

Brain modulation and patent law

Andreas Kuersten¹ & Anna Wexler²

¹United States Court of Appeals for the Federal Circuit, Washington, DC, USA. ²Department of Medical Ethics & Health Policy, University of Pennsylvania, Philadelphia, Pennsylvania, USA.

e-mail: andreas.kuersten@gmail.com

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To the Editor: Neurotechnologies aimed at directly influencing the brain are advancing at a considerable rate. Correspondingly, as shown by Roskams-Edris *et al.*¹, the number of approved patents related to methods for direct brain modulation in the United States has increased considerably over the last two decades. But Roskams-Edris *et al.*¹ argue that such patent rights should not be permitted. We respectfully disagree.

Roskams-Edris *et al.*¹ begin their analysis by flagging the possible problem of overbreadth associated with the patents in question, and patent 9,327,069, which they cite, is an excellent example of such a potential issue². The patent claims, within broad parameters, a method for electrically stimulating numerous brain regions for the purpose of treating a litany of neural maladies. The legal rights carved out are such that those seeking to therapeutically influence the brain with electrical current may be hard-pressed to avoid infringement. Yet, the authors only cite three patents when making their overbreadth argument: two they claim to be overbroad (including patent 9,327,069)³ and one appropriate in scope⁴. Given that they sifted 297 “patents implicating brain regions” from 1976 to 2015, a mixed sample of three hardly illuminates a systemic problem.

Nevertheless, Roskams-Edris *et al.*¹ build on the aforementioned observation to argue that overbroad or numerous “interlocking” patents on methods for stimulating brain regions could functionally result in monopolies over these ostensibly unpatentable areas. “[T]he claim that the brain region itself is not patented,” they state, “would seem to be only an illusory technical-legal one.” The authors then proceed to equate the method patents in question with patents on brain regions, analogizing them to patents on naturally occurring gene sequences, which the US Supreme Court ruled to be unpatentable subject matter in 2013 (ref. 5). But this analogy is flawed. Although patents on naturally occurring gene sequences are barred, method patents covering gene isolation and manipulation techniques are legal as a general matter, and do not functionally claim specific genes. Accordingly, the patenting of one method for influencing a region of the brain does not foreclose the application of other treatments to that region. It also does not generally foreclose the patented method, for two reasons.

First, it is the rare inventor who bothers to invest the money and time necessary to develop a method and obtain a patent without subsequently seeking to recoup those outlays by offering her creation to the public in some way. Second, “medical practitioners” are legally immunized against liability for the “performance of a medical activity that constitutes an infringement.”⁶ Roskams-Edris *et al.*¹ therefore interpret patents covering methods for influencing the brain to be something they are not—patents on naturally occurring brain regions—to argue against their existence, an argument that would seem to preclude method patents aimed at anything naturally occurring, a radical proposition indeed.

Moreover, Roskams-Edris *et al.*¹ present the US patent regime in a one-dimensional manner, as simply providing patent owners with legal rights to their creations to the exclusion of others. The authors argue that this stifles innovation and use. But the system results from language in the US Constitution empowering Congress “to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.”⁷ The regime’s purpose is the stimulation of innovation and use, and, in practice, involves a quid pro quo: “The federal patent system ... embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years.”⁸ Thus, in the words of the Supreme Court, “the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure” and thereby facilitate innovation as actors build on and invent around the publicly available work of others⁸.

Without patent rights, inventors would have less incentive to invest in research and the creation of new technologies, designs and methods because they would be less assured of recouping costs and reaping further financial reward⁹. They would also be encouraged to keep their discoveries secret, thereby denying the public access to products and information and materially hindering advancements that could be made by others. The authors offer no reasons why this system might uniquely fail with regard to the method patents in question.

Finally, Roskams-Edris *et al.*¹ note “the special position of the brain in the architectural framework of cognitive and mental process” as an additional rationale for treating method patents on brain-influencing techniques with added caution. They do not, however, address patents on pharmacological agents that can also dramatically influence cognition and mental processes. Perhaps the authors believe this omission is subsumed in their subsequent proposition for an entirely new patent system for all health care-related innovations: “Taking the view that health care is a moral endeavor, an intellectual property (IP) regime that better indexes compensation to actual health outcomes rather than to global

demand and market share is more palatable.” But how does one define a health care–related innovation? And patent law does not index compensation. Rather, it provides a period of exclusivity to owners, upon whom it is incumbent to realize any financial gains. Are the authors proposing a state-run prize system to incentivize innovation, as opposed to a patent system (see, for example, ref. 10)? Accordingly, their novel healthcare patent regime is underconceptualized, given the extreme changes it portends, and their preceding argument that the “special position” of the brain warrants barring patents covering methods for influencing it is unconvincing.

Roskams-Edris *et al.*¹ ultimately “conclude that the increasing trend toward brain-related patent rights likely introduces more risk than benefit to individuals and society,” and that such rights should not be permitted. But given the deficiencies in their arguments recounted above, we are unable to agree with this conclusion. Method patents covering techniques for influencing the brain certainly raise interesting issues, but addressing them requires greater analytical refinement and more engagement with pertinent court opinions and legal literature.

COMPETING INTERESTS

The authors declare no competing interests.

Andreas Kuersten¹ & Anna Wexler²

¹*United States Court of Appeals for the Federal Circuit, Washington, DC, USA.* ²*Department of Medical Ethics & Health Policy, University of Pennsylvania, Philadelphia, Pennsylvania, USA. e-mail: andreas.kuersten@gmail.com*

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