

Indigenous Self-Determination and Research on Human Genetic Material: A Consideration of the Relevance of Debates on Patents and Informed Consent, and the Political Demands on Researchers

*Constance MacIntosh**

In April, 2005, National Geographic Society and IBM launched a genetics research project which targets indigenous populations, the 'Genographic Project.' They aim to gather and analyze DNA samples from 100,000 indigenous peoples over a five-year period. Genographic Project researchers intend to use these samples to track the migratory pathways through which humans have populated the globe.¹ This project was officially launched just one month after news broke that another human genetics project, the International HapMapProject, had completed Phase I on schedule.² The HapMap Project researchers are studying genetic markers called 'haplotypes',³ which can be used to map genetic inheritance over many generations. The HapMap researchers are looking for patterns of genetic variation, which they believe will illuminate how genetics contribute to disease.⁴ Both the Genographic and HapMap Projects follow on and reflect aspects of an earlier research endeavor, the Human Genome Diversity Project [the "HGDP"], which also sought to collect genetic materials for population-based research. Like the Genographic Project, the HGDP focused on collecting tissue samples from indigenous populations. And, like the HapMap Project, the HGDP had a medical research component.

Presumably, the proponents of both the Genographic and HapMap projects know very well that the HGDP met with broad opposition, primarily from indige-

* Constance MacIntosh is an Assistant Professor, Faculty of Law, Dalhousie University, Halifax, Nova Scotia. The author gratefully acknowledges comments received on earlier drafts of this paper from Chidi Oguamanam, RONALDA MURPHY, and BRIAN NOBLE.

¹ National Geographic, "The Genographic Project: Frequently Asked Questions", online: National Geographic <<http://www3.nationalgeographic.com/genographic/faqs.html>> [Genographic Project FAQ]. (The Genographic Project has also 'invited' members of the general public to participate. In return for a fee of \$100, individuals will be mailed a 'cheek swab' kit, which, upon return, will be analyzed for migratory markers and added to the mapping database. However, the focus of the project remains gathering genetic samples from indigenous populations).

² Up to date information on the status of the HapMap Project is posted on its official web site, online: <<http://www.hapmap.org>>.

³ The website for the Human Genome Project defines 'haplotypes as "groups of closely linked alleles that tend to be inherited together...[and which] can be used to map human disease genes very accurately" online: <<http://www.wellcome.ac.uk/en/genome/thegenome/hg04b002.html>>.

⁴ The International HapMap Consortium, "The International HapMap Project" (2003) 426:6968 *Nature* 789 at 789.

nous groups.⁵ In the end, the HGDP was only marginally successful.⁶ Although its proponents had hoped to collect tissue samples from 500 to 700 target indigenous populations, it only ended up with DNA samples from about 50 populations, many of which were 'donated' from pre-existing collections.⁷

The HGDP's limited outcome reflects the complex context in which the research was to take place. Genetic research involving indigenous populations provokes many legal, ethical and cultural issues.⁸ Like any genetic research project, it incites questions about ownership of genetic samples including the information gleaned from those samples and, of course, about whether human genetic material is or ought to be patentable. As with the debate on the commercialization of indigenous peoples' 'traditional ecological knowledge,' genetic diversity sampling raises questions about access, consent,⁹ exploitation and benefit sharing.¹⁰

⁵E.g. There have been no less than 14 declarations by significant indigenous groups and political organizations, calling for a temporary or permanent moratorium against the HGDP. These include: *Karioca Declaration*, Brazil, June 1992; *Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous People*, June 1993; *The UN Working Group on Indigenous Populations, 10th Session*, July 1993; *World Council of Indigenous Peoples; Maori Congress Indigenous Peoples Roundtable*, June 1994; *Latin and South American Consultation of Indigenous Peoples Knowledge* September 1994; *Declaration of Indigenous Organizations of the Western Hemisphere*, February 1995; *Asian Consultation on the Protection and Conservation of Indigenous Peoples Knowledge*, February 1995; *National Congress of American Indians*, Resolution No. NV 93-118. A more extensive list of declarations is posted on the web site for the Indigenous Council on Biocolonialism, online: [<http://www.ipcb.org>].

⁶The HGDP has developed a small collection, and has led to few publications. In 2002, project proponents announced the availability of "a resource of 1064 cultured lymphoblasted cell lines (LCLs) from individuals in different world populations," H. M. Cann et al., "A Human Genome Diversity Cell Line Panel" (2002) 296:5566 *Science* 261 at 261 [Cann]. According to L. Cavalli-Sforza, by July, 2004, over 56 laboratories had requested samples, leading to about 6 publications thus far. L. Luca Cavalli-Sforza, "The Human Genome Diversity Project: Past, Present and Future" (2005) 6 *Nature Reviews/ Genetics* 333 at 334-5. However, as Cavalli-Sforza notes, the collection is limited by its size and coverage (at 338-9). Regarding organized opposition, the Indigenous Peoples Council on Biocolonialism was formed in 1993 in response to the HGDP and has been active ever since, disseminating their position on research, genetic and non-genetic, involving indigenous peoples. Indigenous Peoples Council on Biocolonialism, online: <<http://www.ipcb.org>>.

⁷Cann, *ibid.* at 261. See also Benjamin Pimentel, "DNA study of human migration - National Geographic and IBM investigate spread of prehistoric peoples around world" *San Francisco Chronicle* 13 April 2005 [Pimentel]; Leslie Roberts, "How to Sample the World's Genetic Diversity" (1992) 257:5074 *Science* 1204 at 1204.

⁸Recent writing in the area is replete with allegations of abused trust and growing mistrust of researchers. See Charles W. Schmidt, "Indi-gene-ous Conflicts" (2001) 109:5 *Environmental Health Perspectives* A216 ("As in other countries, many U.S. tribes are suspicious of genomics and believe geneticists and the biotechnologies they spawn are out to exploit their genes ... for commercial gainGenetic researchers have also developed a reputation among Indian tribes as being culturally ignorant and arrogant" at A218).

⁹There are several high profile examples where indigenous peoples have argued that their genetic tissue was used for academic or commercial purposes without proper consent. The alleged egregious misuse of blood samples taken from the Yanomami Indians of Brazil is documented in Patrick Tierney, *Darkness in El Dorado: How scientists and journalists devastated the Amazon* (New York: Norton, 2000). One upcoming lawsuit involves the Havasupai Tribe of Arizona, which has claimed \$50 million in damages against academic researchers and their institutional affiliates, for allegedly having used their genetic samples for research purposes not contemplated in the consent process. See *Havasupai Tribe et al. v.*

Arguably, of these issues, two dominate the literature. The first is whether human genetic materials are or ought to be patentable, which is often argued against on the basis that such patents offend human dignity generally and are culturally offensive to many indigenous peoples. The second is whether researchers must obtain informed consent from representatives of indigenous groups as a whole before attempting to obtain consent for participation from individual members of that group. This paper is, in part, a call for researchers and those concerned with indigenous/non-indigenous research projects to reconsider whether and how these debates should continue. In particular, I argue that there is limited benefit in continuing to debate the patentability of human genetic material. I also argue that the debate on informed consent is not only about the complexity of ensuring culturally effective knowledge transfer, nor as a simple means of appeasing frustrations of local peoples, but also has to be understood as a manifestation of indigenous political and legal rights aspirations which researchers must consider and address. The through-line in this paper, therefore, is that by virtue of their

Arizona State University et al., Case No. CV-20040146 (D. Ariz. 2004); *Tilousi v. Arizona State University*, Case No. CV-20040115 (D. Ariz. 2004). As discussed below, this case will turn on the question of consent. See Larry Hendricks, "Havasupai tribe files \$50M suit against ASU" *The Arizona Daily Sun* 16 April 2004 [Hendricks]. This law suit is used as a teaching example by the Los Angeles Children's Hospital for consent issues. See their educational materials, online: <<http://www.childrenshospitala.org/documents/CCI/Educational%20Materials/Research%20with%20Human%20Specimens%20and%20Databases.pdf>>. A similar controversy rages in China, where Harvard researchers have been accused of exploiting vulnerable populations for genetic research. Debate continues over whether Harvard's standards for research protocols and ascertaining consent are sufficient or appropriate when working with populations who fear offending those in authority, or who are desperate for basic medical services (which are often promised in exchange for participation). See N. Rose, "Developing our links with China – Sociology and BIOS" (2004) 3:1 Soc. Research News 6 at 7-8.

¹⁰ These concerns lead to the inclusion of Art. 8(j) of the *Convention on Biodiversity 1992*, UN Conference on Environment and Development, UN Doc. [ST/DPI/1307, 31 I.L.M. 818, 824 [CBD]] The CBD was ratified by Canada on 12 April 1999. Article 8(j) called for states to "respect, preserve and maintain knowledge, innovation and practices of indigenous ... communities ... and promote their wider application with the approval and involvement of the holders of such knowledge..." The question of whether the CBD has successfully navigated these issues is open to debate. See, for example, the critical discussion of the CBD and traditional knowledge in U.K., British Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights*, (London: Commission on Intellectual Property Rights, 2002) at 82-104 and the discussion in M. Halewood, "Indigenous and Local Knowledge in International Law: A Preface to Sui Generis Intellectual Property Protection" (1999) 44 McGill L.J. 953 paras. 58-78. Some indigenous organizations, such as the Indigenous Peoples Council on Biocolonialism (IPCB), have concluded that the likelihood of being exploited is so high that indigenous peoples ought to reject requests to be involved in genetic research, or to participate with a great deal of caution. For example, see the Indigenous Peoples Council on Biocolonialism for their list of reasons for why such research is inherently harmful to indigenous peoples. Debra Harry, "IPCB Action Alert to Oppose the Genographic Project" (13 April 2005), online: Indigenous Peoples Council on Biocolonialism <http://www.ipcb.org/issues/human_genetics/htmls/action_gen.html> [Harry]. I find the suggestion of simply refusing all requests to participate in such research to be troubling. It implies that genetics researchers cannot learn, from past experiences, indigenous peoples, and others, how to form just relationships. I do not subscribe to this position, however, the topic of benefit sharing is beyond the scope of this paper. For a thoughtful discussion of benefit sharing, see Lorraine Sheremeta & Bartha Marie Knoppers, "Beyond the Rhetoric: Population Genetics and Benefit Sharing" (2004) 12 Health L. J. 89.

research agendas, both commercial and scholarly scientists have become on-the-ground players in contests over indigenous people's claims of identity and rights.

The paper opens by identifying some of the reasons why scholarly and commercial researchers engage in population-based genetics research, and how commercial, medical and academic research interests often converge. In the second section, I turn to the now virtually defunct HGDP and consider how it was received by indigenous peoples and international organizations. I use the example of the HGDP to explore why genetics research with indigenous populations is so provocative. I then illustrate how the proponents of the Genographic and HapMap Projects have attempted to differentiate themselves from the HGDP. Having established a relatively full contextual map of these past and present research projects, and exemplified key moral and ethical 'hotspots' arising from them, I turn to issues of law, especially in Canadian and U.S. contexts.

The third section analyses intersections between moral, legal and ethical problems. In particular, I show how the potential for exploitation is – or is perceived to be – inherent to population based genetic research with indigenous populations.¹¹ These problems are often reduced to discussions about whether morality demands that patenting law not extend to human genetic material. To do this I analyse how patenting law in Canada, the United States, and the European Union engage with matters of morality. With that, I conclude by raising the limited practical effects of making changes to patenting law such that it might somehow be more responsive to the ethical or cultural concerns of indigenous populations. I also question the practical effects of an outright prohibition on patenting human genetic materials. My premise here is simple: if the debate on patents resulted in a prohibition, the patent would merely be obtained further down the research, commodity, and development chain. If it were not available for a genetic marker, it would be sought on a cell line, if not on a cell line, then on a procedure, *ad nauseum*. Crucially, a prohibition is unlikely to materially affect the *practice* or *terms* under which genetic sampling occurs, or under which genetic samples are *sold*. Such a prohibition would risk creating a perception that the moral issues which are provoked by patenting, such as respect for cultural difference and human dignity, have been addressed. In fact, they simply would have been deferred or deflected.

Finally, I turn from patenting law to consider the law of informed consent, and its underlying principles. The law on informed consent is patchy at best, but is emerging rapidly especially in quasi-legal environments and in human rights discourse. The project of making 'consent' meaningful in the context of population-based research involves legal, cultural, and political challenges. Addressing these challenges requires addressing not only effective information transfer, but also engaging with the fact that for indigenous populations, questions of consent provoke issues regarding claimed rights of self-determination as well as tensions

¹¹ B.M. Knoppers, M. Hirtle, & S. Lormeau, "Ethical Issues in International Collaborative Research on the Human Genome: The HGP and the HGDP" (1996) 34:2 *Genomics* 272 at 280.

regarding cultural, legal and political definitions of group membership. Because these issues underlie consent, any suggestion that authorization is not required from an indigenous group representative is to suggest that the indigenous people are not a rights-bearing political entity. Although a researcher may not believe that an indigenous people has such a status, this presumption must not eclipse the fact that indigenous peoples are likely to claim and actively assert this status.

My position accepts the premise that population-based genetic research has the potential to affect human good, especially by further medical science. However, there are terms which must be present for such research to be legitimately undertaken and researchers, as well as their sponsors, must be alive to the political, moral and legal complexities which are engaged when seeking to work with indigenous peoples, especially in contemporary conditions where indigenous people have widely adopted strong stances on proprietary interests, cultural autonomy, self-determination, and other human rights.¹²

1. The Value of Genes

Population genetics is a discipline which considers “the characteristics of genes within a population as opposed to a description of the genes in a particular individual.”¹³ It is scientific research which is key for the advancement of knowledge on several fronts,¹⁴ including human migratory pathways and the relationship between genetics and disease.¹⁵ In some instances, genetic data is, in and of itself, quite lucrative, even before any medical products have been developed. For instance, cell lines and tissue cultures are estimated to have yielded \$427.6 million U.S. to American genomics companies in 1996.¹⁶ This figure can only have increased over the last decade. More recently, Incyte Pharmaceuticals reported \$220 million U.S. in profits in 2001 for selling access to genes on which it held, or had applied for, patents.¹⁷ Where a genetically ‘isolated’ population¹⁸ is involved,

¹²One prominent example of such stances is illustrated through the *Draft United Nations Declaration on the Rights of Indigenous Peoples*, UN, Subcommission on Prevention of Discrimination and Protection of Minorities, 46th Sess., UN Doc. E/CN.4/Sub.2/RES/1994/45 (1994).

¹³UNESCO, International Bioethics Committee, *Bioethics and Human Population Genetics Research*, (Paris: International Bioethics Committee, 15 November 1995) at 1.1, online: UNESCO <www.portal.unesco.org/ulis/index.html>.

¹⁴L. Gostin, “Ethical Principles for the Conduct of Human Subject Research: PopulationBased Research and Ethics” (1991) 19:4 *Law, Medicine and Health Care* 191 at 192.

¹⁵Henry T. Greely, “The Revolution in Human Genetics: Implications for Human Societies” (2001) 52 *S.C.L. Rev.* 377 at 378-9.

¹⁶*Business Wire*, 28 May 1996.

¹⁷Tabitha M. Powledge, “Can sequences turn a profit?” *The Scientist* (16 May 2002), online:*The Scientist* <<http://www.the-scientist.com/news/20020516/03>>.

¹⁸Not all gene pools are created equal. The increased homogeneity of the gene pool from endogamous populations greatly facilitates the identification of genetic deviance, thus making it much more likely that inherited diseases can be tracked to a gene trigger. There are on-going questions about whether some populations which were seen as ‘genetically homogeneous’ do in fact fit the bill. See Skuli Sigurdsson, “Yin-yang Genetics, or the HSE deCODE Controversy” (2001) 20:2 *New Genetics and Society* 103 (where the genetic homogeneity of Iceland’s population is questioned at 107).

the financial stakes can be surprising. A well-documented example involves a University of Toronto affiliate, the Samuel Lunenfeld Research Institute of Canada, who worked in conjunction with a California genomics company, Sequana Therapeutics.¹⁹ Representatives of the Institute collected blood samples from the 300 inhabitants of the small island of Tristan da Cunha, who were of research interest because of their genetic closeness and high incidences of asthma. The islanders agreed to be sampled *en masse*, in return for which they would receive free pharmaceutical-based treatment if drugs were developed based on information gleaned through the sampling.²⁰

In 1995, Sequana Therapeutics announced it could identify and so eventually patent genes which predisposed people to develop asthma. It then sold the licensing rights to *develop* a genetic diagnostic test to a German company, the Boehringer Institute, for 70 million dollars U.S.²¹ Both Boehringer and the Islanders have gambled that benefits will accrue to them: of note is the distinct disparity between the realized and potential benefits to Sequana and Boehringer, and the potential benefits to the Islanders who will merely receive 'free' pharmaceuticals if a drug-based treatment is ever developed.

Despite these compelling profit figures which may attach to medical research, legal scholar Russel Barsh has concluded that much genetic diversity research with indigenous populations is actually directed to academic advancement.²² Collections of genetic tissue from indigenous populations can indeed be a key source for professional advancement within the academy. A case in point is the 400 blood samples from members of Arizona's Havasupai Tribe, which are at the centre of a lawsuit against Arizona University, and which allegedly formed the basis for no less than 23 scholarly papers, articles and dissertations.²³ Similarly the 833 blood samples taken by Dr. Richard Ward in 1985 from the Nuuchahnulth of Vancouver Island served as the basis for some of his most important career research, leading eventually to his appointment as the Head of the Institute of Biological Anthropology at Oxford University (U.K.).²⁴

It is, however, not uncommon for scholars to work with corporations. Mark Swindells, of Inparmatica Ltd., a pharmaceutical company, has commented that

¹⁹H. Cunningham, "Colonial encounters in postcolonial contexts – Patenting indigenous DNA and the Human Genome Diversity Project" (1998) 18:2 Critique of Anthropology 205 at 217 [Cunningham]; See also Cindy Hamilton, "The Human Genome Diversity Project and the New Biological Imperialism" (2001) 41:2 Santa Clara L. Rev. 619 at 627-28 [Hamilton].

²⁰Paul Salopek, "Genes offer sampling of hope and fear" *The Chicago Tribune* (28 April 1997), online: The Pulitzer Prizes <www.pulitzer.org> (The article was the winner of the Pulitzer prize for explanatory reporting in 1998. This population was considered genetically homogeneous because its members were all believed to be descended from seven British colonial families).

²¹Cunningham, *supra* note 19 at 217-18.

²²Russel Lawrence Barsh, "Pharmacogenomics and Indigenous Peoples: Real Issues and Actors" (2003-2004) 11 Cardozo J. Int'l & Comp. L. 365 at 375.

²³Hendricks, *supra* note 9.

²⁴P. Malik, "Biopiracy" (2005) 21:1 Can. J. Cardiol. 21 at 21.

“the implementation of large-scale genetics and biology is unique in appealing to both commercial and academic spheres simultaneously.”²⁵

For example, Harvard researchers have established an agreement with Millennium Pharmaceuticals to explore links between genetics and respiratory disease. Researchers have gathered tissue samples from a specific population of the Anhui region of China. Referring to the high homogeneity of group members’ DNA, the lead Harvard researcher reportedly told his colleagues that it was “more valuable than gold.”²⁶ According to investigative journalists from the Washington Post, John Pomfret and Deborah Nelson:

Harvard ultimately reaped millions of dollars in federal grants and private investment for the university and the project’s lead research because of its access to Anhui DNA. And Millennium was able to raise tens of millions of dollars from corporate investors.²⁷

The imagined value of genetic information from such populations is so great as to sometimes result in cascades of investment and profit, long before any commercially viable results have emerged. On a much smaller scale, a casual perusal of genetic samples available from the U.S. based Coriell Cell Repositories, a division of Coriell Institute for Medical Research, indicates that cell cultures from various indigenous populations, including the Karitiana Indians of Brazil and a people described only as “Aboriginal Tribe from Taiwan (Ami),” can be purchased for as little as \$85 U.S. a sample.²⁸ Once again, there is an academic connection as these samples originated from academic collectors, from “the Yale-Stanford collection.”

The Genographic Project certainly embraces both academic and commercial spheres, although it does not appear to have an applied medical research component in its conception. At first glance, the Project resonates as a highly scholarly one: most of its regional heads hold academic posts, and its primary products will include creating a public database of anthropological genetic information, and publications

²⁵Mark Swindells, “Is ‘big biology’ a commercial enterprise?” (2002) 3:4 *Genome Biology* comment 2004.1 at comment 2004.4; See also Lopeti Senituli & Margaret Boyes, “Whose DNA? Tonga & Iceland, Biotech, Ownership and Consent” (Paper presented to the Australian Bioethics Association Annual Conference, February 2002) at 2 [unpublished, online: <www.australasian-bioethics.org.au/papers/PaperMargaretBoyesLopetiSenituli.pdf>]; American tax laws may also play a part, see 15 U.S.C. §§ 3701-3717 (1994 & Supp 1997); see S. Krimsky for an overview of industry-university affiliations, and the legislative basis of the rapid commercialization of genetic information, Sheldon Krimsky, “The Profit of Scientific Discovery and Its Normative Implications” (1999-2000) 75 *Chi.-Kent L. Rev.* 15 at 28.

²⁶As reported by John Pomfret and Deborah Nelson, “An Isolated Region’s Genetic Mother Lode” *Washington Post* (20 December 2000), pA01.

²⁷*Ibid.*

²⁸Order information can be accessed on-line:

<<http://locus.umdj.edu/nigms/comm/order/catprice.html>>. A listing of samples by ethnicity is found under “Human Variation Collection of the NIGMS Repository”, online:

<<http://locus.umdj.edu/nigms/cells/humdiv.html>>.

on the evolution of key genetic markers and tracking human migration.²⁹ Its secondary products, though not strictly academic and with a commercial value, are certainly scholarly in character. They include "magazine articles, books, television documentaries, and exhibits."³⁰ IBM's corporate interest, as explained by IBM spokesman Jay Cadmus, is the expectation that it will "raise the company's profile as a provider of technology to research institutions, both academic and governmental." They hope to become a major player in the market for life sciences research, which "is projected to grow into an \$34 billion market by 2007."³¹

What of the HapMap Project? Like the Genographic Project, most of its proponents hold prominent academic posts, and it has not joined forces with pharmaceutical companies. Although the stated goal of the HapMap Project is to generate a medical research database that catalogues genetic variation,³² proponents have said from the start that no commercial products will result directly from the HapMap Project. However, like the academic/corporate relationships described above, "in the short term, the main beneficiaries will...[be] researchers, who will gain professional rewards, and companies, that will be able to develop drugs, diagnostic tests or other commercial products from research using the HapMap."³³

And so the global commodification of genetic resources, as a source of profit and professional advancement, as a forum where market-based and academic research may be symbiotic,³⁴ has pushed indigenous peoples, with their allegedly homogeneous genetic lines, to centre stage.³⁵ The Genographic Project, presumably, will sooner or later be a part of this fray.

2. Lessons From the HGDP

The fact that the HGDP would be plagued with controversy and opposition from indigenous groups came as something of a surprise to its original proponents. Indeed, this group of population geneticists, led by star geneticist Dr. Lucas Cavalli-Sforza,³⁶ may have seen themselves as quite progressive, as they had

²⁹The Genographic Project: Mapping the Human Story "Press Release & Fact Sheet". (13 April 2005), online: National Geographic <www.nationalgeographic.com/genographic> ; Sarah Lysecki, "National Geographic's DNA database raises doubts" *IT Business* (18 April 2005), online: IT Business <www.itbusiness.ca>.

³⁰Genographic Project FAQ, *supra* note 1.

³¹Pimentel, *supra* note 7.

³²The International HapMap Consortium, "Integrating ethics and science in the International HapMap Project" (2004) 5:6 *Nature Reviews. Genetics* 467 at 473.

³³*Ibid.*

³⁴Cunningham, *supra* note 19 at 215.

³⁵Donna Haraway, *Modest-Witness@Second-Millennium.FemaleMan-Meets-OncoMouse: feminism and technoscience* (New York: Routledge 1997) at 62.

³⁶The other initial proponents were A.C. Wilson, C.R. Cantor, R.M. Cook-Deegan, and M.C. King. They first published their proposal in a letter to the editor in the trade journal *Genomics.*, see L.L. Cavalli-Sforza, et al., "Call for a World-Wide Survey of Human Genetic Diversity: A Vanishing Opportunity for the Human Genome Project" (1991) 11:2 *Genomics* 490 [Cavalli-Sforza].

already lead a critique of the Human Genome Project (the “HGP”) for its Eurocentricity. They queried how one could map “the” human genome when the genes under examination were an amalgamation of genetic materials gathered from just 5 individuals who self-identified as African-American, Asian, Causasian and Hispanic.³⁷ As one observer stated: when the HGP is complete, “they’ll tell us everything there is to know about one French farmer and a lady from Philadelphia.”³⁸

They proposed the HGDP as a systematic study of the whole range of human genetic diversity.³⁹ Those involved would compile a database of genetic samples from all over the world, and extract white blood cells to create self-replicating samples – so called “immortal cell lines.” The cell lines would then be stored in a non-profit DNA database. The HGDP proponents had great expectations about the research this database could support. They expected it would answer questions about human evolution by revealing “the biological relationship among different human groups” and, anticipating applied research, “may be useful in understanding the causes of and determining the treatment of particular human diseases.”⁴⁰ They posited the samples would give definitive evidence that there is no scientific support for racial distinctions. To maximize the research possibilities, researchers worldwide would also have access to this unified set of samples for their own research agendas.⁴¹

The proponents had a promising budget and time line, especially in comparison to the HGP, which was projected to span 15 years, and cost 3 billion U.S. The HGDP was only expected to take 5 years, and cost 25 million U.S.⁴² An International Executive Committee, standing committees on ethics and infomatics,⁴³ and regional teams for Europe, India, S.W. Asia, the Americas, Africa and China were soon established.

It is now 2005. The HGP finished in 2000, ahead of schedule and under budget.⁴⁴ The HapMap finished Phase I and its sampling activities within 3 years, as planned, and Phase II is proceeding ahead of schedule.⁴⁵ The HGDP, however,

³⁷ Todd R. Disotell, “Human genomic variation” (2000) 1:5 *Genome Biology* comment2004.1.

³⁸ Malik, *supra* note 24; D. King, “The Human Genome Diversity Project” (2002) 10 *GenEthics News*. Neither author, however, identifies who made this comment.

³⁹ Cavalli-Sforza, *supra* note 36.

⁴⁰ North American Committee, Human Genome Diversity Project, “Human Genome Diversity Project: Frequently Asked Questions”, [HGDP, FAQ], online: Morrison Institute <www.stanford.edu/group/morrinst/hgdp/faq.html>.

⁴¹ *Ibid*; Cavalli-Sforza, *supra* note 36.

⁴² H.T. Greely, “Human Genome Diversity: What about the other human genome project?” (2001) 2:3 *Nature Reviews/Genetics* 222.

⁴³ See discussion in Cunningham, *supra* note 19 at 209.

⁴⁴ Bartha Marie Knoppers & Geneviève Cardinal, “Genetics and the Law” in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds., *Canadian Health Law and Policy* 2nd ed, (Markham: Butterworths, 2002) at 433.

⁴⁵ HapMap Consortium, *supra* note 32.

met such opposition that it actualized on a rather limited scale. Where it did operate, it was primarily beneath the reach of the radar of public scrutiny – largely outside of public funding and public institutions, and involving no indigenous populations from within Canada and the United States.⁴⁶ Why such an outcome?

UNESCO offered clear insight on this matter. In a report drafted by its Bioethics Committee in 1996,⁴⁷ it noted that much of the opposition was in response to past experiences where northern parties – corporate and state – collected genetic material and traditional knowledge from indigenous and third world populations, and used these to develop and patent agricultural and pharmaceutical products with little, if any, benefits accruing to the original donors of the material or the knowledge.

UNESCO illustrated its position with reference to the International Board for Plant Genetic Resources, a 1970s project which resulted in a public domain resource of 125,000 plant germplasm specimens, 80% of which came from the South, much of which was identified by indigenous peoples. This database has been the source for the development of product hybrids worth billions of dollars to farmers and agribusiness in the industrialized world.⁴⁸ However, for the most part, the local populations received no benefit, financial or otherwise. A similar pattern holds for pharmaceutical compounds – and so, UNESCO observed, indigenous peoples do not want this history repeated once again, this time with their blood.⁴⁹

UNESCO's comments contextualize the hostility expressed by many indigenous peoples towards the HGDP, who called its proponents 'biocolonialists,' and 'biopirates.'⁵⁰ As the HGDP would collect blood samples, one organization, the World Council of Indigenous Peoples, dubbed the HGDP the 'Vampire Project'⁵¹, a name which stuck.⁵²

⁴⁶ Cavalli-Sforza, *supra* note 6 at 337.

⁴⁷ *Supra* note 13.

⁴⁸ *Ibid.* at s.2.3.2.

⁴⁹ Legal scholar James Anaya has similarly documented the "cultural suffocation" of colonialism, historically experienced by indigenous peoples the world over, which has left "deep wounds which manifest themselves in social, political, economic, as well as social spheres." James Anaya, "On Justifying Special Ethnic Group Rights: Comments on Pogge" in Ian Shapiro & Will Kymlicka, eds., *NOMOS XXXIX: Ethnicity and Group Rights*, (New York: New York University Press, 1997) 222 at 229.

⁵⁰ Some of the opposition activities are documented in UNESCO, *supra* note 13 at s.2.2.2; See also Jenny Reardon, "The Human Genome Diversity Project: A Case Study in Coproduction" (2001) 31:3 *Social Studies of Science* 357 at 369-71 (for documentation and a discussion of some internet-based opposition) [Reardon].

⁵¹ Reardon, *ibid* at 358.

⁵² UNESCO, International Bioethics Committee, *supra* note 13 at s.2.2.2; *supra* note 42 at 225; M. Lasso, "Gene Study Puts Indians on Guard" *Tierramerica* (27 April 2005), online: Inter Press Service News Agency <<http://ipsnews.net/index.asp>> (citing Tacila Rivera, a leader of indigenous and Amazonian women in Peru).

Hoping to avoid such associations, the Genographic Project has made express efforts to distinguish itself from the HGDP. Indeed, one of the 'Frequently Asked Questions' posted on the Genographic Project's web page is "How does the Genographic Project differ from the Human Genome Diversity Project (HGDP) proposed over 14 years ago?"⁵³ The answer begins as follows:

While the goals of the two projects overlap to some extent, there are major differences in the clarity of our mission and the way we are carrying out this project.

This disclaimer is a factually accurate attempt to navigate the climate of suspicion which crystallized around the HGDP. The two projects are, after all, both forms of 'salvage genetics,' in that they are motivated into action by the threat of indigenous populations 'disappearing'. For example, in the HGDPs' proponents' first public formulation of the proposal, they posited with modernist zeal the urgency of the Project in the fact that many populations who were key for understanding evolutionary relationships were on the cusp of becoming culturally and biologically extinct. They wrote:⁵⁴

The populations that can tell us most about our evolutionary past are those that have been isolated for some time, are likely to be linguistically and culturally distinct and are often surrounded by geographic barriers. ... such isolated populations are being rapidly merged with their neighbours, however, destroying irrevocably the information needed to reconstruct our evolutionary history ... It would be tragically ironic if, during the same decade that biological tools for understanding our species were created, major opportunities were squandered.

Similarly, the Genographic Project's proponents linked its urgency with cultural loss:

[The Project will provide an] invaluable scientific resource for the research community. Many indigenous populations around the world are facing strong challenges to their cultural identities. The Genographic Project will provide a 'snapshot' of human genetic variation before we lose the cultural context necessary to make sense of the genetic data.⁵⁵

Describing indigenous communities as endangered objects of study who presented 'major opportunities' for research (the HGDP) or the data source for an 'invaluable scientific resource' (the Genographic Project) puts these projects on

⁵³ *Supra* note 1.

⁵⁴ Cavalli-Sforza, *supra* note 36.

⁵⁵ Genographic Project FAQ, *supra* note 1.

troubled ground.⁵⁶ The HGDP's planning committee hit further trouble when they went on to identify 700 indigenous peoples who would be their sampling priorities prior to contacting or consulting with these communities or any other indigenous political organization. The label they developed for these indigenous communities was "Isolates of Historic Interest," a term which obscured the humanity and history of the subject peoples, while simultaneously divesting them of their own interests.⁵⁷ The NGO RAFI⁵⁸ was quick to publicize this unilaterally created 'Hit List' along with their own rhetorical condemnation of the 'gene hunters' and 'predatory researchers.'⁵⁹ One indigenous organization astutely characterized the HGDP as "a more sophisticated form of collecting and preserving Indigenous Peoples like those collections of yet unreturned mummies taken from their burial caves in violation of Indigenous Peoples' rights."⁶⁰

To prioritize making aboriginal peoples' blood lines immortal rather than addressing the causes of cultural threat was, and is, rather naïve. Opponents to the HGDP calculated that the average cost of each sample under the initial proposal, including administrative costs, would be more than the per capita GNP of any one of the world's 100 poorest countries.⁶¹ As bioethicist Margaret Lock and others point out, Indigenous political organizations quite reasonably perceived the HGDP as having no interest in helping indigenous peoples to survive, or in addressing the social, economic, political or exploitation issues which endanger many indigenous peoples.⁶²

In certain parts of the world indigenous peoples are facing cultural extinction....As their social fabric breaks up, they are in danger of losing their identity and culture. The struggle to survive as a people is a pressing concern of many groups. In this context, the call for researchers to collect genetic materials from indigenous populations before they disappear as distinctive genetic groups may appear to some as grossly insensitive and callous.⁶³

⁵⁶ Such claims seem common in this area of research, e.g. P. Forster and S. Matsumura write that "Time is short if researchers wish to secure data on dwindling indigenous populations such as the Andamanese and the Orang Asli." in P. Forster & S. Matsumura, "Evolution – Did Early Humans Go North or South?" (2005) 308 :5724 Science 965 at 966.

⁵⁷ Reardon, *supra* note 50 at 370-371.

⁵⁸ RAFI, the Rural Advancement Foundation International, is a Canada-based non-profit research organization devoted to political advocacy on intellectual property rights and biodiversity. RAFI has since been renamed Action Group on Erosion, Technology and Concentration (ETC), online: <www.etcgroup.org>.

⁵⁹ See discussion in Cunningham, *supra* note 19 at 209-210.

⁶⁰ As cited by M. Foster, "The Human Genome Diversity Project and the Patenting of Human Life: Indigenous Peoples Cry Out" (1999) 7 Canterbury L.R. 343 at 348.

⁶¹ *Ibid.* at 349.

⁶² *Ibid.* at 350; Margaret Lock, "Genetic Diversity and the Politics of Difference" (1999-2000) 75 Chi-Kent L. Rev. 83 at 92.

⁶³ UNESCO, International Bioethics Committee, *supra* note 13 at s.3.1.1.

In response, the HGDP's North American Committee wrote:

In a world where poverty and disease are widespread, almost any expenditure of funds would relieve more human misery if used for direct assistance. Many of the populations this Project will study live in dire poverty. But \$5 million per year would not go far toward solving those problems.⁶⁴

This response missed the point.⁶⁵ Demonstrating how little the sum of research funds could achieve on the ground would placate no one. The Project, as proposed, simply failed to be relevant for the subject peoples, and did not recognize or respond to their specific interests, pressing needs or concerns. Rather, it served the interests of the scientific community (and, arguably, the interest of general knowledge production). In the eyes of some, it had an unshakable air of colonial exploitation. It is not much of a stretch to find the proposal to be conceptually analogous to collecting updated versions of museum specimens,⁶⁶ late 20thc. science with 19thc. politics.⁶⁷

How does the Genographic Project attempt to differentiate itself on these points? Its proponents write:

Ours is a true collaboration between indigenous populations and scientists. Helping communicate their stories and promoting preservation of their languages and cultures is integral. Before any field work begins, we have been and will continue to seek advice and counsel from leaders and members of indigenous communities about their voluntary participation in the project.

In addition to answering questions of scientific interest to indigenous populations and the general public, we feel it is imperative to give something tangible back to the participating communities through Genographic's legacy project, which will include educational activities and cultural preservation projects...⁶⁸

So the Genographic Project will address the matter of survival through some kind of cultural preservation programming, presumably as developed with or by

⁶⁴ *Supra* note 40.

⁶⁵ Reardon, *supra* note 50 (for examples of interchanges where Project proponents perceived criticism or opposition from Indigenous peoples as merely indicative of scientific misunderstandings, divorced from a broader social, historic, political and cultural context at 370-371).

⁶⁶ *Supra* note 35 at 252; *supra* note 60 at 348.

⁶⁷ See discussion in Cunningham, *supra* note 19 (where she comments upon academics characterizing the project as having a "colonial" flavour, and as treating indigenous populations as "the 19th century anthropological 'primitive', who, envisioned as vestiges of an earlier moment in human history, represented a mirror on to the past" at 212-213).

⁶⁸ *Supra* note 1.

the indigenous community in question. In an interview with *Wired News*, with the catchy title of “We Ain’t No Biocolonialists,” Genographic Project director Spencer Wells elaborates as follows:

We want to plow the majority of the money from the sale of the public participation kits⁶⁹ into development projects with the indigenous populations because we realize there are some real pressures facing many of these groups. Ideally we will work with nongovernmental organizations on the ground on educational or cultural projects, depending on what local groups want.⁷⁰

They also appear to plan to have communities volunteer, instead of being “targeted,” for some of the Project’s products – films and magazine articles – to draw public attention to the stresses faced by indigenous peoples. This approach has not assuaged the Indigenous Council on Biocolonialism, who have condemned the Genographic Project as “essentially a renewed attempt to further the goals of the much protested Human Genome Diversity Project.”⁷¹ As to indigenous communities, it is too soon to tell whether they will give the Genographic Project proponents the opportunity to speak with them, much less predict whether they will agree to participate. Arguably, it is a much better start to the project, and illustrates a greater attempt to structure the project and its outcomes in a way which may benefit indigenous populations, both directly and indirectly.

Intriguingly, the HapMap Project’s proponents seem to be trying to avoid raising ‘indigenous’ issues. The subject populations for Phase I were identified based not just on scientific factors, but also, purportedly, on “ethnic concerns”,⁷² which led proponents to not actively seek genetic samples from North American indigenous peoples. The ‘ethical concerns’ were that population-history findings could conflict with “legal or political claims that relate to land or items of cultural patrimony” or could conflict with “religious or cultural understandings” about origins.⁷³ As discussed in more detail below, such concerns are perhaps better characterized as *legal* and *political* ones.

This decision undoubtedly facilitated the HapMap Project’s research running smoothly. HapMap proponents did meet with North American indigenous representatives, to tell them of the Project. Some indigenous groups may be interested in participating in a later phase – if the research begins to provide information that may be relevant for their own health concerns. This is a strikingly different approach than that adopted by the HGDP. But, do either of these approaches get the

⁶⁹ *Ibid.*

⁷⁰ As cited in Stephen Leahy, “We Ain’t No Biocolonialists” *Wired News* (21 April 2005) online: [Wired News <www.wired.com/news/medtech/0,1286,67289,00.html>](http://www.wired.com/news/medtech/0,1286,67289,00.html).

⁷¹ Harry, *supra* note 10.

⁷² *Supra* note 32 at 469.

⁷³ *Ibid.*

Genographic and HapMap Project past the hurdles which eventually undermined the HGDP?

3. Patenting

3a. The Hagahai Patent

One event which solidified opposition against the HGDP was the U.S. Patent and Trademark Office granting a patent on a cell-line (a human T-lymphotropic virus) derived from an indigenous person's genetic materials, a Hagahai tribesman from Papua, New Guinea. This act inflamed critics of the HGDP, who saw this case as "predictive of what would happen to blood samples of indigenous peoples collected for the HGDP: they would be turned into profitable commodities, though not for the benefit of indigenous groups."⁷⁴

This story started in the mid-1980s, when Carol Jenkins, a medical anthropologist affiliated with the Papua, New Guinea Institute of Medical Research, went on a mission. Around 1983, a 'lost' people, numbering about 300, the Hagahai, had initiated consistent contact with 'outsiders'. They sought assistance for a malaria outbreak, having heard from other indigenous peoples that outsiders may be able to help.⁷⁵

Jenkin's job was to assist in investigating the malaria issue, as well as other causes of their decline, and document the consequences of outside contact for their continued biological and cultural survival. Jenkins and her team collected ethnographic, demographic, linguistic, nutritional information and blood samples.⁷⁶ As an aside, it is important to note that Dr. Jenkins received funding for this investigation from National Geographic.⁷⁷

Anthropologist Hillary Cunningham documents that in 1987, an analysis of the blood determined the Hagahai were among a small number of known indigenous groups infected with a variant of T-cell leukemia lymphoma virus. Usually the virus results in severe leukemia, but the variant in Hagahai blood was benign. The T-cells were separated from the blood, and sent to the National Institute of Health (NIH), Washington DC, for further research.⁷⁸

⁷⁴Ricardo Ventura Santos, "Indigenous Peoples, Changing Social and Political Landscapes, and Human Genetics in Amazonia" in Alan A. Goodman, Deborah Heath, and M. Susan Lindee, eds., *Genetic Nature/Culture: Anthropology and Science Beyond the Two-Culture Divide*, (Berkeley: University of California Press, 2003) 23 at 31-32.

⁷⁵Gary Taubes, "Gene Patenting – Scientists attacked for Patenting Pacific Tribe" (1995) 270:5239 Science 1112

⁷⁶Cunningham, *supra* note 19 at 210-11.

⁷⁷*Ibid.* at 210

⁷⁸*Ibid.* at 211.

Then, in 1990, the American government patented the immortal cellular preparation which it had derived from the genetic sample of a particular Hagahai individual.⁷⁹ One can surmise, as Cunningham does,⁸⁰ that the incentive in applying for the patent was commercial – the potential of generating considerable revenue based on either developing, or licensing the rights to develop, diagnostic tests and vaccines.

The patent became public knowledge a few years later. There was outcry from indigenous groups, political activists, religious leaders, and academics, who condemned the patent. Their rhetoric flowed easily and emotionally: this was biocolonialism in action, sponsored by a powerful northern state who hid behind its property laws.⁸¹ Some described the situation as the NIH or the American government, ‘owning’ this Hagahai tribesman.⁸² This characterization is clearly both scientifically and legally incorrect, but may resonate with cultural understandings such as those articulated by Maori leader Aroha Te Pareake Mead, that “a physical gene is imbued with a life spirit handed down from the ancestors, contributed to by each successive generation, and passed on to future generations.”⁸³ Culturally and politically the NIH had touched raw nerves and indigenous peoples were not about to split hairs to justify the fact that their sense of human dignity had been violated.

After-the-fact commitments to direct commercialization benefits to the Hagahai were greeted as attempts to assuage an angry public, taken as evidence that public scrutiny was essential to ensure equitable outcomes, and that the law could not be relied upon to play such a role. Although the samples were not drawn under the HGDP’s auspices, connections were drawn between figures involved in both endeavors. One prominent member of the Papua, New Guinea team, Jonathan Friedlander, had been a strong supporter of the HGDP while Director of the Physical Program at the American National Science Foundation. As Cunningham notes, for some observers, Mr. Friedlander was proof that the HGDP had a hidden agenda, to patent indigenous DNA for commercial profit.⁸⁴

Much of the public assault took the form of a claim that human genetic material should not be patentable, and that the patent was doubly offensive here because it offended the cultural values of the Hagahai.⁸⁵ The NIH defended itself.

⁷⁹ *Ibid.* at 211. Apparently, the American National Institutes of Health (NIH) was listed as the ‘assignee’ of the patent, while Dr. Jenkins and four American government researchers were listed as the ‘inventors’, “U.S. Patent on Tribesman’s blood raises ethical questions. Can a Government claim rights over parts of your body?” Associated Press (20 April 1996), online: <<http://coombs.anu.edu.au/SpecialProj/PNG/htmls/AP.html>>.

⁸⁰ Cunningham, *supra* note 19 at 211.

⁸¹ *Ibid.*

⁸² *Supra* note 75.

⁸³ *Supra* note 60 at 353.

⁸⁴ See generally Cunningham, *supra* note 19 at 212.

⁸⁵ *Supra* note 15 at 388.

Their primary ground was that the patent was lawful, and that it was defensible under American law. That is, they put forward the fact of property rights as an answer to, or deflection from, moral scrutiny.

3b. Patenting Law, Inevitability and Moral Scrutiny

The NIH's defense was correct in law. Such a patent would also be upheld under Canadian law. Our *Patent Act* is similar to the corresponding American legislation, in part because our definition of invention was based upon the American definition.⁸⁶ A patent entitles its holder to exclusive commercial proprietary rights over new, useful and inventive creations – their ‘invention’ – for a limited period of time.⁸⁷ These rights include being able to prevent anyone else from making, emulating, or selling the patented invention, or any other invention that achieves substantially the same result in substantially the same manner. In return for this grant of limited commercial exclusivity, the patent holder must disclose the invention in a manner that enables others to replicate the invention for experimental purposes during the life of the patent, and to freely use it once the patent has expired.

To qualify for a patent, an ‘invention’ has to meet several technical requirements.⁸⁸ ‘Utility’ (meaning industrial application and functionality), ‘novelty’ (it must be something new, and not a product of nature in its “raw state”), ‘inventiveness’ (there must be an element of non-obviousness to the invention) and ‘enablement.’ Enablement refers to being able to provide a standard of disclosure which would allow other researchers to reproduce the invention without undue experimentation. In Canada, enablement can be achieved through disclosing how you isolated the sequence, and in the case of biological materials can be assisted by depositing a sample.⁸⁹

Canadian and American domestic legislation have been interpreted to find that DNA sequences are no different than any other complex chemical substance, and so their patentability is largely considered a settled matter. The utility of human genetic sequences tends to be supported by a potential for diagnosis or treatment. Although genes and DNA are a natural part of the human body, novelty is considered to be found in the product being isolated and purified, as the new form is substantially different than the natural form.

Our *Patent Act*, like that in the United States, was designed to be a technical statute, to “advance research and development and encourage broader economic

⁸⁶ *Patent Act*, R.S.C. 1985, c. P-4 [*Patent Act*]; *Harvard College v. Canada (Commissioner of Patents)* [2002] 4 S.C.R. 45 at para 3, 2002 S.C.C. 76 [*Harvard College*] (dissenting decision, but not on this point).

⁸⁷ *Patent Act*, *ibid.* at s.44; Marie Hirtle, “Patent Law and Human DNA” in Bartha Knoppers, Timothy Caulfield & T. Douglas Kinsella, eds., *Legal Rights and Human Genetic Material*, (Toronto: Emond Montgomery Publications, 1996) at 119.

⁸⁸ *Patent Act*, *supra* note 86 at s.27-28.

⁸⁹ *Ibid.* at s.38.1.

activity.”⁹⁰ Its terms do not permit any discretion to consider moral concerns when assessing patentability, such as whether granting a patent on human genetic material is exploitative, or whether the genetic material was obtained in an ethically responsible fashion.⁹¹ The frustration which arises when a patent’s subject matter is entangled with inherently moral issues was evidenced by the Supreme Court of Canada’s decision in *Harvard College v Canada (Commissioner of Patents)*⁹² – the “Oncomouse” case. This decision was about the patentability of higher life forms: to wit – a very special lineage of mice, whose ancestors had been altered genetically at the embryonic stage such that they were predisposed to develop cancer. About half of the offspring of any one Oncomouse would carry the altered gene – a very valuable tool for cancer research.

What was controversial about the patent was that it was not just for the process of genetic manipulation at the embryonic stage. The patent was for the *whole mouse*, and *any offspring* which carried the gene – despite the fact that the mice reproduced naturally.

In the two sets of reasons written for this case, both the majority and the dissent found the *Patent Act*’s terms allow no discretion to consider moral or ethical issues regarding whether something *ought* to be patentable. Hence, the issue of the patentability of higher life forms had to be determined on the basis of strict statutory interpretation: Did the patent application meet the technical criteria of the Act?⁹³ This finding resulted in the members of the Court clothing their analyses – which were arguably predominantly about moral and ethical issues, and indeed, even included discussing the patenting of human beings – within the rubric of merely searching out legislative intention. Although the decision could not turn on policy concerns, but only on statutory interpretation, the split between the majority and the dissent, which coincided with whether or not the judge was Catholic,⁹⁴ certainly hints to a moral encroachment.

The *Patent Act* is intended to be acultural, amoral, where decisions about patentability are reached on purely scientific and objective grounds. Some of the consequences of attempting to create a decision-making process which is outside of a cultural process are discussed by legal scholar Chidi Ogumanam. He presents an extensive analysis of how indigenous people’s knowledge is de-cultured and thus debased when forced into a patenting regime, in which aspects that are not relevant for the technicalities of patenting law are discarded as “excessive cultural

⁹⁰ *Harvard College*, *supra* note 86 at para. 185.

⁹¹ Of course, moral factors can find their way in through less direct routes, such as banning public funding for certain types of research. This allows the state to express a moral position which may be shared by its constituents, without hindering private researchers. For a general discussion, see Cyril R. Videgar, “Biomedical Patenting: Permitted, But Permissible?” (2002-2003) 19 *Santa Clara Computer & High Tech. L.J.* 253.

⁹² *Harvard College*, *supra* note 86 at para. 185.

⁹³ *Ibid.*

⁹⁴ This split in the bench was pointed out to me by Teresa Scassa.

baggage.”⁹⁵ It is as though determinations of which features are legally ‘relevant’ is not a reflection of western cultural practice.

This approach to patents, as one of filtering through relevant (scientific/technical) and irrelevant (cultural/social) factors, was most starkly summed up in a comment attributed to Joseph Straus of Germany’s esteemed Max Planck Institute. At a University of Washington symposium in the late 90’s on intellectual property protection for biotechnology, he allegedly warned his fellow participants against engaging with “ethics and other irrational concerns.”⁹⁶ This sort of position reflects the role of the scientist within the modernist paradigm, which Haraway describes as “modest witnessing”: We observe and record, while claiming not to judge.⁹⁷

Canada’s *Patent Act* was revised to remove any suggestion that decisions about patentability should involve moral engagement. The last vestige of such concerns having relevancy was erased when the prohibition against patenting inventions with an illicit purpose was repealed in 1993. And, unlike the legislation in some European jurisdictions such as France, we do not even have a general exemption clause based on public morality.

Such state-based exemption clauses are, however, subject to overarching international agreements. Despite the existence of public morality exemption clauses in some European states’ legislation, member states of the European Union [EU] have formally lost the discretion to find that patenting human genetic materials offends public morality.

On July 30, 1998, the EU’s Directive on the Legal Protection of Biotechnological Inventions came into force. The Directive states that “an element isolated from the human body ... including the sequence or partial sequence of a gene, may constitute a patentable invention,”⁹⁸ and requires member states to amend their domestic patenting legislation to expressly recognize the patentability of human genetic material. This effectively ousts public morality clauses which could otherwise be drawn upon by those who felt that an application ought to subject to ethical inquiries.

⁹⁵ C. Oguamanam, “The Protection of Traditional Knowledge: Towards a Cross-Cultural Dialogue on Intellectual Property Rights” (2004) 15 Australian Intellectual Property Journal 34 at 45.

⁹⁶ Quote included by Professor Philip Bereano of the University of Washington in Philip Bereano “Some Environmental and Ethical Considerations of Genetically Engineered Plants and Foods” (no date), online: Washington Biotechnology Action Council, <<http://washbac.org/archive.html>>; also cited by Foster, *supra* note 60 at 452; UNESCO’s International Bioethics Committee has, rather optimistically, concluded that this approach to scientific research is a thing of the past, to wit: “Unfortunately, scientists have at various times in history believed themselves to be working in a value free domain, gathering pure crystals of data and indeed trumping other human values and concerns in their pursuit of even higher degrees of scientific knowledge”, *supra* note 13 at s.3.1.

⁹⁷ *Supra* note 35.

⁹⁸ “EC, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] O.J.L. 213/14 at Art 5(2), online: <http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf>.

The European Directive has been controversial.⁹⁹ The Netherlands brought an action to the European Court of Justice to have the directive declared void on several grounds, including the allegation that it violated human dignity.¹⁰⁰ Although Italy and Norway joined as intervenors in support of the Netherlands, this action was quashed in October of 2001. Despite the Directive mandating implementation by member states by July 30, 2000,¹⁰¹ as of July, 2004, only seven states had done so.¹⁰² The remaining eight “renegade” states, the Netherlands, Portugal, Austria, Luxemburg, Sweden, Italy, France, Belgium and Germany, face an enforcement action which continues to crawl through the European Court.¹⁰³

Although Canada has interpreted its legislation to allow such patents, it is not yet under any positive duty to expressly recognize them, and so *could* modify its domestic legislation to go beyond strictly technical criteria and, in the case of genomic-related patents, consider whether the patent offends human dignity or if the supporting research was conducted within ethical boundaries. Both NAFTA and WTO-TRIPS describe some types of inventions which must receive patent protection, such as micro-organisms and pharmaceutical products, but human genetic materials are not yet on the list.¹⁰⁴ As well, both NAFTA and TRIPS provide that contracting states may *exclude* from patentability inventions the exploitation of which would be contrary to *ordre public* or morality.¹⁰⁵

So Canada would not be in violation of its international commitments if it modified its domestic legislation to regulate or prohibit the patenting of human genetic materials or more generally required patent officers to consider whether a proposed invention offended the *ordre public*. Indeed, Oguamanam has linked the

⁹⁹Despite the controversy, in practical terms, a human gene sequence is patentable in the European Union, as most patents are filed not with states but with the European Patent Office, which follows the Directive, and whose patents apply through out Europe.

¹⁰⁰*Kingdom of Netherlands v. European Parliament and Council of the European Union*, Case C-377/98, Judgment 9 October 2001, online: <<http://www.ipjur.com/data/011009ECJ-C-377-98.pdf>> (The action was brought on October 19, 1998 and quashed in October of 2001).

¹⁰¹*Supra* note 98 at art. 15.

¹⁰²These states are: the United Kingdom, Denmark, Greece, Ireland, Finland., Spain and Portugal. EC, Commission of the European Communities, *Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Life Sciences and Biotechnology – A Strategy for Europe/Second Progress Report and Future Orientations*, (Brussels:COM(2004) 250 final07.04.2004) at 8.

¹⁰³EC, Press Release, “Industrial Property: eight member states referred to Court for failure to implement directive on legal protection of biotechnological inventions.” IP/03/991 (10 July2003), online: <<http://europa.eu.int/rapid/setLanguage.do?language=en>> (The author is at a loss to explain how the directive passed, given that over half of the member states have aggressively resisted its implementation.)

¹⁰⁴*North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States of America* 17 December 1992, Can. T.S. 1994 No. 2, 32 I.L.M. 289 (entered into force January 1, 1994) [NAFTA], art. 1709(2); *Agreement on Trade-related aspects of Intellectual Property Rights*, World Trade Organization, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (1994) 25 I.L.C. 209, 33 I.L.M. 1997 (entered into force April 15, 1994) [TRIPS], art. 27(2).

¹⁰⁵TRIPS, *ibid*.

ordre public exception to “inventions that impinge upon indigenous cultural sensitivities,” concluding that indigenous values “can form the basis for making a determination regarding what is deemed *ordre public*, and by extension, what is offensive thereto.”¹⁰⁶

That said, such a move is unlikely, especially given the 2002 recommendations of the Canadian Biotechnology Strategy, (the CBS). The CBS agreed that moral issues were relevant for the question of patenting, but only in so far as finding it immoral for patents to be granted on human bodies at any stage of post-conception development, that is, from zygote to adult. However, they advised that patents should continue to be available for DNA sequences, stem and other cells, gametes, and artificial organs.¹⁰⁷ In other words, moral concerns merit a blanket prohibition on specific categories of items, but importantly do not merit inclusion as a *general discretionary element* when assessing the patentability of a proposed invention.

The CBS’s ‘proposal’ is entirely consistent with the existing patent system and jurisprudence. A human zygote or a human body would not pass the existing technical requirements for patentability under our current legislation. The CBS thus basically made a call to maintain the status quo.

The formal elision of morality in state determinations about patentability does not, however, put an end to the issue. Regardless of what patenting law says, project proponents still must win over the participation of indigenous peoples, and they are certainly concerned about whether patents will issue from their tissue samples. The HGDP’s proponents were decidedly uncomfortable discussing patents and the collected genetic material. Overall their approach was poorly thought out, and perhaps “naive.”¹⁰⁸ As documented by the NGO RAFI:¹⁰⁹

Confronted with questions about whether genes collected by the project could fall under patent monopoly, the project’s representatives repeatedly shifted their position on the issue. As first, they gave no consideration to concerns about patenting, claiming that the material had no commercial value. Later, project leaders argued that the project would have important medical benefits Even though they acknowledged the possible medical benefit of the project, they continued to deny that the material would have any commercial value. Nonetheless, they agreed that (in the unlikely event that the material was commercially useful) the HGDP itself would not seek patents. The HGDP went on to declare that if the research did prove to be commercially useful,

¹⁰⁶ *Supra* note 95 at 56-57.

¹⁰⁷ Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues* (Ottawa, June 2002) at x, 9, online: <http://strategis.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/h_ah00094e.html>.

¹⁰⁸ Hamilton, *supra* note 19 at 635.

¹⁰⁹ *Supra* note 58.

the peoples involved should benefit financially. Observers found it difficult to keep up with the shifting assumptions embodied in these statements.¹¹⁰

Such shifting positions were also generally observed by the American National Research Council, who, when it drafted its report on the HGDP, “found there clearly was no sharply defined proposal that the committee could evaluate.”¹¹¹

HGDP supporter, and legal scholar, Henry Greely responded to critics of the NIH’s patent by asserting that opponents misunderstood the true nature of the patent. First, it did not patent a human being, and second, an NIH patent was a good thing because it would create certainty as to who had commercial rights to the Hagahai sample, thus preventing private commercial parties from patenting the sequence.¹¹² Greely’s responses provided an example of “a clash of philosophy and cultural insight” about what was at stake, as “[f]or many indigenous peoples, the dignity of their ancestors is ‘in our blood, our hair, our mucus, our genes...’”¹¹³ His call to reframe statements of opposition as misunderstandings of scientific ‘truths’ beckons to an incommensurability, which may have prevented these parties from being able to have a mutually meaningful exchange about what patents mean to indigenous peoples, and thus whether there were any terms under which such research could have the blessing of an indigenous population.

The Genographic Project has once again taken steps to learn from the HGDP, and seeks to entirely avoid the issue of patenting. They have asserted up-front and in no uncertain terms that they will not file for patents on any collected genetic material.¹¹⁴ But what does this really accomplish, especially given that the blood samples will be available for other researchers to work with, who may in turn file patents based upon their ‘discoveries,’ including discoveries based on derivative material? The existence of this secondary set of users, who will undoubtedly turn the samples to commercial ends, are expressly acknowledged by the HapMap proponents.¹¹⁵ Indeed, these secondary sets of users are key if the genetic database

¹¹⁰RAFI, News Release, “Phase II for Human Genome Research – Human Genetic Diversity Enters the Commercial Mainstream” 21 January 2000, *supra* note 58; *supra* note 40; Cunningham, *supra* note 19 at 225-226.

¹¹¹Committee on Human Genome Diversity, Commission on Life Sciences, National Research Council, *Evaluating Human Genetic Diversity*, (Washington D.C.: National Academy Press, 1997) [NRC] (The committee further wrote “In its fact-finding, it became apparent to the committee that the precise nature of the proposed survey was more elusive than the committee had initially envisioned; different participants in the formulation of its consensus document had quite different perceptions of the intent of the project and even of its organizational structure” at 12).

¹¹²Gary Taubes “Scientist Attached for ‘Patenting’ Pacific Tribe” (1995) 270:5239 *Science* 1112; Hilary Cunningham, “Colonial Encounters in Postcolonial Contexts: Patenting Indigenous DNA and the Human Genome Diversity Project” (1998) 18:2 *Critique of Anthropology* 205; Charles Schmidt, “Indigenous Conflicts” (2001) 109:5 *Environmental Health Perspectives* 216.

¹¹³*Supra* note 13 at s.3.1.4.

¹¹⁴Genographic Project, FAQ, *supra* note 1.

¹¹⁵*Supra* note 32 at 473.

is to lead to medical innovation! Does this gesture – of denying that the researchers themselves will directly seek patents or commercial gain actually resolve the potential for genetic research leading to exploitation or offending human dignity, the twinned concerns which seem to surface repeatedly in this area?

‘Human dignity’ is difficult to define: it has to do with respect, and with inherent worth – but what does it look like? ‘Human dignity’ has no specific manifestation, rather it serves as an ideological *foundation* for identifying or interpreting substantive human rights.¹¹⁶ Hence to address concerns about dignity, one must consider practices and consequences. If the Genographic Project itself does not file patents, or if the protesters win their moral debate, and legislation is amended to prohibit the patenting of human genetic material, then the patenting activity simply occurs further down the research and development chain – with the invention of a diagnostic tool or a pharmaceutical treatment based upon later experimentation with the human genetic materials. Any “victory” of prohibiting patents on human genetic material, or including a moral component to patenting criteria, would be important for its symbolic value, but would not necessarily prevent the commercial exploitation of indigenous populations, or result in respect for an indigenous people’s approach to human tissue.

The risk of focusing on the issue of patentability as the fundamental moment for moral engagement is that one risks substituting a debate over how many steps removed you must be from a human being for a patent – or profit – derived from bodily materials be morally defensible, instead of the underlying concerns which crystallize in the face of patenting, regarding issues of exploitation and human dignity.¹¹⁷

For example, the NIH eventually abandoned the patent on the Hagahai cell-line, on International Human Rights Day in 1996. However, the blood samples remain within the public domain. Samples can be purchased by anyone, and turned to any purpose, from the American Type Culture Collection for \$216 (U.S.). Once again, although the collector did not retain a patent, others who use the material to develop diagnostic tools will stand to make financial gain based on information gleaned from the genetic make-up of an indigenous person, and will certainly patent their findings.

¹¹⁶Canadian Biotechnology Advisory Committee, Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms, *Human Rights Issues Related to Patenting of Human Biological Materials* by Barbara von Tigerstrom (Ottawa, Canadian Biotechnology Advisory Committee, 2001) at 15.

¹¹⁷Bitá Amani and Rosemary Coombe have produced a somewhat scathing analysis of how intellectual property regimes, and debate regarding these regimes, has evaded engaging with even the most basic political debate. See Bitá Amani & Rosemary Coombe, “The Human Genome Diversity Project: The Politics of Patents at the Intersection of Race, Religion, and Research Ethics” (2005) 27:1 *Law & Policy* 152.

So researchers will likely continue to attempt to collect tissue samples from indigenous populations, regardless of the ability or interest of the collector to immediately patent the human genetic material, *per se*. Where is there room for meaningful exchange, which engages the underlying concerns regarding exploitation, respect for cultural difference, human dignity? And can a legal framework be of assistance? One possibility lies in the manner in which relationships are built and maintained. Researchers often see the process of obtaining informed consent as the key moment for exchange between the parties. Can this concept or practice be of assistance here? The fact that Canada has adopted UNESCO's non-binding *Universal Declaration on the Human Genome and Human Rights*¹¹⁸ becomes relevant. By signing the Declaration, Canada committed to making efforts to incorporate its guiding principles into our domestic legislation, which include establishing state-specific genome research frameworks,¹¹⁹ which ensure sampled persons provide free and informed consent.¹²⁰ Below I turn to the question of whether the law of informed consent – or the principles which support it – can enable exchanges based on mutual understanding and respect instead of contests between Western 'scientific truths' versus Indigenous "cultural truths"?

4. Informed Consent

The term 'informed consent' usually refers to a liberal-democratic concept, philosophically grounded in two primary values: self-determination of the individual and respect for persons.¹²¹ A widely followed definition of informed consent for research involving human subjects was proposed by the Council for International Organizations of Medical Science (CIOMS):

Consent is informed when it is given by a person who understands the purpose and nature of the study, what participation in the study requires the person to do and to risk, and what benefits are intended to result from the study.¹²²

The adequacy of this definition to achieve the principled goals of self-determination and respect is questionable in the context of genomic research with indigenous populations. First, there is the technical matter of what 'informed' means in various cross-cultural contexts, and second, whether an individualist concept of consent is appropriate when conducting population research with

¹¹⁸ UNESCO, *Universal Declaration on the Human Genome and Human Rights*, (Paris, 29th Sess., Nov 11, 1997), online: UNESCO <<http://unesdoc.unesco.org>>.

¹¹⁹ *Ibid.* at arts. 13-16.

¹²⁰ *Ibid.* at arts. 5-9.

¹²¹ E.g. *Hopp v Lepp*, [1980] 2 SCR 192, (1980) 112 D.L.R. (3d) 67 (S.C.C.); Bernard M. Dickens, "Informed Consent", in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds., *Canadian Health Law and Policy* 2nd ed., (Butterworths, 2002) at 129.

¹²² CIOMS, "International Guidelines for Ethical Review of Epidemiological Studies" (CIOMS: Geneva, 1991) at 12 (The Guidelines are currently being revised and the March, 2005 draft is online: <www.cioms.ch/epiwebdoc.pdf>).

indigenous peoples. This second matter leads to complex questions about group definition and membership, and requires navigating a very tricky terrain landscaped with political and legal tensions and contests. A third difficulty is a pragmatic one, regarding enforcement. That is, who oversees the consent process, and ensures that the researcher does not go outside of the authorized research project, both in the short term, and in perpetuity given the potentially limitless lifespan of collected materials or their derivatives.

4a. Consent And Culture

UNESCO's Subcommittee on Bioethics and Population Genetics concluded that identifying an act of meaningful consent is tricky in a cross-cultural context:

...individualized notions of obtaining consent which tend to dominate in liberal Western societies cannot be applied *carte blanche* to people of other cultures. In secular liberal societies consent is seen as an 'informed' expression of an individual's self-will and autonomy. Consent is deemed to be informed if the subject is exposed to all relevant information, including risks. Other cultures of course may place greater emphasis on the advice of leaders who represent the continuity with conventional wisdom, or with the fate of family or group members. Relevant factors for moral decision-making in communitarian societies may derive from sources not as empirically accessible as medical data.¹²³

Can rules be written for determining whether informed consent has been obtained? When Robert Levine was asked by the CIOMS to provide a definition of informed consent which would be "widely applicable to different countries and cultures," he wrote that "in recognition of the vastly different perspectives on the nature of 'person,' I cannot do this," and he warned against relying upon "any person situated in any culture to provide a universally applicable definition of informed consent."¹²⁴ UNESCO went so far as to conclude that "the need for consent to be 'informed' may be objectively impossible to achieve."¹²⁵

Given these comments, where can the principles of informed consent take us? Various bioethicists who have considered the process and meaning of 'consent' have concluded that researchers must be sensitive to differing cultural mores and

¹²³ *Supra* note 13 at s.2.2.1

¹²⁴ R. Levine, "Informed Consent: Some Challenges to the Universal Validity of the Western Model" (1991) 19:3/4 *Law, Medicine and Health Care* 207 (Instead, Levine advocates for researchers conducting cross-cultural research to adhere to the standards set out by CIOMS, and to have the research consent procedure reviewed both within the initiating country as well as by an appropriate board in the country in which the research is to be performed. Levine does not specifically address how to incorporate the collectivity issue at 210).

¹²⁵ *Supra* note 13 at s.2.2.1.

values, and that, in some cases, community consent may be more culturally appropriate.¹²⁶ UNESCO agreed that, at the very least, “[t]he form in which consent is given will need to be discussed and agreed upon by each community.”¹²⁷ UNESCO made the following observations regarding obtaining consent from indigenous populations:

The ways of approaching the communities must always take account of the particular social and cultural organization and laws. Sometimes the leader of the individual chief of a family or familial group is the person who gives consent for the other members of the community to participate in the enquiries and biological sampling.¹²⁸

This sense of self within a community is especially relevant for genetic research projects, because the research value resides in the blood of the group, not of the individual. It is truly the group, or collective, which is being studied. Although individual ‘western-style’ consent may not be appropriate for some indigenous populations, “[i]t remains to be seen whether such ‘consenting populations’ can so easily be identified,” or how “the presumption of a uniform, shared consensus on cultural values and authority” will play out.¹²⁹ The HGDP, at least in theory, dared this assumption.

Two years after the Hagahai patent was abandoned, so some six years after the HGDP was initiated, the HGDP’s proponents published a draft model protocol for collecting human genetic material.¹³⁰ This protocol, which considered the questions of informed consent as well as benefits for the research community, was responsive on many levels to the special character of the research subjects and the purpose of the research itself.

The HGDP’s Draft Protocol gave a nod to the principle of collective consent, while asserting a right to opt out. The Protocol proposed that samples should only be collected from members of a population where informed consent had been obtained both from the individual, as well as from the group’s culturally appropriate authority, “where feasible.”¹³¹ They envisioned working with communities, for up to a year in advance, through anthropologists, to identify who could stand as an authority to give group consent.

¹²⁶ Charles Weijer, “Community Support for Genetic Research” (1997) 349:664 *The Lancet* 647.

¹²⁷ *Ibid.*

¹²⁸ *Supra* note 13 at 2.2.1.

¹²⁹ *Supra* note 11 at 274; For a recent discussion of how poorly research protocols address group consent, see Alice Hsieh, “A Nation’s Genes for a Cure to Cancer: Evolving Ethical, Social and Legal Issues Regarding Population Genetics Databases” (2003-2004) 37 *Colum. J.L. & Soc. Probs.* 359 at 383, 400–411 [Hsieh].

¹³⁰ North American Regional Committee of the Human Genome Diversity Project, “Proposed Model Ethical Protocol for Collecting DNA Samples” (1996-1997) 33 *Hous. L. Rev.* 1431.

¹³¹ *Supra* note 42 at 225.

A difficulty here is that if consent by a group representative is not 'feasible,' then it is contentious whether consent has in fact been garnered merely through the fact of individual 'consent.'¹³² As political scientists Will Kymlicka and Ian Shapiro note, "the familiar liberal-democratic set of civil and political rights" may not adequately recognize or protect "legitimate interests which emerge in the context of ethnocultural group membership."¹³³ Many indigenous peoples have autonomous systems of governance, including customary and written laws,¹³⁴ which they can draw upon in determining whether or not a representative *must or ought* to speak for the group in various situations. Where these laws are present, 'feasibility' is simply not relevant. The protocol drafted by the HGDP reflects a partial understanding of cultural difference and power dynamics, assuming that a liberal individualist approach to consent can always, in the end, stand for consent. This approach does not build relationships or promote mutual understanding. Nor does it respect indigenous populations as political entities. Insensitivity to this consequence is reflected even more strongly in the American National Research Council's review of the HGDP, which concluded that requiring group consent was "too extreme," given that individuals may want to participate even though their communities refuse.¹³⁵ Having found a *carte blanche* in the fact that "current international policy does not address whether a community should be able to veto the voluntary participation of individual members in legitimate research"¹³⁶, the NRC identifies the key concern with performing research in defiance of a community as follows:

...when doing research that is opposed by a specific community, [researchers] will also have to take into account the possible impact of doing such research on the likelihood that other communities will cooperate with other genetic-variation researchers in the future.¹³⁷

In other words, working with individuals despite the community having rejected the project is problematic because it may make future research hard to undertake! I submit that the approach advocated by the NRC is obscenely self-absorbed, contrary to multiple international legal agreements, and, on a practical level, likely to worsen relationships between researchers and indigenous communities. This takes me to the topic of group rights.

¹³²L. Gostin, "Informed Consent, Cultural Sensitivity, and Respect for Persons" (1995) 274:10 JAMA 844 at 844.

¹³³W. Kymlicka and I. Shapiro, "Introduction" in Ian Shapiro & Will Kymlicka, eds., *NOMOS XXXIX: Ethnicity and Group Rights*, (New York: New York University Press, 1997) 3 at 4.

¹³⁴See generally *supra* note 49 at 226.

¹³⁵NRC, *supra* note 111 at 63-64.

¹³⁶*Ibid.* at 63-64.

¹³⁷*Ibid.* at 63.

4b. Consent As An Act Of Political And Legal Engagement

Numerous international legal instruments have acknowledged the concept of group-based rights. Most often, it is linked to a right of self-determination (which, as noted above, is one of the pillars which manifests through the practice of obtaining informed consent). For example, the *International Covenant on Civil and Political Rights* requires its signatories to recognize that all peoples have the right to self-determination.¹³⁸ In the United Nation's Comments on Implementation for the Covenant, it positions this collective right as particularly important because its realization is an essential pre-condition for the effective guarantee and observance of individual human rights, and for the promotion and strengthening of those rights.¹³⁹ The *International Covenant on Economic, Social and Cultural Rights* mimics the *Covenant on Civil and Political Rights*, by asserting in its initial articles that states will recognize the right of peoples¹⁴⁰ to self-determination.¹⁴¹

Whereas these instruments speak to groups of peoples as having the right to self-determination, the *Universal Declaration on the Human Genome and Human Rights* draws a connection between genomic research and group rights. It requires that "[n]o research ... concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people."¹⁴² These instruments support the position that individual consent by itself cannot necessarily be legitimately taken as consent for researchers to engage in population research.

The practice of obtaining consent shifts when we move out of a doctor's office in Vancouver, for instance, and into indigenous communities. It is no longer merely about *imparting sufficient knowledge* to a research subject (because the machinery of informing, and abiding by the subject's subsequent decision, are sufficient to support the principled goals of respect and self-determination), rather it has become a highly *political* act. By denying the right of an indigenous population to give or refuse permission for a researcher to approach its members for samples, the scientific body is making an assertion that the indigenous population is not a 'people,' is not a legitimate political entity, that it has no practical form of agency.

¹³⁸ *International Covenant on Civil and Political Rights*, GA Res. 2200A (XXI), UNGAOR, 21st Sess., Supp.No.16, UN Doc. A/6316 (1966) at 52.(Canada adhered to this Covenant, May 19, 1976.)

¹³⁹ Office of the High Commissioner for Human Rights, "General Comment No. 12: The right to self-determination of peoples (Art. 1): 13/03/84" *CCPR General Comment No. 12* at para. 1.

¹⁴⁰ The meaning of 'peoples' is a bit of a bugbear. In the *Reference re Succession of Quebec*, [1998] 2 S.C.R 217, [1998] S.C.J. No. 61, the Supreme Court of Canada found 'peoples' may include only a portion of a population of an existing state, and that the term must not be restricted to being synonymous with existing nations. The court did not present a test for identifying whether a group qualifies as a 'people' beyond noting that such characteristics as common language and culture would be relevant (at para. 125).

¹⁴¹ *International Covenant on Economic, Social and Cultural Rights*, GA Res. 2200A(XXI), UNGAOR, 21st Sess., Supp. No. 16, UN Doc. A/6316 (1966). (Canada adhered to this Covenant May 19, 1976)

¹⁴² *Universal Declaration on the Human Genome and Human Rights*, *supra* at note 118.

Such an approach runs contrary to the key findings expressed in United Nations Special Rapporteur Dr. Erica-Irene Daes' 1995 report in the analogous area of protecting indigenous heritage, including traditional ecological knowledge.¹⁴³ The report's through-line policy was that indigenous heritage can only be meaningfully protected when the indigenous right to self-determination is respected. Dr. Daes wrote: "indigenous peoples should be the guardians and interpreters of their heritage which they hold communally: only the group in its entirety, be it a 'family, clan, tribe or other kinship group,' should be able to agree to the sharing of its heritage."¹⁴⁴

Dr. Daes noted that in some situations, ownership or consent may be an individual matter. But this conclusion cannot be an initial presumption. Recommendation 14 of the Report reads:

Every element of an indigenous peoples' heritage has owners, which may be the whole people, a particular family or clan, an association or community, or individuals... The owners of heritage must be determined in accordance with indigenous peoples' own customs, laws and practices.

Thus a necessary precursor to obtaining individual personal consent is not to seek 'group consent,' per se, but rather to obtain *authorization* to engage in the research with the members of the collective, where each individual will then also be asked for their personal consent prior to participating. This reconceptualization, from consenting to authorizing, from knowledge transfer to recognizing assertions of peoplehood, means scientists undertaking population research must take a position on claims of indigenous self-determination.

Anthropologist of science Jenny Reardon characterizes research regarding genetic diversity as engaging issues of identity and authority "that have the potential to affect who will have a voice, rights, resources and authority in emerging governmental and legal orders around the world."¹⁴⁵ In part, her point is that in defining an indigenous population to be sampled for genetic markers, genetic researchers are entering the world not only of who legitimately *speaks* for a specific people, but whether that people *exist* as a *group*, and who is a *member* of that people. They are engaging in a political debate over the existence and status of cultural groups and what terms legitimately dictate membership or exclusion.

¹⁴³Erica-Irene Daes, *Human Rights of Indigenous Peoples: Report of the Seminar on the Draft Principles and Guidelines for the Protection of the Heritage of Indigenous People*, UN ESCOR, 52nd Sess., Agenda Item 7, UN Doc. E/CN.4/Sub.2/2000/26 (2000); also reproduced in its entirety at (2000-2001) 13 St Thomas L. Rev. 391.

¹⁴⁴Siegfried Wiessner & Marie Battiste, "The 2000 Revision of the United Nations Draft Principles and Guidelines on the Protection of the Heritage of Indigenous People" (2001) 13 St. Thomas L. Rev. 383 at 383-4. Dr. Daes was charged with creating this report by the United Nations Sub-Commission on Prevention of Discrimination and Protection of Minorities.

¹⁴⁵Reardon, *supra* note 50 at 359.

4c. Identifying and Engaging Indigenous Authorities

This is not easy terrain to walk. In Canada, the disjuncture between cultural, legal, and other mappings of indigenous group membership has become familiar through the arbitrary and shifting state definitions of Aboriginal peoples. These definitions include status, non-status, on-reserve, off-reserve, married-in, married-out, Metis, metis, and Bill C-31. Each definition has financial, social and political consequences for inclusion and exclusion of individuals of Aboriginal ancestry.¹⁴⁶

Add to this the painful history of Canadian indigenous groups such as the Mohawk of Kahnawake, who, frustrated with shifting and imposed state definitions of who is an 'Indian,' turned to biological notions of membership, and adopted blood quantum rules.¹⁴⁷ Many American indigenous peoples made the same choice.¹⁴⁸ Faced with increasing numbers of individuals claiming membership, perhaps following casino riches or federal benefits, perhaps due to a lessening of social stigma, many tribes introduced blood quantum rules. As a result, an individual may only be eligible for membership in a tribe (and thus can access assorted medical and housing benefits, etc.) if they can prove that they have a certain percentage of 'blood' from that tribe, ranging from 1/2 to 1/64th.¹⁴⁹ Cultural practices, such as speaking an indigenous language, are displaced, their relevancy ominously subsumed by biological data.

Blood quantum rules have resulted in scores of individuals suddenly losing membership.¹⁵⁰ Such individuals' self-identity is denied legitimacy by the group they call their own. Engaging in genetic population research with such groups means addressing the legitimacy of this blood-based approach to inclusion, and becoming enmeshed in the internal conflict and social division engendered by blood quantum rules.¹⁵¹ Ironically, blood quantum requirements have created a niche market in genetic testing services. Genetree, a DNA testing centre located in California, advises that it can test for genetic markers which " 'can definitively determine questions' regarding Native American ancestry"¹⁵²

¹⁴⁶For a more detailed discussion of these definitions and their consequences, see C. MacIntosh, "Jurisdictional Roulette: Constitutional and Structural Barriers to Aboriginal Access to Health" in C. Flood, ed., *Just Medicare: What's In, What's Out, How We Decide* (Toronto: Univ. of Toronto Press, 2006).

¹⁴⁷Robert Paine, "Aboriginality, Multiculturalism, and Liberal Rights Philosophy" (1999) 64:3 *Ethnos* 325.

¹⁴⁸American indigenous peoples have a similar history to those who live in Canada, having been subjected to a myriad of federal and tribal classifications. The categories, and their consequences, are well-documented in Eric Beckenhauer, "Redefining Race: Can Genetic Testing Provide Biological Proof of Indian Ethnicity" (2003/2004) 56 *Stan. L. Rev.* 161 [Beckenhauer].

¹⁴⁹*Ibid.* at 167.

¹⁵⁰*Ibid.* at 167-172.

¹⁵¹Hamilton, *supra* note 19 at 633-634.

¹⁵²As documented by Beckenhauer, *supra* note 148 at 184.

What of the voice of research in America? The National Research Council (NRC), quite disturbingly, sees social, political or legal groupings as creating noise which a scientist must negotiate, positing that “[t]he fact that a group name exists for political purposes can be scientifically misleading.”¹⁵³ However, a scientist can get past this and make “accurate identification of population units for sampling purposes” by drawing upon published ethnographic studies.¹⁵⁴ If ethnographies are not available, then researchers must turn to consultations with “local leaders, experts and researchers.”¹⁵⁵ In other words: either the indigenous group cannot be trusted to identify its own membership, or the group’s sense of self is illegitimate in the eyes of these scientists. Only an outsider, such as an anthropologist, can find the truth which is hidden behind culture, law, and politics, and wrongheaded understandings of a people’s history and ancestry.

The delineation between political and scientific groupings cannot be so easily drawn or imposed. Although scientific evidence clearly supports the conclusion that ‘races’ do not exist as discrete biological units, “this is not the same thing as saying races don’t exist.”¹⁵⁶ As biological anthropologist Johnathan Marks reflects, “Jews and Muslims, Catholics and Protestants, exist and act regardless of whether their gods do; and very little of American social history and politics can be understood outside the context of race, regardless of whether it is a biological unit or not.”¹⁵⁷

Thus for genetic population research that targets indigenous populations to be defensible, researchers must find an approach to group membership which expressly engages how and by whom groups are defined in a social order, which also structures relations of authority. It must have a principled approach regarding the role of legal or political definitions of inclusion, and what to do where the question of who has authority to speak remains contentious.¹⁵⁸ Only then is the groundwork in place for the researcher to legitimately proceed in seeking effective community authorization.

¹⁵³ NRC, *Supra* note 111 at 61.

¹⁵⁴ *Ibid.* The contrast between self-defined cultural groups, externally defined legal groups, and ‘scientific’ grouping is well-documented by bioethicist and medical anthropologist Margaret Lock. She found that the HGDP approached the Tuchi Indians of Oklahoma for tissue samples, explaining that the Tuchi’s status as a unique and distinct Indian tribe merited preserving their DNA for posterity. The Tuchi were somewhat chagrined by this request, as their very existence had recently been denied by the American Bureau of Indian Affairs, to whom they had applied for recognition as a Tribe. The San People of Southern Africa were near the top of the HGDP’s list of populations to be sampled. This people includes three different language groups, suggesting a rather recent formation as a single group. The Eta of Japan are also on the list, although the ‘Eta’ legally ceased to exist in Japan 50 years ago. Lock, *supra* note 62 at 94-98.

¹⁵⁵ NRC, *supra* note 111 at 62.

¹⁵⁶ J. Marks, “The Profound Relevance and Irrelevance of Biology” (2005) 11:2 *General Anthropology* 1 at 5.

¹⁵⁷ *Ibid.*

¹⁵⁸ For a general framework for approaching health research with Aboriginal communities in Canada, see Policy Research Unit, *Ways of Knowing, A Framework for Health Research* (Ottawa: National Aboriginal Health Organization, 2003), online: National Aboriginal Health Organization <www.naho.ca/english/pdf/research_waysof.pdf>.

4d. Enforcing Understandings and Responsible Practice

Even if a relationship is established, through which an appropriate form of permission and consent is identified and undertaken, questions of enforcement and oversight still remain. As legal scholar and bioethicist George Annas has observed, enforcement is a “generic problem for all human experimentation ... We really haven’t figured out how to do effective oversight of human experimental regulations.”¹⁵⁹ For example, at present, neither Canada nor the United States have enacted comprehensive legislation to regulate all research involving humans. Instead, the legal requirement for informed consent largely arises under common law, or pursuant to some provincial statutes under which the common law has been codified,¹⁶⁰ and is activated whenever a person receives medical treatment or undergoes a medical procedure at the hands of a health care practitioner.

The requirement for informed consent for research involving human subjects, where the researcher may or may not also be a health care provider, also arises pursuant to a number of guidelines and statutes which are linked to a researcher’s funding sources, or professional association. For example, in the USA, a statutory obligation is only imposed on researchers who obtain funding from federal sources, or for studies involving trials of new drugs.¹⁶¹

Where the researcher is not a health care provider, then in Canada we are largely left with professional guidelines, requirements imposed by specific funding sources, such as SSHRC and the MRC,¹⁶² and institutional guidelines.

¹⁵⁹ As cited by V. Foubister “Research reservations: As researchers increasingly look to DNA of Native American tribes and other groups for clinical answers, is an ethical imperative to seek community consent emerging?” *American Medical News* (Jan 31, 2000), online: American Medical News <www.amednews.com/2000/prsa0131>.

¹⁶⁰ For an excellent overview of the scattered mechanisms which touch on informed consent, see *supra* note 44 at 475-79. One key exception to this is the Northwest Territory’s *Scientists Act*, R.S.N.W.T. 1988, c. S-4. Under this act, with the exception of wildlife research, no research, including social science research, can proceed unless the researcher has obtained a license. Now, neither the Act, nor its associated regulations require informed consent of human research subjects, but there is authority under the Act to make a license for research conditional on obtaining consent, and to require the researcher to return any samples which are collected during the research process. Unfortunately, the penalty for violating this Act is only a fine up to \$1000, so it may have in fact have little deterrence power.

One of the few types of legislation which regulates the use of human tissue in all common law provinces is the various versions of the *Human Tissue Act*. These Acts all provide that tissue can only be donated in accordance with the statute, and also regulate the commercial dealing in bodily tissue. However, regenerative tissue – blood and blood constituents- is expressly excluded from the Acts. See e.g. *Human Tissue Gift Act*, R.S.B.C. 1996, c. 211; *Trillium Gift of Life Network Act*, R.S.O. 1980, c. H-20; *Human Tissue Gift Act*, R.S.A. 2000, c. H-15.

¹⁶¹ 45 C.F.R. 46; See discussion Kathleen Cranley Glass & Trudo Lemmens, “Research Involving Humans” in Jocelyn Downie, Timothy Caulfield, & Colleen Flood, eds., *Canadian Health Law and Policy* 2nd ed. (Markham: Butterworths, 2002) 459 at 476.

¹⁶² Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Medical Research Council, 1998) at 8.2.

As a consequence of the patchwork character of legislation and the fact that funding-based guidelines only apply to researchers drawing upon those funding sources, some researchers collecting genetic sample could fall outside the parameters of these guidelines and legal instruments. For example, a researcher who is not a health care provider, or who is not funded under any of the triggering sources, would not be subject to any overseeing authority when it comes to consent issues.¹⁶³ If such a researcher “betrays” his or her subject, the victim can only seek remedy under the common law, through such routes as battery (which is available for non-consensual touching), or a breach of a fiduciary duty (if the researcher was in a relationship of trust and influence over the research subject). So although the law of informed consent sends us down a road of promising principles about respect and self-determination, there is a vacuum in terms of protocols to ensure private researchers are held accountable to these principles.

The problem is amplified in the case of indigenous persons. As legal scholar Cindy Hamilton notes, “no one international organization claims to have authority” over the industry of “bioprospecting” indigenous populations, as this industry appears to have expanded “more quickly than modern legal and social policy can govern.”¹⁶⁴

The Genographic Project is signal here, having positioned itself entirely outside of public scrutiny. As all of the Genographic Project’s funding is from private sources, it has no freestanding lawful obligation to disclose its activities or protocols. Thus it is entirely self-monitoring and formally accountable only to its Board of Directors.

Even where researchers are operating in public institutions, monitoring and enforcement issues remain. In the Havasupai case, the alleged misuse of genetic data for unauthorized research activities only came to the attention of the tribe in 2003, some 10 years after it had been collected. It happened because a tribe member was present at a public PhD defence.¹⁶⁵ Similarly, Ward’s allegedly unauthorized research activities involving blood from Nu-chal-nuth people only came to their attention after 20 years of his publications on research findings, again by chance.¹⁶⁶

What happens if you do not have informed consent? Not much, actually. Domestic law in both Canada and the United States is a hodgepodge of professional guidelines, common law, and piece meal legislation. If the whistle is blown on researchers who are under an express obligation to procure informed consent, they risk having their funding cut, professional censure, and related disciplinary proce-

¹⁶³ UNESCO also notes this problem. *Supra* note 13 at s.4.1.

¹⁶⁴ *Supra* note 19 at 632.

¹⁶⁵ Paul Rubin, “Indian Givers: The Havasupai trusted the white man to help them with a diabetes epidemic. Instead, ASU tricked them into bleeding for academia” *Phoenix New Times* (27 May 2004); Rex Dalton, “When two tribes go to war” (2004) 430:6999 *Nature* 500 at 502.

¹⁶⁶ “Blood Promise” CBC NewsOnline, online:

<<http://vancouver.cbc.ca/cgi-bin/templates/view.cgi?news/2000/09/27/bc-blood00092>>.

dures and fines. Some civil remedies are also available. In *Moore v Regents of California*, the California Supreme Court did establish that the failure to inform a person of the potential commercial value of their cell line could be a breach of the duty to inform. *Moore* did not, however, provide any sense of quantum of damages, as the action never proceeded on substantive grounds. And the Court also did not recognize a mechanism for capturing the downstream users of Mr. Moore's tissues, which would include the researchers and their corporate affiliate. In hearings regarding the HGDP held by the NRC, Mr. Moore decried the American legal system for failing to recognize his ownership interest in his cell line, while upholding the patent derived from his bodily tissue in circumstances outside his consent.¹⁶⁷ Mr. Moore's speech provoked a representative of a Colombian group to rhetorically ask: "If this can happen to a U.S. businessman, what chance do we have?"¹⁶⁸

George Annas took a similar position when commenting upon a broken promise to an Apache tribe in Oklahoma. The tribe had agreed to participate in research on the condition that they remain anonymous, fearing, among other things, social stigma based upon disease prevalence. However, this promise was broken when the fact that the genetic research agreement was secured with them was made public in a publication addressing, ironically, university consent processes.¹⁶⁹ Dr. Annas commented that there really were no remedies for the Apache tribe. He said "Sure, you have the possibility of stigma. Is it real? How do you measure it? Did they lose income? What happened to them? That's what the law would ask."¹⁷⁰ Indeed where Canadian courts have heard claims regarding inadequate consent, the remedy has been an award for personal injuries based upon tort principles.¹⁷¹

This question of whether a more satisfactory remedy is available will be aggressively put to the test when the Havasupai case is heard in Arizona. This case will turn on whether there was adequate consent for the various uses to which the tissue samples were put. It is clear that consent was approached in a somewhat haphazard fashion. Barnes and Heffernan document that:

The factual record, as related by experts hired by ASU [the defendant university], reflected great confusion as to whether the informed consent process for all subjects, and the pre-research consultations between the researchers and tribal leaders, included mention of the possibility that tissue from the subjects might be used in later research on topics not related to diabetes.... In short, the primary study generated tissue and data that were used for multiple secondary uses, while the written

¹⁶⁷ NRC, *supra* note 111 at 67.

¹⁶⁸ *Ibid.* at 111.

¹⁶⁹ *Supra* note 159.

¹⁷⁰ *Ibid.*

¹⁷¹ In *Halushka v University of Saskatchewan* (1965) 53 D.L.R. (2d) 436 (Sask. C.A.) the experiment had sent the plaintiff into cardiac arrest, and the plaintiff was left with residual injuries. In *Weiss v Solomon* [1989] R.J.Q. 731 (C.S.) participating in the research killed the subject.

consents were either vague on such future uses or were missing altogether, their consent unknown and unknowable.¹⁷²

It remains to be seen whether such breaches, if proven, will support the claimed damages, which are in the range of millions of dollars.

Over the last 5 years, many First Nations have developed protocols to guide research in their communities, either in response to the lack of effective state oversight or as an assertion of political rights.¹⁷³ These protocols, which are essentially in the form of a contract,¹⁷⁴ are very hard for indigenous communities to monitor and enforce. It took the Nu-chal-nuth of Vancouver Island until 2000, to discover that their genetic materials had been used for the last 20 years contrary to their understanding of the agreement. Why did it take so long? Because no one, other than the researcher, was aware of the agreement's terms and able to match them with the resulting publications in national and international genetic research journals.

After journalists took the story public, Dr. Ward apologized and offered to return the samples. But how can one account for 20 years of misuse? The samples could be returned, but the research analysis and data were now within the public domain, and irretrievable. Meanwhile, Dr. Ward's career was made, despite this apparently unethical trajectory.¹⁷⁵

The need is pressing for Canada to find a way to fulfill its commitments under the *Universal Declaration on the Human Genome*, and to create an overarching structure which respects the rights of groups and always requires informed consent. Canada's delay may in part reflect the complex decisions which it will have to make about aboriginal populations within its border, and how it will address aboriginal group's claim to a right to trump an individual's right to consent to participate (at least while within the jurisdiction of the group.)

Indeed, although there are sophisticated approaches to collective rights in some contexts, it remains largely unnegotiated vis-à-vis Western biomedical law¹⁷⁶ and ethics.¹⁷⁷ It is not clear whether a social and legal regime can emerge which is

¹⁷² Mark Barnes and Kate Gallin Heffernan, "The 'Future Uses' Dilemma: Secondary Uses of Data and Materials by Researchers and Commercial Research Sponsors" (2004) 3:11 *BNA Medical Research, Law and Policy Report* 440 at 445.

¹⁷³ The National Aboriginal Health Organization (NAHO) has been key for mobilizing Canadian indigenous peoples' awareness on this front, online: National Aboriginal Health Organization <www.naho.ca>.

¹⁷⁴ For a discussion of using contract models to achieve the goals of informed consent, see Pollyanna E. Folkins "Has the Lab Coat Become the Modern Day Eye Patch? Thwarting Biopiracy of Indigenous Resources by Modifying International Patenting Systems" (2004) 13 *Transnat'l L. & Contemp. Probs.* 339 at 358-60.

¹⁷⁵ *Supra* note 167.

¹⁷⁶ Hsieh, *supra* note 129 at 383.

¹⁷⁷ See discussion in Reardon, *supra* note 50 at 381.

capable of addressing these highly political issues. Without it however, much research will continue to operate free of any necessary moral responsibility.

6. Some Final Observations

As noted above, the HGDP became operational on very limited level: its research activities have fallen below the radar in North America, and the cell repository planned for the United States never opened.¹⁷⁸ The Project's funding application to the NIH was rejected.¹⁷⁹ Their application to UNESCO for funding and a formal affiliation was also denied. UNESCO found that "although the HGDP has 'expressed urgency' in collecting samples from peoples in danger of physical and cultural extinction, it has not expressed concern about their extinction per se."¹⁸⁰ That said, borrowing Cori Hayden's phrase, the Project's rationale for legitimation continues to function as a 'lightening rod' for critique.¹⁸¹

It is not surprising that the HGDP also received a rather mixed review from the NRC.¹⁸² The NRC's report, released in 1997, was unclearly written.¹⁸³ The NRC did recommend, in general, that U.S. government funding be made available for diversity research.¹⁸⁴ However, the NRC voiced a number of serious concerns about the HGDP. Some were scientific concerns, hinting at doubts that the data would be of little utility given that limited ethnographic data would be collected, and virtually no phenotypic information would be gathered.¹⁸⁵ Concerns were also raised over the quality of information circulated about the HGDP by its proponents. Such information was said to be inconsistent and contradictory.¹⁸⁶

There were also outstanding ethical issues. Perhaps the most scathing comments involved project governance. The NRC concluded that if an international project of this character was to proceed, it must not be overseen merely by regional committees of the HGDP, which were described "as at best elitist and at worst constituting a self-serving cabal."¹⁸⁷ Instead, such a project should be overseen at state levels, and there should be clearly defined relationships and roles as between interested researchers and national and international agencies. The NRC com-

¹⁷⁸ L.L. Cavalli-Sforza, "The DNA revolution in population genetics" (1998)14:2 Trends in Genetics 60 at 65.

¹⁷⁹ *Supra* note 62 at 108.

¹⁸⁰ Declan Butler, "Genetic Diversity Proposal Fails to Impress International Ethics Panel" 377:6548 Nature 373 at 373.

¹⁸¹ Cori Hayden turn of phrase.

¹⁸² NRC, *supra* note 111.

¹⁸³ As Greely notes, the journal *Science* posted the headline: "NRC oks long-delayed survey of human genome project." However, the journal *Nature* bore the headline "Diversity Project does not merit federal funding," a description which they later retracted. Greely, "Human Genome Diversity", *supra* note 42 at 225-6.

¹⁸⁴ *Ibid.* at 226.

¹⁸⁵ *Ibid.* at 225.

¹⁸⁶ NRC, *supra* note 111 at 112.

¹⁸⁷ *Ibid.* at 71.

mented that in the absence of such defining roles, “any global survey would be correctly criticized for substituting a self-appointed set of administrators without official standing in any country for the recognized national and international agencies of government.”¹⁸⁸ To the NRC’s comments I would add the need for indigenous peoples to continue to assert and expand their governing role over these matters.

It is not unreasonable to assume that that more recent Genographic Project’s proponents are familiar with the NRC’s report. If so, the proponents have chosen not to adopt the NRC’s recommendations regarding governance. Like the HGDP, there is no formal role for national or international agencies of government, simply a general sense of good will. However, it is highly unlikely that any organization such as UNESCO or the NRC will have the opportunity to assess the Genographic Project closely. Since the Genographic Project is able to operate completely on private funds, it has no need to seek the endorsement of any institutional body.

Not surprisingly, opposition has already been mounted by the ICB against the Genographic Project. The ICB has posted a petition on their web page, condemning the Genographic Project by describing it as merely the latest incarnation of the HGDP.¹⁸⁹ The connections are easy to make. As noted above, National Geographic funding supported the research which led up to the Hagahai patent. There is topical overlap in both projects. They focus on collecting genetic samples from indigenous populations before they ‘disappear.’ There is even overlap in the membership of their teams. Dr. Lucas Cavalli-Sforza, who was a key originator for the HGDP, sits on the Genographic Project’s Advisory Board. The fact that Cavalli-Sforza bridges the projects is arguably more a reflection of his expertise in population genetics¹⁹⁰ than definitive evidence that the Genographic Project is merely a repeat of the HGDP. Nonetheless, his presence certainly raises eyebrows. It is unclear how Cavalli-Sforza’s participation will play against that of Tammy Williams, who also sits on the Board. Williams is an emerging human rights activist and a lawyer, and a member of one of Australia’s indigenous peoples, the Gypmie.

The context in which the Genographic Project will take place has, if anything, become more divisive and complex over the past few years. A key example of this divisiveness within the indigenous community arose in the Vermont Assembly in 2000. A bill was put forward to “establish standards and procedures for DNA-HLA testing to determine the identity of an individual as Native American...” under which “... [t]he results of such testing shall be conclusive proof of the Native American ancestry of the individual.”¹⁹¹ Many American Indigenous peoples

¹⁸⁸ *Ibid.* at 72.

¹⁸⁹ Harry, *supra* note 10.

¹⁹⁰ Genographic Project, FAQ, *supra* note 1. Given Dr. Cavalli-Sforza’s prominence in the field of population genetics, having authored at least two books and dozens of articles in the area, his presence is not surprising. However, his inclusion may still prove to be a political mistake.

¹⁹¹ Vermont House Bill 809, 1999-2000 Leg Sess. (Vt. 2000), cited in Backenhauer, *supra* note 148 at 185.

opposed this bill. They asserted that the bill reduced 'Indianness' to a 'racial type' instead of a 'spiritual being,' that it equated race with culture and assumed both were biologically detectable, and that it usurped indigenous peoples' rights of self-determination.¹⁹²

Why was this bill actually put forward? Interestingly, the Congressman was acting at the request of an indigenous group. The Western Mohegans had recently been denied tribal status by the federal government, due to a lack of paper-based genealogical documentation to track their ancestry. The tribe approached the Congressman, hopeful that if their state endorsed the validity of DNA testing to prove 'Indianness,' that they could then draw upon biological evidence to prove their legal existence as a people.¹⁹³ Whether faced with outside genetic sampling projects, or choosing to engage in genetics projects, one consistency is that indigenous peoples are capturing the moment to assert their autonomy as self-determining people.

Genetic research involving indigenous populations necessarily engages enmeshed, confused, and blurred concepts about the reality of biological, cultural and legal groupings, and their consequences. It also is a lightning rod for tensions arising from past experiences of indigenous exploitation and colonial denial about the rights of indigenous peoples. Thus matters such as consent protocols prompt questions about whether an indigenous population exists as a people, triggering assertions of the right to self-determination.¹⁹⁴

In this paper, I have sought to illustrate that when indigenous populations accuse scientists of seeing them as "biodiversity resources,"¹⁹⁵ they are not taking a simple position. Their concerns reflect a complex matrix of political and legal issues, which they may only be able to act upon by rejecting participation in research ventures. These issues cannot be reduced to a misunderstanding about the nature of patenting law, and are not addressed merely by drafting a better consent form, or adding an ethics checklist to patent applications.

At its core, much of the debate over genetic research with indigenous populations is sourced in political concerns. Indigenous peoples do not want to fight with scientific researchers about whether they are a people. If genetics researchers willingly acknowledge and respect this claim, then those researchers are far less likely to run afoul of claims of offending human dignity, or exploitation. Although it is more properly the job of a state to work through the meaning of indigenous peoples' claims, states move slowly, if at all. Meanwhile, as argued in the first section of this paper, there is high interest in genetic research with

¹⁹² Beckenhauer, *ibid.* at 186-8.

¹⁹³ *Ibid.* at 184-5.

¹⁹⁴ Consider, for example, the *United Nations Draft Declaration on the Rights of Indigenous Peoples*, *supra* note 12, which clearly enmeshes informed consent with the issue of self-determination.

¹⁹⁵ *Supra* note 35.

indigenous populations. Thus scientists and their sponsoring organizations, in both commercial and academic sectors, are in the effective role of politicians. Through their research, they are players in contests over indigenous people's claims of identity and rights.

