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Regulating the Use of Genetic Sequence Data

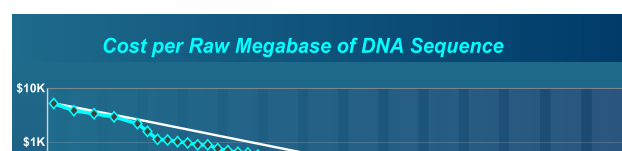
Posted December 15, 2016 by [Daniela Quaglia](#) in [biosecurity](#), [Biotech](#), [Conferences](#), [From the community](#), [Synthetic Biology](#), [Uncategorized](#)

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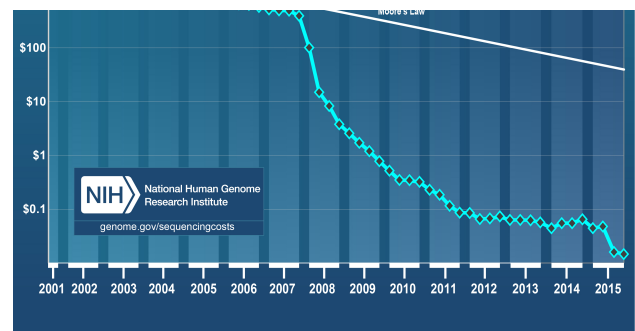
By *Steven Burgess and Dominic Berry*

Last month, researchers from the Universität Marburg reported mixing 12 enzymes from three spheres of life, including plants, humans and microbes, to create an

[artificial pathway](#) that is more efficient at fixing [CO₂](#)
<http://blogs.plos.org/synbio/2016/12/15/regulating-the-use-of-genetic-sequence-data/>



than plants. This achievement is just the latest in a host of projects to generate improved metabolic pathways for catalysis or entirely new ones, ranging from artificial [production of vanillin](#) to [opiates](#). Such work is made possible by the falling cost of [DNA sequencing](#) and [synthesis](#), which means it is possible to 'read-and-write' the DNA required to make a variety of enzymes for less than \$1000.



Genetic sequence data and the Nagoya Protocol

These projects utilize the diversity of enzymes in nature to select the best catalyst for a job. This has raised concerns about the political grounds of bioprospecting and biopiracy (the latter being bioprospecting that exploits plant and animal species by claiming patents that restrict their general use), and resulted in questions about how [genetic sequence data](#) should be regulated in the same way as or in relation to other 'genetic resources' (such as seeds).



Kew Gardens: Kew has taken the decision that **any* item in their collection, *regardless* of when it was collected, cannot be used in industrial research without returning to the original donor country and negotiating a benefit sharing agreement.* – Photo by Michael Button licensed under CC BY-SA.2.0.

These concerns arise out of a long history of exploitation. [For centuries naturalists and entrepreneurs sponsored by empires](#), wealthy families, or private donors, have collected samples around the globe, often with the help of indigenous peoples, [depositing them in centres of collection and using these materials to generate wealth](#) without returning any benefits. Entire sciences, scientific careers, and industries have been made and are made thanks to these collecting campaigns. Despite its importance, it is surprising that collecting only became the subject of international

governance agreements in recent decades. Currently, use of genetic resources is regulated by the [Nagoya Protocol](#) (NP) which sets out the conditions under which they can be transferred from one country to another.

'[These agreements] are potentially win-win' says [Bruce Manheim](#), an expert on regulatory affairs, 'providing access to genetic diversity, and allowing benefits that come from discoveries to be shared.'

This topic is currently under discussion at the [13th Convention of the Parties](#) of the Convention on Biological Diversity (CBD) (COP13). It is argued that, if sequence information is not covered by the Nagoya protocol, it could [undo the work of the CBD](#), opening a new round of exploitation. A representative of Namibia explained 'The widespread and woeful denial of benefit-sharing is undermining NP [Nagoya Protocol]' and as a prime they example pointed to 'the spurious argument that [use of digital genetic sequences](#) isn't 'access' so there are no benefit sharing obligations.' They went on <http://blogs.plos.org/synbio/2016/12/15/regulating-the-use-of-genetic-sequence-data/>

use of digital genetic sequences isn't access so there are no benefit sharing obligations. They went on to state: 'Let's be perfectly clear – such resources are only valuable because of the information they encode'.



Inauguration of the 13th Conference of the Parties to the Convention on Biological Diversity of the United Nations. Photograph by Presidencia de la República Mexicana licensed under CC BY 2.0

Concerns about regulating sequence information

However, others have also [strongly criticised](#) the protocol, particularly as regards to the regulatory burden, with suggestions that it could act as a disincentive to research and development, or causing problems when there needs to be rapid sharing of information, such as [during flu outbreaks](#). Exchanges of material must be authenticated by obtaining an 'Internationally Recognized Certificate of Compliance (IRCC)', a process that is currently time consuming and costly: the [first was issued in 2015](#). There also remains a question over what period of time the protocol applies to – if it covers material collected after it came into force ([2014](#)) or anything following the start of the Convention for Biological Diversity ([1993](#)). Sometimes when people highlight such practical difficulties, it is because they want to depoliticize access and benefit sharing, turning it into a 'purely technical' matter. It is a persistent irony that the latter is one of the most deeply political arguments it is possible to make.

What might regulation of sequence information mean in practice?

Bruce suggests if one is to understand what is likely to happen if sequence information is regulated, it is best to look at what is [already in force for 'physical' genetic resources](#). (For examples of potential answers to 'problem situations' including those raised [in Science](#) refer to the correspondent text box on the left).

Non-compliance could result in patent invalidation or criminal prosecution. There have already been a number of high-profile lawsuits around the use of biological material: [against Monsanto in India](#) for a genetically modified variety of eggplant, [against various companies developing the artificial](#)

<http://blogs.plos.org/synbio/2016/12/15/regulating-the-use-of-genetic-sequence-data/>

Q: What happens if identical DNA sequences are found in species from two different geographical locations?

A: This could be covered by a multilateral system involving the payment of a fixed percentage of benefits into a common fund, which is then redistributed between members. Such a mechanism is used in the the Plant Treaty.

Q: What happens if there is a viral outbreak and information needs to be rapidly shared?

A: A potential solution can be seen in the PIP framework for sharing of information about Influenza viruses, which was set up after concerns material would be used to create vaccines they could not afford.

Q: What happens if the DNA sequence encoding an enzyme is subsequently modified for improved characteristics? Or new enzymes are created from existing scaffolds?

egyptian, against various companies developing the [artificial sweetener Stevia](#) and against Nestlé in South Africa over [patenting of the use of Rooibos](#), a plant native to the country.

A: Such products could be classed as derivative and will likely fall under the Nagoya protocol.

Info box: potential problem situations, and potential answers

Your responses

Concern, fear and hope surround the regulation of digital sequence information, and there are many different views and ideas. Nor do the issues of DNA sequencing and synthesis begin and end with the Nagoya protocol. A full understanding would require considerably more attention to the Convention on Biological Diversity.

Nevertheless, here is an opportunity to join a conversation about what kind of science and industry you want to see in the world, to show different perspectives, rather than assuming or demanding that the way you see things is obviously the 'fairest' or 'most sensible'. By and large, the people involved with the regular use of biological resources tend to have very complex views regarding what should/should not be subject to ABS agreements, and for what reasons. We look forward to hearing from you.

We want to thank Bruce Manheim for an illuminating discussion into the nature and implications of the Nagoya protocol, and Molly Bond and Deborah Scott for feeding into this post with on-the-ground insights from the CBD and NP negotiations, ongoing in Cancún from 4-17 December. Recently the [OpenPlant](#) project at the University of Cambridge and the [Engineering Life](#) project at the University of Edinburgh held a co-sponsored workshop on 'Genetic resources in the age of the Nagoya Protocol and gene/genome synthesis'. A report following this workshop will be published in the next few months. Disclaimer: All views expressed in this article are the private opinions of the authors.

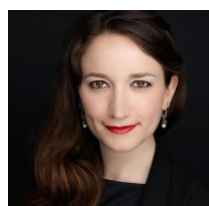
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1 comment

