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.

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- Roskams-Edris, D., Anderson-Redick, S., Kiss, Z.H. & Illes, J. Nat. Biotechnol. 35, 119–121 (2017).
- 2. Foster, A.M. et al. US patent 9,327,069 (2006).
- 3. Wagner, T.A. et al. US patent 9,050,463 (2015).
- Krueger, R. & Weiss, D. US patent 9,283,378 (2012).
 Association for Molecular Pathology v. Myriad Genetics,
- *Inc.* 569 U.S. 576 (2013). 6. 35 U.S. Code §287(c).
- United States Constitution, Article I, Section 8, Clause 8.
- 8. Bonito Boats, Inc. v. Thunder Craft Boats, Inc. 489 U.S. 141 (1989).
- 9. Kewanee Oil Co. v. Bicron Corp. 416 U.S. 470 (1974).
- 10. Abramowicz, M. *Vanderbilt Law Rev.* **56**, 115–236 (2003)

Illes et al. reply: Kuersten and Wexler¹ raise several important points in response to our 2017 paper². Overall, we agree and recognize that the US patent system can promote the translation of science into invention. We applaud successes it has had in this regard. At the same time, we respect the position of other countries in declining pathways for medical method patents in light of concerns that they may interfere with the skill and judgment of physicians who would be forced to consider infringement when making treatment decisions or prevent scientists from advancing their fields (for example, ref. 3).

If the authors are troubled that we may be playing on both sides of the fence here, we clarify that we did not intend either to promote a new patent system or to argue that patent rights for techniques of modulating brain regions should not be permitted. Although Kuersten and Wexler¹ equated our argument to pharmacological agents for depression, what we commented on is more akin to claims of ownership over all possible pharmaceutical compounds that could affect one or more brain regions. That is a big catchment area. Similarly, we raised the analogy to patenting gene sequences not because patents on methods of modulating a brain region are equivalent, but because granting a large number of poorly defined and interlocking patents may have the same effect as patenting a brain region. This would be comparable to

patenting a naturally occurring gene sequence without the corresponding benefit of developing novel therapeutic technologies based on the interlocking patents.

The authors take issue with our choice of only three cases in support of our arguments. We note that the three we selected provide balanced examples of egregious, moderate and relatively acceptable patents that involve the brain. We deliberately did not provide a quantitative analysis of patents other than to document their exponential growth in number, especially in view of the many nonmedical actors coming onto the landscape with relevant applications. As Kuersten and Wexler¹ point out, some may overreach. In our opinion, even one overreach in this context is too many.

Ultimately, the authors miss the critical point of our paper: patents that refer to a loosely interconnected and unfettered list of applications and brain regions undermine, rather than promote, the potential benefit of an invention to users and recipients. We firmly believe that patents that are not clearly explained and entail overly broad claims, where litigation would be required to determine the precise meaning, will create roadblocks to innovation rather than pathways to promote it. We reiterate that we are not opposed to the protection of intellectual property as allowed by law; we uphold our objection, however, to runaway uses of the patent instrument that imply neuroscientific certainty where it does not exist, that pathologize behaviors that are not pathological only to create new conditions for commercial potential, and that place the interests of financial gain over respect for persons and the interests of patients.

We suggest that, rather than dismissing the issues that our interdisciplinary effort raised, legal scholars, ethicists, members of the neuroscience specialties and representatives of industry partner to use their complementary expertise in a timely way to prevent any further downward slide on this slippery patent slope. Indeed, as we suggested, proactive guidance from within the professions is essential to achieving this goal. Jointly and collaboratively, we can, if not ought to, push for better evidence to support patent claims and for patent examiners who are better trained to deal with brain-related claims. We predict that if these goals are not achieved, external restrictions will be placed on patents for nervous system input-output technologies over internally self-regulated systems that can far more desirably and effectively advance ethically and legally sound science and innovation.

COMPETING INTERESTS

The authors declare no competing interests.

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- Kuersten, A. & Wexler, A. Nat. Biotechnol. 37, 18–19 (2019).
- Roskams-Edris, D., Anderson-Redick, S., Kiss, K. & Illes, J. Nat. Biotechnol. 35, 119–121 (2017).
- Canada Intellectual Property Office. Decisions of the Commissioner of Patents – Summary of Decision Number 1343. http://www.ic.gc.ca/opic-cipo/comdec/ eng/decision/1343/summary.html?pedisable=true (2013).

Ten ways in which He Jiankui violated ethics

To the Editor: In late November, the world learned that He Jiankui, an associate professor at the Southern University of Science and Technology in Shenzhen, China, had edited human embryos, at least two of which were brought to term through an *in vitro* fertilization (IVF) pregnancy. At the time of writing, the data describing these experiments had yet to be peer reviewed. Irrespective of the problematic nature of science by press announcement, the methods, timing and procedures

used by He in his clinical trials violate several ethical norms, including international consensus guidelines, national regulations and well-established principles of bioethics. He is not a medical doctor, but rather received his doctorate in biophysics and did postdoctoral studies in gene sequencing; he lacks training in bioethics, responsible conduct of human research, or a background in evolutionary biology that might have informed him of some of the glaring deficiencies in his work.