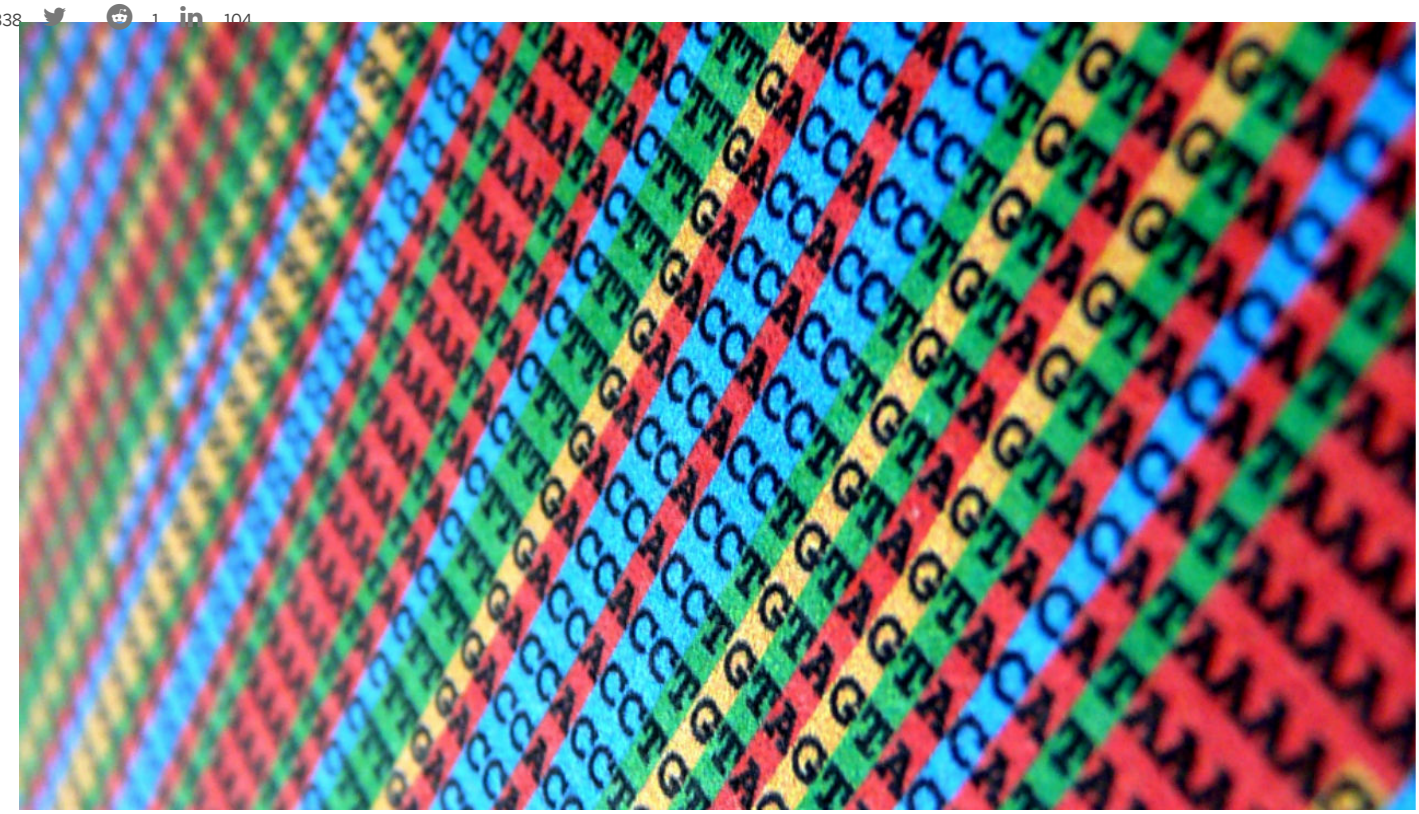

Researchers can use digital DNA sequence data to assemble genes in their laboratories.

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Rise of digital DNA raises biopiracy fears

By Kelly Servick | Nov. 17, 2016 , 12:15 PM

It's possible to forget that genes grow on trees. Chinese wormwood, for instance, holds genes for enzymes needed to assemble the malaria-killing compound artemisinin. But increasingly, the world's genes also exist as information—free-floating sequences in public databases, no harvest required. Those prized wormwood genes, for example, **can now be assembled in a laboratory and inserted into yeast or tobacco** to churn out an artemisinin precursor. And when it comes to portioning out the financial spoils of new biotech products, the use of open-access DNA troves might make things complicated.

At a **meeting next month** in Cancun, Mexico, parties to an international treaty governing the use of genetic resources, from medicinal plants to pest-killing microbes, plan to discuss whether and how the agreement should apply to digital DNA sequences. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, which took effect in 2014, was meant in part to prevent richer nations from unfairly benefiting from genetic resources originating in poorer countries. The protocol requires that users and providers—for instance, foreign commercial researchers that use plant genes, and the indigenous community that provided them—agree on how to divide any intellectual property rights or royalties from products that use a native genetic resource.

But when and how should a company share benefits if it never touches a physical sample? As it gets easier to edit genomes and even synthesize them from scratch, advocates for biodiverse countries argue that genetic databases will undercut hard-fought benefit sharing agreements like Nagoya.

"It makes a mockery of the Nagoya protocol if the technology has moved on," says Jim Thomas, program director of ETC Group in Montreal, Canada, a nonprofit that monitors the impacts of new technologies on poor countries and communities. "It's like having a

But benefit sharing rules for digital DNA would be hard to enforce, and could clash with the open-access culture of research. "Once information goes into the public domain, to keep saying, 'That's mine, and so you're bound by some rule,' seems a very difficult thing to pull off," says Robert Friedman, vice president for policy and university relations at the J. Craig Venter Institute (JCVI) in San Diego, California. "It's one thing, in my view, to access a physical sample. It's another thing to access a sequence."

In 2003, JCVI's Global Ocean Sampling Expedition set out to sequence the genes of marine microbes scooped up in seawater samples, some of them collected inside the territorial waters of nations other than the United States. The institute's agreements with these countries included permission to upload sequences to publicly accessible repositories. And when JCVI set up its own repository, the Community Cyberinfrastructure for Advanced Marine Microbial Research and Analysis (CAMERA), it included the country of origin for each uploaded sample. The database, which has since shut down, instructed users to contact relevant authorities in that country if they had commercial intentions.

Tracking gene origins

But it's still not possible to track which sequences ultimately get used for profit. Though some countries, including China and Brazil, require that patent applications include the origin of any genetic resources used, the United States does not. And for many genetic databases, there isn't even a clear path back to a sample's origin. That system, some argue, opens the door to biopiracy—profiting from biological products or local knowledge without sharing the proceeds.

The question of digital DNA arose throughout years of negotiations leading up to the Nagoya Protocol, a supplementary agreement to the broader United Nations Convention on Biological Diversity (CBD). (Eighty-nine countries have ratified the protocol; the United States is not among them.) And it's getting new attention as member countries now take steps to enact the agreement. Thomas, a member of an expert group on synthetic biology set up by the CBD parties, says the December meeting is unlikely to produce any decision on how to address digital DNA, but he expects biodiverse countries such as Brazil, Mexico, Malaysia, and the Philippines to push hard for the expert group to take up the question and issue advice.

One response would be to require tighter user agreements in public databases, says Edward Hammond, a research associate at the nonprofit Third World Network in Austin. Under such a system, benefit-sharing obligations would kick in if a researcher synthesized DNA and used it in a product or in research that leads to a patent. "Open access doesn't mean irresponsibility toward those that have rights over the sequences," he says.

Such a system would raise new questions. An identical genetic sequence might exist in various organisms scattered throughout the world, especially in the case of marine microbes, Friedman notes. Which country of origin has rights over that sequence? And how much does a particular sequence have to contribute to a new product before the maker should have to share benefits?

A plea for proactivity

Amid the uncertainty, some are encouraging companies to be proactive in figuring out the source of genes they plan to use and setting up agreements. "Those in the synthetic biology industry and in academia should be quite aware of what's going on on this front," says Bruce Manheim, a life sciences attorney at WilmerHale in Washington, D.C. In **a letter published last week in *Nature Biotechnology***, Manheim warns that some countries are already moving to establish digital benefit-sharing requirements in their domestic policies. He cites legislative language from Brazil, Peru, and the Philippines suggesting that genetic information–not just physical samples–will be subject to such requirements. Foreign companies could face an intellectual property challenge, or even civil or criminal sanctions, for ignoring them, he says.

It's one thing to declare that your laws protect digital sequences, and another to actually find and pursue those who violate them, notes Margo Bagley, a law professor at Emory University in Atlanta, who last year wrote **a report on digital DNA** published by the Woodrow Wilson International Center for Scholars. For one thing, Bagley has found that researchers in genetically rich, developing countries are often themselves feeding these databases with new sequences, potentially unaware of any relevant benefit sharing or disclosure of origin laws. And enforcing those laws–even with the support of the other Nagoya signatories–could be beyond the means of many developing countries. "The chances of getting caught, in a sense, in the realm of digital information seem to me somewhat slim ... but you don't want to be the poster child for enforcement," she says. "It's very easy to be labeled a biopirate when you don't have that intention."

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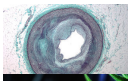

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