FEATURES

Synthetic biology in Africa: time to pay attention

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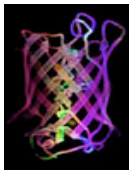
2010-10-07, Issue 499

http://pambazuka.org/en/category/features/67538



Synthetic biology – the design and engineering of biological components that can be used to construct a variety of biological systems – is a hot scientific topic. But with enormous implications for human health, Gareth Jones and Mariam Mayet ask when the very real ethical concerns associated with the technology will be debated.

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'…[synthetic biology] is broadly understood as the deliberate design of novel biological systems and organisms that draws on principles elucidated by biologists, chemists, physicists and engineers…in essence it is about redesigning life.' [1]

The emerging field of synthetic biology has been making waves in the global scientific community recently. Earlier this year, Craig Venter, the doyen of the genomics world, claimed that his company had created the world's first self-reproducing organism.

Scientists have proclaimed that the discipline is on the cusp of opening doors to almost limitless supplies of agro-fuels and pharmaceutical compounds. The ethical implications of this new technology are considerable, as not only will it ultimately offer the potential to create biological systems and organisms that do not occur in nature, but scientists have already been able to synthesise several lethal human pathogens and viruses.[2] However, according to an EU High Level Expert Group (HLEG) on synthetic biology, 'it seems likely that we do not as yet possess a conceptual ethical framework that can provide a common context for such debates.'[3]

As definitions of synthetic biology depend upon the scientific approach taken or the final application of a given project, a standard classification has remained elusive. However, it is generally accepted that the discipline utilises principles drawn from multi-disciplinary fields, including nano-technology, biology, physics, chemistry and genetic engineering, to design and engineer biological components that can be used interchangeably to construct a variety of biological systems. These systems could be constructed for a variety of uses, ranging from the production of pharmaceuticals, chemicals, hydrocarbons and food.[4]

Funding of synthetic biology

Research carried out by the Synthetic Biology Project [5] has revealed that there are currently over 180 organisations in the United States and a further 50 in Europe that are involved in synthetic biology research, development and commercialisation. The current annual research market for synthetic biology is worth an estimated US$600 million, a figure that could potentially exceed US$3.5 billion over the next decade. Other projections from the industry go even further, with one postulating that as much as 20 per cent of the $1.8 trillion global chemical industry could be dependent on synthetic biology by 2015.[6]

Since 2005, research related to synthetic biology has received approximately US$430 million from the US government, while the European Union (EU) and the governments of Germany, the Netherlands and the United Kingdom have spent in the region of US$160 million.

The United States Department of Energy (DOE) is by far the biggest individual source of research funds, with conservative estimates putting its largesse at US$350 million over the period (which could be as high as US$700 million). The US Department of Defence is also reported to have committed US$20 million of its gargantuan budget for 2010/11 towards synthetic biology research, though further information is unavailable to the public.

Synthetic biology was earmarked as a priority research area in the EU back in 2003 and US$53 million in funding has been approved since then. The UK government is estimated to have spent between US$30 million and US$53 million since 2005. In 2008, three Dutch universities (Delft University of Technology, University of Gronigen and the Eindhoven University of Technology) announced an investment plan of US$90 million over the next five to ten years.[7]

Just four per cent of US research spending since 2005 has been devoted to the ethical, legal and social implications of synthetic biology. In Europe the figure is even lower, a paltry two per cent. Most disturbingly, not a single research grant dedicated to the risk assessment of synthetic biology can be identified.[8]

Private funding for synthetic biology research is directed overwhelmingly towards agro-fuel applications, with big-oil leading the way. In 2009, Exxon Mobil, in its first major investment in agro-fuels, entered into a US$600 million partnership with Synthetic Genomics to develop transportation fuels from algae.[9] In 2007, BP announced a US$500 million research agreement with the University of California, Berkeley (UCB), to develop synthetic agro-fuels.[10] Amyris biotechnologies, the company established in 2003 by Professor Jay Keasling, the principle investigator on

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the UCB's artemisinin project, recruited the former head of US fuels at BP to be its first CEO. Its largest stockholder is the French oil and gas giant Total.

This flood of capital into the field has, in the view of at least one professor of biomedical engineering, diverted skills and focus from areas where the discipline could potentially benefit the wider public.[11] The parallels with the genetic engineering of food crops could not be more striking. For the last decade highly lucrative GM commodities such as maize and soy (that are predominantly used to feed the animals raised in industrial agricutural production, which in turn feed the global minority who can afford that meat) have been bringing in record profits for the global agro-seed-and chemical complex. Over the same period the deluge of 'benefits' that were set to emancipate the wretched of the earth from hunger and poverty have failed to materialise.

Malaria, artemisinin and synthetic biology - another 'African saviour'

Ten years ago, when genetic engineering was still in its commercial infancy, its proponents held up the example of 'Golden Rice', genetically engineered for higher Vitamin A content, to dismiss any concerns or calls for precaution regarding the technology. At present, with Golden Rice still not commercially available, a whole new batch of 'climate ready' crops have been promised that will safeguard our future food supplies in the face of increasing climatic instability.

Undoubtedly, Synthetic Biology's own poster project has been the joint research carried out at UCB to create synthetic artemisinin, a key anti-malarial drug. The research began in 2004 and is a joint effort of UCB, the Institute for OneWorld Health (iOWH) and Amyris Inc, a private genomics company established by lead investigator Professor Jay Keasling. Initial funding of US$42.6 million was provided by the Bill and Melinda Gates Foundation (BMGF). It was announced in July this year that the project was ready to move beyond its development phase into full commercialisation, in partnership with French pharmaceutical giant Safoni Aventis and with the aid of a further US$10.7 million grant from the BMGF.[12] It was previously hoped that this would be available by 2009 or 2010.[13]

Malaria, artemisinin and ACTs
The World Health Organisation (WHO) estimates that half of the world's population is at risk of malaria. The WHO recommends that artemisinin-based combination therapies (ACT) are at present the only remaining effective treatment for uncomplicated malaria, and claims that the appropriate use of ACTs works in more than 90 per cent of cases. [14]

By 2009, ACT has been adopted by 80 countries globally as a first-line treatment of uncomplicated P.falciparum malaria.[15] Procurement of ACT doses by the WHO has risen rapidly in the last decade, from 500,000 in 2001 to 160 million in 2009.[16]

The only known wild source of artemisinin is the A. annua plant, which is endemic to China. Its sister species, Artimisia Afra, grows in the wild in South Africa, but does not produce artemisinin itself. Since the discovery of artemisinin as an anti-malarial compound in the 1970s, A.annua has been cultivated in China and Vietnam. In the 1990s, cultivation spread to Africa.[17] The plant takes six to eight months to mature between planting and harvest and the total production cycle can exceed 14 months. Once manufactured most ACTs have a shelf life of 24 months or less, which presents significant logistical constraints, especially in countries where demand forecasting and storage facilities are limited.

Globally, a significant portion of the supply of artemisinin based anti-malarial medicines comes from countries with new, fast-growing pharmaceutical industries, notably China, India, Pakistan and Vietnam, but also many African countries including Ghana, Kenya, Nigeria, Togo, Uganda and Tanzania. A study by the Dutch Royal Tropical Institute concluded that it is possible to cultivate sufficient artemisinin to cure all the malaria patients in the world and that an ACT could be made available at an affordable price within two to three years (writing in 2006). However, achieving this would require significant investment, as well as a complete overhaul of the supply and distribution chain.[18]

In addition, the authors of the aforementioned study were of the opinion that the 'slow and cumbersome implementation of the WHO's 'pre-drug qualified policy' has resulted in a monopoly like situation. Only six companies [19] own a pre-qualified ACT, meaning the retail price is prohibitive for the majority of those who are exposed to threat of malaria on a daily basis.
This is a problem throughout the global pharmaceutical sector and is not just restricted to the case of malaria. In 2009, the pharmaceutical industry accounted for nine of the world's top 50 most profitable companies, with only the financial sector and oil and gas having a larger representation. In 2009, the profits of these nine corporations (in the middle of the greatest contraction in the world economy since the great-depression) were an eye-watering US$83 billion.[20]

The fact that ACTs are still not widely available in malaria endemic areas supports the position in developing countries that the local production of artemisia may be preferable to relying on synthetic production, for both access to its medicinal benefits and for the livelihoods its local cultivation sustains. The cultivation and extraction (with ethanol for example) of A annua can already be done with relative ease in developing countries.

Artemisinin cultivation in Africa

After China and Vietnam, East Africa is now the third most important growing artemisinin region in the world.[21] The high altitude, high light intensity (due to its proximity to the Equator) and cool night temperatures are all conducive to the successful cultivation of A. annua, though poor logistics and lack of market integration have been cited as potential hindrances.[22] That said, a fledgling commercial sector has emerged in Kenya, Tanzania and Uganda. It has been dominated by the activities of one holding company, Advanced Bio-Extracts Ltd (ABE) and two main subsidiaries: East African Botanicals (EAB), Ltd. in Kenya and African Artemisia Ltd. (AA) in Tanzania. In 2005, Novartis made a bridging loan of US$14 million to ABE, largely for expanding processing capacity, and pledged to purchase a significant proportion of production.[23]

In Kenya, where commercial cultivation started in 2002, with just three to four

farmers on 40ha, by 2010 over 7,500 farmers were making their livelihoods from it.[24] One of the advantages, cited by farmers, is that they are less dependent on expensive chemical inputs such as fertilizers and pesticides when compared to more traditional food crops such as maize or wheat.[25] In Uganda, a joint venture between a local company and Indian pharmaceutical giant Cipla is set to take off, with the WHO recently pre-qualifying the processing plant set up to extract artemisinin from locally cultivated A. annua. Cipla has already opened a letter of credit covering a full year's purchase of artemisinin, which will be exported to India to be used in the manufacture of ACTs.[26]

This local cultivation and transformation of artemisinin is threatened by expansion of its synthetic production elsewhere. Following the increase of production to a commercial scale, Sanofi-aventis will now produce synthetic artemisinin in 100,000 litre vats. [27] Details as to where this will take place are scarce, but given that the infrastructure is already in place in California, home to Amyris and the UCB, or indeed Paris where Sanofi-aventis is headquartered, it seems unlikely that Africa would be chosen as a site for capital investment.

If synthetic artemisinin is to be produced in huge vats in the industrialised North, will these new supplies of artemisinin be used to smooth out fluctuations in supply and demand (and therefore price), or will they completely undermine a fledgling industry that is developing in African countries? Issues around intellectual property are also likely to come more to the fore. The resources that Amyris and other Northern players have at their disposal will make this area a virtual non-contest unless sufficient public attention can be drawn to the issue, such as the civil society pressure on the pharmaceutical industry to provide cheap HIV/AIDS drugs for patients in South Africa.

Recent advances in plant breeding have also created hybrid Artemisia strains that can yield up to three times as much artemisinin as their wild counterparts. These plants are now being grown and harvested commercially in Madagascar, and are on trial in South Africa, Uganda and Zimbabwe.[28] What will the fate of this research be, if synthetic artemisinin can be ordered directly from the laboratory? As has been the case in genetic engineering, will the concentrations of expertise and capital divert valuable research funding and ideas into a few high profile 'silver bullets'?

Implications for Africa

As far as we know, there are no national, regional nor international biosafety rules in place to regulate synthetic biology in the world today, despite its ability to have far reaching implications for humanity and the natural world. Nevertheless, the issue is being discussed at international fora, including the Convention on Biological Diversity. At the 14th meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA14), synthetic biology was specifically debated. The report of SBSTTA 14 [29] contains several references to synthetic biology, in square brackets, including a de facto moratorium on the release of synthetic life forms.[30] However, square brackets means that it has not achieved unanimous agreement and will be further discussed at the 10th ministerial meeting of the UN Convention's Conference of the Parties (COP 10) that will take place in Nagoya, Japan between 18 and 29 October 2010.

Although the issue is on the international agenda, it is doubtful whether the proposed moratorium will survive in the face of the huge financial and strategic interests at stake. At the very least, those concerned with the implications of this technology for society and the environment may be able to obtain some form of rules and procedures to govern the use of the technology. Even this route will be highly contested and bitterly fought by those set to benefit the most.

The potential impact of synthetic biology on the African continent requires extensive public debate in an open and transparent manner. Valuable lessons must be heeded from prior experiences where exogenous technology has been imposed on the continent, without there being enough public engagement and adequate local authority and capacity to regulate it.

For the most appropriate example in this instance, one need look no further than what has been happening with biotechnology using genetic engineering techniques in Africa.

Currently, only three countries on the African continent commercially produce genetically modified crops: Burkina Faso, Egypt and South Africa.[31] This has not stopped a deluge of 'capacity building' initiatives, funded in the main by the biotech industry and their PR shock troops at organisations such as USAID and the Gates Foundation, throughout the continent.

While ostensibly the modus operandi of these initiatives is to help Africa to feed itself, in the absence of domestic biotechnology expertise it also conveniently provides the opportunity for the shaping of the biosafety discourse to suit the technologies' developers and others that stand to benefit from the use of the technology.[32] Further, the gains made at the multilateral level for the safe governance of biotechnology, through the Cartagena Protocol on Biosafety, are being undermined by efforts to 'harmonise' biosafety legislation across Africa through its regional economic communities (RECs). For example, from a recent draft GMO policy document from the Common Market for Eastern and Southern Africa (COMESA), it was patently clear that the architects of the policy had close ties to an industry that would benefit enormously should such policies come to fruition.[33]

Conclusion

Synthetic biology offers yet more currency to the hubris that man is 'master' of his environment. Yet this mastery comes with a heavy responsibility. The potential to produce almost limitless amounts of cheap medicine and clean fuels must be tempered by the fact that the technology is still in its infancy, and that its real consequences cannot yet be predicted with any great certainty. As is the case with food, abundance alone does not guarantee availability. Will the provision of anti-malarial drugs be more effective in a centralised system, where a few companies exert exclusive control, or in a more nuanced fashion, where locally source material can be quickly and efficiently processed and distributed to those in most

need?

To date the real money in synthetic biology appears to be following its energy potential, with the world's largest oil companies having already sunk hundreds of millions of dollars into the field. South Africa appears to be banking on the technology as a means to cement its place inside this global event. This unbridled enthusiasm, however, has taken place largely beyond public scrutiny or awareness of what is really and truly at stake.

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* Please send comments to editor@pambazuka.org or comment online at Pambazuka News.

NOTES:

[1] European Commission (2010). 'The Ethics of synthetic biology.' Luxembourg: Publications office of the European Union.
[2] Ibid.
[3] 'Synthetics: the ethics of Synthetic biology.' IDEA League Summer School, August 2007, The Netherlands. http://bit.ly/cA5rKE (accessed 14/09/2010)
[4] European Commission (2010). 'The Ethics of synthetic biology.' Luxembourg: Publications office of the European Union.
[5] The synthetic biology project was established as an initiative of the Woodrow Wilson International Centre for Scholars to 'foster informed public and policy discourse concerning the advancement of synthetic biology'. http://www.synbioproject.org/about/ (accessed 23/08/2010)
[6] Synthetic Biology Project (2010). 'Trends in synthetic biology research funding in the United States and Europe.' Woodrow Wilson International Centre for Scholars. http://bit.ly/9aAx8e (accessed 2/08/2010)
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[10] http://bit.ly/97yfy8 (accessed 23/08/2010)
[11] http://bit.ly/brrDoM
[12] http://bit.ly/bLr72V (accessed 17/08/2010)
[13] 'Extreme genetic engineering' (2007). ETC Group.
[14] 'Drug resistance could set back malaria control success.' WHO Media Centre. 25 February 2009. http://bit.ly/c8UADN
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[19] http://www.who.int/malaria/medicines.pdf (accessed 27/09/2010)
[20] http://bit.ly/cPRFjR (accessed 19/08/2010)
[21] 'Small farmers cash in on Artemisinin production.' All Africa. 21 January 2009. http://allafrica.com/stories/200901210671.html (accessed 14/09/2010)
[22] Heemskerk, Schallig & de Steenhuisjen Piters (2006).
[23] Dalrymple, D. (2006). 'Artemisia, agriculture and malaria in Africa: The interplay of tradition, science and public policy.' http://bit.ly/aF3hVp (accessed 15/09/2010)
[24] Steenkamp, D & Thomas, W. (2010). 'Investing in the bottom of the pyramid' in Leader. http://bit.ly/bRmZRc (accessed 14/09/2010)
[25] 'Small farmers cash in on Artemisinin production.' All Africa. 21 January 2009. http://allafrica.com/stories/200901210671.html (accessed 14/09/2010)
[26] Wakabi, M (2010). 'Uganda in double blow against Malaria - with local drugs' in The East African. http://bit.ly/bswVf0 (accessed 15/09/2010)
[27] Van Noorden, Richard (2010). 'Demand for malaria drug soars' in Nature news. http://www.nature.com/news/2010/100803/full/466672a.html (accessed 16/09/2010)
[28] Ibid.
[29] UNEP/CBD/COP/10/3 http://www.cbd.int/doc/?meeting=sbstta-14 (accessed 12/09/2010)
[30] The precision language on synthetic biology in the biofuels reads as follows:
1: [14. Decides to convene an ad-hoc technical expert group on synthetic biotechnologies and other new technologies that are used or projected to be used in the next generation of biofuels to assess their impact on biodiversity and related livelihoods.]
[16. Urges Parties and other governments, in accordance with the precautionary approach, to ensure that living organisms produced by synthetic biology are not released into the environment until there is an adequate scientific basis on which to justify such activities and due consideration of the associated risks for the environment and biodiversity, and the associated socio-economic risks, are considered.]
(2) This paragraph is in square brackets due to (i) financial implications, and (ii) a lack of consensus from the meeting on the need for the ad-hoc technical expert group and its mandate.
In the paper on new and emerging issues (L.14), the decision 2:
Invites parties, other governments and relevant organizations to submit information on synthetic biotechnology and geoengineering in accordance with the procedure of decision 9-29, for consideration of SBSTTA, while applying the precautionary approach on field releases of synthetic life, cells or genomes into the environment.
[31] James, C (2009). 'Global Status of Commercialised Biotech/GM Crops.' ISAAA Brief No. 41.
[32] GRAIN Briefing (2004). 'USAID: Making the World Hungry for GM Crops.'
[33] African Centre for Biosafety (2010). 'Comments on COMESA's draft policy on GMOs.' ACB Briefing Paper No. 17. http://bit.ly/cM73rF (accessed 27/09/2010)

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