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October 27, 2008

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:

Zarlink Semiconductor Inc. responds to the *ex parte* presentation submitted in these proceedings by ON Semiconductor Corporation ("ON Semi") on September 18, 2008 which asks the FCC to authorize a 300 kHz channel in the 405-406 MHz band for wireless hearing aids.

Zarlink is a world leader in the design and manufacture of medical communications solutions for both implanted medical and hearing aid applications. We have developed MICS band (402-405 MHz) integrated circuits for implanted medical devices and an ISM band (902-928 MHz) solution originally developed for a hearing aid communication application. Both solutions fully comply with all FCC regulations.

Therefore, our industry experience indicates we are well qualified to comment on this *ex parte* presentation.

For the reasons provided below, the ON Semi proposal should be rejected.

- 1) Permitting Audio traffic in the MICS or MEDS wing bands would have a detrimental effect on the ability of the intended use of this band, that being for medical data.
Audio transmissions, including digitized audio transmission, have very different characteristics to medical data, which will lead it to become the dominant channel user, preventing other non-audio applications from making use of these channels.
Error free data transmission, especially audio without data compression, is not required for audio data. This implies that manufacturers do not need to design in pauses for acknowledgment transmissions and retries.
The need for a user perception of gapless audio, and the need to keep buffering delays short for stereo fidelity also requires that the transmission be continuous or near continuous.
Because of this near continuous channel occupancy, communication based on the low power and 0.1% duty cycle rule without LBT will have a very low probability of success. As pointed out in the letter from Medtronic (Medtronic letter of 25th Feb 08) the use of simple devices using a low duty cycle is an essential part of the MEDS band requirement.
- 2) The insistence on a 300 kHz allocation for just one audio channel removes at least three channels from MEDS usage. The loss of channels could be greater as the definition of bandwidth is the -20dB point (see section 3.1 of EN 302 537-1). ON Semi are requesting the full MEDS transmit power, therefore the power at the edge of the 4th channel might not be much below the allowed transmit power of a device operating under the low duty cycle regime.
Zarlink shares the worry expressed in the Medtronic letter (Medtronic letter of 25th September 2008) that ON Semi will later apply for more channels as the number of users increases.

- 3) Upon analyzing the ON Semi proposal, it is clear that they have not applied for all the rule changes required for Hearing Aids to be compliant. It can only be assumed that more rule change requests will follow should this one be successful. I refer here to the LBT threshold requirement. (EN 302 537-1 section 10.2.) The formula given in this requirement gives -100dBm for devices operating in a 100 kHz bandwidth. For the 300 kHz requested by ON Semi this is relaxed to -96dBm. The receiver sensitivity specified by ON Semi (slide 9 Ex Parte Presentation of Feb 7 2008) is -75dBm and the antenna gain is -10dBi. This implies that the required LBT threshold is 41dB below their receiver sensitivity. It is highly unlikely they can detect the presence of signals 41dB below their receiver sensitivity and avoid them. The ON Semi version of LBT is given by this extract "For example if two parties are using wireless hearing aids and one leans in to talk to the other party, there will be no interference because the wireless functionality will temporarily shut-down" taken from their letter of May 1, 2008. Here we see that the ON Semi device is only intended to cease transmission in the presence of a strong signal from another hearing aid in close proximity. With the ON Semi hearing aids using the maximum allowed power of 25 μ W they will have a much greater interference range than the range within which their LBT functions correctly.
- 4) With a hearing aid transmit power of 25 μ W (-16dBm) and a LBT threshold of -100dBm for a 100 kHz bandwidth MEDS device the path loss needs to be greater than 84dB for the signal from the hearing aid to be below the LBT threshold. This equates to a free space path of greater than 93m. Although the practical indoor range will be less than this, it can be seen that the interference range of the hearing aids proposed by ON Semi far exceeds the range at which their LBT functions. Combine this with near 100% channel occupancy and from ON Semi's own material (presentation on 3rd October 08 slide 4) a very large number of users, it is obvious that the three channels requested by ON Semi would be lost to any application requiring the reception of low level signals, such as those from a medical implant, or a body worn device using the lower transmit power of the 0.1% duty cycle regime.
- 5) Systems that use LBT in either the MICS or MEDS bands require the initiating device (base-station) to determine the appropriate channel to use. The very low power sensor (medical device) is then required to sniff various channels for the presence of a base-station that chooses to initiate a communication session. This sniffing process, which may occur every second, can be a large proportion of the sensor current consumption especially in the majority of MEDS/MICS applications that have low duty cycle. The presence of a highly occupied channel was not envisaged in the LBT concepts proposed within the MEDS and MICS standards. Such channels result in many false alarms since the first phase of detection is often a simple RSSI measurement that will terminate the sniff rapidly if no signal is found but continue processing if sufficient signal energy is detected. If a signal is found more extensive processing is required to determine if the signal is a wanted signal. In summary, high channel occupancy can dramatically increase current consumption as the medical sensor must perform more processing to reduce the effect of false alarms. It is very important that low power medical systems, operating with an LBT channel usage model, receive protected spectrum free from continuous interference,
- 6) The claim that Great Britain has approved the use of hearing aids in the MICS bands, made by ON Semi in their presentation dated 3rd October 2008 on page 9, is incorrect. The following is an extract from an email Zarlink received from Robin Donoghue of Ofcom in the UK.
" The latest (1 Oct 09) version of the UK Interface Requirement IR2030 hasn't changed the allocation in this band. The Reference Standard is recorded as EN 301 839 and the note attached to this allocation states the use is ULP AMI."
A check with the Swedish authorities has shown there to be no change of the regulations there either.

- 7) The following is an extract from the minutes of European Commission Mechanical, electrical equipment and Telecom Equipment TCAM Secretariat meeting number 26.

Begin quote:

8.9	<i>Hearing aids, medical devices and the 402-405MHz band</i>	Doc 63.
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- *=The LPRA presented the document regarding a hearing aid which does not comply with the appropriate standard (EN301 839-2) and uses the 402-405MHz band which is reserved for medical implants.*
- *The Chairman stated that if this product is not a medical implant device, the product should be taken out of the market by the market surveillance authorities. He invited the association to contact competent Member State's authorities.*
- *Switzerland and Belgium confirmed that they had received the notification and responded that the product could not be accepted on their markets.*
- *Sweden and Germany stated that no decision is needed because these are non compliant devices and this is therefore under the competence of market surveillance authorities.*
- *Austria also saw no other way to act than to forbid the placing on the market if it is not an active medical implant.*
- *Mr Mezour from LPRA thought that this device should not be accepted in all the national market, not only refused in one of them. He indicated that the manufactured is a German company and his product has been authorised there.*
- *Germany wondered why they had not been informed before, and offered to treat this bilaterally.*
- *Switzerland finally has a doubt on the non conformity. As concluded by TCAM a long time ago, a product which cannot be used in a Member State, or even in not a single Member State, can still be placed on the market. It is using the product, which will be is forbidden. Finally in the present case, there could be no legal ground to take it out of the market.*
- *The Chairman replied that the non conformity in the present case comes from the fact that the manufacturer gave the wrong information that the device could be used. For remaining conformant, the manufacturer should have clearly stated on the packaging and documentation that its equipment may not be used anywhere in the EU. The product is not compliant with the Directive, and if it is on the market, it should be withdrawn. (**Decision 6**)*

End quote

We draw your attention to the closing remarks on this discussion. It is clear that the use of hearing aids in the MICS band is not legal in the EU.

- 8) Suitable bands for short range wireless audio already exist. In Europe The band 863 to 865 MHz is allocated to wireless audio applications allowing both the bandwidth and power that ON Semi are asking for. The relevant ETSI specification is EN_301_357-1. Zarlink Semiconductor already manufactures a suitable device for hearing aid use in this band and the US equivalent band 902 to 928 MHz (see http://www.zarlink.com/zarlink/hs/82_8390.htm). This shows that devices fulfilling the requirements identified by OnSemi and working within the current legislation are possible.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Swift", written over a light grey rectangular background.

Stephen J. Swift
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