Can patents help regulate future experimentation with designer babies?

By Daniel Mak

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Jiankui He, an associate professor of bioengineering who is currently on leave from Southern University of Science and Technology, in Shenzhen, China, has claimed to be the first to successfully bring to life two genetically-edited twin girls, Lulu and Nana. The objective was to prevent the twin baby girls from acquiring HIV infection by modifying their genes.

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Jiankui He's team carried out this procedure using the CRISPR-Cas9. Named breakthrough of 2015 by Science magazine, CRISPR-Cas9 is a gene-editing tool that holds the promise of potentially fixing diseases by precisely cutting and pasting specific gene(s) among the 20,000 human genes.

In this case, by injecting CRISPR-Cas9 into a human egg and implanting the genetically-edited embryos back into the mother, Jiankui He's work specifically targets the CCR5 gene that is responsible for producing a protein that HIV uses to invade the white blood cells. Specifically, his research has knocked out this gene to render the HIV virus unable to infect and confers resistance to the disease.

These claims, which were posted in YouTube videos, are under investigation and have yet to be independently verified. Furthermore, Jiankui He's recent public appearance at the Human Genome Editing Summit at the University of Hong Kong further surprised the world by announcing that a potential second pregnancy is on the way.

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Jiankui He's work has ignited criticism from gene-editing communities around the world. One of the reasons for the swift outrage from the scientific community is that not only was Jiankui He's work illegal and conducted in secrecy; the risk of irreversibly modifying the human genome may far outweigh the potential benefit. The possibility of either introducing unwanted mutations that may adversely affect other cells in the body resulting in cancer development, or yielding an

individual with cells that are partially edited is not unwarranted. Furthermore, there is also the inherent risk of these individuals, with the mutated CCR5 gene, becoming susceptible to other diseases such as the West Nile virus.

Some critics say that the choice of editing CCR5 could also prove controversial. The attempt to damage normal copies of the CCR5 gene in an otherwise healthy embryo to lower the risk of future possible HIV infection, raises ethical concerns of whether the procedure is considered as a treatment or an enhancement. In particular, the procedure does not provide a benefit in curing any disease or disorder that that the embryo may have, but rather creates a disease-prevention benefit similar to that of a vaccine.

While the CRISPR technology has the potential to induce changes to the embryo's DNA, it is also a platform that has applications in many different sectors. However, in order to recognize how CRISPR may be employed, there remain many issues that need to be addressed. One of the issues resides in resolving the intellectual property dispute between the University of California, Berkeley and the Broad Institute concerning CRISPR patents.

Patents provide the right to the proprietor thereof to exclude others from making, using, selling and importing the patented invention. In the case of CRISPR, the patent holder may dictate how licensed parties use the invention to limit the unethical behaviour by providing access to downstream inventions as well as preventing potential abuses, such as the controversial practise of forcing future generations to inherit and subsequently pass on modified genes.

However, in the case of the Jiankui He's work, whether the mutated CCR5 gene may bring about unintended negative effects to the twin girls, as well as future generations, remains to be determined. To that end, it has been proposed that when used well, patenting the use of the CRISPR technology, at a minimum, is one possible tool that can play an important role in governing the ethical use of the invention.

From here, how we approach the issue regarding the editing of human genes will be crucial. The fact that several babies exist with modified genes, means that the world has now entered into the uncharted territory of science and bioethics. Nevertheless, Jiankui He's study has inevitably opened the floodgates that could find more scientists coming out with similar experiments. In the meantime, patents readily exist as a tool that could help regulate the use of the genome-editing techniques on humans, while more formal guidelines are currently being developed.

ABOUT THE AUTHOR

Daniel Mak is a Candidate Attorney at KISCH IP and has experience in Medical science with a focus towards molecular biology and virology, genetics, cancer epidemiology research.