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Genetic rights and wrongs

Australia's decision to uphold a patent on biological material is in danger of hampering the development of diagnostic tests.

It is perhaps unexpected that the United States — the oft-lampooned home of patents on peanut-butter-and-jelly sandwiches and ways to swing a swing — is emerging as one of the most hostile towards patents on naturally occurring genes.

Last week, Australia had the opportunity to join the United States in taking a dim view on such licensing of nature. But a federal court there instead upheld a patent claim on the cancer-associated gene *BRCA1*. In doing so, the country remains with Canada, Japan and several countries in the European Union, all of which, unlike the United States, recognize such patents.

The patent on *BRCA1* has become a touchstone in the debate over 'gene patents', a broad term that can cover a wide swath of patent claims on DNA sequences. Certain mutations in *BRCA1* increase the risk of, in particular, breast and ovarian cancers. And Myriad Genetics, a genetic-testing company in Salt Lake City, Utah, has aggressively defended its patents, which cover the abnormal *BRCA1* sequence and tests to identify it.

In the United States, debate on gene patenting has been tied to clear public-health concerns. Myriad's monopoly bred worry that women would have only a single option for *BRCA1* testing, with no possibility of receiving a second, confirmatory test elsewhere. So when advocates challenged US patents on *BRCA1* and the closely related gene, *BRCA2*, the case provoked a passionate response from the public. The patents were defeated in a landmark decision last year that changed decades of legal practice in the field (see *Nature* **498,** 281–282; 2013).

Australia is in a different situation. The *BRCA* patents have not been enforced there, either by Myriad or by the company that has licensed them in Australia: Genetic Technologies of Melbourne. Despite the fervent involvement in the case of patient advocates, including cancer survivors, the spectre of gene patents in Australia remains more theoretical.

Still, the case, and the attention it has received, shines new light on how such patents will affect the future of medical diagnostics, particularly as genetic tests expand to cover large numbers of genes, and even the full genome.

In the run-up to the US decision on Myriad, an academic subfield was born from a handful of patent lawyers and scholars who wanted to know just how many gene patents might be affected — no easy task in a system that awards around 300,000 patents a year. Answers varied, but the general conclusion was: not as many as you might think. One study found that most patents that mention DNA sequences do not claim the sequences as an invention (O. A. Jefferson *et al. Nature Biotechnol.* **31,** 1086–1093; 2013). Nevertheless, even a few hundred patents on genes can be enough to scare off potential investors and entrepreneurs looking to pioneer methods of genetic testing, because they might infringe on protected genetic property.

In the United States, gene patents were defeated because they ran afoul of a prohibition on patents claiming a "product of nature". An influential brief to the US Supreme Court written by biologist Eric Lander, head of the Broad Institute in Cambridge, Massachusetts, wounded the held idea that isolating DNA changed it from a product of nature to a human product, thereby making it patentable. He pointed out that 'isolated' bits of DNA can be found floating free in the blood, and that the isolated *BRCA1* and *BRCA2* genes had in fact been found doing just that.

In Australia, no such limitation on patenting natural products exists. Instead, the debate there has centred on whether the patent claims a "method of manufacture". Last week, five Australian justices unanimously ruled that it does, because to isolate DNA from its natural setting requires effort. This, they say, describes "an artificially created state of affairs for economic benefit", and is therefore fair game for a patent.

"Debate on gene patenting has been tied to clear public-health concerns."

The plaintiffs in the case are considering an appeal to the High Court of Australia, and some patient advocates are crying for changes to the law to do away with gene patents.

For now, the Australian decision is certain to please patent lawyers and some biotechnology executives. This seems to have been the justices' intent: the bulk of their rulings have focused on preserving incentives for innovation and business. There has been little, if any, attention from the court to what this means for science, or for patient access to information about their genes.

Business concerns are important: the biotechnology industry depends on patents for its livelihood, and many patients' lives depend on the industry. But the business model pursued by Myriad is a fading one, and it is time to look to the future. That future has little place for patents that could hold up the development of bigger and better medical tests. ■

Ebola: time to act

Governments and research organizations must mobilize to end the West African outbreak.

After disproportionate media attention on Ebola's negligible risk to people in Western and Asian countries, the focus seems at last to be shifting towards how to stop the outbreak in West Africa. The grim reality is that medical organizations are struggling: the flood of new cases far outpaces available beds and treatment centres. Many of those who are ill are not receiving the basic health care that could keep them alive.

The tragedy is that we know how to stop Ebola. Well-informed communities can reduce the main routes of spread by avoiding

unprotected home-based care of infected people and by modifying traditional burial practices. Infection-control measures protect health-care workers. Together with rapid identification and isolation of ill people, and tracing and monitoring of their contacts for 21 days (the maximum incubation period of the disease), such measures have stopped Ebola outbreaks in the past.

But the dysfunctional health-care infrastructure of the three countries at the centre of the outbreak — Guinea, Sierra Leone and Liberia, which are poor and struggling to emerge from years of war — is simply not up to the task. The nations need help, and urgently.

The international community must mobilize now. Aid is increasing, but most of those involved, from governments and the World Health Organization (WHO) to researchers, all initially underestimated the threat. This is perhaps because most past outbreaks have been small and relatively straightforward to control.

The WHO has a part to play, but contrary to a widespread assumption, it does not have the in-house capacity to send large teams into the field. The agency's funding for outbreak responses has been slashed, and it has shifted focus to helping countries to reinforce their health systems so that they can respond better themselves. How the international community should best react to outbreaks, and what role the bureaucratic WHO should have, is a debate for after this outbreak is over. The pressing need now is to bring all available resources and talent to bear.

It is a sign of how desperate the situation has become that on 2 September, Joanne Liu, international president of medical group Médecins Sans Frontières (or Doctors Without Borders), called on countries to immediately deploy their military and civilian biodefence teams — units that have been developed to respond to bioterror attacks. The crucial priorities, she said, are to scale up isolation centres, deploy mobile diagnostic labs (see page 145), build a network of field hospitals and establish dedicated air links to shift staff and equipment to where they are needed. In short, a military-style response, with its associated strong chain of command, logistical capacities and speed. The concept makes a lot of sense and is an approach that governments should consider adopting — or explain why, if they choose not to do so. US President Barack Obama indicated last weekend that he would deploy the US military to assist in the outbreak.

It cannot be repeated enough that public-health measures and good old-fashioned epidemiological tracking of the infected and their contacts will bring this outbreak to an end. The priority must be to scale these up, alongside establishing more Ebola treatment centres on the ground. For instance, Ebola's high death rate could be slashed by better patient care, in particular by giving intravenous rehydration.

"The pressing need now is to bring all available resources and talent to bear."

A highly effective Ebola vaccine would be a game-changer. A WHO-convened meeting on 4–5 September agreed on an unprecedented set of measures, including relaxing regulatory requirements so that experimental drugs and vaccines can be quickly tested under the difficult field conditions of this outbreak, and perhaps even widely deployed. The measures will, for example, permit expedited vaccine trials and informal clinical studies of drugs that could produce useful initial data within months.

Regulators and researchers should be applauded for their speed and pragmatism in exploring innovative methods for conducting trials during this outbreak. Crucially, all those who organize trials must be willing to standardize and share the data they collect to maximize their scientific and medical value, and to allow rapid decisions to be made on which products to prioritize.

West Africa's outbreak illustrates the serious weaknesses in the international community's ability to respond to outbreaks of emerging diseases, despite years of debate. It should also hammer home a truism for future planning — the costs of setting up infrastructure to ensure an early response are small compared with the huge social and economic costs of a large deadly disease outbreak. ■

Orbital assembly

The space launch of a 3D printer does not herald a brave new era — but it is a good start.

Perhaps the most famous DIY job ever done in outer space was performed in April 1970 after an explosion disabled *Apollo 13* on its way to the Moon. The three astronauts on board the craft scrambled together a makeshift adapter from cardboard, plastic bags and duct tape to scrub poisonous carbon dioxide from the air.

What if they had had access to a device that could design and manufacture replacement parts to order?

Last year, an engineer demonstrated just such a device: a three-dimensional (3D) printer. Working for Made in Space in Moffett Field, California, the engineer spent an hour on the computer designing an adapter for the *Apollo 13* scrubber, and the rest of the day printing it and demonstrating how it would work. Problem solved?

Perhaps it would be if every spacecraft had a 3D printer. Working with NASA, Made in Space is about to launch the first such printer into space (see page 156). If dreamers have their way, it will be the start of a new generation of manufacturing in orbit.

Imagine a rocket carrying little but a machine that can print the infrastructure for a colony on Mars. Or a spacecraft that can unfurl robotic tethers, printing and braiding giant ribbons into a starshade so that a telescope can stare, unblinded, at extraterrestrial worlds.

If this sounds impractical, it's because it is. For decades, enthusiasts have dreamed up ambitious ways to manufacture structures in space. A 1970s concept known as the beam builder would have welded aluminium tubes together to create huge trusses spilling out of the back of the space shuttle. But in the 1990s, when countries began building hardware components for the International Space Station, they opted to do so in the familiar environment of planet Earth. Each large element was sent into space individually; only once aloft were the parts joined together to form the sprawling complex.

It would be wise to remember such lessons as the enthusiasm for 3D printing runs high. In July, a US National Research Council report concluded that there is a vast gap between what people think the technology can do and what it really can. It is all very well to pack a 3D printer for a journey to deep space — but what should a space traveller do when the printer itself breaks down? Carry a backup?

There is a place for 3D printing in space applications. Among other things, designers on the ground can dream up bizarre and fanciful parts, then print them regardless of many conventional design constraints. In principle, this means slimmer spacecraft that are cheaper to launch. That can be a big deal for an industry that must weigh every nut and bolt.

NASA is even talking about printing CubeSats, small box-shaped satellites that can be launched in flocks from a single launch vehicle or off the space station itself. A PrintSat, a CubeSat printed from a polyamide-based material, is slated for launch later this year as a test for how well such devices might survive in the harsh environment of space.

NASA is not alone. The European Space Agency is developing ways to use plastic and metal printed parts on the space station; the Italian Space Agency is hoping to send its own printer to the station in 2017.

Such experiments may not lead directly to a Martian base, but that is no reason not to encourage the fledgling technology. The maker ethos has permeated everywhere, it seems — even beyond the gravitational pull of Earth. ■

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