulation of nerves to "block" pain signals from propagating.
    - Incontinence stimulators for the treatment of chronic urinary incontinence. These stimulators operate to hold the urinary sphincter muscle closed, and

upon command from the patient, release the urinary sphincter to allow normal bladder emptying.

- Gastric stimulators for the treatment of morbid obesity. These devices work by stimulating various nerve bundles to provide the sensation of "fullness", which deters the patient from further eating.

- CGM (Continuous Glucose Monitoring) is an emerging technology intended to provide chronic measurement of blood glucose concentration in diabetics. The acute "finger stick" method of blood collection is both painful and inconvenient for diabetics, and must be repeated as many as 10 times per day in severe cases. The data from CGM will be used in the future to "close the loop" on an automatic insulin delivery pump.[2]

2. The Number of Devices that Would be Detrimentally Impacted by ON Semi's Proposal Will Be Growing Geometrically Over the Next Several Years, Further Exacerbating the Harm

It is anticipated that in the next few years, the number of medical implant devices using either MICS-band radios or MEDS-band radios will rise to several million units. The currently available devices have recently become readily accepted by the public as well as the health care community, each of whom recognize the tremendous utility of these devices. The use of these devices also will continue to grow rapidly because the average life span of the population continues to rise. Moreover, there are numerous new medical implant devices in very late stages of development that will comply with the existing MICS rules and proposed MEDS rules.

The fundamental clinical problems that will arise from the adoption of the ON Semi proposal (and which are discussed below) relating to both the reduced life span of the medical devices and the interference with such devices will be further exacerbated over time as the number of medical devices increases many fold in the next several years. If the ON Semi proposal is adopted, the problems will be very significant right away, and will just get far worse over time.

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[2] All of the above applications are either already deployed or in late stages of development, and they use the MICS band for communication with external instruments, base stations, device programmers and the like.

3. ON Semi's Proposal Would Cause a Significant Reduction in the Life-Span of Medical Implants, to the Tremendous Detriment of Patients and the Health Care Industry

For the medical implant devices discussed herein, the battery is located inside the device itself. Accordingly, when the battery is depleted of all of its energy, implant device replacement surgery is the only option. Each such new surgical implant, however, entails significant additional risks to the patient, including risks of infection, anesthesia-related issues, and potential psychological effects on the patient. That, of course, is in addition to the significant health care related costs arising from such invasive surgeries. While the incoming administration will seek to do everything it can to make health care affordable to more people, the last thing the Commission needs to do is take steps that increase health care costs, particularly where such increases are also accompanied by serious additional risks to the patients involved. It is a lose-lose scenario.

Therefore, it is critical that the Commission refrain from taking any action that will shorten or otherwise compromise the battery life of medical implant devices. But, unfortunately, that is exactly what adoption of the ON Semi proposal would do.

The typical battery life for medical implant devices using the MICS spectrum is 7 years. However, this life-span will be significantly shortened if the ON Semi proposal (and regardless of which version of the ON Semi proposal, see no. 5 below) is adopted.

Systems that use Listen-Before-Talk (LBT) in either the MICS or MEDS bands, such as the medical implant devices referenced herein, require the initiating device to determine the appropriate channel to use. Accordingly, the medical device must sniff all channels to determine whether there is a signal coming from a base-station that wishes to initiate a communication session.[3] Given the critical health care benefits of these devices, once the device is implanted this sniffing process occurs 24 hours a day, 7 days a week, 365 days a year. Moreover, this process must occur over very short regular intervals to ensure that the user (either physician or patient) has sufficiently fast responsiveness from the device. That is, depending upon the device involved, the sniffing process may occur every second or at least once every 5 seconds.

Accordingly, each year, for a medical implant device there can be as many as tens of millions of initial sniffs of each of the possible channels to determine in each instance whether

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[3] Some older medical implant devices use what is now an outdated technology that does not involve sniffing for a signal, which older technology has been found to be far less effective and beneficial, and much more unwieldy, than the current technology which employs the sniffing process.

there is the presence of a communicating base station. Each of these initial sniffs, however, consumes energy.

Accordingly, for the implant device's battery to last the full 7 years, rather than be cut short, two things are critical. First, it is critical that the amount of energy utilized for each initial sniff be extremely small. Thus, to minimize charge drawn from the battery in the first phase (i.e., during the initial sniffs), rapid detection and low power consuming circuits are utilized. For example, many existing devices employ a simple received signal strength indicator circuit (RSSI) for the initial sniffs since this allows a fast detection method. Moreover, the receiver filters optimize power consumption through use of low order and gradual cutoffs, and thereby rely on present rules that assume the band will be quiet with low duty cycle operations only. This methodology and equipment enables faster settling and detection, so less battery power is drawn, and there is lower overall current consumption. Clearly, optimizing this detection system for low power is vitally important to maintain implanted device longevity.

Second, it is equally critical for the battery life of the medical implant device that the initial sniffs in the first phase must not have many false positives. If no signal is detected in the first phase, relatively little power will be consumed, and the system will go back to sleep after scanning all channels (until it is time for the next regular interval). But if the initial sniffs result in the detection of a signal, the process must then continue to the next phase and far more power will be consumed.

That is, each sniff of a given channel consists of phases with progressively more detailed signal processing at each phase, but the second and later phases of sniffing for a channel are triggered if and only if the first phase detects a possible signal of interest. These later phases extract additional signal characteristics including data in order to discriminate wanted from unwanted signals. Therefore, they consume significantly more battery charge since more complex and unique signal characteristics require more processing. Thus, it is critical to a long battery life that there are few false positives during the first phase.

Yet, ON Semi's proposal could result in literally millions of false positives for a device. That is, the device will detect a signal (but not recognize during the first phase that it is a signal relating to the wireless hearing aid system), and therefore be forced to employ additional phases of detection that consume far more battery charge. As a result, these existing MICS systems will suffer a tremendous increase in current battery consumption if the ON Semi proposal is adopted. Existing systems that scan the MICS band were not designed to – and should not be required to -- accommodate a close high duty-cycle system such as the proposed wireless hearing aids.

Accordingly, if the ON Semi proposal is adopted, given the near 100% duty cycle of proposed wireless hearing aids, there is no question that for medical implant devices the probability of false positives during the initial detection phase (thereby causing unnecessary depletion of the implant battery) will be very high when a hearing aid using the upper MEDS

band and medical implant using the MICS band are in close proximity.[4] In fact, as for both existing medical implant devices and future devices, this detrimental impact to the battery life will occur for any persons with such devices who are in close proximity with a wireless hearing aid user, such as a co-worker, a fellow nursing home resident or even a spouse. It is axiomatic that this detrimental impact cannot be avoided for existing systems because the implant is already in the person's body, and the implant cannot be altered to minimize the effect of wireless hearing aids on battery life. But this detrimental impact also cannot be avoided for new medical implant systems because even if future devices are manufactured at considerably greater costs with greater selectivity and dedicated algorithms and circuits for handling high duty cycle systems such as wireless hearing aids, those medical implant devices themselves then will necessarily consume far more current, especially if the other systems have a high probability of presence.

Moreover, there is a strong movement within the health care industry towards even lower current consumption that will facilitate new applications with very small implants. Adoption of the ON Semi proposal will greatly undermine those plans as well.

4. ON Semi's Proposal Would Cause Interference to MEDS-Band Radios, Thereby Undermining their Functionality and Placing Patient Care at Risk

The use of wireless hearing aids within the MEDS band will result in interference to MEDS devices for many reasons, including the following:

1. Successful operation of an LBT protocol requires that all systems have similar RSSI measurement sensitivity. If a given system has reduced RSSI measurement sensitivity, there is a higher probability of failing to detect existing communication sessions and therefore erroneously using occupied channels. The wider channel bandwidth (300 kHz) of the hearing aid proposal prevents this system from attaining comparable RSSI sensitivity levels to the other MEDS based devices operating with a 100 kHz bandwidth. That is, the wider channel bandwidth for wireless hearing aids and commensurate

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[4] The risks are significant because many devices in the MICS band will hear signals in the MEDS channels neighboring the MICS band due to the previously mentioned relaxed filtering and also the likely broader modulation envelope that will exist for the wireless hearing aids given the 300 kHz channel usage. As to the latter point, as stated by Medtronic in its February 25, 2008 filing in this proceeding, devices with a 300kHz bandwidth (that ON Semi is requesting) typically will have a less steep modulation envelope slope at the band edge as compared to the modulation envelope of a 100kHz device (as proposed in the Petition for Rulemaking), and this will result in a greater energy spill over from the modulation process into the upper edge of the core MICS band at 402-405 MHz.

reductions in RSSI sensitivity (5 dB) will result in poor listen-before-talk (LBT) performance when compared to systems conforming to the desired 100 kHz channel bandwidth.

2. Continuous transmissions in the hearing aid system (occupying 3 channels) will result in an unacceptably high probability of interference with low power systems which communicate using the 0.1% duty cycle mode. For the case of a single MEDS device in close proximity to a hearing aid, the probability of interference may easily reach (3ch/10ch) =30%. This will grow rapidly with the planned deployment of a large array of MEDS devices and ON Semi's claims that their wireless hearing aids will also have a significant growth in deployment over time.

Given that ON Semi's proposal continues to change (see no. 5 below), Zarlink is continuing to perform interference analysis to determine the exact extent of the interference involved. But one thing is certain, as Zarlink will demonstrate in a presentation to the Commission as soon as the analysis has been completed: If ON Semi's proposal is adopted, the result will be significant interference to MEDS devices, thereby undermining their intended functionality and putting patient monitoring and care at risk. Patients and the health care industry can ill-afford such a result given the tremendous benefits these devices will offer.

5. ON Semi's Proposal is a Moving Target

ON Semi's proposal is a moving target, and Zarlink is continuing to analyze all of the problems with ON Semi's ever-changing proposal.[5] Indeed, ON Semi's most recent alteration to its proposal was filed only a couple of weeks ago, on December 19, 2008.[6] Accordingly, if the Commission decides to consider ON Semi's request it should do so only after it develops a full record through a notice of proposed rulemaking. Moreover, as discussed in Zarlink's October 27, 2008 submission, it can only be assumed that ON Semi will apply for more rule changes in that it has not applied for all of the rule changes that would be needed for its wireless hearing aids to become compliant.[7]

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[5] See January 2, 2009 *Ex Parte* Comments of Medtronic at 3, which discuss the repeated changes to ON Semi's proposal.

[6] For all of the reasons set forth in Zarlink's October 27, 2008 filing, as well as Medtronic's filings in this proceeding, ON Semi's claims regarding European approvals are highly misleading.

[7] See October 27, 2008 Letter from Zarlink at 2.

6. ON Semi's Proposal Would Cause Devices Manufacturers who are in Late Stage Development of Medical Implant Devices to be Saddled with Tremendous Losses

If the ON Semi proposal is adopted, every medical communication chip and module that Zarlink has designed and released, and is designing and about to release, would require at the very least substantial redesign to somewhat reduce (but by no means eliminate, because that is not practicable) the detrimental impact from the proposal. This would represent a very substantial cost to Zarlink, conservatively estimated to be $10M. In short, if the ON Semi proposal is approved, the end result on the development work currently underway by Zarlink would be nothing less than catastrophic, as the work will have to be scrapped or undergo a significant re-engineering effort, resulting in delays of years given the long cycles required to design and test integrated circuits and medical implant devices.

Moreover, Zarlink's customers would need to redesign and requalify their medical device products, with a conservative estimate of cost an order of magnitude greater than the approximately $10M that Zarlink would incur. Acceptance of the ON Semi proposal would mean losses undoubtedly in the order of hundreds of millions of dollars for the device manufacturers, who are in late stage development of medical implant devices.

7. The Commission Should, as it did with MICS and Wireless Medical Telemetry Service, Limit MEDS to Non-Voice Applications

ON Semi's proposal seeks to alter the well-reasoned and well-established approach the Commission has taken elsewhere with respect to similar types of medical devices. With regard to both MICS and the Wireless Medical Telemetry Service, the approved rules are limited to non-voice applications because audio requires nearly 100% duty cycle, and therefore would cause countless problems if permitted. ON Semi is asking that in this proceeding the Commission reject that fundamentally sound approach adopted by the Commission with respect to both MICS and Wireless Medical Telemetry Service. But the Commission should not do so. Indeed, the use of voice applications here is even opposed by AdvaMed, whose members produce close to 90 percent of the health care technology purchased in the United States.[8]

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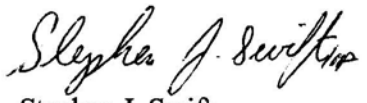
[8] See December 4, 2006 Letter from AdvaMed.

8. Other Spectrum is Available for Wireless Hearing Aids

Wireless hearing aid manufacturers do not need to use the MEDS spectrum for their products. Zarlink, for example, has developed and released a radio transceiver chip that operates in the 902-928 MHz ISM band. The ZL70250 chip was designed as a custom transceiver for a major hearing-aid manufacturer in the U.S., and shows clearly that the 902-928 MHz ISM band is perfectly suitable for use in hearing-aids.[9]

For the foregoing reasons, Zarlink opposes ON Semi's proposal, but if the Commission nevertheless decides to consider ON Semi's request it should do so only after it develops a full record through a notice of proposed rulemaking.

Sincerely,



Stephen J. Swift
Senior Vice President & General Manager
Medical Communications Product Group
Zarlink Semiconductor Inc.
15822 Bernardo Center Drive, Suite B
San Diego, CA 92127
(858) 675-3446

Alan G. Fishel
Arent Fox
1050 Connecticut Avenue, N.W.
Washington D.C., 20036
(202)-857-6450 phone
(202)-857-6395 fax
Counsel for Zarlink Semiconductor Inc.

cc: Charles Mathias
Julius Knapp
Erika E. Olsen

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[9] For all of the reasons set forth in Zarlink's October 27, 2008 filing, as well as in Medtronic's filings in this proceeding, ON Semi's claims regarding European approvals are highly misleading.

Renée R. Crittendon
Angela E. Giancarlo
Bruce Liang Gottlieb
Bruce Romano
Ira Keltz
Geraldine Matise
Ron Repasi
Mark Settle
Alan Stillwell
Gary Thayer