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Before the  
FEDERAL COMMUNICATIONS COMMISSION  
Washington, D.C. 20554

In the Matter of )  
)  
Second Sight Medical Products, Inc. )  
Request for Waiver of Section 15.209(a) of the )  
Commission's Rules to Permit the Operation of )  
Medical Implantable Devices for the Treatment of )  
Advanced Retinal Degenerative Diseases )

File No. \_\_\_\_\_

FILED/ACCEPTED

MAY 27 2011

Federal Communications Commission  
Office of the Secretary

To: The Commission

REQUEST FOR WAIVER

SECOND SIGHT MEDICAL PRODUCTS, INC.

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**REQUEST FOR WAIVER**

**I. INTRODUCTION AND SUMMARY**

Second Sight Medical Products, Inc. ("Second Sight"), pursuant to Section 1.3 of the Commission's rules,<sup>1</sup> requests a waiver of Section 15.209(a) to allow current and future generations of the Argus<sup>TM</sup> II Retinal Prosthesis ("Argus II") System to operate up to 119  $\mu$ V/m at 30 meters. The Argus II System is a medical implant system designed to treat profoundly blind people suffering from advanced retinal degenerative diseases such as retinitis pigmentosa ("RP"). It also may be applied in the future to other retinal degeneration diseases such as age-related macular degeneration.

Grant of the requested waiver will offer substantial health and other public interest benefits, particularly for blind patients with no proven treatment alternatives. Specifically, millions of people in North America suffer from varying degrees of irreversible vision loss due to untreatable retinal degenerative conditions such as RP, which affects an estimated 1.5 million

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<sup>1</sup> 47 C.F.R. § 1.3.

people worldwide, and age-related macular degeneration, which is the leading cause of vision loss in Canada and North America. The Argus II System offers the only approved treatment for patients suffering from end-stage RP. After a successful, ongoing clinical trial involving 30 blind patients around the world and a thorough review of the product's safety and performance by an independent expert body, the Argus II System received regulatory approval in February 2011 to permit its commercial sale in the European Economic Area.

All patients participating in the clinical trial benefited from controlled perception of light, and nearly all could localize small objects and walk along a line on the ground. The majority could recognize large letters and locate the position of objects, and some could even read words. Patients also demonstrated significant improvements in orientation and mobility skills. Based upon the success of the clinical trial, which commenced in 2006, Second Sight is seeking approval from the Food and Drug Administration ("FDA") at this time.

Grant of the requested waiver also will be consistent with the underlying purpose of Section 15.209(a) and will not adversely affect existing licensed systems, which operate at exponentially higher power levels. Conversely, strict compliance with Section 15.209(a)'s emission limit would disserve the needs of the blind and would be contrary to the public interest and Commission precedent. Requiring Second Sight to redesign the Argus II System to comply with the Part 15 rules would render the equipment effectively useless, increase difficulty in the manufacturing process, or require larger or additional components (thus reducing operating efficiencies; increasing the cost, size, and weight of the implant; and severely impacting the patient's comfort). Under similar circumstances, the Commission has granted a waiver of the Part 15 emission limits and should do so here.

## **II. SECOND SIGHT AND THE ARGUS II SYSTEM**

Second Sight was founded in 1998 to develop, manufacture, and market implantable visual prosthetics to enable blind individuals to achieve greater independence. Second Sight has received nearly \$30 million from the National Eye Institute of the National Institutes of Health, and the Department of Energy has spent more than \$75 million to develop future generation implants to be commercialized by Second Sight. The company's private investors have more than matched this federal investment.

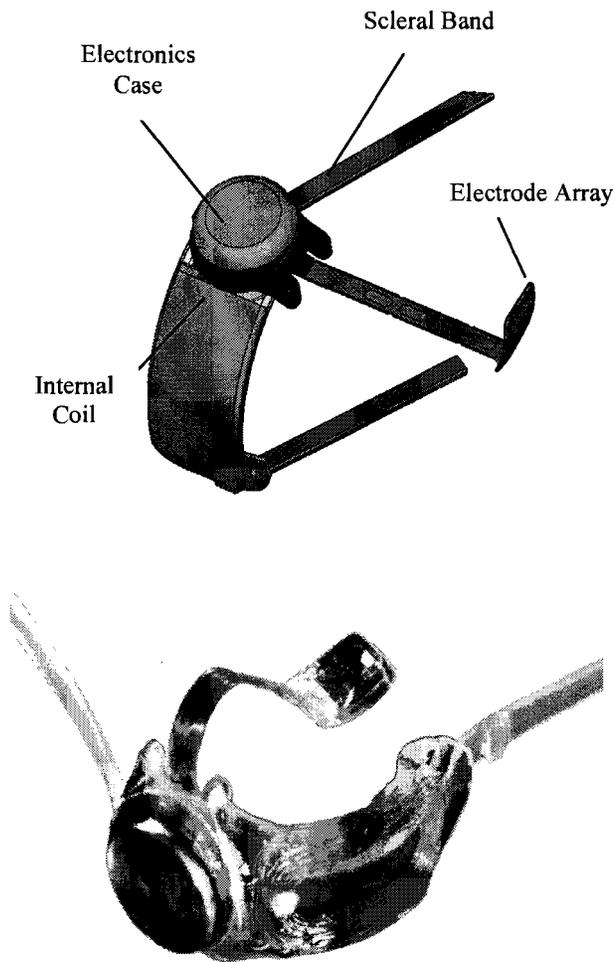
The Argus II System represents the culmination of more than 20 years of research and development to provide a viable long-term treatment for individuals who suffer from advanced retinal degenerative diseases and who have no proven treatment alternatives. It is designed to provide electrical stimulation of the retina to elicit visual perception and restore a level of functional vision to blind patients with severe to profound RP.

In a healthy eye, the photoreceptors on the retina (*i.e.*, cells in the retina that connect with other nerve cells to transmit visual information to the brain) convert light into tiny electrochemical impulses that are sent through the optic nerve and into the brain, where they are decoded into images. If the photoreceptors no longer function correctly due to conditions such as RP, the first step in this process is disrupted, and the visual system cannot transform light into images.

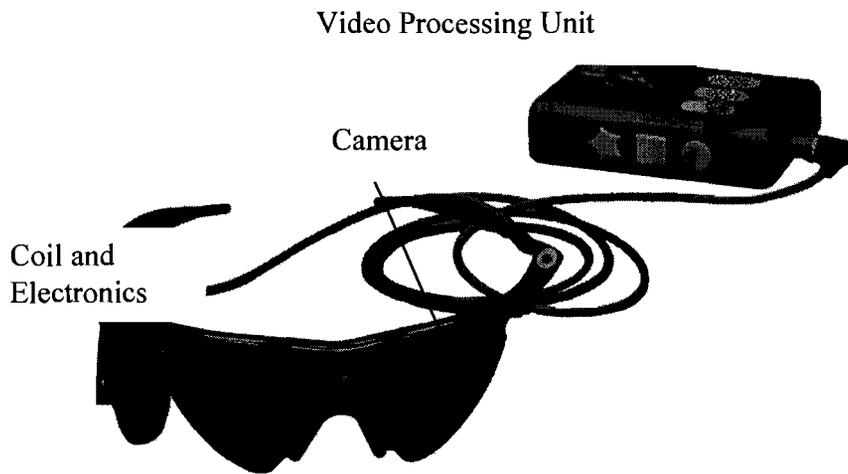
The Argus II System is designed to bypass the damaged photoreceptors altogether by transmitting data signals from an external coil to an implanted receiver, which provides electrical stimulation to the retina to produce patterns of light in the visual cortex. Specifically, as shown in Figures 1, 2, and 3 below, the system consists of (1) a neurostimulator implant device surgically implanted on the eye and containing a receiving coil, an electronics case, and an

electrode array positioned over the retina at the back of the eye; (2) a pair of eyeglasses housing a miniature video camera (mounted at the front and center) and transmitting coil (mounted on the side); and (3) an external, patient-worn video processing unit (“VPU”) connected by a short cable to the eyeglasses.

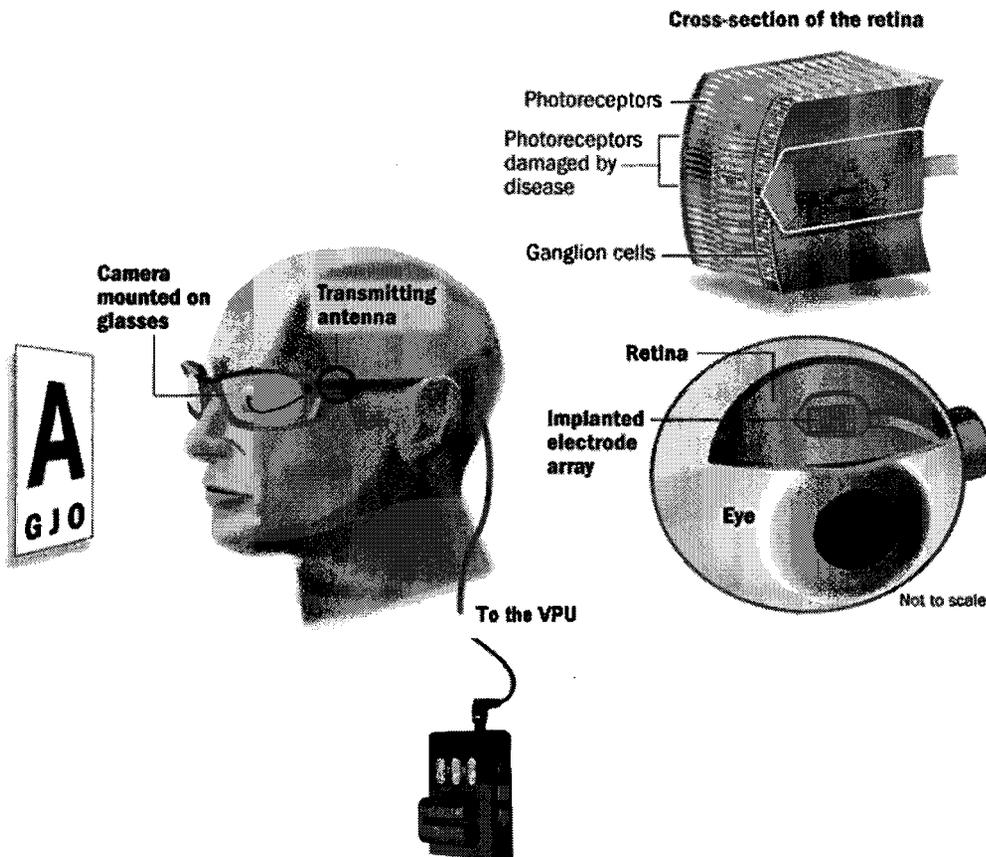
**Figure 1: Neurostimulator Implant (Schematic and Photo)**



**Figure 2: External Unit**



**Figure 3: Argus II System**



The miniature video camera housed in the patient's eyeglasses captures video images, which are then sent through a short cable to a small, patient-worn VPU. The VPU, in turn, processes and converts these video images into instruction signals that are sent back through the cable to the eyeglasses. From there, the instruction signals are transmitted wirelessly to a receiver in the implant and then sent to the electrode array, which uses the instructions to provide small pulses of electricity to the patient's retina. These electrical pulses bypass the damaged photoreceptors by stimulating the retina's remaining cells, which transmit the visual information along the optic nerve to the brain. This process creates in the brain the perception of patterns of light, which can take the shape of an object's outline. Patients learn to interpret these patterns of light as visual patterns, thus enabling them to gain some functional vision. For example, patients might decode three bright dots as the three points of a triangle.

The implant contains no battery and thus requires an external source of electrical power. Consequently, the implant contains a receiving coil to couple with a transmitting coil on the eyeglasses. These coils allow the eyeglasses to transmit both power and data signals inductively *to the implant* on a center frequency of 3.156 MHz. Information transmitted to the implant is modulated onto the carrier with amplitude modulation at a depth of 10 percent (*i.e.*, the data signal varies between 10 percent above and 10 percent below the maximum unmodulated carrier level). Additionally, the implant transmits tiny data signals to provide status information *to the eyeglasses* on a center frequency of 481.5 kHz.

The table below provides certain technical specifications for both the external unit and the neurostimulator implant device:<sup>2</sup>

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<sup>2</sup> During implantation in the operating room, the Argus II System is tested using an external clinician fitting system and a transmitting coil. This coil operates under the same technical specifications as the transmitting coil housed in the eyeglasses.

	External Unit	Implant Device
Transmit Frequency:	3.156 MHz	481.5 kHz
Modulation Type:	10% Amplitude Modulation	Frequency Shift Keying
Field Strength:	Approximately 22 $\mu\text{V}/\text{m}$ to 93 $\mu\text{V}/\text{m}$ at 30 meters	Below the noise floor at 1 meter
Carrier Bandwidth:	13 kHz	20 kHz
End-to-End Power Efficiency:	Up to 30%	
Communications Duty Cycle (when system active)	100%	100%
Communications Duty Cycle (per day)	Approximately 25%	Approximately 25%

The transmission of *power signals from the eyeglasses to the implant* complies with the applicable emission limit of 15  $\mu\text{V}/\text{m}$  at 300 meters under Section 18.305(b) of the Commission's rules.<sup>3</sup> The transmission of *data signals from the implant to the eyeglasses* also complies with the applicable emission limit of  $2400/F(\text{kHz}) \mu\text{V}/\text{m}$  at 300 meters under Section 15.209(a).<sup>4</sup>

Additionally, as shown in Figure 4 below, the Argus II System's communication sidebands comply with Section 15.209(a)'s applicable limit of 30  $\mu\text{V}/\text{m}$  at 30 meters.<sup>5</sup> All spurious emissions also comply with the general emission limits under Section 15.209(a).<sup>6</sup>

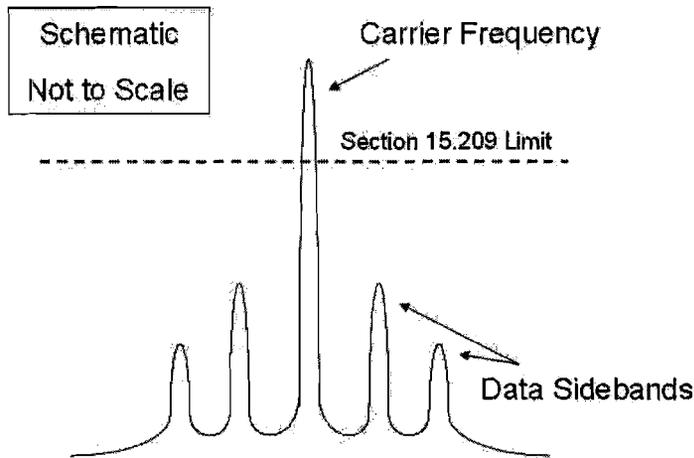
<sup>3</sup> 47 C.F.R. § 18.305(b).

<sup>4</sup> *Id.* § 15.209(a).

<sup>5</sup> *Id.* In fact, the field strength of the largest *data signal* communication sidebands produced by the 10 percent data modulation depth is 7.5  $\mu\text{V}/\text{m}$  at 30 meters.

<sup>6</sup> *Id.* Additionally, a study has been conducted to determine the specific absorption rate ("SAR") and current density in the human eye and head resulting from the wireless telemetry operation of epiretinal prosthesis systems such as the Argus II System. The study demonstrated that these systems will comply with international safety standards. See Vinit Singh *et al.*, *Specific*

**Figure 4: Carrier and Communication Sidebands**



The transmission, however, of *power signals from the eyeglasses to the implant also serves as the carrier for the data signals*, with emissions of approximately 22 to 93  $\mu\text{V}/\text{m}$  at 30 meters,<sup>7</sup> which exceeds Section 15.209(a)'s applicable emission limit of 30  $\mu\text{V}/\text{m}$  at 30 meters.<sup>8</sup> Accordingly, operation of the Argus II System requires a waiver of Section 15.209(a)'s emission limit.

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*Absorption Rate and Current Densities in the Human Eye and Head Induced by the Telemetry Link of an Epiretinal Prosthesis*, 57 IEEE Transactions on Antennas and Propagation 3110, 3110-3118 (Oct. 2009).

<sup>7</sup> Since the implant is powered through induction, the power output of the external transmitting coil is active throughout the duration of the patient's use of the Argus II System. Because the implant is positioned on the eye, the coil coupling between the implant and eyeglasses experiences shifts as the eye moves. Moreover, because of constant and rapid eye movements, the orientation between the implant and external transmitting coil can change by as much as +/-40 degrees from the optimal orientation. Thus, the power output of the transmitting coil is adjusted to use the minimum required power level for a given coil orientation. The resulting emission levels vary from 22 to 93  $\mu\text{V}/\text{m}$  at 30 meters.

<sup>8</sup> 47 C.F.R. § 15.209(a).

### III. GRANT OF THE REQUESTED WAIVER WILL SERVE THE PUBLIC INTEREST

The Commission may waive its rules upon a showing of “good cause.”<sup>9</sup> Good cause, in turn, exists when a waiver would not undermine the underlying purposes of the rule and otherwise would serve the public interest.<sup>10</sup> Good cause also may exist when particular facts would render strict compliance “inequitable, unduly burdensome or contrary to the public interest, or the applicant has no reasonable alternative.”<sup>11</sup>

As demonstrated below, grant of the requested waiver will offer substantial health and other public interest benefits, particularly for blind patients with no proven treatment alternatives. It also will be consistent with the underlying purpose of Section 15.209(a) in preventing harmful interference to existing licensed services. Conversely, strict compliance with Section 15.209(a)’s emission limit would dissuade the needs of the blind and would be contrary to the public interest and Commission precedent.

#### A. The Argus II System Offers Substantial Public Interest Benefits, Including Providing Revolutionary Treatment For Blind Patients With No Effective Treatment Alternatives

Millions of people in North America suffer from varying degrees of irreversible vision loss due to untreatable retinal degenerative conditions such as RP, which affects an estimated 1.5 million people worldwide, and age-related macular degeneration, which is the leading cause of

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<sup>9</sup> *Id.* § 1.3.

<sup>10</sup> See *WAIT Radio v. FCC*, 418 F.2d 1153, 1157 (D.C. Cir. 1969), *cert. denied*, 409 U.S. 1027 (1972); *Northeast Cellular Telephone Co., L.P. v. FCC*, 897 F.2d 1164, 1166 (D.C. Cir. 1990).

<sup>11</sup> 47 C.F.R. § 1.925(b)(3)(ii).

vision loss in Canada and North America.<sup>12</sup> These vision disorders affect young and old people across diverse cultures, ethnicities, and races.

RP, for example, is a leading cause of blindness among people between the ages of 6 and 60.<sup>13</sup> The most common form of RP follows a progressive pattern: loss of night vision, loss of side or peripheral vision, very restricted tunnel vision, and ultimately blindness in some cases.<sup>14</sup> RP typically has a severe impact on a person's quality of life. Initially, patients lose their ability to recognize details and detect motion, which impacts their ability to perform activities of daily living such as driving, reading, walking, and performing social functions. For patients in the more advanced form of the disease, the situation is even worse. Many have abnormal sleep patterns due to Circadian rhythm disruption and are clinically depressed as a result of their vision loss. There is currently no treatment available to these individuals in the United States. Once the retina is affected by RP, it cannot be replaced by artificial lenses, corrected with surgery, or cured with drugs.<sup>15</sup>

Vision loss imposes direct and indirect costs upon both the individual and the overall economy. Chronic eye disease and visual impairment consume a disproportionate share of health care resources—an estimated \$51.4 billion annually in the United States.<sup>16</sup> People with impaired vision visit doctors more often, and many need assistance (*e.g.*, caregivers, guide dogs, and other aids) in performing activities of daily living. For people with vision loss (compared to

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<sup>12</sup> See The Foundation Fighting Blindness, *Retinal Degenerative Diseases*, [http://www.ffb.ca/eye\\_conditions/RD\\_diseases.html](http://www.ffb.ca/eye_conditions/RD_diseases.html) (last visited Apr. 28, 2011).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> Alliance for Aging Research, *The Silver Book: Vision Loss* (Sept. 2007), available at [http://www.agingresearch.org/files/1674\\_file\\_The\\_Silver\\_Book\\_Vision\\_Loss.pdf](http://www.agingresearch.org/files/1674_file_The_Silver_Book_Vision_Loss.pdf).

general population of same age), admission to nursing homes is three years earlier; likelihood of falls is twice as high; incidence of depression is three times as high; occurrence of hip fracture is four times as high; and probability of death is twice as high.<sup>17</sup> A U.S. study found that 16 percent of those 65 and over who are visually impaired and 40 percent of those who are blind reside in nursing homes, compared with 4.3 percent of the total population.<sup>18</sup>

The Argus II System offers the only approved treatment for patients suffering from end-stage RP. After a successful, ongoing clinical trial involving 30 blind patients around the world and a thorough review of the product's safety and performance by an independent expert body, the Argus II System received CE-Mark approval in February 2011 to permit its commercial sale in the European Economic Area.<sup>19</sup> All patients are past one and a half years in clinical follow up, with the longest tenured patient nearing four years. Second Sight has submitted an application for Humanitarian Device Exemption ("HDE") approval from the FDA.<sup>20</sup>

All patients participating in the clinical trial benefited from controlled perception of light, and nearly all could localize small objects and walk along a line on the ground. The majority could recognize large letters and locate the position of objects, and some could even read words. Patients also demonstrated significant improvements in orientation and mobility skills. By

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<sup>17</sup> See World Health Organization, 56th Assembly, *Resolution WHA56.26: Elimination of Avoidable Blindness* (May 28, 2003), available at [www.who.int/pbd/en/WHA56.26.pdf](http://www.who.int/pbd/en/WHA56.26.pdf).

<sup>18</sup> David B. Rein *et al.*, *The Economic Burden of Major Adult Visual Disorders in the United States*, 124 *Arch Ophthal* 1754, 1757 (2006), available at [archophth.ama-assn.org/cgi/reprint/124/12/1754.pdf](http://archophth.ama-assn.org/cgi/reprint/124/12/1754.pdf).

<sup>19</sup> See Press Release, Second Sight, *Second Sight Medical Products Announces European Market Approval of a Retinal Prosthesis for the Blind* (Mar. 2, 2011), available at <http://www.2-sight.eu/en/second-sight-spotlight-2>.

<sup>20</sup> HDE approval represents FDA authorization to market a humanitarian use device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. See 21 C.F.R. § 814.100 *et seq.*

restoring an element of vision, the system could enhance patients' coordination, assist them with daily tasks such as walking and cooking, and allow them to regain a measure of mobility and self-sufficiency. These incalculable benefits, in turn, could reduce the costs of health care or in-home care for patients, while substantially improving their quality of life.<sup>21</sup>

**B. Operation Of The Argus II System Is Highly Unlikely To Cause Harmful Interference To High-Power Licensed Systems**

Operation of the Argus II System pursuant to the requested waiver is highly unlikely to cause harmful interference to other authorized systems and thus will be consistent with the underlying purpose of the Part 15 technical rules to prevent harmful interference to other authorized systems.<sup>22</sup>

First, existing licensed systems in the relevant frequency bands operate at exponentially higher power levels than the Argus II System and are unlikely to receive any harmful interference from Argus II devices. The only Commission-licensed systems operating in the 3.025-3.230 MHz band are maritime (under Part 80) and private land mobile radio (under Part 90) ("PLMR") systems.<sup>23</sup> PLMR systems in the 3.025-3.230 MHz band may be licensed to

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<sup>21</sup> See Maria Cheng, *Artificial Retina Helps Some Blind People* (Feb. 14, 2011), available at <http://abcnews.go.com/Technology/wireStory?id=12909654>; *Bionic Eye Gives Partial Sight to Blind* (CBS News Broadcast Mar. 2, 2011), available at <http://www.cbsnews.com/video/watch/?id=7358218n>.

<sup>22</sup> See *Revision of Part 15 of the Rules Regarding the Operation of Radio Frequency Devices Without an Individual License*, 4 FCC Rcd 3493, ¶ 13 (1989) ("*Part 15 Order*") ("The new [Part 15] rules are designed to provide a balance of our competing goals of eliminating unnecessary regulatory barriers and burdens on the development of new low power RF equipment and maintaining adequate interference protections for authorized radio services and recognized passive users of low level RF signals.").

<sup>23</sup> See 47 C.F.R. § 2.106. The 3.025-3.155 MHz band is allocated for aeronautical mobile (off-route) services (federal government and non-federal government), and the 3.155-3.230 MHz band is allocated for fixed and mobile (except aeronautical mobile route) services (federal government and non-federal government). *Id.*

operate at a maximum power level of 1,000 watts,<sup>24</sup> and most of those systems apparently operate at or well above 100 watts.<sup>25</sup> Similarly, maritime systems in the 3.025-3.230 MHz band are used for communication, not navigation, and may be licensed to operate at a maximum power level of 400 to 800 watts (for public coast stations), 1 kilowatt (for private coast stations), or 150 watts to 2 kilowatts (for ship stations).<sup>26</sup> Thus, these high-power licensed systems should not be even remotely affected by the Argus II System, which operates at a fraction of those systems' power levels.

Second, the risk of harmful interference to licensed systems is further reduced by the operating conditions under which the Argus II System transmits signals. The system transmits both power and data signals by induction, rather than by radiation into space, and the low-power signals are directed toward the implant within the patient's body. As a result, the low-power transmissions have a maximum operating range of approximately 20 millimeters.

Third, many unlicensed Part 15 devices in 1.705-10 MHz band already are allowed under the alternative provisions of Section 15.223(a) to operate at a maximum emission level of 100  $\mu\text{V}/\text{m}$  at 30 meters.<sup>27</sup> Moreover, the Argus II System and other low-power devices also are allowed in Europe to operate at a maximum emission level of 119  $\mu\text{V}/\text{m}$  at 30 meters (or 13.5  $\text{dBuA}/\text{m}$  at 10 meters), in accordance with the Radio and Telecommunications Terminal

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<sup>24</sup> See 47 C.F.R. § 90.205(a).

<sup>25</sup> See Letter from Julius P. Knapp, Chief, Office of Engineering and Technology, FCC, to Mitchell Lazarus, Counsel for EnteroMedics Inc., 24 FCC Rcd 13795, 13796 (OET 2009) ("*EnteroMedics Letter*").

<sup>26</sup> See 47 C.F.R. § 80.215(a).

<sup>27</sup> See *id.* § 15.223(a) (specifying alternative emission limits of 100  $\mu\text{V}/\text{m}$  or lower at 30 meters, based upon measurement instrumentation employing an average detector).

Equipment directive.<sup>28</sup> The permitted operation of many of these Part 15 devices at maximum emission levels of 100  $\mu\text{V}/\text{m}$  or higher in both the United States and Europe suggests that existing licensed systems are not adversely affected by these low-power devices<sup>29</sup> and would not be adversely affected by allowing the Argus II System to operate under the same emission limits.<sup>30</sup>

Finally, allowing the Argus II System to operate under the same emission limit permitted in Europe (*i.e.*, 119  $\mu\text{V}/\text{m}$  at 30 meters) would facilitate global deployment and use of the equipment without increasing the risk of harmful interference to other authorized systems.

**C. Strict Compliance With Section 15.209(a) Would Be Contrary To The Public Interest And Commission Precedent**

Strict compliance with Section 15.209(a) would be unduly burdensome and disserve the public interest by depriving blind patients of revolutionary treatment that is already commercially available in Europe and that could allow them to regain an element of vision along with a measure of mobility and self-sufficiency. Specifically, requiring Second Sight to redesign the Argus<sup>TM</sup> system to comply with the much lower emission limit allowed under Section

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<sup>28</sup> See Directive 99/5/EC, 1999 O.J. (L 91) 10 (July 4, 1999) (Directive of the European Parliament and of the Council of 9 March 1999 on Radio Equipment and Telecommunications Terminal Equipment and the Mutual Recognition of Their Conformity), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:091:0010:0028:EN:PDF>.

<sup>29</sup> See *Part 15 Order* ¶ 24 (“We observe that Part 15 devices already are permitted to operate in the 1.705-10 MHz band at higher limits [than Section 15.209(a)’s general emission limit of 30  $\mu\text{V}/\text{m}$  at 30 meters for emissions between 1.705 and 30 MHz] without known interference problems to the authorized radio services.”).

<sup>30</sup> The Argus II System is specifically designed to deal safely with radio interference, and patients will suffer no harm if the communications link is disrupted by a stronger interfering signal. The communication protocol used in the Argus II System is governed by various header, parity, and 16-bit error detection checks. Any failure in transmission of data forces the system into a safe mode until a reliable data link is regained. Further, in the instructions for use (provided in text and audio form), individuals with an Argus II implant are explicitly directed to continue using other mobility aids (*e.g.*, canes, dogs, etc.) at all times.

15.209(a) would render the equipment effectively useless and incapable of performing critical functions. The reduced power level would be too low to support reliable communications between the transmitting coil on the eyeglasses and the implant.<sup>31</sup>

Additionally, the center frequency of 3.156 MHz is ideal for both ensuring adequate power to the implant and avoiding excessive power dissipation in the patient's body, which would occur at higher frequencies. Operation at higher frequencies also would add difficulty into the manufacturing process, which requires tight tolerances in frequency tuning.

Alternatively, requiring Second Sight to redesign the Argus II System to require power and data transmissions to be performed on different frequencies would require larger electronics and an additional coil antenna in the implant. This, in turn, would reduce operating efficiencies, increase the cost of the device, increase the size and weight of the device, and severely impact the patient's comfort with the potential of requiring a device that may not even safely fit in the available area around the eye.

Under similar circumstances, the Commission has waived the Part 15 emission limits to allow EnteroMedics Inc. ("EnteroMedics") to market its implantable medical devices for the treatment of gastro-intestinal disorders.<sup>32</sup> Specifically, the Commission waived Section 15.209's emission limit of 30  $\mu\text{V}/\text{m}$  at 30 meters (for intentional radiators operating in the 1.705-30 MHz band) to allow the EnteroMedics devices to operate up to 200.2  $\mu\text{V}/\text{m}$  at 30 meters for the

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<sup>31</sup> The human eye's capability for a large range of both horizontal and vertical movement can reduce the efficiency of power transmission between the implant and eyeglasses by more than a factor of five. This effect is compounded by the limits on the size and shape of the implant coil presented by the limited area available for implantation around the eye. Thus, the proposed higher emission level is required to ensure adequate power to the implant device for reliable and effective use.

<sup>32</sup> See *EnteroMedics Letter*, 24 FCC Rcd at 13795.

transmission of both power and communications signals at a frequency of 6.78 MHz.<sup>33</sup> The Commission found that a waiver was consistent with the underlying purpose of the emission limit because existing high-power licensed systems in the frequency band were unlikely to receive harmful interference from the EnteroMedics devices.<sup>34</sup> The Commission also noted that the intended use (*i.e.*, signals are directed into a user's body, rather than radiated into space) and the short distance between the implant and the external antenna will further minimize the risk of interference.<sup>35</sup> The Commission further found that the implant devices were designed to operate optimally and less intrusively by performing both communications and power transmissions on a single frequency, and that no useful purpose would be served by separating these functions on different frequencies.<sup>36</sup> The Commission noted that there is no more interference potential from allowing the EnteroMedics equipment to exceed the Part 15 emission limit than if the equipment used different circuitry to generate separate compliant power and communication signals that, in turn, would be transmitted simultaneously at 6.78 MHz.<sup>37</sup> Finally, the Commission concluded that a waiver would serve the public interest by providing an additional option for promoting weight loss, thus reducing health-care spending and enhancing the quality of life for many people.<sup>38</sup>

In view of the substantial similarities between the Argus and EnteroMedics implant

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<sup>33</sup> *Id.* at 13798.

<sup>34</sup> *Id.* at 13797.

<sup>35</sup> *Id.* at 13798.

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

devices, the Commission should grant a waiver of Section 15.209(a) to allow the Argus II System to operate up to 119  $\mu\text{V}/\text{m}$  at 30 meters.

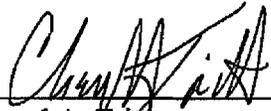
### VIII. CONCLUSION

Based upon the foregoing, Commission grant of this request for waiver will serve the public interest by allowing truly revolutionary medical technology to be commercially available to blind patients with no proven treatment alternatives. The resulting health and cost benefits, including the dramatic improvement in the quality of life and reduction in health-care costs, are immeasurable and more than sufficient to warrant a waiver.

Respectfully submitted,

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