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Genes from Africa: the colonisation of human DNA

Edward Hammond and Mariam Mayet, February 2009

PO Box 29170, Melville 2109, South Africa
www.biosafetyafrica.net

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The African Centre for Biosafety (ACB) is a non-profit organization, based in Johannesburg. It has a long track record of working in the area of biosafety in the context of opposing genetic engineering in food and agriculture. In the recent past, it has expanded its area of work to incorporate the Green Revolution push in Africa, agrofuels and biopiracy.

Acknowledgements

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Introduction

"You people. We thought you folks had taken everything you could. You took our land, you took our homes. You stole our pottery and our songs and our blankets and our designs. You took our language and, in some places, you even took our children. You snatched at our religion and at our women. You destroyed our history and now, now it seems you come to suck the marrow from our bones."

Jeanette Armstrong, an indigenous woman from Canada at a meeting on the Human Genome Diversity Project[i]

Indigenous people's groups and NGOs have waged a long and bitter struggle against the Human Genome Diversity Project[ii] and similar efforts to collect the DNA of indigenous and other peoples without appropriate consent and sufficient safeguards against abuse. The **Human Genome Diversity Project** (HGDP), the brainchild of Italian geneticist Luca Cavalli-Sforza, comprised of a group of scientists who in the 1990s proposed to collect biological samples from over 700 different population groups throughout the world. The HGDP's ostensible aim was to map their DNA and in so doing, build a representative database of human genetic diversity.[iii] This seemingly laudable aim belies the fact that during 1997, the US National Research Council (NRC) found the HGDP's proposed work to be ethically and scientifically inadequate.[iv]

At the time, geneticists associated with the HGDP denied links between their work and commercial gain. For example, Cavalli-Sforza wrote the following in 1993: "*The proposed HGD Project is not and will not be a commercial venture. It is thought the chance that this research will lead to the development of commercially valuable products is very remote.*"[v]

Other pronouncements from the HGDP included the following: "*The Project most emphatically does not want to patent anything from these samples. Its organizers are not involved in this Project to make money, nor do we wish to repeat the sorry story of plant genetic diversity and the developing world. Although we think it is highly uncertain that any products of commercial value will arise from the Project, we are committed to ensuring that financial benefits from any such products flow back to the sampled populations. Implementing that commitment involves tricky questions of U.S. and international patent and contract law, but we will resolve them.*"[vi]

At the time of the controversy, Dr Sarah A Tishkoff was a PhD student, training under the leadership of the HGDP's Professor Ken Kidd, of Yale University.[vii] Kidd stands out in the memories of activists as an opponent of their efforts. Today, the same Dr Tishkoff is a professor at the University of Pennsylvania, with her very own "African Human Genetic Diversity Project", and in October 2007 she filed patent claims at the United States Patent and Trademark Office (PTO) over genetic material she collected from communities in Africa. The patent claims were first published in September 2008.

How is it indeed possible for Dr Tishkoff to stake a legal claim on the natural genetic resources of Africans, which will not only allow exclusive rights to such resources, but also enable her to profit from future medical applications? It is indeed possible, because US patent law extends patent protection to life forms. Indeed, the PTO has granted patents for newly created micro-organisms, living animals, and for human tissues and genes, breaking the long-standing policy that animate life forms were not patentable. The National Institutes of Health, and others, have secured patent rights for fragmented gene sequences, many with unknown function and physical significance. This trend has enabled research institutions and corporations to secure patents for almost 5%[viii] of the entire human genome.

In this paper, we present our research regarding the Tishkoff related patent application and provide additional information regarding Tishkoff's incursion into Africa. We also raise some fundamental social and ethical questions. We trust that this work will make a meaningful contribution to future campaigns to stop the exploitation of African genetic resources.

Part One

The University of Maryland patent application

On the 26th of October 2007, the University of Maryland[1] applied to the US PTO (US 20080220429) for a patent over three genetic variations isolated from blood samples collected from communities in Kenya, Tanzania and the Sudan, following the comparison of the DNA of 43 different communities in these three countries by the university's 'inventors' Dr Sarah A Tishkoff and Floyd Allan Reed. These genes, detected through a DNA test, are called single nucleotide polymorphisms or SNPs, and are associated with the ability to digest milk products (lactose tolerance) in adult African populations. Persons of African descent, who do not have one or more of these SNPs, are generally lactose intolerant (i.e. they cannot comfortably consume dairy products).

The main application of the patent claims is in genetic testing for lactose intolerance. This type of test is used on persons (particularly children) who have difficulty digesting dairy products or with non-specific digestive complaints that a doctor wishes to more narrowly diagnose.

Present genetic tests for lactose intolerance, primarily marketed in North America and Europe, are of limited use because they are often inaccurate for persons of African descent. This type of test requires purifying, amplifying, and sequencing of DNA. It is very expensive, currently costing nearly US $300 to be performed at a lab accredited for medical testing.

Typical of most patent claims in this technology area, the claims are long and repetitive – especially at first filing of the application (before the patent is possibly divided and substitute claims made). The claims include diagnostic tests to detect the SNPs, the isolated SNPs per se (in Claim 22), and the use of the SNP sequence in diagnostic applications. Because the claims cover the isolated SNP and its use in a genetic vector, they probably cover use of the SNP in "gene therapy" (to make people lactose-tolerant) or other biotech applications, although the near-term possibility of this is remote. Gene therapy is developing slowly and lactose intolerance is a normal human trait, and not a disease, the effects of which can be avoided by simply not consuming dairy products. (Most humans are lactose intolerant to some degree.)

Therefore, Tishkoff and Reed's most important claims are those relating to diagnostic tests. An international patent application (PCT application WO2008057265), filed subsequent to the US patent application, designates virtually all countries in the world with patent systems for this patent claim, including most of Anglophone and Francophone Africa. In practice, patent applicants do not always follow through with national claims in every country they designate in a PCT application, however, by designating these countries the University of Maryland has asserted that it intends to do so.

1 At the time the patent application was filed, Tishkoff was a professor at the University of Maryland and Reed a postdoctoral student in her lab. Since the application was filed, Tishkoff has moved to the University of Pennsylvania (Tishkoff lab website: http://www.med.upenn.edu/tishkoff/index.html) and Reed to the Max Planck Institute for Evolutional Biology in Plön, Germany (Reed's web page: http://www.evolbio.mpg.de/english/people/staff/wissPersonal/wissM10/index.html). Both remain the inventors of the patent application, and the University of Maryland its legal assignee.

How the SNPs were detected

The SNPs were found by administering a conventional lactose tolerance test and then analyzing DNA samples from people of 43 different ethnic groups from Kenya, Tanzania, and Sudan.[ix] The underlying scientific observation was that some African groups have been observed to be more lactose tolerant than others, specifically, those that herd animals and drink milk. Thus, the research focused on comparing gene sequences of people determined by conventional testing to be tolerant or intolerant and especially, at an ethnicity level, comparing sequences of pastoralist peoples (more tolerant) against the sequences of peoples that primarily rely on agriculture, fishing, or hunter-gathering (often less tolerant).

By comparing sequences, SNPs related to lactose tolerance were elucidated. For example, 18 of 32 Kenyan Maasai were found to have cytosine at an SNP called G/C-14010, an indicator of lactose tolerance, whereas, only one out of 16 hunter-gatherer Kenyan Sengwer had the same mutation.

DNA from the following groups was used by the 'inventors':
(Here the ethnic names / linguistic families stated in the patent application are used, with the number of persons sampled in parentheses):

Kenya:	"Afro-Asiatic" Burji (8), Borana (8), El Molo (9), Gabra (9), Konso (6), Rendille (8), Somali (1), Wata (1), Yaaku (16) "Nilo-Saharan" Maasai (32), Marakwet (7), Nandi (4), Ogiek (11), Pokot (14), Sabaot (6), Samburu (9), Sengwer (16), Tugen (16), Turkana (13)
Tanzania:	"Afro-Asiatic" Burunge (18), Iraqw (39), Mbugu (30), Fiome (12) "Nilo-Saharan" Akie (14), Datog (4), Dorobo (10), Maasai (19) "Niger-Kordofanian" Mbugwe (13), Pare (10), Rangi (35), Samba'a (3) Khoisan Hadza (18), Sandawe (30)
Sudan:	"Afro-Asiatic" BejaBanuamir (6), BejaHadandawa (11) "Nilo-Saharan" Dinka (9), Koalib (1), Liguri/Logorik (1), Masalit (1), Nuer (5), Ama (2), Shilook (8)

In total, the DNA was compared of 128 Kenyans, 136 Tanzanians, and 44 Sudanese.

All of the DNA samples appear to have been collected by Tishkoff and colleagues on trips to Africa.

Scientific detail

Everyone can digest milk at birth; but as people get older, many lose the ability to consume dairy products. This is because the human body's production of the enzyme that breaks down lactose, called lactase, often declines with age. Some people, however, continue to produce lactase. This trait is often found in people from populations historically involved in animal herding (pastoral) activities, such as many northern Europeans.

But not every lactose tolerant person has the same set of tolerance genes. The key scientific observation underlying the patent application is that the genetic basis for lactose tolerance is different in African populations than in others. This has been suspected for a number of years, but the exact genetic source of tolerance in Africans has not been identified (until now, according to the patent applicants).

The first lactose tolerance SNP to be identified was in people from Finland and is called C/T-13910. 80-90% of Finns have this mutation.[x] Current genetic lactose tolerance tests probe for this "Northern European" SNP; but this mutation is rare in Africa. Most Africans that are lactose tolerant have different SNPs that enable them to digest dairy products. According to the patent application, the inventors have identified these African SNPs. They are called C/G-14010, T/G-13915, and C/G-13907.

How the newly-identified SNPs function, does not appear to be well understood. They are not located within the lactase gene ("LCT") on Chromosome 2, as might be expected. Instead, they are found on a related gene called "MCM 6", which is about 14,000 genetic bases away from (and upstream of) the LCT gene. While MCM 6 is clearly related to lactase production, how MCM 6 functions and varies does not appear to have been fully described.

The names of the SNPs are composed of two letters and a number. The letters of the SNP name refer to the base (molecular) substitutions of the SNP: "C" for Cytosine, "G" for Guanine, and "T" for Thymine.[2] The presence of the substitution (i.e. the base indicated by the first letter) indicates a disposition for lactose intolerance.[3]

The number in the SNP's name refers to its distance, on the DNA chain, from the LCT gene. The SNP C/G-14010 is found 14,010 bases upstream from the start of the LCT gene. T/G-13915 is found 13,915 bases away, etc. The following chart is intended to illustrate terminology used to name the SNPs:

2. Together with adenosine ("A"), which does not appear in these particular SNPs, these four molecules are the "building blocks" of DNA.
3. Confusingly, in medical language, lactose intolerance is sometimes called "lactose non-persistence", and lactose tolerance is termed "lactose persistence".

	Lactose Intolerant Disposition Also called "lactose non-persistence". Called "wild type" in the patent application.	**Lactose Tolerant Disposition** Also called "lactose persistence". Called "variant" in patent application.
G/C-14010	Guanine ("G") at the position 14,010 bases upstream from the LCT gene.	Cytosine ("C") at position 14010
T/G-13915	Thymine ("T") at position 13915	G at position 13915
C/G-13907	C at 13907	G at 13907

Of course, individuals inherit two versions of the MCM 6 gene, one maternal and one paternal. Therefore, for each SNP, the genes of an individual might include two "intolerant" SNPs, two "tolerant" SNPs, or a mix of one of each. Presumably, this variability has a relationship to the fact that many people are not wholly lactose tolerant or intolerant, rather, they have varying ability to comfortably digest dairy products. It does not appear that the patent applicants have fully explored how different combinations of the SNPs within individuals influence lactose tolerance. For example, questions such as "*Is a person who inherits the same tolerance SNP from both parents equally or more lactose tolerant than somebody who inherits tolerance from just one parent?*" do not appear to have been answered yet.

Market issues

The current genetic test, based on the "Finnish" SNP common in people of Northern European heritage, is marketed under the name "LactoTYPE". In the US, the test is performed by Prometheus Therapeutics and Diagnostics of San Diego, California, which charges US $296.00 per result. The Prometheus test is performed under laboratory standards appropriate for use of the results in medical care.[xi]

The test is also directly retailed to wealthy consumers by other companies. One website charges US $99 for a test performed on a DNA sample directly submitted by the test subject (with no doctor involved).[4] Another website, called decodeme.com, sells lactose tolerance testing as part of a 35-test "complete gene scan" that costs US $985.

But these tests generally only yield useful results for people of European heritage. Clearly, a lactose tolerance genetic test that yielded accurate results for persons of African heritage would be a commercial and medical improvement over the current genetic test and could be profitable. It would be likely to be used most in places with large numbers of persons of African origin with access to expensive diagnostics, such as the United States.

4. It's unclear who conducts this test and if it would be considered valid by a medical professional. The website is: http://www.qtrait.com

Western medicine increasingly utilizes genetic diagnostics, and more and more tests are constantly crammed into increasingly automated diagnostic equipment. This trend, combined with the profitable retailing of genetic tests direct to citizens, strongly suggests that in many countries there is a growing market for lactose tolerance testing that is accurate for persons of all ancestries.

Also in the US, marketing of genetic tests specifically to African-Americans has emerged as a new market niche. For example, AfricanDNA.com, which is part of Family Tree DNA, a larger genetic testing company with laboratories run by a University of Arizona professor. While Family Tree DNA's tests are mainly sold to persons of European heritage, the AfricanDNA.com website specifically markets to African-Americans.[xii]

These websites are part of the booming market for biomedical and genealogical genetic testing in North America and Europe.

Companies charge about US $400 for African-Americans, many of whose ancestors were victims of the slave trade, to receive the result of a genetic test that allegedly identifies the modern African country from which they are descended. These tests have been developed through analysis of DNA collected from contemporary African cultural groups. For an additional fee, companies will send a “certificate of ancestry” that purports to certify the place in Africa from which a person is descended.

Prominent African Americans have joined the trend. For example, AfricanAncestry.com claims that its tests have determined that talk show host Oprah Winfrey is from Liberia, actor Morgan Freeman is from Niger, historian John Hope Franklin is from Cameroon, and athlete Jim Brown is from Nigeria.

For US $985, DeCode Genetics (Reykjavik, Iceland), offers to calculate what percentage genetic similarity a submitted sample has to six different African populations (Mandenka, Yoruba, Mbuti Pygmy, Biaka Pygmy, San, as well as Kenyan and South African Bantu speakers).

While intriguing, there are reasons to question the scientific and historical assumptions used in these tests and, as a result, their accuracy.

Part Two

Tishkoff's incursions into Africa

Tishkoff has a track record of highly focused work on Africa. She lists her research interests as "Human Evolutionary Genetics" (comparing human DNA to monkey DNA), the "African Genetic Diversity Project" (collecting DNA samples), "global patterns of linkage disequilibrium in the human genome" and "genetic basis of resistance to infectious disease" (looking for so-called disease genes), "Genotype/Phenotype Association Studies" (looking for genes associated with particular physical characteristics, e.g. tall people, eye colour, finger length, etc.), and pharmacogenomics (in her case studying how Africans metabolize drugs to identify differences from other populations).[xiii]

Tishkoff's high media profile is mainly as a result of university press releases related to her research. These have claimed, among other things, that Tishkoff has pinpointed an African "Eve" (as in Adam & Eve) from Ethiopia or Tanzania as the grandmother of all of humanity, and that she used genetics to determine that the appearance of malaria in Africa coincided with the advent of agriculture on the continent.[xiv]

Tishkoff has been actively collecting blood samples from African populations since at least the early 2000s. Her collections include blood samples taken from communities in Nigeria, Cameroon and Tanzania in 2001; Cameroon between the period 2000-2004; Sudan in 2003; Kenya in 2004 and, more recently, a 2008 trip to Ethiopia, where she planned to collect 600 DNA samples obtained from blood of 20 ethnically diverse populations. These will be added to her large collection of over 5000 DNA samples from more than 80 ethnic groups throughout Africa, including over 2000 samples from Tanzania, Kenya, and the Sudan.[xv] Indeed, Tishkoff has built what is claimed to be the largest repository of genetic samples from Africa in the U.S.[xvi]

Tishkoff has herself said that her research subjects were not participating in a specific scientific experiment, so much as providing raw material to secure and advance her lifelong career as an American professor. Commenting on a University of Maryland publicity website, Tishkoff said of her African collections, "*I hope to be able to use this DNA for the rest of my career.*"[xvii] And, indeed, Tishkoff has repeatedly published new and unrelated studies making use of the same DNA collections. She appears to have taken the African DNA samples as a personal possession from the University of Maryland to the University of Pennsylvania when she recently accepted a professorship at the latter school.

From South Africa's Dr Maritha Kotze, Tishkoff received samples including DNA from !Xun (Vasekela) and Khwe people. These samples were collected in the area of Schmidtsdrift in the north-western Cape region.[xviii] Kotze runs Genecare Molecular Genetics Inc. in Cape Town,xix a genetic testing company that is owned by Netcare Ltd and Cape Biotech.[xx] According to a report in South Africa's Sunday Times, detailed analysis of the South African samples — collected about four years ago — is due to be published later this year in a scientific journal.[xxi]

In 2008, Tishkoff said she'd like to begin DNA collections in Botswana and genetic studies of how Africans digest carbohydrates and fats, because she believes it may help explain the high incidence of diabetes among African-Americans.[xxii]

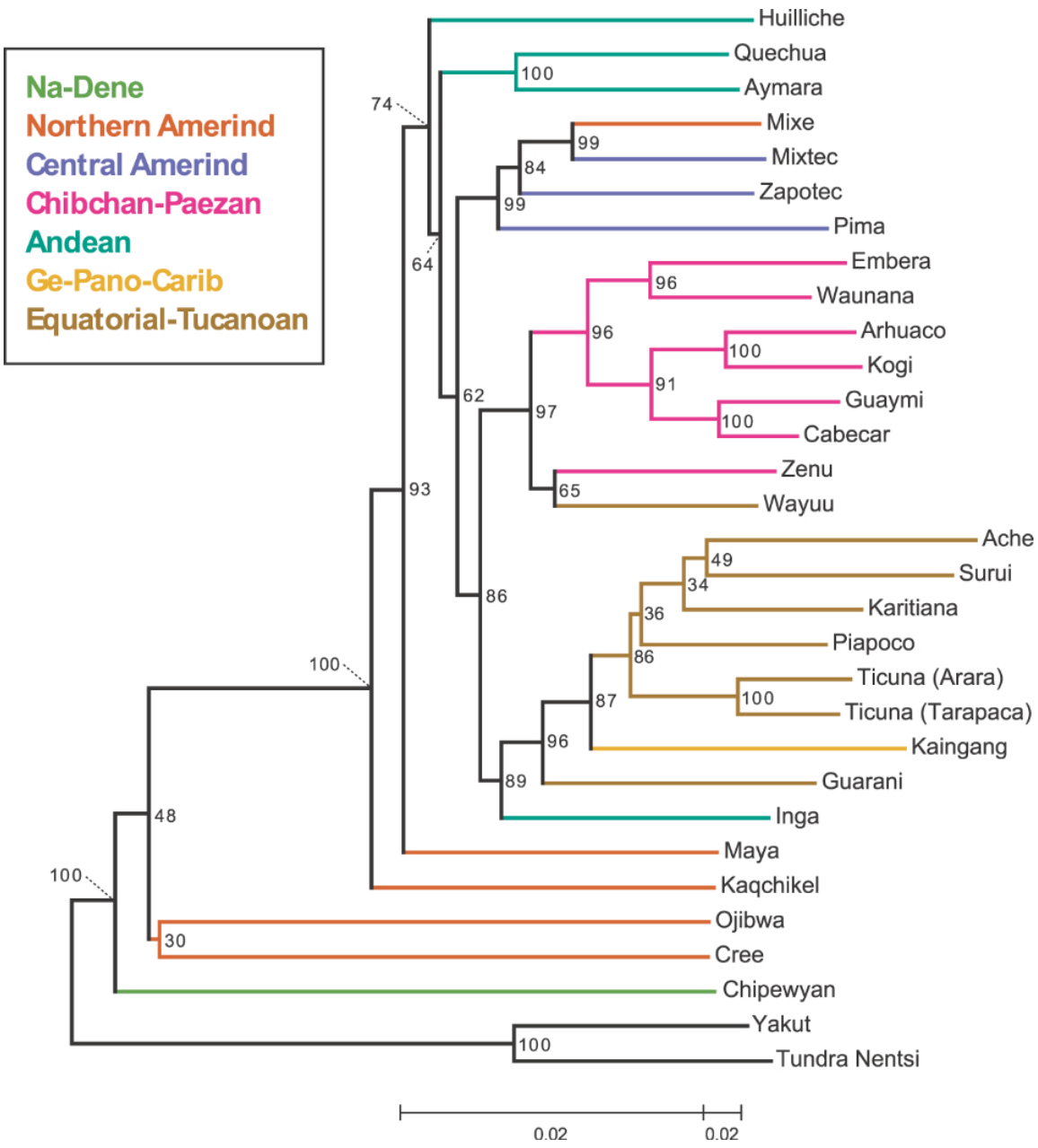
Key concerns

Tishkoff and the University of Maryland's patent application and their incursions into Africa generally, have brought into sharp relief several critically important social and ethical concerns. These include the methods and ethics of obtaining 'informed consent' from the people from whom samples were obtained, and here the following questions arise: How was consent obtained? Did the individuals or groups fully understand the project's intentions, particularly with regards to language barriers and differing cultural views? What does 'informed' constitute in the specific community context? Who would be authorized to actually give consent? How would individuals know what happened to their DNA, and did they know that it would be stored for future uses, undetermined at the time the samples were taken? For how long would their information be kept in DNA databases?

Moreover, did the Kenyan, Tanzanian, and Sudanese populations understand, when they were donating their blood samples, that their DNA would be used in commercial studies, and if they were aware, did they actually consent to University of Maryland patenting and profiting from the samples.

The patenting of human genes is morally reprehensible. Does anyone indeed have the right to own a life form or to commodify parts of the human body? In the past, for example, the US government has lodged patent claims on the cell lines of Indigenous people from the Solomon Islands. The Solomon Islands Government, however, demanded withdrawal of the patent applications and repatriation of the genetic samples, citing an invasion of sovereignty, lack of informed consent, and moral grounds as the reasons for protest. Will the Kenyan, Tanzanian and Sudanese governments follow suit and protect their people in a similar fashion?

Native American campaigner, Debra Harry, points out that it may be extremely difficult or impossible to recover or repatriate samples of blood, tissues, or body parts, once they are removed from people's bodies and stored elsewhere.[xxiii] This scenario became a reality in Colombia in the late 1990s when indigenous people learned that a Colombian university was collecting blood samples from numerous remote communities. The indigenous DNA donors were frequently told that the researchers were collecting samples for the purpose of conducting a diabetes test. In fact, the primary purpose was not diabetes testing, it was to create a DNA bank for long term storage and study of the DNA of Colombian indigenous peoples. The samples began to be shared among scientists internationally and, for example, were sent from Colombia to a lab belonging to the biotech company Roche in California. [xxiv] When indigenous leaders confronted the university, it reluctantly pledged to return the samples, but never made good on that commitment.



This chart is from a recent article comparing the DNA of a number of North and South American indigenous peoples.[xxv] Many of the DNA samples used are from Colombian indigenous peoples (Kogi, Arhuaco, Wayuu, Ticuna, Zenu, Inga, Piapoco, and others). Although Colombian indigenous leaders have objected to sharing of their DNA and demanded the return of many samples that have been collected, the DNA continues to be used in this and other studies.

Sadly, the survival of many of these peoples, such as the Paraguayan Aché, is threatened by a lack of legal protections and land title, as well as disease brought into isolated communities by outsiders. The Karitiana of Brazil's Amazon forest, who barely number 300 people and whose DNA was used in the same study, have said of the geneticists that collected their DNA "We were duped, lied to and exploited... Those contacts have been very injurious to us, and have spoiled our attitude toward medicine and science."[xxvi] Nevertheless, it continues to be shared and used in genetic studies.

Similar DNA collections and studies are underway in Africa.

There are other famous cases. In 1984, American John Moore filed a lawsuit claiming that his blood cells were misappropriated while he was undergoing treatment for leukaemia at the University of California's Los Angeles Medical Centre. Moore's doctor developed a cell line, taken from Moore's spleen, which proved valuable in fighting bacteria and cancer. The UCLA Board of Regents filed a patent claim on this cell line from which they developed commercially valuable antibacterial and cancer-fighting pharmaceuticals. Moore claimed that he was entitled to share in profits derived from commercial uses of the cells, and any other products resulting from research on biological materials taken from his body. In a significant 1990 California Supreme Court decision, the court ruled that Moore did not have property rights over the tissues removed from his body.[xxvii]

Conclusion

DNA isolated from Africans is being patented and used in wealthy countries in commercial products such as genetic tests. Scientists' claims in the 1990s that studies of human genetic diversity would be unlikely to result in commercial products were wrong. Indigenous people, nongovernmental organizations, and others that have warned that some would seek to patent and profit from human genetic diversity studies were correct to raise their voices.

Although geneticists that study human diversity pledged in the 1990s to resolve the conflicts caused by commercialization of human genes, they never effectively engaged indigenous people and traditional communities to find acceptable solutions. Despite this failure, geneticists have continued to collect DNA from traditional communities in many places. These samples are being kept in long term archives, and in some cases, geneticists have even filed for patents upon such materials.

The increasing use of genetic testing, particularly among the wealthy, creates commercial markets for medical and other (e.g. genealogical) assays based on human genetic diversity studies. In the future, this may give rise to the use of diversity studies in medical treatments. The patent application on African lactose tolerance genes is an example of this phenomenon and, in the future, more claims on African genetic diversity are likely. This is particularly the case if wealthy consumers are seduced by the (often historically naïve) idea that genetic code contains more objective "truth" about human identity than folklore, stories, family history, the written record, and other elements of human culture.

Most geneticists studying human diversity at first failed to anticipate the development of commercial markets; but now some have gone from denying the market potential of human genetic diversity to capitalizing upon it, through patent applications like Tishkoff's and companies like Family Tree DNA.

For most indigenous people and traditional communities who have wittingly or unwittingly contributed to the human diversity DNA banks in the United States, Europe, and elsewhere, these studies and products offer little or no benefit. With good reason, some liken the research to ongoing colonial exploitation.

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