

Biopiracy Watch

A compilation of some recent cases
(2013)

EDWARD HAMMOND

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Third World Network

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I

INTRODUCTION

THIS book compiles recent papers on biopiracy published by Third World Network. The cases described here span the developing world, from African and Middle Eastern medicinal plants to South American fruit, to Asian microbes, among others.

What is biopiracy? Put simply, it refers to the theft of genetic resources and traditional knowledge.

In this compilation of cases, biopiracy more specifically refers to the misappropriation of genetic resources and knowledge through intellectual property claims. These are generally patent applications, although they may sometimes include plant breeders' rights or other intellectual property claims, and aim to make money from the commercialisation of these resources (and/or knowledge).

The patent claims discussed here have been made without evidence of the prior informed consent of the people from whom these resources and knowledge were taken, and without the existence of mutual agreement on sharing the benefits from use of the resources.

Biopiracy especially affects indigenous and local communities of developing countries. These groups have utilised biodiversity for millennia - protecting, fostering, breeding, and otherwise caring for and developing a vast swathe of the world's biodiversity, resources on which all human life depends. For too long, these essential contributions have been un-recognised and under-recognised.

Biopiracy further refers to the collection, claiming, and commercialisation of genetic resources without the approval of the governments of the countries from which they were taken. Governments have sovereign rights over natural resources (including genetic resources) found within their borders, as affirmed by the Convention on Biological

Diversity and its Nagoya Protocol. It is therefore incumbent upon bioprospectors that collect, use and stake claim to genetic resources to do so in compliance with the rules established in the countries where they collect. Governments' sovereignty over natural resources is linked to their obligation to protect the rights and interests of indigenous people and local communities within their borders who are the rightful owners of the resources where they live, and of the knowledge they have developed about their use.

Stopping biopiracy is thus both about ensuring conservation and sustainable use of generic resource and about justice, that is, fulfilling moral and legal obligations to respect the rights of the peoples who created and care for the plant, animal, microbial, and other biodiversity on which all of us depend.

The genetic resources of the cases in this book, claimed in patents and patent applications by corporations and universities, have uses in industry, agriculture, foods, and in pharmaceuticals and other health care products. For instance, a herbicide resistance gene from Bolivia poised to be sold in the United States by DuPont, one of the world's largest seed and chemical companies. Or microbes, found in Malaysia by an academic bioprospector, and conveyed into the possession of a biotech company from California.

In many cases, the patent claimants show remarkable disrespect for traditional knowledge and developing country science. For example, Nestlé, the Swiss food giant, is attempting to lay claim to uses of a Middle Eastern medical plant that are widely documented in traditional medicine and dozens of studies by scientists from the region. Or Rutgers University, from the US, whose patent application on a West African and Sahelian tea bush blatantly appropriates traditional knowledge.

The cases also show a disregard for proper access and benefit-sharing agreements among bioprospectors and other users of biodiversity. For instance, after filing no less than three patent applications on African plants, Rutgers University cannot produce material transfer agreements for the plants it has collected, and does not have a cogent benefit-sharing plan. Another bioprospector patented a microbe isolated from a medicinal plant and sold it to Denmark's Novo Nordisk before even trying to obtain proper informed consent of indigenous people, much less enter into a fully developed benefit-sharing plan.

A European Union project is assimilating an enormous collection of seeds of wild relatives of the tomato plant from gene banks, and

systematically probing them for valuable DNA. Industry claims the valuable bits through patents – all without going back to the Latin American countries of origin of these plants to create a benefit-sharing arrangement.

Together, these cases show that biopiracy continues as a problem, and that much remains to be done to stop it. Problems shown here, for instance the practical impossibility of distinguishing between ‘non-commercial’ and ‘commercial’ access to genetic resources, may be addressed by governments in their national legislation on access and benefit sharing, and through implementation of the Nagoya Protocol to the Convention on Biological Diversity, and suggestions are made as the individual cases highlight particular issues.

II

Recent Biopiracy Cases in Medicinal Plants and Cosmetics

The Avon Lady comes collecting Asian medicinal plants

Iconic cosmetics firm seeking to patent numerous Asian medicinal and food plants

AVON Products, the US-based cosmetics firm internationally known for its 'Avon Ladies', has taken a strong interest in Asian medicinal plants, patenting and incorporating them into its skin care products. The company has filed six patent applications on use of Asian plants in skin creams in the past several years. These claims collectively cover 16 different Asian plant species. To date, three US patents have been issued, and Avon is seeking rights in other countries, including inside Asia itself.

Five of the 16 plants claimed in the patent applications are already in use by Avon, and one or more of them can be found in more than two dozen Avon skin and eye care products currently sold worldwide. Four of the company's major skin care product lines contain these patented, or patent-pending, plant ingredients.

All of the plants that Avon claims have traditional medicinal use in Asian countries, and some of them have been used to treat skin disorders. Most of the plants are found in more than one Asian country, and are traditionally used in multiple cultures. It would thus likely prove difficult for any single country to exclusively assert sovereignty over the claimed resources.

This signals the importance of regional cooperation under the Convention on Biological Diversity (CBD) and its Nagoya Protocol on

Access and Benefit Sharing. Because many of the plants Avon claims, and relevant traditional uses of them, occur in multiple countries, collective action is more likely to bring a positive result in cases such as this. Avon's claims also indicate the need for a robust clearinghouse mechanism under the Nagoya Protocol so as to promote awareness of regional access and benefit-sharing issues.

The lucrative skin care market

The skin cream market is bigger business than many might suspect. It is the largest segment of the global 'personal care products' industry which, according to analysts, will reach \$333 billion in annual sales by 2015. Skin care is estimated to account for more than one-quarter of that amount, or roughly \$90 billion per year.¹

To put that large number in perspective, each year across the globe people spend about as much money on skin cream as they do on Sony electronics (\$87 billion), and more than is spent on pet food (\$80 billion). Skin cream sales sum three to four times as much as the United Nations Development Programme (UNDP)'s estimate for the annual cost to provide universal safe drinking water and sanitation services (\$20-\$30 billion).²

Analysts say that the worldwide market growth is driven by the larger number of women over 50 years of age, increases in women's disposable income and greater male interest in skin care products. The skin cream market is particularly strong for products that make 'anti-ageing', 'firming' and 'anti-cellulite' claims.

Not coincidentally, these claims are precisely the subject of Avon's patent applications on Asian plants. In 2009, the Asia-Pacific market for such products was 41% of the world total, or about \$33 billion, and continued expansion in Asia is considered a priority for the industry³, which is dominated by US and European companies.

Avon Products, Inc.

With \$11 billion in annual sales and a market capitalisation of over \$9 billion, US-based Avon is a significant player in the cosmetics and personal care industries. Founded in 1886, the company was a pioneer of multi-level marketing and, in many parts of the world, the 'Avon Lady' is a familiar phenomenon.

The company pursues a similar business strategy everywhere, focusing on what industry calls ‘direct sales’, by putting women into the business of selling Avon products to friends and acquaintances. These saleswomen, in turn, convert some of their customers into dealers themselves, building and perpetuating a sales chain in which transactions largely occur in living rooms and on street corners, rather than in Avon-branded storefronts.

More recently, the company has also started online and kiosk sales, especially in countries that have restrictions on multi-level marketing, including China. The company has also simplified global product lines, with its current offerings varying little from country to country.

Avon is profitable, paying an annual dividend of nearly \$1 per share of its stock. Through a charitable foundation the company claims (in confusing and perhaps misleading language) to be the ‘largest corporate supporter focused solely on women’s issues across the globe’.

The company’s marketing tends toward images of a ‘high-tech’ product development process led by scientists in laboratory coats at a research headquarters in the US state of New York. Although natural products are not the main thrust of Avon’s marketing, review of the Avon product ingredients reveals very frequent use of plant extracts (discussed in more detail below).

Avon appears eager to expand its skin care offerings. In 2010, it bought UK-based Liz Earle, a skin cream company with a different marketing approach, selling in storefronts and on television shopping channels. Botanical ingredients are a matter of emphasis for Liz Earle, whose corporate tagline is ‘naturally active skincare’.

Advertised or not, however, plants are an important part of Avon’s skin products.

Avon’s patent claims on Asian plants

Avon’s intellectual property claims reveal the company to be particularly interested in Asian medicinal and food plants. The company has recently obtained three patents on such plants, and three more patent applications are pending. Collectively, the plants are associated with countries across the region, including South-East Asia, China and South Asia. In total, claims are made on the use of 16 different Asian plants in skin care products. Avon’s patents and patent applications are summarised in the table on page 13, which includes some of the common

names used for the plants that are claimed.

Avon appears to be pursuing its claims not only in the US, Canada, Japan and Europe, but in developing countries as well. Only limited information on the international status of patent applications is available online. However, the World Intellectual Property Organisation (WIPO)'s Patentscope database indicates that at least three patent applications have been lodged in China and two in Mexico. More may exist without being reflected in the WIPO data.

The plants that Avon claims

How Avon accessed the plants that it claims is not known. Some, such as *Eclipta prostrata*, are relatively ubiquitous and could be obtained virtually anywhere. Others, such as *Stephania rotunda*, are far more likely to be sourced from Asia itself, certainly if needed in any considerable quantity. In the past, Avon has maintained company researchers in Asia and relationships with Asian academic institutions. In all of the patents described here, however, Avon company employees based in New York are indicated as the inventors, strongly suggesting that the research and product development occurred there.

The company's claims are of varying specificity. All of the claims relate to use of the Asian plants in skin care products. Some patent applications appear relatively specific, for example, claiming the use of plants to stimulate production of a particular protein by the skin (e.g., application WO2012005876), while others, such as the claims on *Tiliacora triandra* (WO2012002950), are broader and in effect claim use of that plant as an ingredient in any product that improves 'the aesthetic appearance of aging skin'.

Most of the 16 plants Avon claims are familiar food and medicinal plants in different Asian countries, including the following examples:

Bignay: In patent application WO2012005876, Avon claims use of four different Asian plants used in skin care products that stimulate production of a skin protein called MAGP-1. Among them is the bignay (*Antidesma bunius*), a fruit tree grown across Asia. Also called 'mao luang' or 'currant tree', the bignay's striking strands of multicoloured fruit are a popular food in Indonesia, while in the Philippines and Thailand, the fruit is both eaten and made into a wine. Bignay is very frequently cited among inventories of medicinal plants of diverse cultures across the region.

Elephant foot yam: In US patent 7,618,662, Avon claims use of six different Asian plants in products that stimulate fat production by the skin (which is said to improve appearance). Among the plants claimed is *Amorphophallus campanulatus*, an aroid known in English as the elephant foot yam. Grown for its edible tuber, the elephant foot yam plant has a pungent odour and many documented traditional medicinal uses, including to treat skin disorders.⁴

Agati: Also claimed in US patent 7,618,662 is *Sesbania grandiflora*, or agati (sometimes ‘agathi’). Frequently grown in South-East Asia and India, the plant’s leaves are used for food and, in Thailand, its flowers used in soups. It is also used in both Ayurvedic medicine and traditional medicine in South-East Asia, including for skin problems.

Bai yanang: Avon claims use of *Tiliacora triandra* in skin care products in patent application WO2012002950. With no English common name, the plant is usually called bai yanang, or simply yanang, its name in Laos and Thailand. Bai yanang is closely associated with the foods of Laos and the Isan culture of Thailand, where the leaves of this commonly cultivated plant are used in soups. In Vietnam, the plant is used to create a popular jelly.

False daisy: In patent application WO2011156136, Avon claims *Eclipta prostrata*, known as false daisy, as a cellulite treatment. False daisy is a native of the Americas that is widely distributed around the world. It can be considered Asian, however, because its medicinal use has mainly been developed there. In China, its use for many health problems was advised in the manual for that country’s famous ‘barefoot doctors’,⁵ while it also appears in accounts of Indian traditional medicine, including use to treat skin problems.⁶

Alisma orientale: Avon has obtained exclusive rights to another Chinese plant in US patent 7,410,658, which claims use of *Alisma orientale* to treat skin problems. Known as *dong fang ze xie*, the plant grows on the margin of lakes and ponds in a large part of China and in some surrounding countries.

Binh vôi: In US patent 7,514,092, the company claims skin treatments using any of three Asian plants, including *Stephania rotunda*, an unusual plant cultivated in Vietnam. There it is called binh vôi, meaning ‘lime pot’. The name refers to the shape of the plant’s unusual tuber, which is mostly above the soil, and which resembles the shape of ceramic pots used to hold lime (for betel nut chewing). English sources sometimes give the plant’s name as ‘saboo leard’.

Avon's Objects of Desire: Asian Medicinal Plants

PATENT/ APPLICATION NUMBERS	TITLE	GENERAL TOPIC	PLANT CLAIM
WO2012002950 US2012003331	Use of <i>Tiliacora triandra</i> in cosmetics and compositions thereof	Skin care products	Use of bai yanang (no English common name), food and medicinal plant used in Laos, Thailand, Vietnam, Cambodia, etc. (dây sưng sâm [VN], ស្រូវរាជ [LA], ໄພ່ນາຈ [TH]).
WO2012005876 US2012003332	Compositions and methods for stimulating MAGP-1 to improve the appearance of skin	Skin care products that work by stimulating production of microfibril-associated glycoprotein 1 (MAGP-1)	Claims several Asian plants that may be used to create MAGP-1 skin care products. These are: <i>Antidesma buniis</i> : bignay [PH], buni [MY], wooni [ID], etc.; <i>Operculina turpethum</i> : turpeth, pitohri [IN], St. Thomas lidpod; <i>Ixora chinensis</i> : pechah priok [MY], siantan [ID], etc.; <i>Clerodendron lindleyi</i> : 尖齿臭茉莉 jian chi xiu mo li [CN] The patent application claims additional plants when they are mixed with an extract of the above plants, or a functionally equivalent chemical.
US7618662 WO2006068777 MX/a/2007/007376 JP2007548241 EP2005825815 CN200580035328.6	Use of natural plant extracts in cosmetics compositions	Skin care products that work 'to stimulate lipid production, adiponectin production, adipocyte differentiation, PPAR-gamma induction, and/or any combinations thereof'	Claims several Asian plants that may be used to create skin care products of the invention. These are: <i>Humulus scandens</i> : 葎草 lü cao [CN], widely naturalised; <i>Amorphophallus campanulatus</i> : elephant foot yam, etc.; <i>Pouzolzia pentandra</i> (syn: <i>Gonostegia pentandra</i> Roxb. Miq.); <i>Rhinacanthus nasutus</i> : snake jasmine, kabutar ka phul [IN], etc.; <i>Sesbania grandiflora</i> : agati, agathi, food plant, widely distributed; <i>Piper betel</i> : betel nut
US751492 WO2006068786 CN200580040937.0 CA2588128 EP2005852369 JP2007548242	Compositions and methods of their use for improving the condition and appearance of skin	'A method of ameliorating, reducing, or treating progressive degradation of a dermal-epidermal junction and/or degradation of a cell-cell cohesion in skin'	Claims several Asian plants that may be used to create skin care products of the invention. These are: <i>Plumbago indica</i> : scarlet leadwort, India native, widely grown; <i>Sapindus rarak</i> : lerak [ID], 'soap nut'; <i>Stephania rotunda</i> : binh vôi [VN], 'saboo leard'
US7410658 WO2006068776 EP2005825830 MX/a/2007/007510 CN200580036088.1	Use of <i>Alisma orientale</i> in cosmetics and compositions thereof	Treatment to reduce cellulite	Claims use of <i>Alisma orientale</i> (东方泽泻 dong fang ze xie) to treat skin problems.
US20110305781 WO2011156136	Use of <i>Eclipta prostrata</i> and other PPAR-GAMMA inhibitors in cosmetics	Treatment to reduce cellulite	Claims <i>Eclipta prostrata</i> (false daisy) for cellulite treatment. Widely distributed, with traditional Asian medicinal use on skin.

Note:

CA – Canada; CN – China; EP – European Patent Office; ID – Indonesia; IN – India; JP – Japan; LA – Laos; MX – Mexico; MY – Malaysia; PH – Philippines; TH – Thailand; VN – Vietnam; WO – World Intellectual Property Organisation patent publication

Soap nut: Also claimed in US patent 7,514,092 is *Sapindus rarak*. This species is one of several that are sometimes called 'soap nut' in English. *S. rarak* is particularly well known in Indonesia, where it is called lerak. As its English name implies, the plant's seeds produce soapy compounds and, in Indonesia, lerak is favoured for use in washing traditional batik

fabrics. Like many other plants claimed by Avon, lerak is well known in Asia for traditional medicinal uses, including on the skin.

The Fountain of Youth: Asian medicinal plants in Avon products

The ingredients of Avon products were reviewed to determine how the plants that the company claims are being used. To date, five of the plants claimed in the patents and patent applications can be found in Avon's skin care products: false daisy (*Eclipta prostrata*), elephant foot yam (*Amorphophallus campanulatus*), agati (*Sesbania grandiflora*), *Pouzolzia pentandra*⁷ and soap nut (*Sapindus rarak*). Because each plant is used in several items within an Avon skin care product line, the five plants can collectively be found in more than 24 Avon products.

Like a modern commercial version of the Fountain of Youth legend, all of the four product lines that contain the Asian plant extracts consist of items that claim to make the skin of users appear younger. Each product line is marketed to women of a particular age range, for whom the product is allegedly specifically formulated. For example, 'Anew Platinum' products are marketed to women over 60 years of age.

The company's financial statements report all 'beauty' sales together; thus, specific figures for sales of products containing the patented and patent-pending ingredients are unavailable. As they constitute a large proportion of Avon's entire skin care offerings, however, they are likely

Plant	Related patent claim	Avon products
<i>Eclipta prostrata</i>	WO2011156136	'Anew Ultimate' and 'Anew Rejuvenate' product lines
<i>Amorphophallus campanulatus</i>	US7618662 WO2006068777	'Anew Reversalist' products
<i>Sesbania grandiflora</i>	US7618662 WO2006068777	'Anew Reversalist' products
<i>Pouzolzia pentandra</i>	US7618662 WO2006068777	"Anew Platinum" products
<i>Sapindus rarak</i>	US7514092 WO2006068786	'Anew Platinum' products

to be a significant part of the company's approximately \$8 billion annual beauty category sales.

Avon's formidable marketing promotes the products as restorative of youth, with claims that can approach the absurd, such as the assertion that after using one product '75% of people felt like they had new skin overnight'.⁸

A stable of Hollywood stars makes global product endorsements – Jacqueline Bisset for the older set, Reese Witherspoon for the 30- and 40-somethings, etc. These actresses are supplemented by regionally known fashion models and celebrities who push sales at events hosted by Avon's national sales offices. "I am excited to be working with Avon on the Anew Platinum Collection, as it specifically addresses the needs of women with my skincare concerns," reveals Jacqueline,' gushes one Avon press release, quoting the 67-year-old star of the late 1960s and 1970s.⁹

Biodiversity Convention and Nagoya Protocol implications

Where and when did Avon acquire the plants it claims, and what, if any, benefit-sharing arrangements are in place? The answers to these questions may clarify the implications of Avon's patent claims for countries that are CBD Parties, particularly those that have joined the Nagoya Protocol or that already have national access and benefit-sharing (ABS) laws. Unfortunately, however, there is little concrete information available.

No documentation could be located regarding any benefit-sharing agreements in relation to Avon's patent claims, and it appears unlikely that any exist. All of the inventors in Avon's patent claims are indicated to be at Avon's research facility in New York. Avon's philanthropic arm, the Avon Foundation, is exclusively focused on funding breast cancer research and programmes aimed at preventing violence against women. While worthy causes, these do not appear to have any benefit-sharing relationship with the company's use of biodiversity, particularly considering that the Foundation's publications do not reflect any interest in environment, biodiversity or traditional knowledge issues.

What is clear, however, is that all of the plants that Avon has claimed are native to more than one Asian country or have been long used in more than one Asian country. It is also unmistakable that in at least some cases, Avon's use of the plants in skin care products was preceded by use of the same plants to treat skin ailments in traditional medicine. This situation

is indicative of the need for a robust clearinghouse under the Nagoya Protocol and for regional cooperation when plants and knowledge about them spill over borders. For example, in the case of bai yanang, it appears that cultivation and traditional use is common in Laos, Vietnam and Thailand, and that any response to Avon's patent application would be stronger if it included participation of more than one country.

A robust clearinghouse mechanism under the Nagoya Protocol would increase the possibility of early detection and response to cases involving genetic resources found in more than one country. For example, Avon's use of *Eclipta prostrata* may implicate traditional knowledge, even if the plant itself could be obtained from a variety of locations. Similarly, *Pouzolzia pentandra* is a herb that could be sourced from several countries, although traditional knowledge pertinent to Avon's use of the plant may not be held in all of those places.

Conclusion

Avon Products, Inc. is freely availing itself of Asian medicinal plants, with patents or patents pending on 16 different species at the time of writing. Five species under patent claim are already incorporated into commercialised Avon products that anchor its skin care business worldwide. The plants are found in countries across Asia and frequently have traditional use in multiple cultures. Avon's patent claims are of varying breadth and, in some cases, appear to mimic traditional uses. Because the plants and their uses are diffused through the region, cooperation among countries appears key to addressing the situation.

What can be done? Firstly, documentation of the relevant traditional medicinal uses (e.g., on the skin, in eye care) of these plants should be assembled. Most of this knowledge may be held by indigenous peoples and traditional communities and/or otherwise recorded in countries of origin. This information may be important in any discussions with the company.

Secondly, governments may ask Avon to produce documentation of where, when, and with what informed consent and benefit-sharing arrangement it has collected plants and possibly knowledge. Because the plants and knowledge are geographically dispersed, and because several patent applications claim multiple plants, this request to Avon would be most appropriately advanced by countries working in cooperation with

each other. It appears likely that informed consent and benefit-sharing arrangements are inadequate, and may be non-existent.

With those facts established, the degree of Avon's respect for the CBD and pursuant national ABS legislation can be gauged. Although Avon is a US-based company (the US has not ratified the CBD), it is engaged in the skin care business through subsidiaries it controls in Asia, where all countries are CBD Parties. This business is important for Avon. Current sales and future sales growth in Asia are critical to the company's long-term success, and this factor may be used to encourage the company to redress the present situation and to undertake to respect CBD obligations, ABS law and traditional knowledge in its future business use of plant ingredients.

Rutgers University chases profit from West African medicinal plants

In 2006, the biopiracy report 'Out of Africa: Mysteries of Access and Benefit Sharing'¹⁰ highlighted the effort of Rutgers University (New Jersey, United States) to patent and profit from kombo butter. An extract of the African nutmeg tree (*Pycnanthus angolensis*), kombo butter has a wide variety of traditional medicinal uses in Central and West Africa.

Seven years later, in 2012, the Rutgers team is still headed by the same professor, James Simon, and is still trying to convert its work in West Africa, funded by the US Agency for International Development (USAID), into profits for the New Jersey school.

Simon and his Rutgers colleagues have recently lodged a new claim over kombo butter extracts as pharmaceuticals, and have another new patent application on extracts from a second African plant. That plant, kinkéliba (*Combretum micranthum*), is a West African shrub grown for its tealeaf. It also has a number of known medicinal properties.

Rutgers, a public university, has developed a benefit-sharing policy for these claims. It did not make its benefit-sharing policy public, however, until a request was made to it under freedom of information laws. First discussed here, Rutgers' benefit-sharing policy is an embarrassment to the institution. The policy is so poorly conceptualised and crafted that it is highly unlikely to be successful, and falls short of any reasonable interpretation of compliance with the Convention on Biological Diversity or its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits.

New claims on kombo butter

To update the original story from 2006, according to records acquired under the New Jersey open records law,¹¹ Rutgers initially licensed its interest in the kombo butter claim to BioResources International, a small and elusive company that specialises in providing African plant products to companies and other foreign requesters. BioResources lists its headquarters as being in Ghana or at various addresses in the US, including private residences located near Rutgers University.

BioResources is headed by Kodzo Gbewonyo, a biochemist who formerly worked for pharmaceutical giant Merck.¹² Gbewonyo is a US citizen¹³ of Ghanaian origin.

BioResources' original effort to commercialise kombo butter appears to have been unsuccessful. In January 2011, however, Rutgers asked the company to sell back to the University a four-year option on the 2008 patent,¹⁴ which claims anti-inflammatory uses of kombo butter, and was profiled in 'Out of Africa'.

Rutgers' move to reacquire rights to the 2008 patent may relate to a new patent application it has filed on kombo butter, this time for use of several plant extracts as 'neuroprotective agents', meaning to treat diseases such as Parkinson's and Alzheimer's, as well as for administration to patients who have suffered a stroke (and have consequent nervous system damage). This new kombo butter claim was published by the US Patent Office in May 2012, and is pending there. International claims are also before the Patent Cooperation Treaty (PCT) and European Patent Office.¹⁵

Medicinal use of kinkéliba: Rutgers' latest dubious 'invention' from West Africa

Rutgers' other new African plant patent claim is on the kinkéliba bush. Kinkéliba, or *Combretum micranthum*, is a familiar plant in dry regions of West Africa and the Sahel, where it is harvested for use as tea and for medicine. The plant is widely known in West Africa. Through international commerce for a century or longer, it is also somewhat familiar in other regions. Within Africa, kinkéliba is highly regarded and used for a variety of purposes, including tealeaf, and medicinal uses ranging from treating fevers to weight loss.

Rutgers, in its patent application WO2011140066, claims that it has discovered several chemicals isolated from kinkéliba leaves. The patent application claims these compounds as matter, claims methods for their extraction, and claims their use to treat diabetes (and related glycemic disorders). The latter uses, Rutgers alleges, are its own discovery.

Rutgers' patent application and related scientific publications¹⁶ concede that kinkéliba has wide use in traditional medicine in Africa, but these discussions do not mention traditional use for the treatment of diabetes. It is a very curious omission, because a brief Internet search reveals several reports that predate the Rutgers patent application and which indicate that kinkéliba is in fact traditionally used to treat diabetes.

For instance, in 2006, an African study on use of traditional remedies for diabetes was published in *Diabetes & Metabolism*.¹⁷ The Guinean researchers surveyed 397 diabetes patients at Conakry University Hospital, of whom 131 (33%) said they used traditional treatments. Asked to identify the plants they used, they collectively identified 31 species. Of these, kinkéliba was the third most frequently cited plant, used by 19% of the respondents. This indicates that use of kinkéliba in Guinea to treat diabetes not only exists, but is also commonly known.

In light of the readily available information indicating that kinkéliba is used traditionally to treat diabetes, Rutgers' failure to mention this fact in its publications and patent application is difficult to explain as anything other than a self-serving deception. After all, the Rutgers team purports to be expert in African medicinal plants, and the entire PhD dissertation of a student of James Simon is focused on medicinal use of the kinkéliba.

Some of the evidence of traditional use of kinkéliba was reported in the international patent search report on the Rutgers application, including the Guinean paper, although the questions the PCT search report raises about the patent application primarily centre on other issues (publication of the PhD dissertation before filing of the patent application).

The patent application is in its relatively early stages, however, and it is too soon to predict a result. Rutgers may modify its claims, or file a follow-on application, as it has with kombo butter. But no matter how Rutgers modifies its claims, it is quite clear that Rutgers has not invented the use of kinkéliba to treat diabetes.

After three patent applications, here is Rutgers' idea of a benefit-sharing agreement

Under a formal open records request, Rutgers was asked to produce the benefit-sharing agreements and material transfer agreements (MTAs) that the University has executed with African partners for plant samples it has obtained, including kinkéliba.

The University could not locate any MTAs for the materials it possesses and has patented, and the only 'agreement' it could find was an odd four-page paper titled 'Agreement on Benefit Sharing Policy Related to African and International Inventions', which the University describes as a 'departmental policy'.¹⁸ Although the University calls this document an 'agreement', it could not produce any signed or countersigned copies, indicating that it had actually been put into effect.

While the policy/agreement's preamble says that the University is committed to benefit sharing, what follows is a convoluted mess of language that lacks intellectual rigour. Indeed, the policy/agreement does not appear to have been given much serious thought at all. The following paragraphs attempt to describe it, although the document is so illogically constructed that it is difficult to do so clearly:

Among its most basic problems, Rutgers has drawn up its benefit-sharing structure independently, with a 'one agreement fits all approach' whose basics appear to have been unilaterally decided by Rutgers. These circumstances make prior informed consent and mutually agreed terms difficult, perhaps impossible, to achieve.

Rutgers' policy/agreement dismisses the issue of traditional knowledge with a farcical claim. The University says that whatever intellectual property it claims is 'distinct from validating traditional uses and applications of medicinal plants which would overlap with Traditional Knowledge (TK) related issues'. Traditional knowledge is thus dismissed from any role in the remainder of the so-called benefit-sharing agreement, because by Rutgers' own determination, anything that it seeks to patent does not involve traditional knowledge.

The example of traditional use of kinkéliba to treat diabetes clearly shows that Rutgers' distinction between its patent claims and traditional knowledge is false, nevertheless, Rutgers' policy/agreement simply snuffs out traditional knowledge with the unqualified assertion that any of Rutgers' claims don't 'overlap' with such knowledge.

In the agreement/policy, the University does not actually make any

commitment for benefit sharing – even in its own benefit-sharing plan. Rutgers asks the companies that license its African patents to share benefits but not the University itself. Thus, none of Rutgers’ patent income goes to benefit sharing. Instead, the commercialising company is asked to make payments directly to entities in the country of origin. (An odd structure considering that the licensee may have no familiarity with the country of origin, much less the skills necessary to work effectively with entities there. In addition this unilateral one-size-fits-all approach ignores the fact that in most national laws there cannot be any transfer of rights even if Rutgers legitimately accessed the genetic resource or traditional knowledge in the first instance.)

But benefit sharing by the licensing company is not even mandatory. The applicability of the provision to share benefits in this convoluted policy/agreement boils down to:

‘[Rutgers] requests that the private sector company must be committed to adhering to a benefit sharing policy based on the commercialization of a patent, invention, or discovery.’

Rutgers ‘requests’ that the company ‘*must be committed*’ to ‘*a benefit sharing policy*’ (what policy?) ... in a document that is a university ‘departmental policy’ but whose title declares that it is an ‘agreement’? The verbiage is obviously meaningless.

The benefit-sharing substance of Rutgers’ document comes in its final three paragraphs. These items Rutgers would take effect through the University’s request that they be inserted into a licensing agreement signed by the company.

In the first of these convoluted paragraphs the University and private company say they ‘*believe in sustainable development*’ (a statement with no practical effect) and ‘promise’ to develop a benefit-sharing plan. These are essentially recitations, and no concrete commitments are made.

Then, terms of the plan to be developed under the first paragraph are somewhat contradictorily specified in the second, which states (sloppily): ‘*5% or 10% of all sales/profits generated as a result of this invention*’ will be provided to (1) an NGO in the source country involved in medicinal plants, (2) ‘communities involved’ in collection and processing of the plant product, and (3) a ‘*leading institution of higher education*’ in the source country, which must use the funds to further the plant-export industry.

Rutgers' commercial relationship with the company – e.g. the royalties and other payments the University receives – is defined separately, and none of its terms are part of the benefit-sharing agreement/policy.

The third and final paragraph of Rutgers' alleged benefit-sharing agreement is intended to make sure that nobody on the outside would ever get to the bottom of Rutgers' laughable approach to benefit sharing, even in the unlikely event that its policy/contract actually took effect. This paragraph reads, in its entirety (punctuated as in the original):

'Both parties agree not to publish the above agreement on Benefit Sharing but to provide a highlight declaring and showing to the public that a benefit sharing policy is in place. [This last statement has been requested by the private sector].'

Thus Rutgers has a secret 'agreement' to publish a 'highlight' of a 'benefit sharing policy' which is so poorly thought out and written that it can never practically function. Yet this convoluted arrangement to 'provide a highlight' without releasing the actual agreement terms could be used to create the false impression that benefit sharing is taking place, without permitting the actual terms to be examined.

From its title to its conclusion, Rutgers' agreement/policy is ill conceived and unworkable. But the University continues to lodge new patent claims. The numerous inconsistencies of Rutgers' policy plainly show that little thought or expertise went into its creation, suggesting cynicism about benefit sharing. The structure of its policy/agreement ensures that even if an attempt to implement it was made, its failure wouldn't be apparent.

The only thing that is sure is that the agreement/policy enables Rutgers and its business partners to claim that benefit-sharing arrangements have been made, even if they are not implemented and unworkable to begin with. And perhaps that's just what Rutgers, its USAID funder, and its business partners want: To be able to say that benefit sharing is being taken seriously, even if in reality it is not.

Meanwhile, Rutgers continues to file more patent applications on African medicinal plants, hoping to finally achieve patent control over breakthrough products.

Food giant Nestlé claims to have invented stomach-soothing use of *habbat al-barakah* (*Nigella sativa*)

The world's largest food company, Nestlé, is seeking a patent on the use of *Nigella sativa* to prevent food allergies, claiming the plant seed and extract when they are used as a food ingredient or drug. Commonly known as *habbat al-barakah* in Arabic, and frequently called 'black seed', 'black cummin' or 'fennel flower' in English,¹⁹ *Nigella sativa* is an ancient food and medicinal crop.

The Swiss giant's claims appear invalid, as traditional uses of *Nigella sativa* clearly anticipate Nestlé's patent application, and developing country scholarship has already validated these traditional uses and further described, in contemporary scientific terms, the very medicinal properties of black seed that Nestlé seeks to claim as its own 'invention'.

Black seed

The date and location of domestication of *Nigella sativa* is not clearly established, but the plant was certainly under wide cultivation more than 3,000 years ago, when it was placed in the tomb of Egyptian King Tutankhamun. Historical evidence also shows contemporaneous, or earlier, black seed cultivation in Jordan and Iraq. In addition, wild types of *Nigella sativa* grow in Turkey, Syria, and Iraq, suggesting domestication may have originally occurred there.²⁰

In ancient times, *Nigella sativa* cultivation ranged at least from North Africa across the Middle East and into South Asia, where the plant has also been used in traditional medicine for 1,000 years or more. Today, black seed is sown in its traditional range as well as in more southerly parts of Africa, in Europe, and elsewhere in the world.

Because black seed is widely cultivated, unlike some medicinal plants, obtaining plant seeds is very easy. The Nestlé *Nigella sativa* story is not about piracy of physical materials, but instead about appropriation of traditional knowledge.

Nestlé's claims: Broad and directed toward natural foods

Nestlé's international patent publication (WO2010133574), published in November 2010, is directed towards use of *Nigella sativa* to stimulate

opioid receptors in the human body, thereby preventing or reducing allergic reactions to foods. Nestlé researchers demonstrated this effect by inducing an egg protein (ovalbumin) allergy in mice, and then co-feeding the rodents the allergen and a compound called thymoquinone, which is a major chemical constituent of black seed oil (as well as the herb thyme). With the addition of thymoquinone to their diet, the mice exhibited a less severe allergic reaction to the egg protein.

From a food company's perspective a great advantage of claiming thymoquinone is that it can be delivered in the form of *Nigella sativa* seed, which is a familiar food in many parts of the world. In addition, because it has been widely consumed for so long, it does not require stringent regulatory review as a drug or as a new food additive. It can also be labelled 'natural', to attract consumers that seek to avoid highly processed foods or artificial ingredients.

Thymoquinone from black seed has been the subject of significant formal scientific interest since the 1990s, with many studies focusing on its potential use as an antioxidant (to prevent fat build-up in arteries) and as a potential cancer treatment.

On its face, it might seem that Nestlé has discovered a new application for thymoquinone, but dig a little deeper, and Nestlé's claim of novelty vanishes quickly.

Nestlé claims any use of an opioid receptor-stimulating compound to treat or prevent allergies, specifically thymoquinone and, more specifically, administration of thymoquinone in the form of *Nigella sativa* plant material (seeds).²¹ The type of food allergy of greatest focus is upset stomach and diarrhoea.

Nestlé claims pure thymoquinone and/or whole *Nigella sativa* in a huge range of doses. These go from 0.1 to 90 *milligrammes* per kilogram of body weight per day for pure thymoquinone, to up to 50 *grammes* if administered in the form of plant seeds. Thus, for a 75 kg adult, Nestlé claims a daily dose of *Nigella sativa* ranging anywhere from 7.5 milligrammes of pure thymoquinone, deliverable in a small pill, to a whopping 3.75 kg of *Nigella* seed, surely more than enough to satisfy the biggest appetite.

Nestlé claims any use of thymoquinone or *Nigella sativa* for the purpose of mitigating food allergies (including as an oral or injected drug). However, the patent application is particularly directed toward foods, including 'NaturNes', a baby food brand that the company markets in Europe. 'NaturNes' is the corporate giant's 'green' baby food product

aimed at EU parents concerned about chemicals and the environment. 'Nature Nes' marketing materials pledge '100% natural ingredients'. With the addition of black seed, Nestlé may add product claims about easier digestibility or decreased incidence of food reactions.

Traditional use and developing country science

But on the scientific front, thymoquinone's action on opioid receptors is not a Nestlé discovery. Existing literature establishes this effect, including a paper in 2000 by an Egyptian pharmacology researcher²² and trials in Pakistan using thymoquinone to help recovering drug addicts.²³ In 2004 and 2005, Iranian scientists studied thymoquinone use against *petit mal* epileptic seizure, concluding beneficial effects were likely due to thymoquinone's interaction with opioid receptors.²⁴ Thus, Western-style science, and developing country science in particular, has already established thymoquinone's activity on opioid receptors.

But what would cause Nestlé's researchers to link thymoquinone to treatment of allergic reactions? A brilliant discovery by a team of PhDs in white laboratory coats at Nestlé's sparkling facilities in Switzerland? That does not appear to be the case.

In traditional medicine, for hundreds and probably thousands of years, *Nigella sativa* has been used to treat digestive ailments. Further suggesting an anti-allergic effect, black seed is also traditionally used to treat asthma and respiratory inflammation. These traditional uses are well known, and have led scientists who study traditional remedies from Eastern Mediterranean, Middle East, and Asian countries to validate traditional medicinal uses of *Nigella sativa* by using formal scientific methods. This has resulted in dozens of confirmatory studies, including studies validating traditional use of black seed for gastrointestinal and allergic indications that Nestlé claims are its invention. These studies include:

- In 2001, Pakistani scientists tested traditional uses of *Nigella sativa* to treat diarrhoea and asthma, concluding that black seed extract acts as a muscle relaxant and bronchial dilator, anticipating Nestlé's claims.²⁵
- In 2003, in the *Journal of Ethnopharmacology*, Egyptian scientists reported that *Nigella sativa* oil and thymoquinone protected against stomach lesions in rats, as indicated by traditional medicinal use.²⁶
- In 2005, Egyptian gastroenterologists compared *Nigella sativa* to a synthetic drug for treatment of allergic asthma. They concluded that

Nigella sativa has anti-inflammatory and immunoregulatory effects that may be useful against allergic reactions.²⁷

- In 2008, Saudi Arabian medicinal plant researchers tested a traditional preparation of *Nigella sativa* seed used for gastrointestinal problems. Rats given the remedy developed fewer stomach problems than a control group when they were both given damaging doses of alcohol. Their conclusion: ‘The results of the present study... substantiates [Nigella sativa] use against gastric disorders in Unani and Arab traditional medicine.’^{28,29} Another Saudi study in 2001 (among others) demonstrated analgesic and anti-inflammatory effects of black seed oil,³⁰ properties related to controlling allergic reactions.

- In 2005, Turkish researchers conducted a study similar to the Saudi experiment, also concluding that *Nigella sativa* and, specifically, thymoquinone in black seed oil, protected the stomach.³¹ A 2006 follow-on study concluded that the protective effect may be due to an antihistaminic effect of thymoquinone.³² (Antihistamines are a primary treatment for allergic reactions.)

Conclusion: Unashamedly appropriating traditional knowledge

In claiming use of *Nigella sativa* against food allergies, Nestlé’s scientists have not innovated beyond what was already known in traditional medicine from Egypt to India and beyond. Moreover, prior to Nestlé’s claim, researchers in those countries used formal scientific methods to demonstrate the efficacy of traditional use of black seed to treat allergy symptoms. Those simple facts, however, have not deterred Nestlé from advancing its claim. In November 2011, Nestlé’s patent application in Europe was published. Other national (or regional) applications may exist but have yet to be published.

Recently, the Patent Cooperation Treaty (PCT) released a search of scientific literature related to the application, and found problems with Nestlé’s claim to have made an invention, citing some of the same research that is noted in this report.³³ The PCT opinion, however, is not binding on national patent offices, and Nestlé may submit modified claims. Thus, while the opinion is a blow to Nestlé’s application, it doesn’t mean that the claims are dead.

Like well-known biopiracy cases before it, such as patents on uses of neem, Nestlé’s unashamed attempt to appropriate traditional

knowledge reflects an ethical lapse and shows profound problems with the company's intellectual property practices. It can be hoped that Nestlé's claim will be turned down by patent authorities, but the fact that patent claims over traditional knowledge that preceded it have result in patents shows that intellectual property offices sometime share industry's disregard for traditional knowledge. Indeed the fact that a corporation with the resources of Nestlé would pursue a patent on such an obviously pilfered 'invention' at all is indicative of the need to improve patent review standards so that such applications are not worth filing in the first place.

III

Recent Biopiracy Cases in Agriculture, Food, and Fuels

Marker-assisted biopiracy

Ex situ wild tomato collections, genetic breeding techniques and patent claims

WHERE people rely upon supermarkets for their fruits and vegetables, the tomato is a food that sometimes loses its attraction. An often-heard complaint is that supermarket tomatoes are unripe, hard and unpalatable. It seems that traits that lend themselves to processing (for canning and fresh sale) simply don't make for good fresh eating.

Much of the blame lies with industrial agriculture, particularly mechanically harvested tomato varieties and large-scale hothouses. These homogenised operations are an important source for table tomatoes in urban (and some rural) areas, and can be found in the US, Canada, Mexico, the Netherlands, Turkey, Egypt, Kenya, China and many other places, producing and shipping tomatoes worldwide. While some may still savour tomatoes produced by more traditional methods, for most of the world, the tomato is increasingly an industrial product.

The expansion of industrial tomato farming has been accompanied by a rise in patent claims over tomato traits and genes. The eight patent applications discussed in this report include claims over seedless tomatoes, disease resistance, growth habits, higher yields and harder fruit (a desirable trait in industry). Other claims cover tomato genes that yield precursor molecules for the pharmaceutical and chemical industries.

The cases underscore difficulties in achieving equity in the use of biodiversity when *ex situ* collections are the source of patented materials. They also exemplify unsettled issues of access and benefit sharing for the

range of agricultural biodiversity that is not included in the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). In addition, in one case, the origin of tomato genes claimed cannot be determined from the patent documents, underscoring the need for patent applicants to be obligated to divulge the geographic origin of materials they claim.

Finally, this case study of patent claims on tomatoes shows how genetic breeding techniques related to marker-assisted selection (MAS), a biotechnology that (unusually) is generally positively regarded by industry and NGOs alike, can have a darker side when put in the context of biopiracy. It is through these techniques, applied to wild relatives of tomatoes, that the patented tomato genes discussed in this report were identified. With the combination of these genetic techniques and adroit patent lawyering, it has become possible in some cases for patent applicants to reach over the top of national access laws and, in effect, claim biodiversity that has never left its country of origin.

Background

A search of the World Intellectual Property Organisation's Patentscope database was performed to identify claims on tomato (*Solanum lycopersicum*) filed since 2007. Eight patent applications were selected for further investigation (see table, pp34-35). In seven of these cases, the materials claimed come from a wild relative of the cultivated tomato obtained from a seed bank. Genes from these related species can be introduced into commercial tomato varieties and, in some cases, other organisms. In the eighth case, the patent application contains insufficient data to determine the origin of genes claimed.

Since Europeans took them from the Americas, cultivated tomatoes have spread across the world. The tomato has approximately 17 species of wild relatives,³⁴ however, and these remain critical sources of traits for plant breeders. The centre of genetic diversity of these wild relative species of tomatoes is in Andean South America, especially Peru and Ecuador, and to a lesser extent nearby countries, particularly northern Chile.

These wild tomato species have yielded, and continue to provide, important traits for the cultivated tomato. For example, endemic tomato species from Ecuador's Galapagos Islands (*S. galapagense* and *S. cheesmaniae*) have provided salt tolerance and a growth habit trait ('jointless fruit stalk') that is widely used in the tomato industry today.

Tomato genebanks

Despite being cultivated globally, large *ex situ* tomato collections available to commercial plant breeders and allied academics are relatively few. Tomatoes are not among the crops in the ITPGRFA Multilateral System, meaning that new collections of tomato seeds are (generally) governed by the access and benefit-sharing provisions of the Convention on Biological Diversity (CBD), and by national regulations.

Largest Tomato Producers, 2009³⁵	
Country	Production (1000 MT)
China	46366
USA	14142
India	11149
Turkey	10746
Egypt	10000
Italy	6877
Iran	5888
Spain	4604
Brazil	4311

Major *ex situ* collections of tomato seeds, including wild relatives, can be found in the US and Europe. A US Department of Agriculture (USDA) facility in Geneva, New York holds the US government's collection,³⁶ while the University of California at Davis' Tomato Genetic Resources Centre (TGRC) is the genebank with greatest emphasis on diversity of tomato wild relatives.³⁷ The latter is a legacy of Charles Rick, a geneticist whose 1940s-1980s studies not only contributed to many new tomatoes (including, indirectly, some of the patent claims discussed in this paper), but also pioneered molecular selection and breeding techniques that are now widely applied to other crops.

In California's central valley, the TGRC is located in close proximity to the seed production, farming and processing operations of some of the world's largest tomato-growing companies, such as Campbell's Soup and Heinz. Many of these companies produce their own processing tomato varieties, tailored for specific products such as soups, juices and salsas. As these companies have tomato-breeding programmes and have enjoyed a long-standing relationship with the TGRC, it is quite likely that their privately held collections are substantial; however, no public catalogue of these holdings is available.

Since 2006, the European Commission, through a project based in the Netherlands, has brought some of its agricultural research resources to bear on tomatoes. The 'EU-SOL' programme, which also works on potatoes, aims to 'extract the under-exploited natural biodiversity present in [tomatoes] *to improve consumer-driven and environmentally-*

directed quality of tomato fruits...? A key aim of the project is to create 'new elite genotypes to boost our knowledge and provide a blueprint for novel high quality varieties to be developed by EU breeding companies'.³⁸

The seeds branch of the EC programme is a group of Dutch, Italian and Israeli scientists from the private and public sectors. They have assembled a core collection of 7,000 tomato seed types, and are working to create a comprehensive set of research and breeding lines (introgression lines) to enable the systematic identification and transfer of genes from wild relatives into cultivated tomatoes.³⁹

The EU-SOL programme's collection is mainly composed of accessions acquired from genebanks around the developed world. These include seeds from the USDA, IPK Gatersleben (Germany), and Dutch and Italian collections, among others. For tomato wild relatives,⁴⁰ EU-SOL has overwhelmingly relied on seeds acquired from two related US sources: the TGRC in California, and Steven Tanksley, a professor at Cornell University and a former student of Charles Rick, the TGRC founder.

One international agricultural research centre, the Asian Vegetable Research and Development Centre (AVRDC) in Taiwan, possesses a significant tomato collection. The tomato wild relatives held by AVRDC, however, are relatively few and mainly come from California's TGRC. In addition to the TGRC material, AVRDC has a small number of other accessions, mainly from Mexico and Chile (the latter via Kew Gardens, UK).⁴¹

Few recent collections publicly available

The major international tomato genebanks distribute very few recent collections from the tomato's Andean centre of diversity. Most seeds of wild relatives in genebanks were collected from the 1930s through the 1980s. On the one hand, this may be attributable to the fact that, in comparison to some crops, tomato specialists feel that existing collections are relatively good (except a few remote Andean areas that remain relatively unexplored).

On the other hand, it appears that collections have also slowed in part due to changes in national law and policies in the countries of origin. Foreign scientists may feel these policies discourage collections, while governments would likely assert that the drop-off in collections reflects unwillingness (or institutional inability) on the part of some scientists to

collect under modern, post-CBD access and benefit-sharing terms.

Exceptions to the general state of affairs include 2001 and 2005 collections in northern Chile by TGRC researchers,⁴² and a 2009 expedition to Peru by a consortium of US academics funded by the US government. In the latter case, while many tomatoes were collected, it appears that export permits were never granted by the Peruvian authorities. The wild relative samples were left at the International Potato Centre (CIP), the research centre in Lima which facilitated the collecting mission.⁴³

The Chilean seeds, however, are being freely distributed by the TGRC with a highly substandard material transfer agreement that simply states that in the event of commercial use of the seeds, the recipient 'should consider' benefit sharing with Chile. The MTA does not include any Chilean signatory.⁴⁴

Wave of new patent claims on tomatoes

Whether the apparent decline in new collections of tomatoes and wild relatives in South America is the result of new national policies, or of scientists stuck in the political past, or both, the apparent scarcity of newly collected germplasm hasn't stopped US and European companies and universities from filing new claims on tomato wild relatives.

Indeed, developing new tomato genotypes from tomato wild relatives, for use by the private sector, is an explicit goal of the publicly funded EU-SOL programme. Gene giants Monsanto and Syngenta have presented tomato patent applications, along with smaller seed firms and universities. These patent claims are summarised in the table on page 34-35 and in the paragraphs below.

In its patent application WO2009021545, **Enza Zaden B.V.**, a Dutch breeding company, has claimed higher-yielding tomato plants. The source gene is a growth trait identified in LA0716, a seed bank accession from the TGRC in California. LA0716 is an *S. pennellii* accession that was collected in 1959 near the town of Atico in the Arequipa Province of southern Peru.⁴⁵ Enza Zaden is a participant in the EU-SOL programme, with responsibilities in evaluating wild relatives' potential for the private sector.⁴⁶

In an overlapping patent application (WO2010147467), **Monsanto** has claimed the same gene from LA0716 because it imparts a growth habit (a specific form of a trait called sympodial index) that results in more

and heavier fruit per square metre in hothouse tomatoes. Monsanto's subsidiary De Ruiter also participates in the EU-SOL programme.

A frequently studied tomato type, LA0716 (also written LA716) was also the subject of a patent claim by Cornell University in 2000 (US patent 6,066,482). One reason why LA0716 has been the source of so many claims is that it is self-fertile,⁴⁷ an unusual trait for the species that makes this particular seed easier to use in research. It has also been used in genetics and breeding tools called introgression lines, explained below.⁴⁸

In patent application WO2007123407, **Monsanto** has claimed tomato genes and plants resistant to botrytis, a mould infecting many fruits and vegetables. The resistance comes from *S. habrochaites*, another tomato wild relative. Monsanto's source for the resistance is LYC 4,⁴⁹ a seed from the IPK Gatersleben seed bank in Germany. Although IPK Gatersleben's seed database lists LYC 4 as being of unknown origin, native populations of *S. habrochaites* are found in Peru and Ecuador.

Pennsylvania State University (PSU) has claimed high-lycopene tomatoes in its patent application WO2009117423. Lycopene is the red pigment in tomato fruit, and is thought to be an 'antioxidant' when consumed by humans. Studies have linked antioxidants to protection against cancer and improved cardiovascular health. PSU's high-lycopene trait was found in LA2093, a wild relative from the TGRC collection. LA2093 is an *S. pimpinellifolium* seed that was collected in 1980 on a roadside in south-western Ecuador in the town of La Union in El Oro Province.⁵⁰

Western Seed, a Dutch company, has claimed seedless tomatoes in patent application WO2009005343. The seedless trait, called parthenocarpy, comes from a set of genes found in LYC 4, the same *S. habrochaites* accession from which Monsanto has patented mould resistance. Some cooks prefer to remove tomato seeds before cooking or serving tomato dishes; thus, Western Seed is seeking a market advantage in selling a tomato that already comes with few or no seeds.

In patent application WO2011038244, the **University of Michigan** (US), **Hebrew University** (Israel) and the **Salk Institute** (US) have together claimed genes that code for chemicals called methylketones. Members of this class of chemicals are naturally produced in tomato wild relatives where, scientists speculate, one of their roles is to help repel pests. Methylketones have potential as insecticides and can be used as an 'ingredient' in chemical manufacturing processes ranging from pharmaceuticals to industrial coatings.

PATENT PUBLICATION	TITLE	OWNER	SUBJECT/CLAIMS	COMMENT
WO2007123407	Tomato plants having a high level of resistance to Botrytis	Monsanto (US)	Transfer of botrytis resistance genes from <i>S. habrochaites</i> (LYC 4/78) to cultivated tomatoes, and related genetic regions/markers.	Claims cover any source of <i>S. habrochaites</i> , but LYC 4/78 in particular. LYC 4 is a seed from the IPK Gatersleben in Germany.
WO2009005343	Parthenocarp genes in tomato	Western Seed Intl (Netherlands)	Cultivated tomatoes with genes from <i>S. habrochaites</i> coding for seedlessness.	Gene source is also LYC 4. This species typically comes from Ecuador and Peru. Old name: <i>Lycopersicon hirsutum</i> Dunal.
WO2009021545	Promoter sequence and gene construct for increasing crop yield in tomato	Enza Zaden B.V. (Netherlands)	SP3D sequence inserted into cultivated tomatoes in order to boost yield.	The preferred form of the SP3D gene, whose sequence is claimed, comes from LA0716, a TGRC tomato collected 1959, at Atico, Arequipa, Peru.
WO2009117423	High lycopene content tomato plants and markers for use in breeding for same	Pennsylvania State University (US)	Claims high-lycopene tomato plants and ways of breeding them. Lycopene is thought to have human health benefits.	Specific source is <i>S. pimpinellifolium</i> LA2093 from California's TGRC. LA2093 was collected in 1980 at La Union, El Oro, Ecuador.

WO2010147467	Tomato plants resulting from the introgression of a trait from <i>S. pennellii</i> into <i>S. lycopersicum</i>	Monsanto (US)	Patents use of SP3D gene coding for a trait ('average symphydial index of 2'), and related breeding methods to use the gene in hothouse tomato varieties.	Source is LA0716. (See Enza Zaden above.)
WO2011020797	Disease-resistant tomato plants	Syngenta (Switzerland)	Claims tomato plants resistant to botrytis and related genetic markers and DNA primers.	Resistance identified in <i>S. habrochaites</i> 04TEP990312. This seed cannot be identified in any genebank and the patent application does not explain its origin.
WO2011038244	Methylketone synthase, production of methylketones in plants and bacteria	Univ. of Michigan (US), Hebrew Univ. (Israel), Salk Institute (US)	Methylketones are used in industrial chemical and pharmaceutical manufacture. Claims methylketone-related gene sequences and their use, and similar sequences in other tomatoes and other species.	The key original sequence in this patent application comes from PI 126449, an <i>S. habrochaites</i> accession collected in 1937 near Yaso, Peru.
WO2011051120	Tomato fruit having increased firmness	Syngenta (Switzerland)	Genes for firmer tomatoes, their use in breeding, and resulting tomato plants/seeds.	Claimed genes originate in LA0716, the same TGRC tomato claimed above. LA0716 has been used in introgression lines to identify genes and to cross wild relatives with cultivated tomatoes.

Salk and the universities' claim primarily focuses on PI 126449, an *S. habrochaites* accession from the US Department of Agriculture collection. According to the USDA, the wild relative was collected in 1937 in a Peruvian town named Yaso.⁵¹ Also claimed is a similar gene found in LA1708, an *S. peruvianum* accession from the TGRC that was collected in 1977 near the town of Jaén, in Peru's north-eastern Andes. The patent claims the methylketone genes as matter, their insertion into bacteria and other microorganisms and plants, and the resulting organisms. One use the inventors clearly have in mind is production of methylketones in bacteria genetically engineered with tomato genes.

Not to be left out of the patenting fray, Switzerland-based giant **Syngenta** has two claims of its own. In patent application WO2011020797, Syngenta claims botrytis-resistant tomatoes (the same moulds targeted by Monsanto). The source of the resistance is an *S. habrochaites* accession identified as '04TEP990312'. No *S. habrochaites* accession with this name (or anything similar) could be identified in a major seed bank.

The Syngenta patent application is not helpful with respect to the seed's origin. No information is provided on where 04TEP990312 comes from, when and how it was collected, or how it came to be part of the Syngenta research programme. (As previously noted, however, native populations of *S. habrochaites* are found in Peru and Ecuador.)

In another patent application (WO2011051120), **Syngenta** claims harder tomatoes (it says 'increased firmness'). The gene for harder fruit was identified in *S. pennellii* LA0716, the same source of genes patented by Monsanto and Enza Zaden. 'Firmer' tomatoes have a variety of uses in industrial tomato production and processing.

Introgression lines and patent claims

At a glance it seems as if two specific tomato wild relatives – LA0716 and LYC 4 – have specific characteristics that lend themselves to commercial interest. The frequent citation of these seeds in patent-related research, however, mainly has to do with their use in tomato introgression lines. These lines are crosses between wild tomatoes and their cultivated cousins (see below) that are particularly useful for identifying and isolating genes and loci of interest.

Having found a useful trait, and identified its gene(s) and locus (the place where it occurs on a chromosome) in a specific introgression line, companies then have patent attorneys draft claims that seek to cover not

only the specific gene sequence found in the introgression line, but also other, similar sequences and similarly useful forms of the gene. Thus, in many cases, even if the examples of the patent application refer to one wild relative, for example, LA0716, the language of the patent claims will often attempt to cover similar genes that might be found in other accessions of tomato wild relatives.

The way introgression lines work is that a wild tomato species is crossed and then backcrossed, often over several generations, with a domesticated tomato variety. From these crosses, a number of lines are selected, each incorporating some chromosomes, or partial chromosomes, from the wild genome (which breeders can identify using molecular markers). The goal of the interspecies effort is to produce a set of lines that together include all of the wild type's genes expressed in the domesticated tomato's 'genetic background'. These introgression lines then facilitate gene identification and marker-assisted breeding.

Several tomato introgression lines have been created, and LA0716 (*S. pennellii*) and LYC 4 (*S. habrochaites*) have each been used as a representative of their species in the crosses. As a result, LA0716 and LYC 4 are frequently cited in scientific and patent documents.

But many patent claims that refer to wild relatives used in introgression lines also claim the same or similar genes when found elsewhere. For example, a growth trait first found in LA0716 introgression lines may also be present in other *S. pennellii* seeds different from LA0716, including genetic variants that may prove equally or better suited to the purposes of the patent claim.

The companies (and universities) lodging patent claims are aware of this, and may take measures to try to prevent their patent claims from being dodged by somebody discovering a slightly divergent gene in another wild relative. So, companies write patent claims to not only cover the specific diversity they have identified in the introgression lines, but to also try to claim other forms of the same gene and/or trait that are in genebanks or the wild, but which have yet to be specifically described.

For example, in patent application WO2010147467, after claiming the growth habit found in the Peruvian LA0716 accession, Monsanto proceeds to attempt to claim any other red tomato breeding line with that same growth habit, whether it comes from LA0716, any other *S. pennellii* seed or, in fact, any other plant in the *Solanum* genus.⁵²

Similarly, Western Seed's patent application WO2009005343 describes seedless tomato genes isolated from introgression lines made

with *S. habrochaites* LYC 4. In claims, however, the company asserts that any low- or no-seeded cultivated tomato with a combination of those genes (even if from a different source) is its intellectual property. Thus, other *S. habrochaites* types or other wild relatives with functionally equivalent genes in the same chromosomal location are encompassed. Interestingly, the international patentability search under the Patent Cooperation Treaty (administered by the World Intellectual Property Organisation) raised questions about the novelty of most of Western's claims. Nevertheless, the patent has been issued in Canada with the original claims intact, and is pending in many other jurisdictions.

Conclusion

Seed bank collections of tomato wild relatives are of strong interest to major agriculture multinational corporations as well as universities and smaller companies involved in developing proprietary tomatoes. Despite the new Nagoya Protocol on Access and Benefit Sharing that was adopted in October 2010, discussions at the Convention on Biological Diversity have yielded little concrete progress on the thorny issue of *ex situ* collections. Tomatoes in particular show how *ex situ* agricultural germplasm that is not covered by the ITPGRFA Multilateral System may be appropriated for private gain without benefits accruing to countries of origin. The issue of benefit sharing from new uses of germplasm collected before the entry into force of the CBD was also unresolved during the Nagoya Protocol negotiations and again the tomato cases reinforce the continuing injustice on countries of origin.

Patent claims on tomato wild relatives are accelerating, despite the fact that new collections of these seeds in their centres of diversity appear to have been limited since the entry into force of the CBD. Increased patents on old seeds might seem paradoxical, but can be explained by the economics of the expansion of industrial tomato production and, most importantly, by newer genetic and breeding technology that makes it easier to identify valuable genes in seed banks.

With tomatoes, the combination of genes and loci identified through introgression lines and crafty drafting of patent claims over them is allowing companies and universities to remotely reach into centres of origin by identifying genes in one wild relative collected years ago, and then using the language of patent claims to try to also control the same (or similar) genes found in as yet uncollected, or unstudied, wild seeds (i.e.,

controlling the relevant loci insofar as possible under law).

Thus, while marker-assisted selection and related biotechnological breeding techniques have escaped the wrath of environmentalists because they don't necessarily result in genetically modified crops, the situation with tomato wild relatives shows that these techniques can add to the potential for biopiracy. This is particularly the case for crops like tomatoes, in which combining domesticated types with related wild species is relatively easy.

In addition, whether from a new collection or a seed bank, Syngenta's patent application on a mould-resistant tomato, in which the origin of the claimed gene is not identified, shows that patents continue to be possible without revealing the origin of materials made proprietary. This emphasises the urgency for an unequivocal international solution to close this crucial gap, again something that was rejected by developed countries in the Nagoya Protocol negotiations. The current provision in Article 10 is for the following:

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilisation of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

However, there is no time frame for this to be established; the issue was taken up at the second meeting of the preparatory Intergovernmental Committee for the Protocol in July 2012. As expected, the recommendation is for more discussion that will take several years of negotiations starting with the 'need' issue.

Countries of origin will need to speedily put in place comprehensive and strong national access and benefit-sharing regulations and work internationally to press user countries to legislate benefit-sharing obligations with effective compliance systems. One aspect of the compliance system must be patent offices requiring the mandatory disclosure of the origin of a claimed gene, evidence of prior informed

consent and evidence of a fair and equitable benefit-sharing agreement(s).

Agrochemical giant DuPont to sell Bolivian sorghum gene

Introduction

In 2012 multinational giant DuPont plans to begin selling sorghum varieties containing a valuable gene taken from a sudangrass that was collected in 2006 in Bolivia.⁵³ DuPont has branded the gene 'Inzen A II', and it makes sorghum plants tolerant to herbicides made by DuPont and other companies. DuPont has acquired an exclusive licence to the Bolivian herbicide tolerance gene from Kansas State University. The latter has filed for patents in the US and under the Patent Cooperation Treaty⁵⁴ on the gene and plants that contain it.

DuPont hopes to expand its position across the sorghum seed market with the Bolivian resource by producing and selling Inzen A II sorghum, and licensing the gene to other seed companies. Inzen A II sorghum will be co-marketed with the herbicide quizalofop, which DuPont sells under the brand name 'Assure II'.

Sorghum is harvested on about 3 million hectares in the United States every year, and DuPont's subsidiary, Pioneer Hi-Bred, also sells sorghum seed in countries such as Argentina, Australia, Brazil and Mexico.

The case appears to be one of biopiracy by a US university in collusion with a major multinational chemical and biotechnology corporation.

Kansas State University (KSU), DuPont and the two professors who claim to be the 'inventors' of the Bolivian gene have refused to explain how they acquired the Bolivian seed. The seed that yielded the gene was collected on a Bolivian farm in 2006, 12 years after Bolivia's 1994 ratification of the Convention on Biological Diversity (CBD).

Despite repeated requests, KSU, DuPont and the so-called inventors of the Bolivian gene have produced no documentation of prior informed consent or an access and benefit-sharing agreement with a legally competent entity in Bolivia, yet they are poised to profit from the Bolivian gene. Citing the information as confidential business, KSU also refuses to reveal the financial terms of its agreement with DuPont.

Unless KSU or DuPont have made such arrangements without making them public, the case is almost certainly biopiracy. This could

result in demands against the company and the university at the CBD and in countries where the gene is patented or sold, particularly outside the United States.⁵⁵

Background: Sorghum and sudangrass

An African native, cultivated sorghum (*Sorghum bicolor*) is now grown all over the world, especially in warmer semi-arid regions. It is technically a type of grass and is closely related to several other grasses. Some of these, such as johnsongrass (*Sorghum halepense*), are often considered weeds. Other relatives, including sudangrass (*Sorghum bicolor* ssp. *drummondii*),⁵⁶ can be crops themselves.

Cultivated sorghum crosses with some of its grassy relatives, including sudangrass. This can create fertile offspring that can be further bred, including crossing the hybrid back to sorghum cultivars (and vice versa). By using this method of conventional plant breeding, KSU and DuPont scientists transferred the Bolivian herbicide tolerance trait to commercial sorghum varieties. There is also a developed commercial market for sorghum-sudangrass hybrids themselves.

As its name suggests, like cultivated sorghum, sudangrass has been spread from Africa to other parts of the world. Sudangrass can be grown for grain, but is far more typically grown as forage or hay for livestock. The date that sudangrass was introduced to Bolivia is unclear. In several other Latin American countries, it was introduced in the early 20th century and has since become adapted to these countries.

Research interest in sorghum, including sorghum-sudangrass hybrids, is growing for two reasons. Firstly, sorghum has low water requirements compared to maize and other crops. Drought and water scarcity are set to become more frequent problems as a result of climate change, and this has revived interest in sorghum because it may be particularly well suited for future climate conditions.

Secondly, sorghum's flexibility has attracted the biofuels industry. About one-third of the sorghum grain grown in the United States now goes into the production of ethanol⁵⁷ rather than feeding people or animals. In addition, the juice of sugar-producing sweet sorghum varieties is fermented into biofuel ethanol. Forage-type sorghum can also produce large amounts of biomass in a short time, making it a potentially efficient source of cellulosic ethanol.

The patent applications

KSU lodged US and international patent applications on the Bolivian gene on 11 January 2008. The international application (WO2008089061), under the Patent Cooperation Treaty, was published on 24 July 2008. Publication of the US application (US20100115663) was delayed until 6 May 2010.

Among its claims, the KSU patent application covers the Bolivian ACC⁵⁸ herbicide resistance gene, which was isolated from a sudangrass accession denominated Bol-71, and ACC-herbicide-tolerant sorghum plants produced with it. The patent application also claims any sorghum hybrid that is resistant to ACC herbicides. Patent examiners have, however, cast doubt on the novelty of these broadest claims. (Scientists have previously suggested that ACC tolerance genes from other sources might be genetically engineered into sorghum.)

While some of the broader claims may not survive patent examination, the core claims on the Bolivian gene and plants produced from it appear likely to proceed. The international patent application declares that KSU will seek patents across the world, including Bolivia's neighbour Brazil and most of Africa and Asia.⁵⁹ World Intellectual Property Organisation (WIPO) data indicates that KSU is pursuing patent applications in 34 European countries (including Turkey), Russia and Australia, although this data is incomplete and further patent applications may exist that are not recorded by WIPO.

The KSU patent application does not provide any information about the source of the Bolivian gene except that it came from 'wild' sorghum called 'Bol-71'. No further information about Bol-71 is given, apart from the fact that it was collected in Bolivia along with 82 other sorghum accessions. A review of scientific literature yields no scientific publications concerning the Bol-71 accession, leaving its origin a mystery.

The lead 'inventor' of the Bolivian gene is Mitchell Tuinstra, an American geneticist and plant breeder. Since the patent applications were filed, Tuinstra has left KSU and he is now a professor at Purdue University. Tuinstra's co-inventor is Kassim Al-Khatib, a weed scientist originally from Iraq. Al-Khatib has also left KSU and is now at the University of California at Davis.

A month after the patent applications were filed, in February 2008, KSU and DuPont jointly announced that DuPont had exclusively licensed the gene for commercialisation.⁶⁰ The financial terms of the

deal were not released. The agreement also included a KSU-identified tolerance gene for ALS-type herbicides. That gene reportedly comes from a variety of sorghum from the United States.

ACC herbicide tolerance in Bolivia

Although KSU's patent applications refer to the gene source only as 'wild sorghum', in recent interviews, Al-Khatib has clarified that Bol-71 is a sudangrass.⁶¹ In January 2010 he told the US farm press: 'We identified a resistant gene in Sudangrass. Resistance is strong and is a single gene. We back-crossed to elite lines of sorghum and found exceptional resistance.'⁶²

It is notable that the gene comes from sudangrass because in 2000 an investigator for Bolivia's Centro de Investigación Agrícola Tropical (CIAT-BO)⁶³ first reported resistance to ACC herbicides in Bolivian sudangrass. The resistant plants, possibly weeds, were growing in or near soya fields located north and east of the city of Santa Cruz de la Sierra, in the Provinces of Obispo Santiesteban, Sara and Chiquitos. This remains the only reported case of ACC herbicide resistance in sudangrass in the world, according to the International Survey of Herbicide Resistant Weeds.⁶⁴

Tuinstra and Al-Khatib thus did not originally identify ACC herbicide resistance in sudangrass. Bolivian public sector researchers were the first to do so. Subsequent to the CIAT-BO report, Tuinstra and Al-Khatib apparently decided to acquire and screen Bolivian sudangrass. Motivations to do so are obvious: Kansas is the leading US state in sorghum production (closely trailed by Texas) and Pioneer Hi-Bred (a DuPont subsidiary) maintains a sorghum research facility in Manhattan, Kansas, where KSU is also located. It is potentially profitable for both if they can patent new herbicide resistance genes.

Tracking the origin of Bol-71

Where exactly did the Bolivian gene come from? Who collected it, when and how did it get from South America to Kansas? Since there are no scientific publications on Bol-71, the answers lie with those that are claiming it as their invention.

Before publication of this report, KSU, DuPont, Tuinstra and Al-Khatib were all contacted with a number of questions. DuPont and

Al-Khatib did not reply. Tuinstra replied 'you are looking for intrigue where none exists' and declined to provide details, citing a confidentiality agreement with KSU.⁶⁵

The KSU Research Foundation, which manages the University's intellectual property, enigmatically replied, 'The germplasm was collected in 2006 from random weed samples in soybean fields in Bolivia pursuant to a contract. No one from Kansas State University collected these samples.'⁶⁶

While providing a date, and again confirming the Bolivian origin, KSU did not identify: who collected the seed; the parties to the contract, or how the seed came into KSU's possession.

A 2006 KSU Agronomy Department publication⁶⁷ reveals that it has maintained a long-term relationship with 'a large soybean grower in the Santa Cruz region'. This is the same area of Bolivia where CIAT-BO identified ACC resistance in sudangrass. Two KSU agronomy professors have repeatedly made working visits to the soya operation. One of the professors is a herbicide resistance specialist. The 2006 publication noted that the KSU agronomists went to Santa Cruz five times between 1998 and 2005.⁶⁸

Oddly, no scientific publications that directly relate to the long-term Bolivian research could be identified from either professor. If there are no research publications, then the nature of the collaboration remains unclear.

While KSU's refusal to provide additional details makes it impossible to conclusively link the two with information currently available, it seems likely that KSU's relationship with the large soya grower in Santa Cruz is related to the collection of Bol-71.

KSU was asked what benefit-sharing agreement it has in place with the Bolivian government or other Bolivian institution(s). It replied by refusing to confirm or deny the existence of an agreement, stating 'This is considered business confidential.'⁶⁹

KSU was repeatedly requested to provide the contract under which it claims Bol-71 was collected. There was no reply to these requests.

Mystery agreement between Kansas State University and DuPont

The agreement between KSU and DuPont defines who is profiting from the Bolivian gene, but its terms have not been made public.

Typically in the United States such a technology licence would provide for an initial cash payment from DuPont to KSU, followed by royalty payments based upon DuPont's sales of the licensed product. A percentage of KSU's proceeds would be paid to the 'inventors', as determined by a pre-existing intellectual property agreement between KSU and its research employees.

The timing of the licence agreement indicates that DuPont knew about the research at an early stage. The agreement was announced in February 2008, only a month after the patent applications were filed and well before their publication. This suggests that KSU and DuPont had agreed to cooperate on sorghum herbicide resistance well before 2008. It is possible that the cooperation predates acquisition of the Bolivian seeds in 2006, making DuPont not only the licence holder, but also potentially a participant in the procurement of the Bolivian germplasm.

KSU, DuPont and the 'inventors' of the Bolivian gene would not answer questions about their financial arrangements and relationship. Although KSU is a public entity, it declined to disclose what money it has received from DuPont and what royalties it and the 'inventors' will receive, saying the information is 'business confidential'.

In response to enquiries as to where it will pursue patent rights, KSU replied that this 'will become known to the public as the applications are published'. KSU also declined to clarify if DuPont's licence to the gene is global or only for certain countries, again saying the information is 'business confidential'.⁷⁰

Prior informed consent and benefit-sharing agreement (or lack thereof)

KSU's assertion that Bol-71 was collected 'pursuant to a contract' outwardly suggests that some form of prior informed consent (PIC) and/or benefit sharing may exist. Closer examination, however, casts strong doubt on whether such consent and agreement – if any exists at all – meets ethical and CBD standards or those required by Bolivian law.

There is no indication that KSU has any relation to government or other entities in Bolivia in this matter other than a mysterious cooperation with a Bolivian soya producer. In the case of the producer (and/or collector), KSU has not produced the purported contract or explained its scope.

Even if the alleged contract that KSU refuses to make public contains

PIC and benefit-sharing arrangements with KSU's collaborator in Santa Cruz, it does not appear that these would satisfy the requirements of Bolivian law. In Decree 24676 of 1997, Bolivia implemented Andean Community Decision 391 on Access to Genetic Resources. Among other provisions, Bolivia's implementation of Decision 391 requires that those seeking access to Bolivian genetic resources obtain permission and execute an access contract with the Bolivian government. This contract, among other things, requires a governmental partner in the research programme and for the Bolivian government to assume a just and equitable interest in any economic benefit or technology arising from the genetic resources.⁷¹

Further, Bolivia's political constitution of 2008 prohibits private appropriation and exclusive use of Bolivian biodiversity, establishes the right and responsibility of the state to defend, recover, protect and repatriate its biodiversity, and establishes that illegal trafficking and use of biodiversity will be criminally sanctioned.⁷²

This report conclusively determines that the ACC herbicide resistance gene was taken from Bolivia in 2006 and has been privately appropriated by KSU and exclusively licensed to DuPont. The investigation found no evidence that KSU has complied with the requirements of Decree 24676. It also appears that the patenting, licensing and sale of the gene does not comply with the Bolivian Constitution.

Bolivian experts should study these legal matters further. KSU must produce the contract under which they say the Bolivian gene was collected without delay.

DuPont's plan

While DuPont's licence of the Bolivian gene was announced in 2008 (before the gene's origin was revealed), it was not until 2010 that DuPont began to seriously promote its new product to US farmers.

The public relations campaign opened in March 2010 at a large farming industry gathering. DuPont's biggest selling point for the Bolivian gene is that the sorghum will tolerate 'over the top' applications of tank-mixed herbicides. In other words, farmers can spray the chemicals directly onto their plants, killing susceptible weeds, while leaving the crop unscathed. This method of weed control, massively popularised in the US by Monsanto's 'Roundup Ready' glyphosate-tolerant crops, has previously not been possible with sorghum.

DuPont's brand name for herbicide-resistant sorghum seeds is 'Inzen'.⁷³ Seeds that contain the Bolivian gene are called 'Inzen A II'. The 'A II' refers to 'Assure II' (quizalofop p-ethyl), DuPont's brand of ACC herbicide. The ALS resistance trait in sorghum from KSU that DuPont also licensed is called 'Inzen Z', for 'Zest', a DuPont brand of ALS herbicide.

The main weeds Inzen A II/quizalofop target are sandbur (*Cenchrus longispinus*), johnsongrass (*Sorghum halepense*) and shattercane. Shattercane is thought to have resulted from crosses between forage sorghums and other plants in the Sorghum genus and is particularly closely related to cultivated sorghum.

The Bolivian gene is scheduled to go on the US market in 2012, initially as a single trait in sorghum varieties. The company says it will begin to stack the Bolivian gene with the ALS resistance gene (in conventional varieties) in 2013, resulting in plants that resist both ACC and ALS herbicides.

In addition to selling the Bolivian gene in DuPont's own Pioneer Hi-Bred sorghum seed, DuPont says that it is negotiating with a number of other sorghum seed companies to license the trait to them, meaning that 'Inzen A II' sorghums with the Bolivian gene may be sold by other companies. In 2010, DuPont showcased the Bolivian trait in field trials to farmers in 11 US states.⁷⁴ DuPont says that it will provide information on seed prices in 2011.⁷⁵

There are questions as to how long the resistance genes will work in the field. ALS-herbicide-resistant shattercane has already been reported in seven US states, and ACC- or ALS-resistant johnsongrass has also been reported in seven US states and on large acreage in nearby Mexico.⁷⁶ DuPont says that it is developing plans to avoid resistance. It also says resistance in sorghum may be managed in conjunction with management of glyphosate resistance in other crops, through farmers adopting rotation systems that rely on using multiple herbicide modes of action in different years.⁷⁷

Conclusion

Kansas State University and DuPont have privately appropriated a valuable herbicide resistance gene collected in Bolivia in 2006. They are pursuing patents around the world on the gene and intend to commercialise it in 2012. The gene has a high commercial potential.

KSU and DuPont have refused repeated requests to explain exactly how they acquired the gene and what makes them believe that they are its rightful owners. Unless the two are inexplicably hiding valid access and benefit agreements, KSU and DuPont have colluded to commit biopiracy.

As a Party to the Convention on Biological Diversity, Bolivia has constitutional and other legal protections over its biodiversity that appear to have been flouted by KSU and possibly others involved in this case. It appears likely, but there is no certainty, that KSU's long-term relationship with a large soya grower in Bolivia's Santa Cruz region is linked to KSU's acquisition of the Bolivian sudangrass.

There is a heavy ethical and legal burden on KSU, DuPont and the 'inventors' of the Bolivian gene to explain and justify their actions, something that they have refused to do thus far by hiding behind 'business confidential' claims. No confidential business claim can justify theft and biopiracy, or abrogate KSU and DuPont's responsibilities.

A number of steps must be taken to publicly establish more facts and to stop this highly probable case of biopiracy:

First, KSU (a public institution) and DuPont must immediately produce all agreements and material transfer documentation relating to the collection of Bol-71 in Bolivia and its export to the United States, so that the facts regarding the physical collection and shipment of the accession may be assessed and verified by the Bolivian government and independent experts.

Second, KSU must immediately suspend its pursuit of patent claims over Bol-71 until the validity of its acquisition and possession of Bol-71 can be established. If it cannot be established, then KSU must abandon these claims.

Third, DuPont's move to commercialise the gene must be suspended due to unresolved biopiracy questions. This must include the suspension of DuPont's efforts to sub-license the 'Inzen A II' gene to other sorghum seed companies. Those seed companies should be made aware that DuPont and KSU's claim to exclusive ownership of this Bolivian gene may be invalid.

Chinese sorghum to enrich Texas agrofuel industry

A sorghum plant collected in 1956 at a Chinese government agricultural experiment station is under patent claim by Texas A&M University in the United States. Texas A&M says the sorghum is valuable because of a trait that permits hybridisation between sorghum and other species that can be used to create new agrofuel crops.

Texas A&M obtained the Chinese sorghum from the John Innes research centre in the United Kingdom, which itself received the sorghum from a German seed bank. Texas A&M did not breed the Chinese sorghum to obtain the key trait it claims, rather it was already there and was described in scientific literature at least 20 years ago.

In Patent Cooperation Treaty publication WO2010011935, as well as US patent applications 20100064382 and 20100050501, Texas A&M claims the hybridisation gene from the Chinese sorghum, its use in sorghum breeding, the resulting sorghum plants, the creation of crosses with other species, and the resulting interspecies hybrids themselves.

Texas A&M sees the Chinese gene as a profit centre for the University and as the way for it to become a major player in the development of agrofuel crops. Texas A&M already has a huge collection of sorghum seeds, many of which originate in Africa. With the Chinese gene, the University will be able to move traits from the diverse sorghum collection it holds into new kinds of agrofuel interspecies hybrids.

Texas A&M's first goal is to acquire firm patent control over the gene and plants containing it. Its first product goal is to create sorghum-sugarcane hybrids for agrofuel production. In parallel it is proceeding with a longer-term programme to cross sorghum with maize and other species, and selecting resulting plants for agrofuel purposes.

Texas A&M has existing agrofuel partnerships with seed companies including Ceres and energy companies including Chevron. It is now discussing additional investment with energy giant Shell, specifically to develop agrofuel plants using the Chinese gene. The University's ambitious plans even include a proposal to the US Department of Defence to power US Air Force jets with fuel from plants bred from the Chinese sorghum.

The case draws attention to the urgent need for the following:

- Assessing the importance of the Nagoya Protocol on Access and Benefit Sharing under the Convention on Biological Diversity, and

understanding how it would apply to *ex situ* collections of germplasm acquired before the entry into force of the Convention and of the Protocol;

- Patent and other intellectual property rights offices as a checkpoint to monitor and expose potential biopiracy;
- Awareness among policy-makers, academia and the public on the inequitable nature of patents and other intellectual property rights claims over genetic resources; and
- A comprehensive national law on Access and Benefit Sharing in developing countries.

How did a sorghum collected in China more than 50 years ago come to be claimed as the property of Texas A&M University in the United States?

Background: Kaoliang sorghums

Sorghum was domesticated in Africa but has a long history in China. Exactly when sorghum arrived in China is the subject of scholarly debate, although it came at least 2,000 years ago and perhaps much earlier.⁷⁸ Sorghum arrived in China after first stopping in India, where it is also an important crop. Over the millennia that sorghum has been grown in China, Chinese farmers have adapted it to their conditions, including those in the country's north, at notably higher latitudes than most of Africa and India.

The distinct sorghum varieties that Chinese farmers have created are collectively called 'Kaoliang sorghums'. Kaoliang is a Chinese word meaning sorghum that is also the name of a liquor distilled from sorghum grain. Kaoliang sorghums have distinctive characteristics, including cold tolerance, early maturity, and photoperiod insensitivity,⁷⁹ which reflect selection by Chinese farmers for their environmental conditions.

Collection of the Texas A&M Kaoliang sorghum

Texas A&M's acquisition of the Kaoliang sorghum that it is seeking to patent is an ironic accident of 1950s international socialist solidarity. Although research firmly establishes that the sorghum came from China, Texas A&M does not admit to the full set of facts regarding its Chinese origin, including in its patent applications.

The sorghum can be traced to a government agricultural research

station in Hulan (呼兰区), outside the city of Harbin in China's northeastern Heilongjiang Province (formerly called Manchuria). It was collected in 1956 by scientists from Leibniz Institute of Plant Genetics and Crop Plant Research (called IPK-Gatersleben) in what was then the communist German Democratic Republic (East Germany).

With precision, the IPK-Gatersleben scientists' account of their expedition specifies that they visited the Hulan Experiment Station (*landwirtschaftlichen Versuchstationen*) on 2 and 3 August 1956, and states that they collected sorghum seeds there.⁸⁰ Seven sorghums that they collected at Hulan were returned to East Germany and deposited in the IPK-Gatersleben gene bank.

The sorghum claimed by Texas A&M is recorded by IPK-Gatersleben under the name 'SOR-7'; but in more recent UK and US scientific literature it is referred to by the name 'Nr481' (the sequence number originally given to it by the collecting expedition scientists).⁸¹

Unfortunately, there is no information in Western scientific literature to indicate what exactly the Chinese agronomists at Hulan were doing with Nr481, nor does the German expedition report explain why Nr481 was selected to take to Germany. Nr481's presence at the experiment station establishes that Chinese scientists found it worthy of attention. It is unclear, however, if it is a farmers' variety collected for a breeding programme, an unusual type collected for a specific characteristic, germplasm bred at Hulan, or of some other origin.

At some point before the late 1980s, the seed was acquired from IPK-Gatersleben by Cambridge University in the UK.⁸² In a 1989 study, Cambridge and Kew Botanical Gardens researchers identified that Nr481 was unusually permissive to pollination from other species, although in their brief experiment they failed in their objective to viably hybridize Nr481 with maize.⁸³ The Cambridge University researcher who documented Nr481's pollination oddities in 1989 later moved to the UK's John Innes Centre, taking Nr481 with him.

Texas A&M acquired Nr481 from the John Innes Centre in 2003 or 2004.⁸⁴ With government research funding, in 2006, A&M researchers published results indicating they had crossed it with different species in the *Sorghum* genus.⁸⁵ By July 2008, they had gone a step further and filed for a patent, covering use of Nr481 and its genes to cross sorghum with more distantly related species, particularly sugarcane, but also millets, maize, and other plants. The patent applications claim all crosses and resulting plants that use the Nr481 genes, particularly crosses with other

grasses that share the C4 photosynthesis pathway.

Texas A&M officials have little to say about Nr481's origin. They profess to be ignorant of, and uninterested in, where Nr481 came from. When asked directly if they are aware that the sorghum was collected at a Chinese government agricultural experiment station, the inventor and senior A&M research officials did not respond.⁸⁶

In reply to a formal legal request for information about how they acquired the Chinese sorghum, Texas A&M merely stated that Nr481 came from the John Innes Centre⁸⁷ in the United Kingdom '*sometime around 2003 or 2004*'. And as if to pre-emptively cast doubt about the origin of the sorghum, A&M attributes information about a Chinese origin to British researchers, unwilling to confirm so much itself.

A memorandum prepared by the 'inventor', William Rooney, further suggests that Nr481 might not be a Kaoliang sorghum but be of another sorghum group (durra), although he concedes that Nr481 '*possesses traits typical of the Chinese Kaoliangs*'.⁸⁸ Texas A&M's patent application and other documents,⁸⁹ including A&M funding proposals, also muddy the waters by suggesting that Nr481 has '*wild*' parentage, that its key gene(s) are '*wild type*', and that it has '*poor genetic background*' with '*very undesirable agronomic characteristics*'.⁹⁰

Even as they patent its genes and stake very broad claims for its use in plant breeding, A&M repeatedly suggests that Nr481 is undesirable. The historical record, however, establishes that Chinese scientists first noted value in Nr481, that it was selected in the 1950s by German scientists for further evaluation, and that its unusual pollination characteristic was identified more than 20 years ago by British scientists. And, of course, the process of moving genes from a plant adapted to one place and set of conditions (1950s China) to a different genetic background (e.g. Texas ethanol production in 2010) is the *sine qua non* of most plant breeding programmes, including Texas A&M's.

A&M's 'badmouthing' of Nr481 thus appears disingenuous - a bit of wilful historical ignorance calculated to suggest that A&M has created immense value from a worthless wild weed. That is, by confusing and diminishing the significance of Nr481's origin, A&M is seeking to increase the appearance of innovation by the University. In fact, A&M did not breed Nr481 to obtain its key characteristic, and A&M has done little other than to appropriate existing knowledge and resources that were already identified as valuable and provided by others.

A&M's plan: Leverage Nr481 to become a key player in the agrofuel industry

Texas A&M imagines the blossoming of a very large-scale agrofuel industry based on hybrids between sorghum and other species enabled by an Nr481 gene called 'iap'.⁹¹ The University articulated its vision in a 2009 funding proposal submitted to the Defence Advanced Research Projects Agency (DARPA), a research arm of the US Department of Defence. With substantial salesmanship – Texas A&M describes the Nr481's trait as a '*wide-hybridization technology platform*'.⁹²

Texas A&M University will create and deliver advanced high-yielding energy sorghums and new energy crops through a novel, non-GMO, wide-hybridisation technology platform. These unique energy crops will be sustainable, high yielding, widely adapted, drought tolerant, optimised for biofuels and biopower generation, thereby significantly improving US biofuels and biopower production capability and long-term energy security.

Although Texas A&M is a public institution, it has determined to take a highly proprietary and business-oriented approach with the

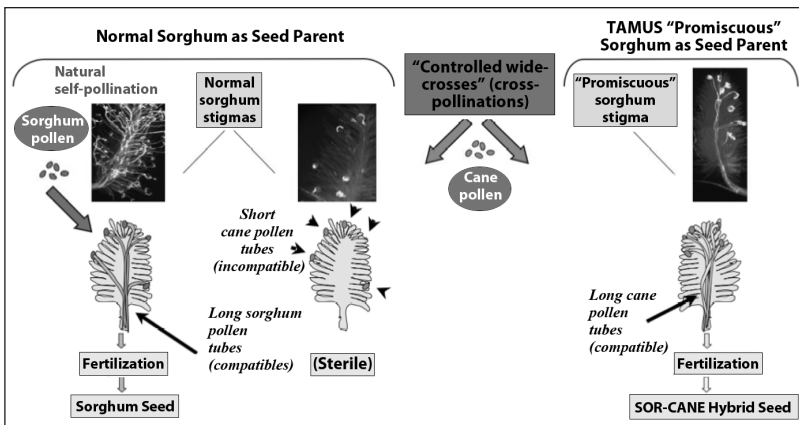


FIGURE 3: Diagrammatic representation of wide-hybridization technology for sorghum (*Sorghum bicolor*): normal sorghum stigmas are highly “self-compatible”, i.e. with sorghum pollen (left), but highly incompatible with alien (center), pollen tubes of which are forced to cease growth soon after emergence, thus precluding fertilization. In the specially bred TAMUS “promiscuous” lines of sorghum, the alien pollen is much more compatible (right) resulting in pollen tube growth, which thus permits fertilization, embryogenesis and formation of F1 seed.

(From Texas A&M University. 2009. High-Biomass Energy Crops for US Energy Security.)

Chinese sorghum technology. A&M is marketing ‘wide hybridisation’ (or ‘promiscuous sorghum’ in the illustration below) to the seed and energy industries under complicated licensing schemes and non-disclosure agreements, leaving A&M’s other partners and farmers out in the cold, and with no consideration for the Chinese origin of A&M’s ‘invention’.

As Texas A&M officials paint the scenario, they feel obliged to be secretive and proprietary about the Chinese sorghum because they allege that private industry has previously used A&M crop research (notably in cotton) without adequately compensating the University.⁹³ Thus, A&M has assembled a commercialisation team for Nr481 that includes a former senior GE crop developer for DuPont and an intellectual property staffer from the University of California at Berkeley, where he was involved in a highly controversial deal that gave Syngenta (then part of Novartis) significant rights over university research.⁹⁴

In personal communications and internal e-mails obtained under the Texas Public Information Act, Texas A&M officials have no detectable sensitivity to the fact that others, including Chinese and African farmers, may feel that Texas A&M’s patent claims are unfair to them in a manner similar to how A&M feels about how it has been treated by multinational seed companies. Texas A&M’s officials feel that their massive sorghum germplasm collection, which rivals (and duplicates much of) that of the Consultative Group on International Agricultural Research, belongs to Texas A&M and nobody else.

The University has resisted and delayed responding to public information requests about Nr481. Through what that has been made available, however, particularly an accidentally released funding proposal to the US Defence Department, much of A&M’s plan has been revealed.

A&M’s early targets for ‘wide hybridisation’ include creating fertile agrofuel sorghum-sugarcane hybrids grown from seed. These unusual hybrids would contain the full genome of each parent plant, and would mix traits from both species. As sugarcane is normally reproduced by vegetative propagation, the hybrid seed is potentially a new market for seed companies and a labour-saving development for farmers.

A&M also plans to use the Chinese gene to create at least 10,000 new crosses between sorghum and other C4 grasses every year for the next five years. In parallel, it is seeking new funding to ‘digitally genotype’ its sorghum seed collection to bring forward agrofuel traits. A&M’s goal is to winnow these large populations of new crosses down to about 1,000 that show development promise by 2015.⁹⁵ In addition to funding from

the US Defence Department, Texas A&M is also seeking a deal with Shell Oil for Nr481 development.⁹⁶

Conclusion

One of the most controversial and difficult issues for the negotiations of the Nagoya Protocol on Access and Benefit Sharing, that was adopted by the Conference of the Parties to the CBD on 29 October 2010, was benefit sharing from the utilisation of genetic resources acquired before the entry into force of the CBD and the Protocol, most of which are now in *ex situ* collections in developed countries.

Developing countries argued that ‘new and continuing’ uses of such *ex situ* genetic resources should be covered by the Protocol so that the country of origin or country that provided the resource in accordance with the CBD can also have its fair share of benefits. As this case of the Chinese sorghum shows, the country of origin of an important genetic resource with tremendous commercial value can be left with no share of the benefits. Worse, foreign institutions now claim the ‘ownership’ of the important traits and indirectly of the resource.

The Protocol provides for a new global multilateral benefit-sharing mechanism. It states that:

‘Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilisation of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.’

In this mechanism, the benefits will be used ‘to support the conservation of biological diversity and the sustainable use of its components globally’ and it is not clear how the sharing will be done with the country of origin. Therefore it will be necessary to interpret and understand what this provision means when the Protocol enters into force. Will a case such as

China's sorghum be included? And will countries in such a situation be able to receive some of the benefits?

This case study also shows the importance of patent and other intellectual property rights offices as a checkpoint to monitor and expose potential biopiracy. Developed countries rejected the explicit inclusion of these offices as a mandatory checkpoint established under the Protocol – China together with all developing countries strongly wanted this but the final compromise did not make this mandatory. It is now up to each Party to the Protocol to decide if patent and other IPR offices will be a checkpoint.

More fundamentally this case study again illustrates the inequitable nature of patents and other intellectual property rights claims over genetic resources, and it would be useful for developing countries to continue to participate actively in the review of the patenting of life form provisions in the WTO Agreement on Trade-related Aspects of IPRs (TRIPS).

Finally, developing countries urgently need to establish and implement a comprehensive national law on Access and Benefit Sharing so as to prevent biopiracy of their biodiversity and associated traditional knowledge, and to ensure that they get their fair and equitable share of benefits.

US researchers file for patent on the lucuma fruit, a 'flagship product' of Peru

US researchers are seeking a patent on the lucuma, fruit of the lucumo tree (*Pouteria lucuma*), a native of Andean valleys that is highly esteemed in its native Peru. Rutgers, the state university of New Jersey (US), filed the application. The University claims that its scientists have discovered that lucuma seed oil has beneficial effects on the skin, but research suggests that Rutgers' 'invention' is in fact taken from traditional knowledge.

An international patent application (WO/2010/056908) published in 2010 seeks patent rights in Europe, Asia, and other regions. US and European patent applications have also been published.⁹⁷ If granted, the patent will give Rutgers exclusive rights over the use of lucuma seed oil on the skin. The University already has a commercial partner, Lipo Chemical,⁹⁸ which is owned by a large Miami-based investment firm named HIG Capital.⁹⁹

In Peru, one of the reasons why lucuma is considered special is its native status and its strong association with the country's rich cultural heritage. Nowhere else is lucuma grown and consumed so much, and the fruit has been a part of the Peruvian diet for millennia. The remains of lucuma have been found at several of the oldest and most iconic archaeological sites in the country, and the fruit is represented on some of Peru's most famous textiles and ceramics, created by diverse cultures over thousands of years.

The lucuma bears resemblance to some of the fruits collectively called *sapotes*, such as canistels and mameys, although different kinds of 'sapote' are not necessarily close relatives. The lucumo tree is technically not tropical, as it can be found at high elevations in the Andes (up to 3000 metres), preferring relatively dry locations.¹⁰⁰

In 2005, the Peruvian government selected lucuma as one of 10 national 'flagship products' (*productos bandera*) linked to the country's international identity. According to Peru's governmental intellectual property institute, INDECOPI, '*Flagship products of Peru are products or cultural expressions whose origin or transformation has occurred on Peruvian territory with characteristics that represent the image of Peru outside of the country.*'¹⁰¹

But Rutgers University apparently did not get the memo.

The Rutgers patent application declares, among other questionable claims, that there is '*virtually no information on the effects of lucuma on human health*', an assertion revealed as dubious by research on traditional use of the fruit and plant. In fact, sources available on the Internet, much less specialised library holdings, contradict many of Rutgers' assertions and raise a direct challenge to the University's claim of an invention.

Rutgers' patent application seeks to control use of lucuma nut oil in pharmaceuticals, cosmetics, and other preparations applied to the skin to heal wounds and promote skin health. It claims the nut oil as matter, no matter how it is extracted. It also claims standard nut oil extraction techniques when applied to lucuma. Rutgers has tried to more specifically identify active component(s) of the oil, but its published efforts have thus far been unsuccessful.¹⁰²

But use of lucuma in traditional medicine has been amply documented for many years. For instance, a new world medicine text published in Paris in 1864 (*El Medico botanico Criollo*) notes that the latex of the immature fruit is used to treat skin problems, including warts and wounds.¹⁰³ An 1888 French text notes that the seed is used to treat

stomach and urinary tract problems¹⁰⁴ and, also in 1888, the Society of the Chemical Industry (UK) noted medicinal use of seed extracts to treat bladder problems.¹⁰⁵

In contemporary times, benefits of using lucuma on the skin are known in Peru and touted in product claims and media reports. In a report by Peru to the UN Food and Agriculture Organisation in 1995, government scientists placed lucuma among the country's most important plants with food and medicinal uses, noting that the latex is used to treat skin lesions and infections.¹⁰⁶

In addition to its patent application, Rutgers has devised a new English common name for the lucuma, dubbing it 'Incan Golden Fruit', and has noted ancient Peruvian ceramics that resemble the fruit.¹⁰⁷ (Those ceramics, however, were made by the Moche culture, which is distinct from that of the Inca.) Available documents don't state why Rutgers is renaming lucuma, but it is reasonable to assume that the University believes that 'Incan Golden Fruit' will sound attractive to consumers shopping for skin care products.

Peruvians, however, are unlikely to embrace Rutgers' new name. On top of the patent, the University appears intent on hijacking images of Andean cultural heritage to promote sales, which is notably ironic considering that Rutgers ignores information about traditional medicinal use of lucuma in its patent application.

The patent and marketing efforts of Rutgers call attention to an important issue facing countries that have ratified the Nagoya Protocol to the Convention on Biological Diversity. While the Protocol's Article 8a says that 'simplified measures' for access to genetic resources should be afforded to non-commercial researchers, a defensible definition of 'non-commercial research' is hard to find. Many projects that appear, or start out, without commercial ends change over the course of time into research with commercial aspects.

Rutgers, a public research university that is part of the government, also shows yet again that public and non-profit entities such as schools and research institutes cannot be assumed to be conducting 'non-commercial' research and cannot be afforded less stringent access rules without facilitating biopiracy.

Rutgers' failure to cite traditional medicinal uses of lucuma, and its rebranding of lucuma as 'Incan Golden Fruit' also highlight the need for access laws to address complex interrelationships of genetic resources with traditional knowledge and culture. How else to respond to Rutgers'

attempt to market lucuma by means of its cultural associations, even as it dubiously claims a novel invention?

Unfortunately, this paradox is not unusual in the cosmetic and nutraceutical industries. There, products often rhetorically link beauty and health to themes of ‘traditional wisdom’ and the ‘exotic’. These efforts, however, are much less about respect for indigenous people and knowledge than they are about appropriating images that sell products.

Smithsonian seeks to patent Panama research and claims work of others as its own

Piracy and ethical questions swirl around patent application on biological control for leafcutter ants

Long considered an icon of curatorship and research, the Smithsonian Institution, the quasi-governmental operator of museums and research institutes based in Washington, DC, is poised to trade its elite image for an unenviable listing in the biopiracy hall of shame.

The reason is the Smithsonian’s bold, broad, and bogus patent claim over biological control of ant colonies. Based on its own research in Panama, and research by others, the Smithsonian claims ownership over use of parasitic fungi as biological control agents for leafcutter ant species found in tropical and warm temperate climates of the Americas.

The claim is notable not just for its audacity – spanning two continents, three entire genera of fungi, and nearly four dozen ant species – but also for the suspicion that it will cast upon the fabled Institution. The ‘invention’ that the Smithsonian claims as its own was described years ago in papers by Latin American scientists from several countries, and the Smithsonian’s ‘inventors’ were aware of this. One of them was even a reviewer of a Brazilian paper that describes most of the alleged invention, and which was published four years before the patent claim was filed.

The Smithsonian’s claim will raise eyebrows among scientists because of its disrespect for other researchers, its lack of novelty, and its lack of invention. It should also attract the attention of governments, because the Smithsonian’s patent audacity suggests that the Institution’s access to genetic resources should be monitored or restricted, and because it brings into doubt the wisdom of the Institution’s participation in the Global

Environmental Facility's first funded project to implement the Nagoya Protocol on Access and Benefit Sharing, taking place in Panama.

Background: Leafcutter ants, fungi, and agriculture

Two genera of new world ants, *Atta* and *Acromyrmex*, are together called leafcutter ants. The 47 described species of leafcutters are found in most warm regions of the Americas, from Louisiana in the United States to northern Argentina. The sophisticated social structures and behaviours of these ants are frequently discussed in popular science media. Leafcutters trim foliage from green plants, harvesting leaves in small sections. They carry the leaves back to elaborate colonies in famous 'marching' lines that extend across the ground. Images of these ant 'parades' are iconic, especially as lasting images of neotropical forests.

Less well known is what leafcutter ants actually do with the leaves once they have been carried home. The cuttings are not, as one might suspect, ant food. Rather, once inside the colony, the leaf pieces are taken to colony chambers where they are used as a substrate on which the ants 'farm' a particular species of fungus. That fungus, strains of *Leucoagaricus gongylophorus*,¹⁰⁸ in turn is the ants' primary food. Some scientists describe the ants' ancient relationship with the fungus as the first farming system on Earth, while others caution against such anthropomorphisms.

Leafcutters' symbiotic relationship with *Leucoagaricus* fungus is thought to have begun tens of millions of years ago in the Amazon Basin, and it is studied as a model of mutualistic relationships between species. Without the fungus, the ant colonies die. When migrating to establish new colonies, leafcutter queen ants carry pellets of the fungus with them, perpetuating the relationship between insect and fungus species.

Like human farmers' fields, the ants' fungus farm can have problems with 'weeds'. These include parasitic *Escovopsis* fungus that specialises in attacking *Leucoagaricus*, denying the ants their food source. To fight off *Escovopsis*, the ants carry bacterial cultures which produce antibiotics that kill the parasite. Despite the ants' chemical defence, *Escovopsis* and other parasites sometimes win the fight, taking over the ants' prized food source.

While leafcutters have pest problems of their own, in human agriculture, the ants themselves are a potential enemy. They can quickly devastate row crops, citrus, cassava, coffee and other plants, and can be a particular problem in highly disturbed ecosystems and monocultures.

As a result, some farmers try to eliminate the ants, typically with chemical insecticides such as chlorpyrifos (Lorsban). In poor communities especially, sometimes queen ants are found and killed (a difficult and labour-intensive process), or petrol is poured into ant holes and then lit.

Because of their ecological and agricultural importance, for many years, researchers from Brazil,¹⁰⁹ Mexico,¹¹⁰ Colombia,¹¹¹ Venezuela,¹¹² Costa Rica,¹¹³ and other countries have studied leafcutters, including their role as pests. Some of these studies, including work at the Smithsonian's Tropical Research Institute (STRI) in Panama, have elucidated key aspects of the complex leafcutter-fungus relationship. Scientists have developed understandings of how parasitic fungi, particularly *Escovopsis*, can cause the collapse of leafcutter colonies, and some research has considered use of *Escovopsis* and/or other fungi as biological control agents.

The Smithsonian's alleged 'invention', and its scientific context

For reasons only fully known to it, and which cannot be reconciled with the published record, the Smithsonian Institution has boldly claimed that use of *Escovopsis* to control leafcutter ant colonies is its own invention. It further claims that use of two other fungal genera to control leafcutters, *Trichoderma* and *Acromonium*, is its patentable idea as well.¹¹⁴

Claims that these previously described ideas are a new 'invention' would be an embarrassment to any reputable scientific institution. They should be acutely embarrassing, however, to one with the posturing of the Smithsonian, which calls STRI – source of the patent claim – '*the world's premier tropical biology research institute*'.¹¹⁵ In truth, rather than a scientific honour roll, in view of the mendacity of the patent application, the Smithsonian might instead appear in a biopirate's hall of shame.

The patent application was lodged at the US Patent and Trademark Office on 28 September 2011. Its international (Patent Cooperation Treaty administered by the World Intellectual Property Organisation) homologue was published as WO2012050857 on 19 April 2012. It claims any strain of *Escovopsis*, *Trichoderma* or *Acromonium* fungus used as a biological control against any of the 47 known species of leafcutter ants, including fungal spores mixed in different ratios with inert carriers.

While the patent application takes the approach of claiming use of any strain of the three fungus genera against any of 47 kinds of leafcutter ants, the patent text is particularly directed toward three *Atta* species that

Species	Reported Distribution (south to north)
<i>Atta colombica</i>	Colombia to Guatemala
<i>A. sexdens</i>	Brazil to Panama
<i>A. cephalotes</i>	Brazil to Mexico
<i>Acromyrmex octospinosus</i>	Brazil to Mexico, also Caribbean
<i>A. subterraneus</i>	Brazil, Paraguay
<i>A. landolti</i>	Brazil, Guyanas, Venezuela
<i>A. lundii</i>	Argentina to Brazil
<i>A. striatus</i>	Argentina to Brazil

the inventors have studied at STRI (see table).

The species claimed by name in the patent application claims are summarised above:¹¹⁶

The Smithsonian was far from the first to explore the idea of using *Escovopsis* and other fungi that attack the ants' gardens as a biological control. In fact, it has been a subject of experiments since at least the early 1990s, and began to be discussed in scientific literature more than 15 years before the Smithsonian's patent application.

In 1993, scientists at the *Corporación para Investigaciones Biológicas* in Colombia¹¹⁷ conducted laboratory and field experiments with potential biological control agents for *Atta* ants, including a *Trichoderma* strain intended to attack the ants' food fungus.¹¹⁸ In 2001 the studies continued, and more *Trichoderma* were demonstrated to be active against *Leucoagaricus* fungus.¹¹⁹

In Brazil, a research group at the State University of São Paulo (*Universidade Estadual Paulista*) has actively researched fungal biocontrol of leafcutter, publishing articles predating the Smithsonian's patent application. Among these is a 2006 study on the susceptibility of *Leucoagaricus* to attack by other fungi, a study conducted with a view to creating a biological control for ants.¹²⁰ In the research, the Brazilian scientists tested *Escovopsis*, *Trichoderma*, and *Acromonium* cultures against *Leucoagaricus*, concluding that under laboratory conditions *Escovopsis* was the most effective.

Escovopsis, *Trichoderma*, and *Acromonium* are the same three fungus genera claimed in the Smithsonian patent application.

Particularly notable about the 2006 Brazilian study is that it was reviewed before publication by Cameron Currie, a University of

Wisconsin professor. Professor Currie is listed as a co-inventor of the Smithsonian patent claim, which was filed about four years later. Given the extensive overlap between the Brazilian study and the Smithsonian claim, significant scientific ethics issues seem to be raised.

Similar leafcutter biocontrol studies were also conducted in Costa Rica, and their publication also predates the Smithsonian's attempt to patent the approach. In 2009, a student at CATIE,¹¹⁹ a Costa Rican graduate school in biological sciences, published thesis research on development of a practical (granular) biological control for leafcutters using *Trichoderma* strains.¹²² The thesis was part of a larger project to develop alternatives to chemicals for the control of leafcutters supported by CONICIT, the government's national science council.¹²³

On what basis novel or inventive? None

If Colombian, Brazilian, and Costa Rican (and perhaps other) scientists are already selecting and testing *Escovopsis*, *Trichoderma*, and *Acromonium* as biological controls that attack leafcutters' food source, both in the lab and in the field, on what basis can the Smithsonian assert that its patent claim is novel and inventive (two of the criteria for patent eligibility)?

The answer is that it can't. The Smithsonian's claims specify that the fungal spores be delivered in a dry form, and mixed with an inert carrier (e.g. wheat flour), and are mainly (but not exclusively) directed toward introducing the fungus to the colonies by injecting it through ant holes, such as by means of a common hand-operated plunger duster.

None of the specifics in some of the Smithsonian's claims, however, are novel or include an inventive step. Other researchers have already conducted experiments including use of inert carriers for the fungus and delivery of the biocontrol in a dry form. The use of a plunger duster to deliver fungus to attack leafcutter gardens is hardly an innovation either. The duster is a standard device used to disseminate insecticides, and is a recommended means by which chemicals are applied to leafcutter ant colonies.

The Smithsonian's claims extend to mixing one or more of the three types of parasitic fungus with other fungi, termed entomopathogens, which directly attack the ants (rather than their food source). This idea isn't novel either. In fact, the approach has also been studied since at least 1993, when it was used in Colombian research.

Although it is unreliable when it comes to identifying foreign prior art, in this case, the US Patent and Trademark Office, serving as the International Search Authority under the Patent Cooperation Treaty, found some of the studies cited in this paper (notably the 2006 Brazilian paper), and its search report questions the validity of the Smithsonian's claims. As a result, the patent application, as presently written, appears unlikely to be granted.

As is often the case, however, the current patent application may simply be a prelude to a modified or follow-on application seeking to patent a more specific leafcutter biological control system. Only the Smithsonian and its 'inventors' know for sure.

Conclusion: Putting the Smithsonian's move in context

Whether or not the Smithsonian ultimately obtains a granted patent over fungal biocontrol of leafcutter ants, the bigger question is why the Smithsonian filed this patent application at all, and what it means for the Institution's biological research partners in Panama and elsewhere.

Historically, the Smithsonian has not been an aggressive patent applicant. The Institution has generally eschewed commercially oriented science in favour of more 'pure' documentary pursuits, such as taxonomy and characterisation of ecosystems. This tradition has likely aided the Institution's researchers in obtaining access to genetic resources, because the Smithsonian has not often been associated with profiteering or allegations of biopiracy.

The leafcutter ant patent application, however, may signal a notable change in the Institution's policies with significant implications. If the Smithsonian is entering the business of patents in the biological sciences, then its researchers must now be placed together with those of companies and commercially oriented universities when it comes to access to genetic resources. Access by the Smithsonian will need to be conditioned on strong benefit-sharing provisions, as would naturally be applied to the private sector, because the Institution's patent activity is a clear indication that it has adopted commercial goals.

Also troubling is that the Smithsonian's 'inventors' are undoubtedly aware that they are appropriating the published work of Brazilian, Colombian, and Costa Rican scientists with their patent application. One of them was even a reviewer of the 2006 Brazilian paper with striking similarities to what the Smithsonian now claims is its own invention.

As a result, potential collaborators of the Tropical Research Institute (in particular) should now view the Smithsonian cautiously. Working with the Smithsonian could result in intellectual or biological piracy: Disingenuously, none of the Brazilian, Colombian, and Costa Rican papers (or other relevant studies) are even cited in the Smithsonian patent application, much less given due consideration. In some respects this is unsurprising, because proper discussion of the prior art from Latin American scientists would have revealed the Smithsonian's patent application as the false representation that it is.¹²⁴

Finally, the Smithsonian is playing a key role in the Global Environmental Facility's first project to implement the Nagoya Protocol¹²⁵ with the Panamanian government. The fact that the Institution may be refocusing on commercially-oriented, patent research, and that it is capable of lodging such an abusive patent application on the basis of its research in Panama, raise questions as to if the Institution should have a place in the GEF project at all. Not only is the Smithsonian a quasi-governmental body of a non-Party to the Convention on Biological Diversity, it has also now demonstrated itself to be fully capable of biopiracy.

IV

Recent Biopiracy Cases Involving Microbes

The patenting professor: Montana's rebellious microbe man

DUBBED the 'Indiana Jones'¹²⁶ of fungal bioprospecting by *Forbes* magazine, at 72 years old Gary Strobel of Montana State University (the USA) shows little sign of slowing down his career of collecting and patenting fungi from across the world. A peripatetic bioprospector for two decades, Strobel has a track record of rebelling against regulation, while his list of microbes under patent maps his far-flung collecting expeditions.

An academic by profession, Professor Strobel has laid patent claim to fungi from Bolivia, Chile, Costa Rica, Honduras, Peru, Venezuela, Malaysia, Papua New Guinea, and even an aboriginal community in northern Australia. The Montana State University professor has collected fungus samples from many more places. The patents Strobel has obtained from bioprospecting have been bought by a variety of companies, including Denmark's Novo Nordisk, pharmaceutical giant Eli Lilly, and Synthetic Genomics, led by the ever-controversial geneticist Craig Venter.

The story of Gary Strobel's profitable career as a bioprospector offers a cautionary tale as countries move to implement the Nagoya Protocol to the Convention on Biological Diversity. The Protocol, in its Article 8, calls for countries to adopt 'simplified measures' for access to genetic resources when the access is for 'non-commercial purposes'.

University-based bioprospectors like Strobel typically characterise their work as 'academic' or 'educational', on its face suggesting a 'non-

commercial' purpose. However, in reality, as the Strobel case exemplifies, academic bioprospectors are usually linked to commercial aims – either through established relationships with companies or, increasingly, a personal and institutional intent to patent and profit.

It would thus be quite short-sighted for countries implementing the Nagoya Protocol to make any presumption in law or policy that academic-affiliated bioprospectors have a 'non-commercial' purpose. Indeed, the opposite should be the case. Academic bioprospectors should be presumed to have a commercial intent, unless they expressly disavow intellectual property claims and can convincingly demonstrate that the knowledge and materials they collect will not be patented by themselves, their institution, or any onward recipient. Failing such guarantees, academic bioprospectors must be treated as commercial entities.

Collecting endophytes

Strobel collects endophytes, which are organisms that live at least part of their life cycle on or inside other species. His specialty is collecting fungal endophytes that live in plants. To isolate endophytes, he first takes a plant sample. The surface of the plant sample is later sterilised, then the sample is broken up and microbes living inside are cultured and isolated.

By focusing his collection effort on known medicinal plants, traditional knowledge has helped Strobel patent more than a dozen fungus strains. These fungi produce compounds that, Strobel says, are sometimes responsible for the medicinal effects attributed to the host plant.

'One of the things that we do [is to] ... selectively pick plants that have a known history or background as being medicinal, so we'll talk to the medicine men, we'll talk to local scientists, we'll talk to people who practice, who literally stay healthy by using plants in their environment.' – **Gary Strobel, 2006**¹²⁷

The fungi Strobel has patented have been licensed to companies for agricultural and medical applications of great potential value, while Strobel's incessant exploration of the world's forests and knack for isolating fungus species have made him a mycological legend.

But when it comes to the implementation of the Convention on Biological Diversity, the professor's activities may earn fame of a different sort.

An avowed rebel

Montana State University's patenting professor cultivates a maverick image and has flirted with the law, mixing science with a disregard for the rules in what he terms 'civil disobedience'.

Strobel first came to public attention in the 1980s for his defiance of the US Environmental Protection Agency (EPA). In 1987, Strobel sought to conduct an outdoor test of a laboratory-mutated bacterium that he sought to use as a biological control for Dutch elm disease, which infects trees.

The EPA advised Strobel that a permit was required that would take some months to be issued. This was not satisfactory to Strobel, and according to the professor himself, he told the regulators 'I think you people are crazy.' He began the outdoor experiment anyway, without a permit.¹²⁸

After a visit from law enforcement and threats to the University's research funding, Strobel ended the experiment. According to a Ciba-Geigy (now Novartis) representative quoted by the *New York Times*, Strobel felt pressure to demonstrate his bacteria because he was in a race with Dutch competitors developing a similar biological control.¹²⁹

Strobel took revenge, however, by publicly attacking the EPA.¹³⁰ He tearfully cut down the trees he had illegally inoculated with the biocontrol in front of television news cameras, claiming that a scientific breakthrough was being lost.

He later testified before the US Congress, but rather than regretting his actions, he painted himself as a victim of government environmental bureaucrats. He dismissed the University's biosafety committee, which opposed him, as a 'kangaroo court'.

Strobel proclaimed that government regulation of microbiology was so onerous that he drew comparisons between his plight and civil rights issues, saying that he had conducted the experiment without permission as an act of 'civil disobedience', rather than being driven insane by the burden of complying with safety and environmental regulations.

In interviews in 2006 and 2008, an older Strobel maintained his position in the matter.^{131,132}

Teaching people to value the rainforest ... while patenting their microbes

When it comes to biodiversity conservation, however, Strobel shows an interest in native cultures that is pronounced and seems genuine. Strobel says that tropical forests have great value as storehouses of endophytes that can be used for medicinal and other purposes, and that it is urgent to educate people in developing countries to value biodiversity before forests are lost.

In that regard, Strobel credits himself with motivating Malaysians, Brazilians, and others to conserve and study forests. He says hundreds came to hear him speak in Brazil, and that *'I was ... in Malaysia [in 2007] giving lectures, encouraging people to get out, and now there's a whole contingent of folks located in several places including Borneo that realise that their biodiversity is something they need to study and grab onto.'* Brazilians, Malaysians, and others may not share Strobel's view of his own centrality to their biodiversity conservation efforts.

Of course Strobel wasn't in Malaysia merely on a mission to educate Malaysians about their tropical forests. Strobel was also there in search of valuable fungi to sell to the private sector. He found what he was looking for. In 2010, two patent applications on a Malaysian fungus strain useful in treating plant disease were published. Strobel is an inventor, and he collected the fungus, but the applications are owned by the Synthetic Genomics, the California company headed by Craig Venter.

The dissonances between Strobel's embrace of the patent marketplace and his self-assigned mission to educate people in developing countries about biodiversity conservation appear to be lost on the professor himself. Yet others may appreciate that even if Strobel considers his work to be academic, even charitable (in 'educating' Malaysians and others), in the context of access under the Nagoya Protocol, his activity is unmistakably commercial.

Strobel has more than 10 US patents (with international equivalents) on microbes that he has bioprospected abroad, and is an inventor in at least six more pending applications. The table on page 70 identifies most of these. The patents and applications are identified by their US patent application number. Corresponding international (Patent Cooperation Treaty), European, and other publications can be found for each.

Where in the world is the Professor?

Strobel has collected endophytes in many places, including the countries indicated below. Countries in *italic* have been identified as the source of strains under patent claim.

Americas	Africa	Asia/Oceania
<i>Bolivia</i>	Madagascar	Indonesia
Brazil*	South Africa	<i>Malaysia</i>
<i>Chile</i>		Nepal
<i>Costa Rica</i>	<i>'My travels have taken me to</i>	<i>Papua New Guinea</i>
Ecuador	<i>virtually all the world's rainforests,</i>	Yemen (Socotra)
Guyana*	<i>with one major exception.</i>	
<i>Honduras</i>	<i>I haven't been to the Congo.</i>	
<i>Peru</i>	<i>But I'm heading that way</i>	
<i>Venezuela</i>	<i>within the next year or two.'</i>	
	(G. Strobel, 2011)	

(*As discussed on page 72 Strobel claimed that he was not sure when he was in Brazil, Guyana or Venezuela on one of his collecting expeditions.)

Who buys Strobel's microbes?

Strobel's customers range from major multinational corporations to smaller start-up companies. In agriculture, his patents have application combating disease in oil palm and bananas, among other crops. Pharmaceutical companies have licensed Strobel's microbes for antibiotics, perhaps the most potentially lucrative application. In other fields, a Strobel-patented microbe can be used to treat human wastes, and has been licensed by a manufacturer of field latrines.

Strobel's most notable scientific discovery – that endophytes can produce the \$1-billion-a-year cancer drug paclitaxel (taxol) – has wound up as the property of pharmaceutical giant Bristol Myers Squibb (BMS). Strobel found the endophytes in the US, Venezuela, Nepal, and possibly other places. He sold the patents to a company named Cytocolonal, which subsequently sold them to BMS.

BMS's original patents on taxol covered production from tree bark, but the supply of the very profitable drug was limited by the relative scarcity of the Pacific Yew tree, the original taxol source. Semi-synthetic

taxol production methods were developed and acquired by BMS to overcome this limitation. BMS also bought Strobel's patents, covering production of taxol by fungal fermentation, although it does not appear to have used the process in commercial production, suggesting that the move may have been to limit potential competition.

'Gary is a treasure trove of natural products that have made a difference for a lot of people's lives.' — Paul Stewart, Manager, Eli Lilly Company (2006).

Pharmaceutical giant Eli Lilly has also done business with Strobel, licensing antibiotic compounds patented by the professor. According to Paul Stewart, a manager of global business development for Lilly, 'Gary is a treasure trove of natural products that have made a difference for a lot of people's lives.' Michael Rodriguez, a Lilly researcher, says the company is interested in compounds from plant endophytes because they may be less toxic to humans than compounds from soil microbes, a more traditional source of antibiotics.¹³³

In agriculture, recent Strobel patent applications cover use of the Malaysian fungus to treat disease in oil palms, owned by Synthetic Genomics. Strobel says that he has made other discoveries useful in treating sigatoka disease in bananas, although it is unclear if this has resulted in a commercial product. According to Strobel's curriculum vitae, he has worked with the Dole Company (a major producer of bananas) and Dow Chemical (producer of agricultural chemicals).

Perhaps the most promising agricultural microbe patented by Strobel is *Muscodor albus*, first isolated in Honduras in 1997. *M. albus* does not appear to be toxic to humans, but produces volatile organic compounds that inhibit growth of other fungi, as well as bacteria and nematodes. Sachets of *M. albus* are now being placed in boxed shipments of table grapes, in order to prevent mould growth in shipment, and to extend shelf-life. One of Strobel's commercial partners, Agraquest (Davis, California) is developing *M. albus* for uses including as a biological alternative to the environmentally unfriendly soil fumigant methyl bromide.

Strobel has numerous other commercial arrangements, including a Bolivian microbe licensed to Jeneil Bioproducts of Germany and a Venezuelan *Serratia* bacteria sold to HVM Corporation (Utah). Presently, with US government funding, Strobel is developing a fungus from Chilean Patagonia that he claims will produce biodiesel fuels. This

is also patented, and Montana State University is currently seeking to license the microbe to the private sector.

Questions about access and benefit-sharing agreements

While the circumstances of Strobel's many different collecting expeditions undoubtedly vary, Strobel generally appears to prioritise personal objectives over legal requirements, a trait that first came to public attention in his fight with the US Environmental Protection Agency in 1987.

At times, Strobel's haste to collect endophytes without proper access and benefit-sharing arrangements has proven costly. In 2000, he travelled to Australia to collect Aboriginal medicinal plants in the Northern Territory. Although Strobel apparently did not make prior arrangements with Aboriginal people before setting out into the bush with scissors and plastic bags, he encountered an Aboriginal cooperator while in the field.¹³⁴ One of the medicinal plants that Strobel collected, the snakevine (*Kennedia nigricans*), yielded an antibiotic-producing bacteria that he licensed to Denmark's Novo Nordisk.

After filing for patent and beginning work with Novo Nordisk, Strobel then unilaterally drafted an after-the-fact letter that he termed an access and benefit-sharing agreement. The deal took the form of a letter from a representative of the Aboriginal community of Manyallaluk addressed to himself.¹³⁵ The letter was a single page, and Strobel presented the letter to a community representative who was filmed signing it.

But Strobel then found himself in conflict with the Territorial government, which unsurprisingly considered the agreement to be insufficient. Reprising his 1987 narrative about meddling officials, Strobel claims that the Territorial government was unreasonable, and that it asked for a deal signed by all community members, something which Strobel says was 'next to impossible'.¹³⁶ The Australian government's position, Strobel says, rather than his failure to follow the rules, provoked the collapse of commercial development of the drug.

Australia isn't the only place where Strobel has encountered trouble. In Venezuela, the NGO Vitalis has conducted a review of Strobel's 1998 bioprospecting trip to the *tepuis* (isolated mesas) in the southern part of the country. This trip resulted in discovery of both a taxol-producing microbe (like those found in Nepal and the US) and a *Serratia marcescens* strain effective against oomycete pathogens (e.g. *P. infestans*, the causative

agent of late potato blight). Strobel has twice patented the *Serratia* strain, and the taxol strains (now owned by BMS) are encompassed in broader patents covering fungal sources of taxol.

Vitalis' investigation of the collecting expedition bluntly concludes that Strobel violated Venezuelan law:¹³⁷

'It has been well-documented that [Strobel's] access to genetic resources ... was made in an illegal and illegitimate manner, failing to comply with, on one hand, the CBD, [regional, and national access law] and, on the other, with national law on collection of biological materials in protected areas and indigenous communities.'

In his defence, Strobel reportedly told Vitalis that he tried and failed to contact Venezuelan authorities, and that he wasn't sure at times if he was in Venezuela, Brazil, or Guyana¹³⁸ (although the patent on the *Serratia* strain expressly states that it was collected in Venezuela).

Strobel may have collected other endophytes at times with proper permits and benefit-sharing agreements. He declined, however, to provide copies of any benefit-sharing agreements he has entered into, except the letter signed with the Manyallaluk community representative in Australia.

New publicity for his collections and patents in the context of the Biodiversity Convention may bring additional scrutiny that sheds light on Strobel's compliance with access procedures in the many countries he has visited. Recently, these include a university course that Strobel teaches with his son, a Yale University professor, in which students are taught to collect and isolate endophytes themselves. Course participants have collected large numbers of samples in Ecuador and Peru, in recent years, taking them back to Yale for analysis.

Conclusion

From the Biodiversity Convention perspective, there is much to criticise about Gary Strobel's 20-plus-year career as a bioprospector. There is scant evidence that he has paid access and benefit-sharing issues their due. And the word to describe bioprospecting without appropriate access and benefit-sharing arrangements is biopiracy.

For all of Strobel's apparent failures to seek equity, to respect indigenous peoples' rights, and to recognise national sovereignty over

Gary Strobel's Patent Portfolio (partial) ¹³⁹

US Patent Ref.	Item Claimed	Origin (date) ¹⁴⁰	Patent Assignee/Licensee
AP: 20100285543	<i>Muscodor albus</i> strain	Honduras (1997) <i>Jardin Botanico Lancetilla</i>	Agraquest, Inc (California)
AP: 20100272690	<i>Muscodor crispans</i> strain	Bolivia (2007) <i>Heath River PN Madidi</i>	Jeneil Bioproducts (Germany)
AP: 20100266641	<i>Colletotrichum dematium</i> strain	Costa Rica (2006) 'privately owned forest'	(unknown)
AP: 20100255124	Fungi & molecules against <i>Ganoderma</i> Basal Stem Rot in oil palm.	Malaysia (2007) <i>Forest south of Kuala Lumpur</i>	Synthetic Genomics (California)
AP: 20110182862	<i>Muscodor strobelii</i> strain (self-named species)	Malaysia (2007) <i>Forest south of Kuala Lumpur</i>	Synthetic Genomics (California)
AP: 20090142816	<i>Gliocladium</i> spp. (isolate C-13)	Chile (2001) <i>Near Alerce Andino Park</i>	<i>Licences offered by Montana State U</i> <i>US Department of Energy funding.</i>
PAT 7858362	<i>Muscodor albus</i> strain	Peru (unknown)	Philips Enviro. Products (Montana)
PAT 7387888	<i>Streptomyces</i> sp. antibiotics	Peru (2003) <i>Manu, Madre de Dios</i>	Novo Nordisk (Denmark)

PAT 7754203	<i>Muscador albus</i> strain	Honduras (1997) <i>Jardin Botanico Lancetilla</i>	Agraquest, Inc (California)
PAT 7267975	<i>Muscador vitigenus</i> strain	Peru (circa 2000) <i>Bahuaja Sonene Park</i>	Montana State University (MSU)
PAT 7259004	<i>Streptomyces munumbi</i> strain	Australia ¹⁴¹ (2000-2002) <i>Manyallaluk, NT</i>	MSU / Novo Nordisk (Denmark)
PAT 7192939	<i>Pestalotiopsis microspora</i> compound	Papua New Guinea (c. 1998) <i>Sepik River</i>	Montana State University
PAT 6926892	<i>Serratia marcescens</i> strain	Venezuela (1998) <i>Carrao River / Angel Falls</i>	HMV Corporation (Utah)
PAT 6911338	<i>Muscador albus</i> strain <i>Muscador roseus</i> strain	Honduras (1997) Australia (1997?)	Unknown
Numerous	Taxol-producing microbes	Venezuela & others (1990s)	Bristol-Myers Squibb ¹⁴²

genetic resources, it should be said that his scientific accomplishments are not inconsequential. He has palpably demonstrated the scientific (and economic) potential of an unusual line of biodiversity research, endophytes, repeatedly identifying (and patenting) useful strains. He has done so despite entering the field of pharmaceutical bioprospecting just as the drug development momentum shifted away from natural products and toward combinatorial chemistry and similar methods.

From the perspective of development of law and regulations to implement the ABS provisions of the Biodiversity Convention, particularly the Nagoya Protocol, the most important lesson that Strobel's career offers is that a bioprospector may represent interests different from those that (s)he appears to.

In Strobel's case, the putative applicant for access to genetic resources is an academic, from a public university, with an avowed interest in biodiversity conservation. Despite this, the very same applicant has, time and time again, acted as a conduit between tropical forests and industry, collecting resources as a professor but delivering them into the hands of companies like Bristol-Myers Squibb, Novo Nordisk, Eli Lilly, Synthetic Genomics, and more.

What this means is that no *a priori* presumptions can be made that academics, public, or non-profit entities qualify for simplified 'non-commercial' access (Nagoya Protocol Article 8) to genetic resources. To do so would be to take a quaint view of contemporary Western academic biological science, wherein professors, universities, and research institutes are major owners and brokers of patented biodiversity.

Perhaps, as Gary Strobel claims, collecting endophytes could lead to a new blockbuster drug, or alternatives to synthetic agricultural chemicals. Or, in a more down-to-earth application, better field latrines. It is an iffier proposition, however, that such discoveries will translate into concrete biodiversity conservation in the developing world.

For that promise to actually happen, developing countries will have to treat academic bioprospectors like the commercial entities for whom they usually toil. And developed countries, who will push to see their academics granted 'non-commercial' access under the Nagoya Protocol, will have to squarely recognise that the intellectual property and educational systems that they have created have intertwined university-based in the biological sciences and commercial interests in so tight a manner that the two cannot be reliably distinguished in access and benefit-sharing agreements.

V

University Intellectual Property Policies and 'Non-Commercial' Access to Genetic Resources under the Nagoya Protocol

Introduction

Parties to the Nagoya Protocol on Access and Benefit Sharing to the Convention on Biological Diversity need to ensure that their domestic legislation on access and benefit sharing is consistent with both their national objectives and the Nagoya agreement. One item that they must consider is the Protocol's Article 8, which says that Parties should 'create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries' and these include 'through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research'.

While 'non-commercial' research sounds as if there are no financial stakes, there are substantial dangers for provider countries inherent in this provision of the Protocol. Implementation that is not careful could easily lead to valuable resources being spirited out of the country under the guise of 'non-commercial' access, only to be converted into patented products and profits once the resources are beyond the country of origin's effective control.

The reason why this is a dangerous problem is that the distinction between 'non-commercial' and commercial research is always difficult, and frequently impossible, to make. This means that the circumstances under which simplified access should be granted are unclear and may be impossible to predefine.

In fact, through a combination of law, policy, and employment contracts, the concept of 'non-commercial' research in the sense of the Nagoya Protocol no longer exists at most developed countries'

universities and research institutes, despite the fact that they are not-for-profit entities.

This paper situates academic and other non-profit biodiversity collectors in the commercial and intellectual property systems. To shed light on the policies that many academic bio-prospectors are bound to, this paper briefly discusses pertinent provisions of the intellectual property policies of universities in a number of developed countries, from Australia to Norway. While policies vary from country to country and from institution to institution, common themes can be found that bring into doubt the very existence of ‘non-commercial’ research at many institutions.

The modern situation of Northern universities and other non-profit research entities with respect to biodiversity patents and research commercialisation

While some companies directly collect biodiversity for research and product development, more acquire biodiversity, and rights to it, through an intermediary, such as an academic, a gene bank, a botanical garden, or some other collector or *ex-situ* collection. Most of these entities are not-for-profit institutions. Their work, however, is bound to commercial interests in their role as resource and intellectual property ‘re-providers’ (partners) with industry.

In addition, while use of genetic resources may be contemporaneous to collection, it may also occur years or even decades later. For example, a pharmaceutical company may open a line of research that leads it to study a botanical garden plant collected a century ago, before the contemporary research was even remotely conceived. This ‘new use’ issue poses conundrums for access and benefit-sharing laws – how to anticipate future changes in the purposes to which samples are put to use?

Public and private universities and other not-for-profit entities are not only partners to industry, they are increasingly in business for themselves. To maximally capitalise on research, they require employees to report all inventions and take ownership in them. In some countries, particularly those that have laws modelled on the United States Bayh-Dole Act (such as Japan), the patent and marketing process isn’t optional: Universities are required to commercialise results of publicly funded research.

Yet the myth of the professor’s intellectual autonomy and non-commercial orientation persists. In reality, in many fields in the

biological sciences in many developed countries, if a professor's research consistently does not produce marketable results, the professor may lose his or her job. If not, he or she may be relegated to the smallest office, an unequipped laboratory, allocated the least staff support, sentenced to a lifetime of teaching of introductory courses, or other forms of academic penury. Thus, to maintain the good graces of his employer, the life sciences professor's job is increasingly about making money.

The professors and other researchers who are the human face of bioprospecting are therefore subject to sophisticated institutional intellectual property rules that incentivise patent claims and provide personal economic benefits. These rules must be followed as a matter of contract and/or employment law.

In other words, although not-for-profit research entities might claim 'non-commercial' institutional objectives, often they nevertheless patent and profit from biodiversity research, alone or in cooperation with the private sector. They may even be prohibited from overlooking commercial possibilities by laws that require patenting and marketing inventions.¹⁴³ They are definitely not 'non-commercial' users in the sense of the Nagoya Protocol.

Bioprospectors may not be free to negotiate provisions of access and benefit-sharing agreements, particularly intellectual property provisions, as they are bound by rules made by the administrators who manage such functions at their institutions. And at a time of constrained public budgets, those university officials are often under pressure to 'show the value' of public research institutions (and private institutions receiving public grants) with intellectual property income statements.

These pre-existing commitments and other limitations on the power of bioprospectors to structure access and benefit sharing (ABS) agreements may not always be clear to resource providers, who may cling to naïve ideas about academic disinterest in profit. It means, however, that if a professor or other 'non-profit' collector negotiates an ABS agreement, and makes pledges about 'non-commercial' research, the bioprospector may be exceeding his authority in doing so, and the agreement may not be valid or enforceable.

Therefore it is necessary to be wary when negotiating access to biodiversity with representatives of not-for-profit research institutions, particularly from the North, where they are likely to be subject to aggressive intellectual property policies. It follows that it should never be presumed that a 'non-commercial' institution, such

as a university, should merit ‘non-commercial’ simplified access to genetic resources in the sense of the Nagoya Protocol’s Article 8.

Some typical intellectual property and innovation-related policies at Northern not-for-profit research institutions

While there is some variation between countries and institutions within them, there are a number of common legal and policy aspects related to innovations that can be found at most Northern non-profit research entities. These include:

1. *Inventions belong to the employer*

Many non-profit research institutions require their researchers to assign rights to inventions to the institution, as a condition of employment. For example, the policy applicable to all campuses of the University of California, which is typical for a university in the United States, reads:

An agreement to assign inventions and patents to the University, except those resulting from permissible consulting activities without use of University facilities, shall be mandatory for all employees...¹⁴⁴

In Norway, the University of Oslo places a similar obligation on its researchers, whose contracts establish that the University ‘*is entitled to acquire all rights*’ to work outputs, including ‘*patentable and non-patentable inventions*’, ‘*other technology which has potential for commercial exploitation*’, ‘*varieties of plants*’, and ‘*physical objects made from organic, inorganic or biological material, including substances, organisms and crops*’.¹⁴⁵

Universities have learned the hard way that if they wish to profit from professors’ inventions they must use such aggressive terms in their policies and contracts with their employees, and enforce them.

In 2010, Australian universities learned this in a case that has reverberated in other parts of the world. In the *University of Western Australia (UWA) v. Grey*, the university lost a legal battle for a share of the proceeds from a cancer treatment developed by one of its professors and sold to a drug company.¹⁴⁶ The reasons why UWA lost the case included failure to strictly implement its own intellectual property policies and

because the professor's employment contract did not stipulate that inventions must be assigned to the University.¹⁴⁷

It's thus unsurprising that Australia's University of Sydney bluntly '*asserts ownership of all intellectual property created by a staff member in pursuance of the terms of his or her employment*'.¹⁴⁸

Germany, Sweden, and some other countries have slightly different situations. In Germany, for example, public university employees are afforded greater rights over their work, however, the country's Law on Employee Inventions allows universities to '*demand a reasonable share of the proceeds*' in cases '*where the employer made available special resources for the research work*' (presumably money, staff, and/or specialised facilities).¹⁴⁹

In the policies reviewed in the course of preparation of this paper, none were found that appeared to enable a research employee to negotiate the rights of his or her institution. Academic bioprospectors from the North are therefore unlikely to possess authority to execute ABS agreements on behalf of their institutions, and may not have ownership of research results, even if the bioprospector is collecting materials for his or her own use.

2. Duty to report innovations to the employer

The same rules under which employers claim the inventions of their employees also typically require academic researchers to report potentially commercial discoveries to their institution's technology transfer office. In other words, professors typically cannot legally keep patentable results to themselves, or transfer them to somebody other than their employer without the employers' agreement.

At the University of California, all employees '*shall promptly report and fully disclose the conception and/or reduction to practice of potentially patentable inventions to the Office of Technology Transfer or authorized licensing office*'.

Similarly, the UK's Oxford University demands that all of its researchers report any inventions to the University, which then either assigns rights to a funding agency or company (if required by pre-existing research contract), or the University may claim the invention itself, whereupon rights go to Oxford's technology commercialisation office.¹⁵⁰

At the University of Tokyo, a duty to report exists,¹⁵¹ while in Spain,

national law obligates university researchers who invent anything to immediately report their inventions (and assigns ownership of the inventions to the university).¹⁵²

3. Researchers (and technology transfer offices) incentivised to claim inventions by profit sharing

Although there are cases where university researchers may keep at least some rights to their own inventions (e.g. Germany), more typically the researcher and his or her institution will have a pre-existing arrangement that spells out terms for profit sharing from patents assigned to the university. At some institutions these terms are fixed, while at others they may vary from department to department or even researcher to researcher.

At Oxford University, a published regulation spells out specific terms for division of net revenues (subject to modification under funding agreements):¹⁵³

Total net revenue	Researcher(s)	General Account	Revenue Department(s)
Up to £50k	86.2%	13.8%	
£50K to £500K	45%	30%	25%
Over £500K	22.5%	40%	37.5%

Similar arrangements are made in the United States, including making income-based financial incentives to university technology transfer offices. For example, at Texas A&M University, profit-sharing arrangements in the University's agricultural research division allocate 37.5% of proceeds to be paid as personal income to the inventor(s), 37.5% to furthering the research that resulted in the patent, and 25% to the University's Technology Transfer office.

Interestingly, none of Texas A&M's patent income is allocated to educational purposes, much less to providers of biodiversity, and the technology transfer office's income is linked to licensing agreements. This creates a strong incentive for technology transfer officers to find, take over, and market research from the University (and raises questions as to if such arrangements are suitable for a public educational institution).

In Spain, the same law that assigns professors' inventions to

University patent data from the United States

THE Association of University Technology Managers (AUTM) is, in effect, the trade group and lobbying branch of university technology transfer staff in the United States. It conducts an annual survey of its members to highlight the income that technology transfer offices generate for US schools. While some of the data should be interpreted cautiously - for example, university technology transfer offices often 'forget' to deduct their substantial operating costs from their income figures – the survey does provide an overview of patenting activity by US universities.

According to the latest available annual (2009) survey:¹⁵⁴

- In 2009, US universities reported \$2.3 billion in intellectual property income.
- That year, US universities filed 8,364 new US patent applications and 1,322 new overseas applications. The total number of pending US patent applications from AUTM members was over 18,000. In 2009, the universities received 3,419 granted patents.
- Many of those patent applications were in biodiversity-relevant fields, including: 1,388 in biological sciences, 3,272 in medical sciences (including pharmaceuticals and vaccines), 225 in veterinary science, 128 in environmental science, 348 in agrochemistry, and 698 in 'other life sciences'.
- As a proportion of the total number of university patent applications, biodiversity-relevant research sectors outstripped all other fields of science in number of patent claims filed. Medical applications constituted nearly a quarter (24.5%), and non-medical life sciences another 15.6%. There were substantially fewer applications from other areas, including the fields of computer science (9.6%), electrical engineering (7.8%), and mechanical engineering (5.1%).

universities also mandates profit sharing with professors, the details of which are defined by institutional policies adopted by each research campus.

Summary

While aspects of policy and law vary from country to country, across the North, it can consistently be observed that academic bioprospectors:

1. Must report all inventions to their employer;
2. Must convey rights to inventions (or proceeds from them) to the employer, either as a matter of law or terms of employment;
3. Receive payments as personal income from their employer in return for their compliance;
4. May not waive or negotiate the intellectual property interests and policies of their institution in an access and benefit-sharing agreement.

Further complicating matters is the fact that even if a particular project is genuinely intended to be non-commercial in nature (e.g. a purely taxonomic study), the possibility of incidental discoveries cannot be ruled out, nor in many instances can commercial research by onward recipients necessarily be stopped. There are no provisions in university intellectual property policies reviewed for this paper to exempt incidental discoveries from the same processes applied to more anticipated research results.

Thus, even the most academically minded professor, with no personal commercial intent, is likely to be bound to report and patent an accidental or otherwise unintended discovery. These problems are, to an extent, anticipated by the Protocol's Article 8 with the phrase 'taking into account the need to address a change of intent for such research'.

So in almost all circumstances, academic research cannot be considered to be 'non-commercial' in the sense of the Protocol's Article 8. As many universities look to patents for a greater proportion of their income, the possibility of non-commercial research by these institutions is increasingly precluded by an unfortunate mixture of laws, policies, and labour contracts.

Another result of these policies and laws is that the professor or other researcher who is seeking access to biodiversity is unlikely to be legally competent to execute the associated ABS agreement, because she or he is not permitted to negotiate terms or to commit the institution. These

powers are more likely to lie with the technology transfer officers of not-for-profit research institutions.

Recommendations

With these circumstances in developed countries, provider countries must presume in their national ABS laws that academic researchers have commercial intent, without regard to the fact that they come from public and/or not-for-profit institutions.

How, then, should a biodiversity collector be afforded the simplified access procedures required by Nagoya Protocol Article 8? And what should those procedures look like? This paper suggests two possibilities:

First, a Party to the Nagoya Protocol may quite defensibly conclude that it is generally impossible to confidently assign 'non-commercial' status to *any* foreign biodiversity collector. This analysis of university intellectual property rules supports such a conclusion.

In this case, the 'simplified' access procedures offered under national law for 'non-commercial' requesters would not greatly diverge from those offered to commercial requesters. That is, they would contain the same conditions for access and requirements for benefit sharing as those imposed upon companies. In this case, the procedure might still be described as simplified because it would not be necessary to, for example, request information on ownership or certification of good legal standing from a well-established public entity.

Alternatively, a Party to the Nagoya Protocol may wish to offer a substantially simplified procedure for genuinely 'non-commercial' access but place very high requirements upon the bioprospector in order to qualify for it. The legal enforceability of these requirements would have to be certain, and they would need to contain an unalterable commitment on the part of the bioprospector and his or her institution not to seek intellectual property rights or other commercial benefit from the samples taken, the progeny, parts, and derivatives thereof, nor from research results. The bioprospector must also be enjoined from transferring the samples, progeny, parts, and derivatives to any third party, including by means of sequence data.

Such requirements would also mandate the destruction or return of samples upon completion of the non-commercial research specified in the access agreement or, in any event, on or before a specific date. As an added assurance, the requirements for simplified access could require

reporting and assignment of all intellectual property generated from use of the biodiversity to the competent authority and/or relevant indigenous people in the country of origin.

While such requirements would enable offer of a substantially simplified access procedure, the laws and policies governing most academic institutions in developed countries would not permit them to avail themselves of it. So a simplified access procedure with such assurances would likely be infrequently utilised. While this is unfortunate, it is an appropriate situation so long as Northern universities persist in policies that do not permit their employees to conduct genuinely non-commercial research, and which mandate patenting biodiversity and related research results.

Endnotes

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53. Sudangrass (*Sorghum bicolor* ssp. *drummondii*) is also written as 'Sudan grass'. Because this report makes frequent reference to the names of countries, for the sake of clarity the spelling 'sudangrass' is used.
54. The Treaty is administered by the World Intellectual Property Organisation, and the filing of a single application has the same effect as national applications filed in the countries of interest to the patent applicant. An applicant seeking patents may file one application and request protection in as many PCT member states as it wants. This process saves time and money for a patent applicant.
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59. Bolivia itself is not a member of the Patent Cooperation Treaty; neither are its immediate neighbours, except for Brazil. KSU may pursue patents in non-PCT countries through national patent offices. Bilateral agreements with the US may also impact KSU's international rights when a US patent is issued.
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The biopiracy of genetic resources including seeds, medicinal plants and microbes, as well as of the traditional knowledge of uses of those resources from developing countries, has been going on for too long.

There was hope that the United Nations Convention on Biological Diversity would reduce, even prevent, biopiracy and further ensure that the benefits from the utilisation of genetic resources will be shared fairly and equitably with the countries, indigenous peoples and local communities concerned. The Convention being inadequate since it came into force in 1994, several years of new negotiations resulted in the Nagoya Protocol on Access and Benefit-Sharing to the Convention in 2010. In the meantime, biopiracy is unabated.

This compilation of recent papers on biopiracy published by Third World Network describes cases that span the developing world, from African and Middle Eastern medicinal plants to South American fruit, to Asian microbes, among others.

The genetic resources of these cases, claimed in patents and patent applications by corporations and universities, have uses in industry, agriculture, foods, and in pharmaceuticals and other health care products. In many cases, the patent claimants show remarkable disrespect for traditional knowledge and developing country science. The cases also show a disregard for proper access and benefit-sharing agreements among bioprospectors and other users of biodiversity.

Together, these cases show that biopiracy continues as a problem and major injustice, and that much remains to be done to stop it. Problems shown here, for instance the practical impossibility of distinguishing between 'non-commercial' and 'commercial' access to genetic resources, may be addressed by governments in their national legislation on access and benefit sharing, and through effective implementation of the Nagoya Protocol, and suggestions are made as the individual cases highlight particular issues.

Edward Hammond directs Prickly Research (www.pricklyresearch.com), a research and writing consultancy based in Austin, Texas, USA. He has worked on biodiversity issues since 1994. From 1999 to 2008 Hammond directed the Sunshine Project, an international non-governmental organisation specialising in biological weapons control. He was Programme Officer for the Rural Advancement Foundation International (now the ETC Group) from 1995 to 1999. Hammond holds MS and MA degrees from the University of Texas at Austin, where he was an Inter-American Foundation Masters Fellow.

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