Biohacking Patent Law

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Biohacking includes a diverse variety of science experiments such as tracking of sleep and diet, under-skin implantation of computer chips and other technology, ingestion of "smart drugs" and sub-clinical levels of LSD, transplantation of gut and skin microbiomes, infusion of "young blood" to reverse aging, and genetic modification of bacteria, yeast and human cells. At its core, biohacking is the concept of bringing science out of the laboratories of academia and industry and into the grasp of citizen scientists. These experiments may be conducted in garage laboratories, but there are also community laboratories springing up across the country that allow interested people to have space to conduct biology experiments without having to build a home laboratory.

Many of the reagents and methodologies used in biohacking are patented. One prominent example is the genetic modification technique, CRIPSR. In addition to being a groundbreaking molecular biology process that has revolutionized the ability to engineer genomes with relatively simple tools, CRISPR has also been the subject of a drawn-out patent battle and several large patent licensing deals. Lots of money has been invested in the development and intellectual property protection of CRISPR.

Therefore, in addition to the myriad of regulatory hurdles that biohackers must face, they may also liable for patent infringement by performing patented methods. It is true that patent holders are unlikely to sue individuals infringing in a garage. However, biohackers buy supplies and laboratory kits and manuals that are growingly being marketed to the biohacker community. The sale of these products, while not themselves infringing, may open the seller to contributory or inducement liability if the end user infringes. This increased potential for liability could limit the resources available to biohackers and in turn limit access to science.

This article seeks to describe the scope of this patent problem and formulate solutions. One potential solution is the use of the experimental use exception (EUE) defense to patent infringement. The two forms of the EUE defense – common law and statutory – have very different applications. The statutory EUE defense is based on an intersection with regulatory approval that may be inapplicable to most biohackers since most regulatory approvals are often tied to potential commercialization. The common law EUE defense relies on the infringing use have no business purpose; however, its application has been severely curtailed over the past twenty years. Therefore, this article disentangles the potential uses of each EUE defense by the biohacking community and re-integrates them into a solution to aid in the growth of community access to science.