



Backgrounder: J. Craig Venter Institute's patent application on World's First Human-Made Species

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On 31 May 2007 the US Patent & Trademark Office (US PTO) quietly published a remarkable patent application that signals a major break with evolution as we know it. US Patent application number 20070122826, entitled "Minimal bacterial genome," describes the laboratory creation of the first-ever entirely synthetic living organism (or 'syn') – a novel bacterium whose genetic information is constructed from chemically synthesized DNA.¹ It claims exclusive ownership of a "*free-living organism that can grow and replicate*" made from a set of essential genes also claimed in the application. The existence of the patent application isn't proof that the synthetic organism functioned at the time of the filing (October 12, 2006); however, the applicants are confident enough of their process to pursue exclusive ownership of it – publicly and legally. The patent assignee is the US-based scientific institute led by genomics mogul J. Craig Venter. An international patent application has also been filed at the World Intellectual Property Organization (number WO2007047148, published April 27, 2007). ETC Group, an international civil society organization based in Canada, will challenge the patent application.

What is a Synthetic Organism? A Synthetic organism (or syn) is the result of "extreme genetic engineering." Syns differ from genetically modified organisms (GMOs), where sections of DNA from one naturally-occurring organism are inserted into another naturally-occurring organism (taking a section of DNA from a soil bacterium and inserting it corn, for example). Syns aren't just about substituting a few ingredients in the recipe of life – they are making the ingredients from scratch in a laboratory and combining them in unprecedented ways. If researchers at the J. Craig Venter Institute are on the cusp of manufacturing the world's first living, fully synthetic organism as described in this patent application, it will also be the first human-made species in history. In the patent application, this "original syn" is given the taxonomic name, "*Mycoplasma laboratorium*." In the tradition of naming groundbreaking genetic creations (e.g., "Dolly" the cloned sheep), ETC Group has dubbed this laboratory life-form "Synthia."

Synthetic biologists have already synthesised fully working viruses including a deadly flu virus and poliovirus (viruses are not considered living organisms because they require a host to replicate).

How was Synthia made?

Craig Venter first announced the project to build a synthetic life form in 2002.² His colleagues Clyde Hutchison and Nobel Prize winner Hamilton Smith (who are named as inventors on the patent) removed genes from an existing bacterium found in the genital tract (*Mycoplasma genitalium*) in order to determine the smallest set of genes necessary for a living organism – a basic recipe for life. According to the patent application, these 381 genes are then synthesized and inserted into a “ghost cell” – a bacterial cell whose genetic material has been removed. The cell is then cultured in a nutrient-rich broth (known as SP4 composed of yeast extract and fetal cows’ blood). It is not clear from the patent application whether the applicants have successfully achieved all of these steps. They have nonetheless claimed monopoly ownership of the final organism.

What will Synthia be used for?

Venter and his colleagues have described their syn as a basic platform or “chassis” for building other industrially-useful synthetic organisms, acting as the genetic equivalent of a computer operating system such as Microsoft Windows. In theory, by adding functionalised synthetic DNA cassettes, the bacterium could be instructed to produce plastics, drugs, fuels or even bioweapons. The patent application specifically claims an organism that can make either hydrogen or ethanol for industrial fuels. In a recent interview in *Newsweek* Venter boasted, “If we made an organism that produced fuel, that could be the first billion- or trillion-dollar organism. We would definitely patent that whole process.”³ In 2005, Venter founded Synthetic Genomics, Inc. to commercialize synthetic microbes for use in energy, agriculture and climate change remediation.

What does the patent application claim?

US Patent application no. 20070122826 claims exclusive monopoly on:

- A set of genes that make up a “minimal bacterial genome.”
- The synthetic organism made from those genes.
- Any version of the organism that can make ethanol or hydrogen.
- Any method of hydrogen or ethanol production that uses such an organism.
- A scientific method for testing gene function by inserting other genes into a syn organism.
- A digital version of the organism’s genome.
- A set of non-essential genes. The patent claims ownership of a syn organism lacking in certain genes that the inventors have identified as “non-essential.”

The breadth and fundamental nature of the claims in this patent application indicate that Venter’s enterprises are positioning themselves to be the Microsoft of synthetic biology, putting foundational technologies under monopoly ownership and control.

Does this open the way to Syn plants, Syn animals and Syn people?

In theory, yes. In 2004 Craig Venter predicted that “engineered cells and life forms will be relatively common within a decade.”⁴ According to synthetic biologist Drew Endy of Massachusetts Institute of Technology (MIT): “There is no technical barrier to synthesising plants and animals, it will happen as soon as anyone pays for it.”⁵ Indeed, in a recent interview (November 2006) Endy predicted that it should be possible to synthesise an entire human genome within a decade.⁶ Craig Venter is known for a series of breakthroughs related to commercial genomics. In 1996 he was the first person to sequence (decode) a bacterial genome. Five years later he led the commercial race to decode the entire human genome. If not checked by society it seems likely that the creation of *de novo* synthetic organisms will advance at a similar pace.

How will synthetic organisms be controlled and regulated?

Synthetic biology is being developed without proper societal debate concerning socio-economic, security, health, environmental and human rights implications. Venter and his colleagues are accelerating the science of artificial life long before society has had a chance to properly discuss or assess its implications. Environmentalists worry that synthetic microbes will have unforeseen ecological impacts if intentionally – or unintentionally – released. Security experts are concerned that synthetic biology now enables rapid design and production of previously inaccessible bio warfare agents. In 2006 a coalition of 38 civil society organizations called on synthetic biologists to withdraw proposals for self-governance of the technology and begin an international dialogue with society. Many of the companies and scientists propelling synthetic biology will be meeting from 24-26 June in Zürich, Switzerland at Synthetic Biology 3.0 conference. ETC Group will speak at the event.

For more background information on Synthetic Biology see “Extreme Genetic Engineering – An Introduction to Synthetic Biology,” ETC Group (January 2007), available here: www.etcgroup.org/upload/publication/602/01/synbioreportweb.pdf

See also, the text of the open letter from civil society organizations to synthetic biologists, 19 May 2006, available here:

www.etcgroup.org/en/materials/publications.html?pub_id=8

¹ The patent application is available at www.uspto.gov. Search for published application number 20070122826.

² See Clive Cookson and David Firn, “Breeding bugs that may help save the world: Craig Venter has found a large project to follow the human genome,” *Financial Times* (London), September 28, 2002.

³ J. Craig Venter quoted in interview with Barrett Sheridan, *Newsweek International*, 4 June 2007, available on the Internet: <http://www.msnbc.msn.com/id/18882837/site/newsweek/>.

⁴ Dan Ferber, “Microbes Made to Order,” *Science*, 9 January 2004: Vol. 303. No. 5655, pp. 158-161.

⁵ ETC Group, interview conducted with Drew Endy, Boston, 6 October 2006.

⁶ Podcast, “Futures in Biotech 8: Drew Endy on Synthetic Biology,” 9 November 2006, available online at <http://www.twit.tv/fib8>