

February 5, 2020

Mr. Ron Repasi
Acting Chief, Office of Engineering and Technology
Federal Communications Commission
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Washington DC 20554

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Terry G. Mahn
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Re: Request of Long Term Confidentiality, FCC ID: 2AEEGX

Dear Mr. Repasi:

This concerns the above-referenced certification application, filed by Axonics Modulation Technologies, Inc. (Axonics), for the Implantable Pulse Generator (IPG), Model 1101 (FCC ID: 2AEEGX). Short term confidentiality was granted for the internal photos, external photos, setup photos and the user manual submitted with the application. Short term confidentiality is set to expire on March 21, 2020.

Axonics is now requesting long-term confidentiality for all internal photographs submitted with this application in accordance with *KDB 726920 D01, Confidentiality Request Procedures v01r02* and based on similar confidentiality requests granted by the Commission to Mala GeoScience AB for FCC ID: QLA250MHZ, and to Geophysical Survey Systems, Inc. for the following devices:

FCC ID: QF750400
FCC ID: QF762000
FCC ID: QF75103A
FCC ID: QLAMID
FCC ID: QLA500MHZ
FCC ID: QLA800MHZ

I. FACTUAL BASIS FOR CONFIDENTIALITY REQUEST

Ordinarily, the Commission does not grant confidentiality to internal photographs of a device submitted for an equipment authorization on the ground that they contain information that is freely available to a competitor by simply purchasing the device and removing the enclosure. However, *KDB 726920 D01, Confidentiality Request Procedures v01r02* sets forth conditions and procedures under which long-term confidentiality may be granted for internal photos. For example, long-term confidentiality will be granted whenever the circuit board and/or internal components are not accessible to users.¹

¹ *KDB 726920 D01, Confidentiality Request Procedures v01r02 at page 3.*

Here, the Axonics IPG functions as an integral part of a larger system, the Axonics r-SNM System, which is a prescription medical device that is not available to the general public and costs thousands of dollars. To gain access to the views shown in the interior photographs of the Axonics device, a competitor would first have to obtain a doctor's prescription for the Axonics r-SNM System and then purchase it directly from Axonics. The competitor would then have to open the hermetically sealed titanium enclosure to access the IPG's circuit board. Using any type of a cutting tool to open the hermetically sealed enclosure would destroy the IPG circuit board. Because of the way the IPG is constructed, any type of disassembly of the IPG would result in the destruction of the circuit board and the hermetically sealed enclosure. Furthermore, during disassembly of the hermetically sealed enclosure, other parts such as the feedthroughs (connectors to outside the enclosure) that connect the circuit board to header would also be destroyed. The feedthroughs are soldered to the circuit board and outside header, and the header is encapsulated in epoxy, an attempt to disassemble the device would require the destruction of these feedthroughs. Therefore, once opened (or attempted to open), the IPG device cannot be re-assembled for use, as the enclosure, connectors and the circuit board would have been destroyed.

Axonics has never released instructions on how to disassemble and re-assemble its units, and does not answer questions on how to do so. The information is kept confidential and is internal to the company. The internal photographs are stored in secure environment, and only limited number of people have authorization to access that information. Furthermore, as explained above, due to the way the IPG device is constructed, it is not serviceable since any opening of the device would destroy the entire device. Therefore, instructions and information on the assembly of the IPG devices have not been, and will never be, made available to third parties for servicing purposes or otherwise.

The posting of internal photographs on the Commission's website would allow a competitor to bypass this difficult and expensive disassembly and access highly confidential business materials that contain trade secrets related to the manufacturing and design techniques, and thereby gain an unfair market advantage. Competitors could also use such information to assist in determining the relative costs of manufacturing, the man-hours required for device construction and assembly and the compatibility/incompatibility with other designs (which in effect would greatly simplify a reverse engineering of the product and producing a schematic), and the age of the electronic design (which gives valuable competitive information on upgrade and R&D efforts).

Axonics respectfully submits that it should not be required to hand over to competitors, the fruits of its many years of expensive engineering.

II. LEGAL BASIS FOR REQUEST

The Freedom of Information Act (FOIA) protects from disclosure "commercial or financial information obtained from a person and privileged or confidential."² Information is confidential if it is "the kind of information 'that would customarily not be released to the public by the person

² 5 U.S.C. § 552(b)(4).

from whom it was obtained,”³ and would cause “substantial harm to the competitive position of the person from whom the information was obtained.”⁴

In *Worthington Compressors*, the D.C. Circuit addressed the specific issue underlying the present request, to wit, the “additional wrinkle that the requested information is available, *at some cost*, from an additional source.”⁵ Here, of course, the additional source is the acquisition, disassembly and destruction of an Axonics device for inspection. According to the *Worthington* court, availability of the information through alternate sources triggers two additional inquiries: (1) the *commercial value* of the information, and (2) the *cost of acquiring* the information through the other means.⁶ Importantly, the court acknowledged that the submitting party can suffer competitive harm if the information has commercial value to competitors,⁷ as would be the case for interior photographs that disclosed a great deal of expensive and proprietary engineering. Further, the court said that if competitors “can acquire the information [by other means] only at considerable cost, agency disclosure may well benefit the competitors at the expense of the submitter.”⁸

The court went on to note that competitors may get “quite a bargain” and a “potential windfall” if they can acquire hard-won proprietary information at FOIA retrieval costs⁹ and that “[s]uch bargains could easily have competitive consequences not contemplated as part of FOIA’s principal aim of promoting openness in government.”¹⁰ In the case of photos posted on the Commission’s website, a competitor need not even file an FOIA request but can simply download the material at no cost whatsoever.

The cost of acquiring interior photographs, if they are not available on the Commission’s website, amounts to the retail cost of a medical device and the time and effort required for complete disassembly. This fact alone warrants protection from disclosure under applicable court precedent.

Lastly, the Commission has established conditions and procedures for long-term confidentiality as noted above, and the Axonics IPG clearly meets the Commission’s requirements.¹¹

III. CONCLUSION

Federal law protects information submitted to an agency that is capable of causing substantial competitive harm to the submitter and is difficult and/or expensive to acquire by other means. Unlike many other product photographs, the interior photographs of Axonics’ devices meet these criteria and, therefore, are entitled to protection against public disclosure.

³ *McDonnell Douglas Corp. v. NASA*, 180 F.3d 303, 304-05 (D.C. Cir. 1999), quoting *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 879 (D.C. Cir. 1992) (en banc). See also *National Parks & Conservation Ass’n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974).

⁴ *Worthington Compressors, Inc., v. Costle*, 662 F.2d 45, 51 (D.C. Cir. 1981), citing *National Parks & Conservation Ass’n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974).

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ See fn. 1 *supra*.

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Importantly, Axonics does not request a final ruling on the issue at this time. Axonics asks only that the Commission refrain from posting any internal photographs on its website pursuant to Sections 0.457(d) and 0.459(d)(1), unless and until the Commission receives a properly framed request for inspection of the photographs is filed based on the requirements of Section 0.461 and Axonics is given an adequate opportunity to challenge their release.

Respectfully submitted,

/Terry G. Mahn

Terry G. Mahn
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cc. Element Materials Technology Portland – Evergreen