

Beyond Recombinant Technology: Synthetic Biology and Patentable Subject Matter

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Even though it is not yet clear as a matter of law that isolated biological materials are indeed patentable subject matter, patents over such materials continue to be granted throughout the world. Recently, Craig Venter, the man who wanted to patent the human genome, made history again. This time he has built a synthetic bacterium from the ground up—in a laboratory. The bacterium, *Mycoplasma genitalium*, is a naturally occurring thing. It is the smallest known bacterium consisting of 582,970 nucleotides. Venter's version of this bacterium is identical, except that he made it. Does this make it an invention? Indeed, Venter has in mind to use this synthetic bacterium, and other synthetic biological materials, as plasmids within which to insert genetic material that is foreign to that organism. The idea is to use these plasmids to manufacture other biological materials. It is a repeat of Cohen and Boyer's idea, which they also patented, but this time the plasmid itself will be a human construct. Is the patent system ready for Venter and his "invention"?

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One hundred years after Louis Pasteur, the famous French chemist and microbiologist, was granted a US patent over an improved beer-making process, which included a claim to purified yeast,¹ Stanley Cohen, an associate professor of medicine at Stanford University, and Herbert Boyer, a biochemist at the University of California, San Francisco, discovered that it was possible to cut DNA (made of nucleic acids) from the genome of one organism and splice it into the genome of another (called a plasmid) and have that plasmid produce the protein (consisting of amino acids) coded by that DNA (Cohen *et al.*, 1973; Morrow *et al.*, 1974). Their discovery, like Pasteur's discovery of "pernicious germs", was so revolutionary that it changed scientific thinking forever, contributing to a body of knowledge that finally enabled scientists to adapt nature's processes to the manufacture of biological materials in vast quantities and with a purity that was hitherto thought impossible. They were acknowledged as inventors on a US patent,² and although it was their university, not them, that received millions of dollars in royalties,³ Stanford never exercised its patent rights to exclude others from using the "invention" made possible by their discovery (Hughes, 2001). Rather, the university's policy of non-exclusive licensing enabled Genentech, a company that Boyer co-founded,⁴ to go on to use the patented technique or method to develop and patent bacterial plasmids containing the genetic material of the human gene that encoded