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Medical Methods Patents in Neuromodulation

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There is a rapidly growing number of patents on methods of modulating brain regions. Despite this trend, and the massive potential of neuromodulation for treating patients, researchers and physicians who use neuromodulation techniques and technologies often have little idea of the significant ways these patents could affect their work. This article describes medical method patents, including a brief history of their development, and analyzes their potential direct and indirect effects on neuromodulation treatment and research efforts. As neuromodulation rapidly matures into a commercial and medical reality it is important to consider these effects in a forward thinking and value driven manner. The paper concludes with recommendations concerning how neuromodulation method patents may be used, or not, depending on the values of the inventor.

Keywords: Law, neuromodulation, patents, research, treatment

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INTRODUCTION

Neuromodulation relies heavily on new devices, or new ways of using old ones, to modulate the nervous system. Stimulators, stimulation trains, and implementation methods are examples of some of the tools used. Here we review one way these tools come into commercial application––the medical method patent. The medical method patent is a legal instrument used to turn methods of therapeutic intervention into property, the use of which can be controlled for a limited time by its inventor-owner. The acceptance of medical methods as patentable subject matter varies between countries. Here we discuss the United States as its system allows medical method patents and accounts for a large share of those who treat with, and do research on, medical neuromodulation techniques.

Last year we published an article in Nature Biotechnology (1) exploring the rise in the use of brain regions in these method patent claims. Most of the patents in the data set were for medical methods directed toward treating one or more neurological disorders. It became clear, through the research and writing process, that many in the neuromodulation community did not know how medical method patents work, how they might affect practice, and how they can be used. It is troubling that this important legal instrument, which has the capacity to influence care and development, was not better understood.

This article attempts to remedy that situation. First, we review fundamentals of patent law, how they apply to medical methods and how the medical method patent developed historically. Second, we discuss how medical method patents may be applied to the field of neuromodulation. Third, we conclude with a discussion of how physicians and researchers might use patents, depending on their values concerning how the methods they create ought to be used and developed. The goal of this review article is not to provide a comprehensive legal analysis of all relevant components of patent law. It should instead be considered a primer attempting to translate and clarify legal concepts for the neuromodulation knowledge user. Most of the patent references we cite are freely available through USPTO.gov (for patent guidelines) and supremecourt.gov or supreme.justia.com (for cases). Relevant sections of the patent act were accessed via law.cornell.edu/uscode/text/35. The full text of some older cases requires access to a legal database, though case summaries are often freely available through Google searches.

OVERVIEW AND HISTORY OF MEDICAL METHODS PATENTS

Basic Concepts in Patent Law

Patents turn innovations in the creation of materials, machines, or processes into protected property and are meant to strike a balance between the interests of inventors and the public to encourage innovation. If the inventor describes how an innovation works in the form of a patent, the government grants the inventor the power to control how others use the innovation (2). During the 20-year life of the patent the owner can bring a suit to stop others from using or manufacturing the innovation without permission (3). If the courts determine that infringement has occurred, they can impose monetary awards, an injunction order to stop using or making the invention, or both (4).

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Patent law has a long history and is still evolving. There are still ongoing debates about what exactly is patentable (5,6). Nonetheless, foundational principles provide guidance to the inventor. The invention must fit into the four subject matter categories of "process, machine, manufacture, or composition of matter" (7). The innovation must be "novel" (7,8), "useful" (7,9), and "non-obvious" (10,11). Finally, the patent document itself must enable a person of ordinary skill and knowledge in the relevant field to practice the innovation; if the patent is vague such that a practitioner of ordinary skill could not use the information contained therein, and the knowledge common to the profession, to realize the promised useful result, then the patent is invalid (12).

Some important exceptions accompany these principles. Natural phenomena, abstract ideas, and mental processes cannot be patented (13). Even if substantial work and resources are put into the discovery of a mathematical formula or a newly identified brain region, neither by itself is patentable (6). Textbooks, such as "Intellectual Property and Health Technologies," provide more detail on this subject (14).

Historical Development of the Medical Method Patent

In the 1860s two Boston dentists obtained a patent for the process of using ether to render a patient insensitive to pain during surgery (15). The patent was not for the ether compound, nor any device to deliver it, but on the method of using ether to bring about insensitivity to pain. When other physicians used the method without permission the owners sued for infringement of their right to control the use of the patented process.

This case is old enough that the true motivations of the patent owners are difficult to ascertain but, given the revolution in surgery brought about by the use of effective anesthetics, it is easy to appreciate the potentially substantial financial gain. The patent was eventually declared invalid for being insufficiently inventive, but the decision did not rule out the patentability of methods of treating the human body. This example also illustrates the important point that a granted patent is only presumptively valid and, subject to litigation, may be declared invalid later by a court (16).

For decades after the ether decision, the patentability of medical methods remained uncertain. Some early decisions declared medical method patents invalid because of the risk that they may deceive the public into believing the method would work in all patients (17). It was not until 1954 that the patentability of medical methods became widely accepted (7,18).

The practice of patenting medical methods became more enticing in the early 1980s, likely because of a combination of court decisions and laws enacted during that time. The Bayh-Dole Act allowed for the patenting of inventions supported by federal funding (19). Supreme Court decisions clarifying the patentability of processes (20), and accepting novel biological organisms as patentable (21), indicated an increased acceptance of biotechnological advancements as patentable. The establishment of the Federal Circuit Court of Appeal as a central forum for patent disputes (22) further added momentum to the trend of encouraging, clarifying, and streamlining patenting in medicine and biotechnology. The result of these changes was an increased financial incentive to patent medical materials and methods and a simplification of the process of patenting.

Even with this increasing incentive there is little evidence that the associated rights were being enforced through infringement suits until the 1990s when a case dealing with a patent on a method of performing cataract surgery brought medical method patents to the public consciousness (23). The cataract case was the catalyst for the Ganske Compromise Law (24). The Ganske Compromise attempted to strike a balance between the position of the medical profession––that medical methods should not be patentable––and the support for medical method patents held by the biotechnology industry. The resulting compromise maintained the validity of medical method patents, but exempted healthcare practitioners working at healthcare institutions from the penalties of infringement. In simple terms, no physician who used a patented method to treat a patient could be successfully sued for doing so (25).

Exempting licensed medical practitioners and related healthcare entities from penalties did not, however, spell an end to the importance of medical method patents. Because of the increasing use of diagnostic testing outside the clinic, patent owners could still sue these external providers for infringement of diagnostic method patents (6). Furthermore, liability could be found for induced or contributory infringement, for example if a company marketed a kit or tool especially suited to perform a patented method they did not own (26).

In 2012, in the famous case of *Association of Molecular Pathology v. Myriad Genetics*, Inc. several methods patents were declared invalid by the Federal Appeals Court because the only inventive step therein was the mental process of comparing tumor or patient gene sequences to a list of mutations known to be related to developing cancer (5). The patents at issue in *Myriad* were challenged only when industry competitors were barred from offering a much cheaper version of the test, thereby providing a significant monetary incentive to test the patent's validity (27). This is generally the norm—potential profits drive the testing of medical method patents.

There are few cases dealing directly with neuromodulation method patents. One instructive example is *Nevro Corp v. Boston Scientific Corporation* (28). Both companies filed patents on methods of performing high-frequency spinal cord stimulation to treat pain. Nevro claimed that Boston Scientific developing the technology in a clinical trial (the ACCELERATE trial) infringed on the Nevro patent. The case is ongoing and complex—it has recently been appealed to the Federal District Court and already has 487 individual motions and orders logged by courtlistener.com (29). In short, however, if the Nevro arguments are upheld Boston Scientific may be precluded from bringing their product to market, which may impact patient care by reducing the number of treatment options available. We predict the number of disputes like this will only increase as neuromodulatory techniques become more practical and profitable.

The Medical Method Patent Today

As long as a method is sufficiently grounded in a specific real world process that brings about a transformation in the body, patented methods for treating the human body are valid today in the United States. In this regard, a novel, useful, nonobvious, and adequately disclosed medical method for neuromodulation which claims well-defined stimulation parameters on a specific nervous system region and serves a specific therapeutic purpose would be patentable. Table 1 shows a sample of the brain regions, disorders, and technologies claimed in the patents collected for our Nature Biotechnology article (1). The numbers and variety suggest that there is no area of neuromodulation that is insulated from the increasing trend to patent.

Table 1. Sample of Disorders, Brain Regions, and Technologies With the Number of Patents Listing Each of These in Brackets.

Disorder	Brain region	Technology
Parkinson's or movement disorders (24)	Thalamus (40)	Electrical stimulation (25)
Addiction (7)	Substantia nigra (17)	Magnetic stimulation (11)
Depression (27)	Basal ganglia (14)	Infusion (30)
Anxiety (18)	Caudate (15)	Ultrasound (15)
Eating disorders (7)	Cingulate (25)	Transcranial direct current (3)

MEDICAL METHOD PATENTS AND NEUROMODULATION: CLINICAL PRACTICE AND RESEARCH

In a world where technologies and techniques develop quickly, and where the law is unsettled, anticipatory consideration of future events is a worthwhile undertaking. Here we explore how the medical method patent may affect stakeholders involved in neuromodulation practice and research both in the immediate and longer term. These considerations may be broken down into two categories: direct effects that impact what a physician or researcher can do, and indirect effects that impact the design and dissemination of the tools they use.

Direct Effects on Physicians

The primary way in which physicians could be held directly liable for infringement of a method patent is the exception to the immunity provided by the Ganske Compromise (24). The immunity does not include "the use of a patented machine, manufacture, or composition of matter in violation of such patent." In this context, if practicing a method requires the use of a patented device ("machine") then the physician must still have permission to use the device, either through a sale by, or a licensing agreement with, the patent owner. This exemption prevents physicians from using a patented device and claiming that, because the device was used to perform a method, they are immune from the penalties of infringing the patent on the device.

Physicians may also be the subject of an infringement suit if they induce others to use a patented method. This can be done personally, for example one physician telling another how to practice a patented method, or by writing an article, which instructs others how to practice the patented method (26). Induced infringement is covered more fully in the section on indirect effects, and there are protections in the form of knowledge and intent requirements on the part of the person relating the information, but we flag it here as a possibility.

Direct Effects on Researchers

Patent ownership grants broad rights to control the use of the patented innovation. While the default position is that this control extends to any use of the patented invention, there are two exceptions relevant to neuromodulation research: 1) a judicially created exception—that is one created by the courts—relating to knowledge generation; and 2) a legislative exception relating to the disclosure of information required under federal law.

Judicial Exception

The judicially created experimental exception appears to be very narrow and relates to research purely for the sake of "gratifying a philosophical taste, or curiosity, or for mere amusement" (30,31). In other words, if a researcher uses a patented method purely to examine its underlying mechanisms, the judicial exception would seem to apply. Any research conducted using a patented method for a commercial business purpose, however, would not be exempted. Some cases suggest that even use in an academic institution or other not-for-profit that could lead to publishable results would not be exempt because of the potential reputational benefit to the researcher of the published research (32).

Legislative Exception

The legislative exception exempts would-be infringing activities which are "reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products" (33). Though originally drafted to deal with creating generic equivalents of patented drugs and biologicals, it was expanded in 1990 (34,35) to include devices the FDA categorizes as Class 2 and 3 medical devices. Class 2 includes transcranial magnetic stimulation (TMS) systems and EEG, while Class 3 includes most implanted devices. The court has affirmed that the exception extends to patented methods (36).

In its original formulation this exemption allowed generic drug manufacturers to use a patented drug for the purpose of developing a biologically equivalent generic version, before the end of the original patent term, without the risk of an infringement suit. As expanded to the device and method context this means that, if a patented method of using a device is used for a commercial purpose, that use is only exempted from infringement if the use is "reasonably related" to generating data to be submitted to the FDA. For example, if a patented method of using a deep brain stimulation device to treat Parkinson's disease is used by a researcher attempting to develop a new alternative therapeutic treatment, regardless if that be a new drug regimen or novel TMS method, that use is only exempt if those results are "reasonably related" to a submission to the FDA, for instance to show equivalency.

The same concerns noted above concerning induced infringement apply in the research context as long as they are outside judicial or statutory exceptions. If, for example, a researcher were to instruct a physician, or another researcher, on the use of a patented method, or write an article to that effect, the researcher could be found liable for inducing infringement (26).

Indirect Effects on Physicians and Researchers

Contributory infringement and induced infringement are two indirect effects of patents not often considered by physicians and researchers. They both have to do with cases where one party, for example a physician, has been induced to use a patented innovation by another, likely a device manufacturer or seller in the neuromodulation context. This is one of the reasons that we must disclose to the audience whenever we are presenting a nonapproved use of a device in our field.

To be found liable for contributory infringement, a company or individual must have knowledge that a patent on a method exists, create a device that is particularly suited to performing that method, and intend that the device be used in a way that infringes the patent (37). In other words, the company must sell a

device which it knows is specially suited to practicing the patented method and which has little or no other practical medical use.

To be found liable for inducing infringement, a company or person must know of a patented method and intentionally encourage the use of a device in a way that infringes that patent (40). For example, if a company were to sell a device and include in the package instructions for using that device to perform a patented method, those instructions may induce the user to practice the patented method.

Future practice may be affected, therefore, by how device manufacturers design and market their devices in light of indirect infringement. It may be commercially advantageous for device manufacturers to develop and market devices that can only perform methods owned by the company, or concentrate on developing and patenting methods that can only be performed with their devices. Conversely, manufacturers may design devices that are not well suited to implementing the methods patented by others for fear of being liable for contributory or induced infringement. A potential result is the creation of a large number of devices specifically designed to perform only a subset of methods, each with their own set of prices and permissions. This highly specialized and limited set of tools, along with the highly limited research exceptions, will affect the tools available to researchers.

This scenario is further complicated by the trend of transforming methods into programs that can be run on a computer as part of a closed-loop device. Instead of a physical device limited by its design to a small number of patented methods, the device could instead be of more general use, but limited by the software it is allowed to run. In a scenario like this, it is not the physician who is performing the modulation but the system itself. The distinction can be understood by analogy to a physician operating with a surgical device as compared to using a device that has been programmed to perform the surgery. The former case is an example of the physician using expertise and skill to practice a method and would be immune from infringement; in the latter case, the method has been turned into a patentable software product so there is no similar immunity.

Many of the patents in the dataset we analyzed (1) include the implementation of patented methods through software. Indeed, it is becoming increasingly common for a patent that includes method claims to also invoke claims related to a "device," "apparatus," or "system" through which a method is to be applied, and claims for "computer-readable," "computer-implementable," and "computer-executable" programs which apply the method.

Effects on the practice of neuromodulation in the future may also depend on how easily neuromodulation interventions can be performed outside of healthcare institutions covered by the Ganske Compromise. It is possible that treatments may not all take place in a hospital or physician's office, but will be handled in external settings not covered by an exemption, as is the case with many diagnostic methods today. This may affect the ability of patients to access services, if these external providers have to pay the owners of the method patent to avoid infringement suits.

USES OF MEDICAL METHOD PATENTS

The decision to pursue a medical method patent depends on the values and goals of the inventor. Here we lay out the three potential choices:

To Not Pursue a Patent

This option is to not use a patent strategy at all, and simply publish instead. The paradigm example of this option is the open data movement—open sharing of the fruits of intellectual labor is favored more than cordoning it off as property to be traded on the market.

Enforcement Only of Perceived Ethical Infringements

This option only enforces patent rights when the patent holder believes an unethical violation has been committed. Two historical events illustrate this approach. In the 19th century, B. Frank Palmer invented and patented the first artificial limb. In a form of benevolent profiteering, he sold his invention at a relatively marginal profit but used the rights associated with it to make sure that any artificial limbs that followed his design were only of the highest quality (39). More recently, outside the medical field, Tesla Motors released their patents for use by anyone, asserting an enforcement of rights to patented technologies only if used to harm the overarching project of replacing internal combustion vehicles with electric cars (40).

Monetize

Under this standard approach, an inventor creates a method and pursues a patent. Once granted, the associated intellectual property rights can be sold, licensed, or used as security for a loan to finance further development. It should be noted here that along with the sale of a patent comes the possibility that the buyer of the rights may enforce them differently than the previous owner. While the previous owner may have tolerated potentially infringing activities or been waiting for those activities to reach a certain level of commercial viability before bringing a suit, the new owner may decide to bring a suit immediately upon purchase for the reasons they deem most viable for their market position. A patent may, for example, be bought by a nonpracticing entity (sometimes called a "patent troll") to use as a bargaining chip in the market. Parties that have been using, and even advancing, a technique for years may suddenly become targets of litigation. Enforcing patents in this way can be a serious hindrance to innovation and thereby patient access to care.

There are good arguments for and against each of the three approaches. Proponents of the first two argue that greater good can be accomplished by sharing methods widely and publicly. Proponents of the third approach argue that not obtaining and monetizing an invention removes the financial incentive for development and stalls innovation. This argument deserves ethical investigation and will be the subject of further work.

CONCLUSIONS

As ever increasing knowledge is gained about the nervous system and the techniques that can be used to alter its activity, the number of patents that relate to modulating the brain/spinal cord and peripheral nerves will increase (1). As more combinations of brain regions, techniques, and disorders are privatized through patenting, the possibility of infringing a patent right will also increase. What once may have been an exploratory experiment, or attempted treatment, may newly become infringement. The risk of an infringement suit being brought increases as neuromodulation becomes a more profitable

commercial and medical reality and patent holders attempt to monetize their patented techniques.

In recent years, companies such as Facebook, Google, and Neuralink (41–43) are advancing into the neuromodulation arena. The substantial resources these entities can bring to bear, and the default position in the biotechnology industry that a patent is a prerequisite to investment, may contribute to the number of brain related method patents and a new thicket of rights that must be navigated. Overall, the world of neuromodulation and the interface with legal protections is moving fast. The medical method patent in the neuromodulation sphere, whether viewed as an opportunity or impediment, should be understood by physicians and researchers and used in a conscientious and value-driven manner.

Authorship Statement

Dylan Roskams-Edris performed data collection, legal and scientific literature review, and drafted the article. Stacey Anderson-Redick provided important support, edits, and comments on data collection and patent analysis. Drs. Judy Illes and Zelma H. Kiss suggested this topic be reviewed, published, and revised the manuscript for intellectual content.

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REFERENCES

1. Roskams-Edris D, Anderson-Redick S, Kiss ZH, Illes J. Situating brain regions among patent rights and moral risks. *Nat Biotechnol* 2017;35:119–121. https://doi.org/10.1038/nbt.3782.
2. The Patent Bargain. *Nature*. 2013;504:187–188. doi:10.1038/504187b.
3. 35 USC § 154(a). https://www.law.cornell.edu/uscode/text/35/154.
4. 35 USC § 281, 283, 284. https://www.law.cornell.edu/uscode/text/35/281, 283, 284.
5. Association for Molecular Pathology v. Myriad Genetics, 569 U.S. 12–398 133 S. Ct. 2107. https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf.
6. *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc*. 566 U.S. 66. https://supreme.justia.com/cases/federal/us/566/66/.
7. 35 USC § 101. https://www.law.cornell.edu/uscode/text/35/101.
8. United States Government, USPTO. (2015). *Anticipation — Application of 35 U.S.C. 102* (R-11.2013). Washington, DC. USPTO.gov. https://www.uspto.gov/web/offices/pac/mpep/s2131.html.
9. United States Government, USPTO. (2015). *Guidelines for examination of applications for compliance with the utility requirement* (R-11.2013). Washington, DC. USPTO.gov. https://www.uspto.gov/web/offices/pac/mpep/s2107.html.
10. 35 USC § 103. https://www.law.cornell.edu/uscode/text/35/103.
11. United States Government, USPTO. (2015). *Examination guidelines for determining obviousness under 35 U.S.C. 103* (R-07.2015). Washington, DC. USPTO.gov. https://www.uspto.gov/web/offices/pac/mpep/s2141.html.
12. United States Government, USPTO. (2015). *The enablement requirement* (R-11.2013). Washington, DC. USPTO.gov. https://www.uspto.gov/web/offices/pac/mpep/s2164.html.
13. United States Government, USPTO. (2015). *Patent subject matter eligibility* (R-07.2015). Washington, DC. USPTO.gov. https://www.uspto.gov/web/offices/pac/mpep/s2106.html.
14. Brougher JT. *Intellectual property and health technologies: Balancing innovation and the Public's health*. Springer: New York, NY, 2013.
15. *Morton v. New York Eye Infirmary,* Circuit Court, 17 F. 879 (1862). https://law.resource.org/pub/us/case/reporter/F.Cas/0017.f.cas/0017.f.cas.0879.6.pdf.
16. 35 U.S.C. § 282(a). https://www.law.cornell.edu/uscode/text/35/282.
17. *Ex parte Brinkerhoff,* Off Gazpat 349 (Comm'r pat off 1883)
18. *Ex parte Scherer,* 103 USPQ (BNA) 107 (1954)
19. An act to amend the patent and trademark laws, Pub. L. 96–517, 1980, 94 Stat 3015. https://history.nih.gov/research/downloads/pl96-517.pdf.
20. *Diamond v. Diehr*, 450 U.S. 175 (1981). https://caselaw.findlaw.com/us-supreme-court/450/175.html.
21. *Diamond v. Chakrabarty*, 447 *U.S*. 303 (1980). https://supreme.justia.com/cases/federal/us/447/303/.
22. Court of Appeals for the Federal Circuit Act of 1981, Pub. L. 97-164, 1982, 96 Stat 25. https://www.gpo.gov/fdsys/pkg/STATUTE-96/pdf/STATUTE-96-Pg25.pdf.
23. *Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995).
24. 35 U.S.C. § 287(c). https://www.law.cornell.edu/uscode/text/35/287.
25. 35 U.S.C. § 287(c)(2)(C). https://www.law.cornell.edu/uscode/text/35/287.
26. Moulton E. Inducing immune infringement: The interplay of section 287 (c) and section 271 (b). *Colum Sci & Tech L Rev* 2011;13:206.
27. Sherkow JS, Scott C. Myriad stands alone. *Nat Biotechnol* 2014;32:620–620. https://doi.org/10.1038/nbt.2944.
28. Nevro Corp. v. Boston Scientific Corp., No. 16-cv-6830-VC, 2018 WL 2111164.
29. Court Listener. Nevro Corp v. Boston Scientific Corporation. 2018. https://www.courtlistener.com/docket/4545951/nevro-corp-v-boston-scientific-corporation.
30. Russo AA, Johnson J. Research use exemptions to patent infringement for drug discovery and development in the United States. *Cold Spring Harb Perspect Med* 2014;5. https://doi.org/10.1101/cshperspect.a020933.
31. *Poppenhusen v. Falke*, 19 F. Cas. 1048
32. Madey v. Duke *Univ.,* 307 F.3d 1351. https://openjurist.org/307/f3d/1351/mj-madey-v-duke-university.
33. Drug Price Competition and Patent Term Restoration Act, Pub. L. 98-417, Sep. 24, 1984, 98 Stat 1585. https://www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf.
34. *Eli Lilly & Co v Medtronic, Inc.,* 496 U.S. 661, 110 S. Ct. 2683
35. *AbTox, Inc. v. Exitron Corp*., 122 F.3d 1019, 43 U.S.P.Q.2d 1545
36. *Classen Immunotherapies, Inc. v. Biogen IDEC,* 659 F.3d 1057
37. 35 U.S.C § 271 (c). https://www.law.cornell.edu/uscode/text/35/271.
38. 35 U.S.C § 271 (b). https://www.law.cornell.edu/uscode/text/35/281.
39. Lieffers C. Patents, profit and the public good: The case of a 19th-century artificial limb manufacturer. *Can Med Assoc J* 2016;188:824–825. https://doi.org/10.1503/cmaj.150871.
40. Tesla, Inc. (2014). *All our patents are belong to you*. https://www.tesla.com/en_CA/blog/all-our-patent-are-belong-you.
41. DARPA (2018). Towards a high-resolution. Implantable Neural Interface. https://www.darpa.mil/news-events/2017-07-10.
42. Winkler R.. Elon musk launches Neuralink to connect brains with computers. The Wall Street Journal. 2017. https://www.wsj.com/articles/elon-musk-launches-neuralink-to-connect-brains-with-computers-1490642652.
43. Constine J. Facebook is building brain-computer interfaces for typing and skin-hearing. TechCrunch. 2018. https://techcrunch.com/2017/04/19/facebook-brain-interface/.

COMMENT

Over the last 20 years, neurotechnology has become big business, and quite recently has attracted the interest of large companies like Facebook and Google. In this paper, Roskams-Edris and colleagues raise attention to how a changing landscape of medical patents can influence how neuromodulation discovery and treatment opportunities may emerge in the future.

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Comments not included in the Early View version of this paper.

