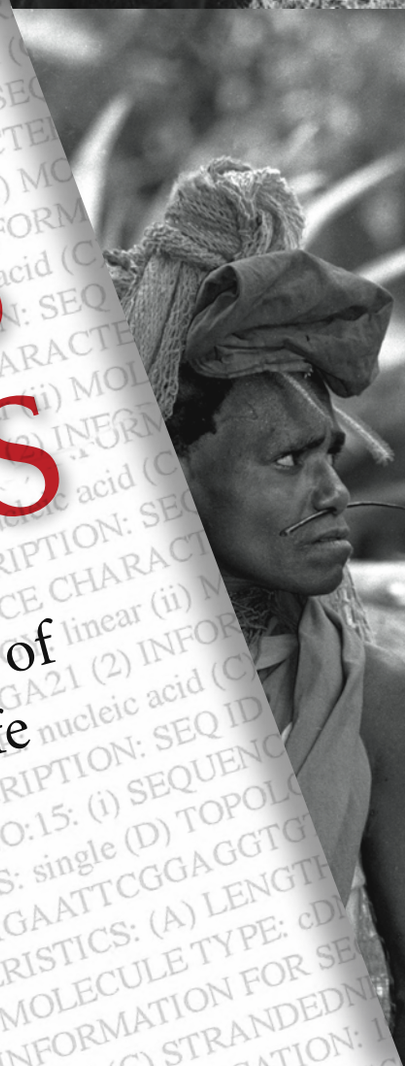

# PACIFIC GENES & LIFE PATENTS

## Pacific Indigenous Experiences & Analysis of the Commodification & Ownership of Life

Editors: Aroha Te Pareake Mead and Steven Ratuva

PACIFIC GENES & LIFE PATENTS

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Published in 2007 by:

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www.vms.vuw.ac.nz


The University of the South Pacific, Pacific Institute of Advanced Studies in Development and Governance www.usp.ac.fj/piasdg



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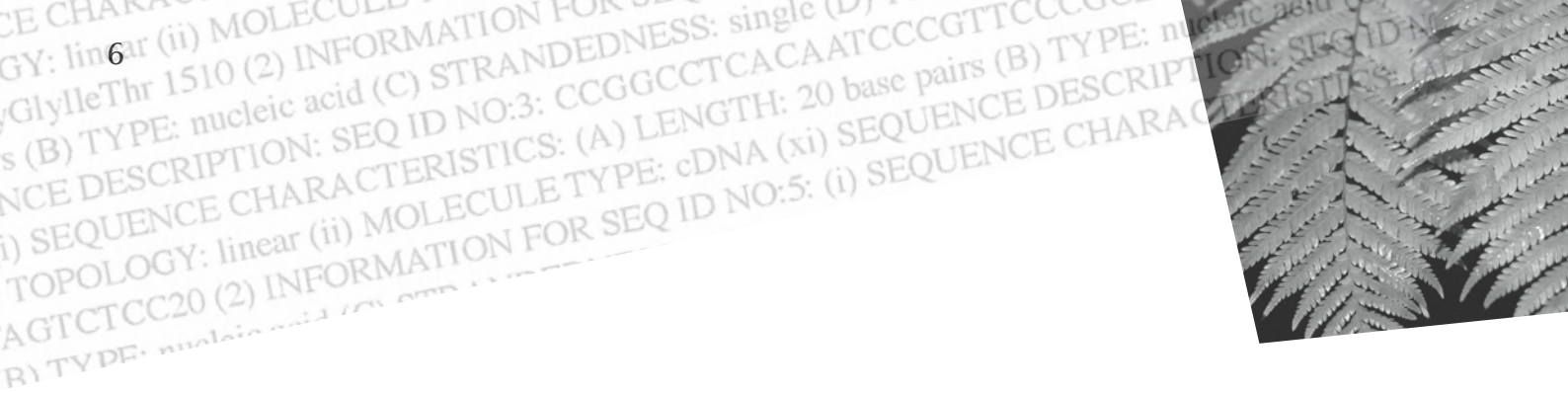
## SECTION TWO

PACIFIC INSTRUMENTS RELATING TO GENES AND GENE PATENTS



# PREFACE

Many international organizations are seeking to engage with indigenous communities in a mutually beneficial relationship, and in ways that enable indigenous communities to have greater visibility in national and international processes affecting them. Call of the Earth, Llamado de la Tierra (COE) is a global initiative on indigenous intellectual property policy that is wholly indigenous and has as one of its major aims the profiling and publication of indigenous analysis on cultural and intellectual property issues. The United Nations University Institute of Advanced Studies (UNU-IAS) is fortunate to have established a collaborative relationship with COE in 2001. It is through this collaboration with COE, that UNU-IAS has been able to contribute to this groundbreaking publication on Pacific Genes and Life Patents.

The South Pacific is a unique and highly complex region that has the world's largest ocean and is home to some of the greatest cultural, linguistic and biological diversity in the world. It is also a region where the majority population is indigenous and still retains much of their traditional knowledge and the values of their communities. The cultural and biological diversity of the region however is under threat due to a series of factors, including population growth, over-fishing and poverty.

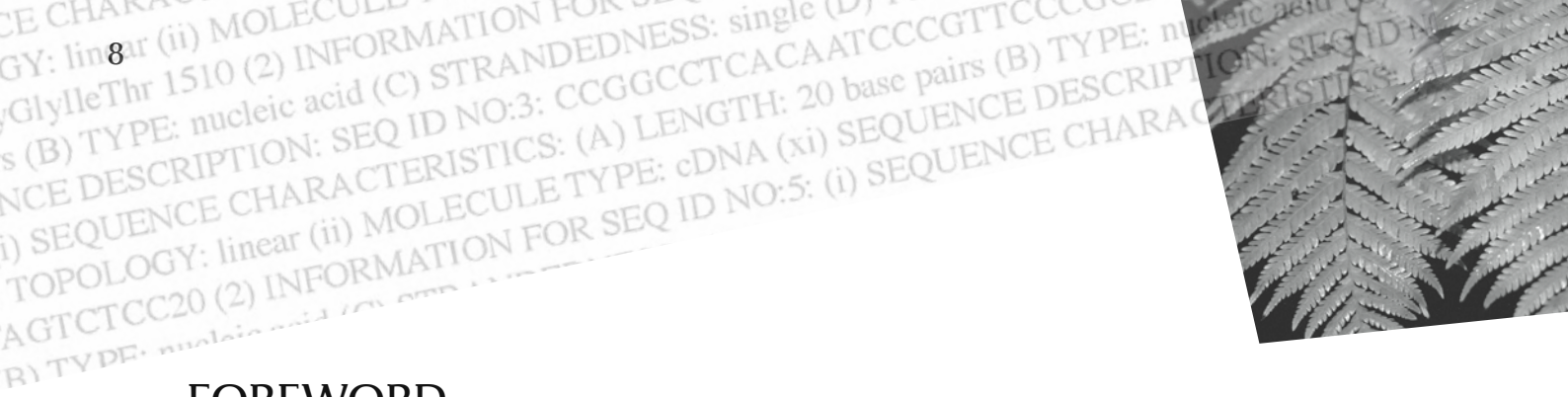
As a region, the Pacific has experienced more than its fare share of external experimental research that has resulted in the commodification and misappropriation of important components of their ancestral inheritance. For others, it might be difficult to understand how a plant could be regarded as a living ancestor, or that human blood retains its life spirit even after it has been collected for medical research and synthesized and isolated for specific DNA qualities. Such values are still very much a part of the daily lives and analysis of Pacific communities.

This publication provides the first of its kind report on specific cases that have been experienced by Pacific communities in Polynesia and Micronesia. First of a kind because the case examples are written by Pacific indigenous writers who are from the communities affected and/or were actively involved in the resultant community responses.

It is the aim of this COE and UNU-IAS report to provide to students, policy analysts, legislative drafters, biotechnology companies, patent owners and indigenous communities an educational resource that documents and records Pacific responses to genetic research and products and patents on life forms. It is hoped that readers will gain a greater understanding of and respect for the views of Pacific communities.

The United Nations University Institute of Advanced Studies (UNU-IAS) was established in 1996 as a research and training centre of UNU to undertake research and postgraduate education on emerging issues of strategic importance for the United Nations and its Member States. Pursuant to its Statute, UNU-IAS undertakes its work in an independent, neutral and objective manner. A key purpose of the Institute is to promote interaction between the UN System and other bodies. Collaboration with Call of the Earth on this Pacific report fits comfortably within the Institute's wider programme on traditional knowledge and biodiversity, which includes initiatives on traditional communities ability to adapt to climate change and traditional management of wetlands. The programme is also working with Call of the Earth to examine certificates of origin for traditional resources and associated knowledge.

Professor A H Zakri
Director, United Nations University, Institute of Advanced Studies,
Yokohama, Japan



# FOREWORD

*"Considering that traditional and local knowledge systems, as dynamic expressions of perceiving and understanding the world, can make, and historically have made, a valuable contribution to science and technology, and that there is a need to preserve, protect, research and promote this cultural heritage and empirical knowledge, …The nations and the scientists of the world are called upon to acknowledge the urgency of using knowledge from all fields of science in a responsible manner to address human needs and aspirations without misusing this knowledge."*

*Excerpts from the UNESCO Declaration on Science and the Use of Scientific Knowledge, 1999*

This book has been developed to inform the global audience at large on biotechnology and cultural and intellectual property issues in the Pacific. In addition, it seeks to provide guidance for Pacific policy makers, advice and caution for bio-pirates and inspiration for young Pacific scholars and activists who are eager to transform things for the better for future generations.

This book comprises the offerings of sixteen indigenous Pacific writers and presents the first publication of its kind in the region in terms of profiling the direct experiences of Pacific indigenous communities who have had an acrimonious encounter with science, biotechnology and intellectual property rights from inside the communities concerned. It records these events and the efforts Pacific activists and communities have gone through in order to 'put right' research, policy and legislation that has either gone askew or was not developed to adequately and appropriately address the issues that come about when science, culture and property rights interface.

As with any endeavour, there was a process behind this publication and a significant number of supporters who brought this work to fruition. It is only appropriate to acknowledge them.

In June 2005, a small gathering of Pacific activists was convened in Suva, Fiji. The Suva gathering brought together a unique collective of inimitable individuals whose passion for the specific issue of commodification and ownership of life is only eclipsed by their unwavering commitment to the integrity of their communities and peoples, as well as to the Pacific as a socio-political cultural and physical region. The participants had all directly participated in community and national interventions of government and/or foreign ownership assertions over genetic information and materials of Pacific indigenous peoples and other cultural resources.

The purpose of the Suva meeting was threefold:

(1) To provide a forum to take stock of the incidences that have occurred in the Pacific concerning genetic research and life patents that have required activism and community intervention;
(2) To reflect on the degree to which past experiences have informed policy and legislation at community, national, regional and international levels; and
(3) To promote research and publication as a constructive tool to increase awareness of Pacific indigenous issues, analysis and visions at local, national, regional and international levels.

The meeting was organised by the Pacific caucus of Call of the Earth Llamado de la Tierra, a global initiative on indigenous cultural and intellectual property policy, in partnership with the Pacific Institute of Advanced Studies in Development and Governance of the University of the South Pacific, and the World Council of Churches – Pacific Desk. This partnership brought together an indigenous network specializing in intellectual property issues, an academic institution very active in the region and the Churches who play a fundamental role in Pacific communities.

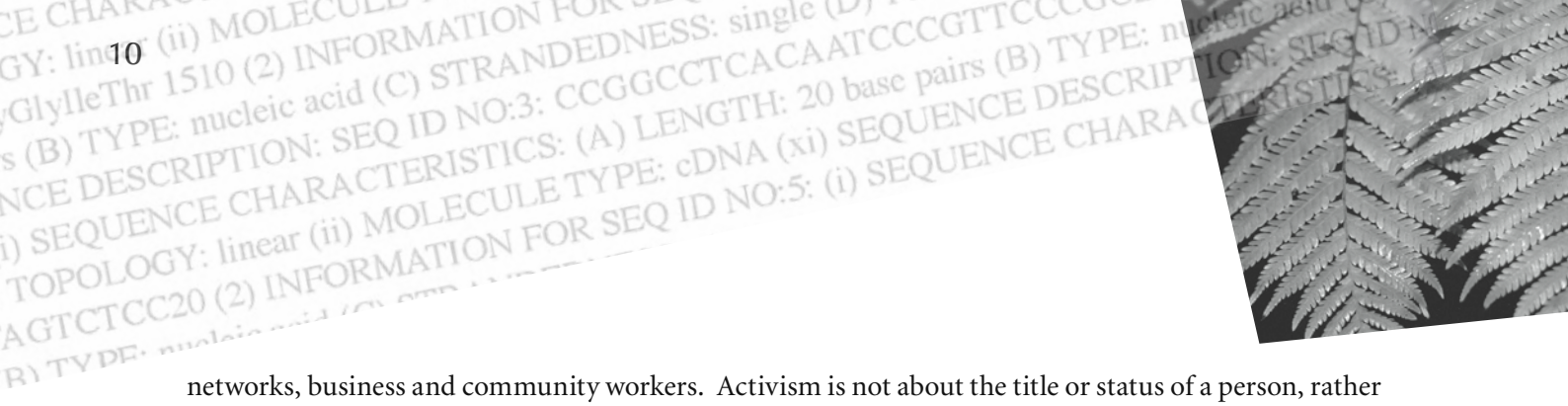
The collaboration came through a network of personal relationships, typical of how things are often done in the Pacific. As such, the Editors wish to acknowledge the following members of the Suva Organizing Committee: Kingi Gilbert, Te Tika Mataiapo Reid, Clark Peteru, Rahera Smith and Feiloakitau Tevi without whose efforts it would have been difficult to bring this particular gathering together.

Regional meetings can only occur when there is sufficient financial backing as the Pacific is a very expansive and expensive region in which to bring people together. Likewise, a publication of this nature also requires financial and 'in kind' support.

We therefore acknowledge with thanks the following organizations that contributed to the Suva meeting and/or to this publication;

- Call of the Earth Llamado de la Tierra,
- Nga Pae o te Maramatanga National Institute of Research Excellence in Maori Development,
- Pacific Institute of Advanced Studies in Development and Governance of the University of the South Pacific,
- United Nations University – Institute of Advanced Studies,
- United Nations Environmental Programme – UNEP,
- United Nations Development Programme – UNDP,
- Victoria Management School – Victoria University of Wellington,
- World Council of Churches – Pacific desk, and
- IUCN Commission on Environmental Economic & Social Policy Theme on Culture & Conservation.

Activists tend to be stereotyped as 'anti-government trouble makers', but activism takes many forms, and activists themselves transform into many different career paths over time. Activists are people who care and are confident enough to articulate their views even if they are contrary to government policy and/or public consciousness. Activists are family and community members who take on many career roles including being family, community, village, tribal or national leaders. Activists can also be members of parliament, public servants, academics, media, environmental and socio-cultural-political



networks, business and community workers. Activism is not about the title or status of a person, rather it is about the values and beliefs they hold to be irrefutable.

Some of the Suva participants wanted a Declaration or Statement to come forward from the meeting as it became apparent very early in the proceedings, that Pacific communities have suffered and been traumatized by the lack of regulation and control over unethical research and intellectual property assertions for many years, and very little progress has been made to address these issues. The Pacific has a strong record of developing powerful Declarations over the years and many of these are profiled here in this publication. It was always the vision of the Suva meeting to turn activism into reflective writing and produce a publication that could be distributed to a wider global audience. This is how this publication has come to be. Special thanks to the contributing authors who were willing to share their analysis.

The book is divided into two major sections. The first section consists of country-based articles and case studies and the second section is a collection of formal instruments and agreements related to genes, gene patents and intellectual property rights in the Pacific.

Aroha Te Pareake Mead sets the tone by providing a comprehensive overview and analysis of the situation of biotechnology in the Pacific, in particular with how it is linked to commercial activities, use of patents and other intellectual property mechanisms to facilitate, promote and protect outcomes and products. Mead makes the strong point that commodification and ownership of life through intellectual property systems are not compatible with many Pacific cultural values and norms.

This strand of argument is taken up and reinforced further by Jessica Hutching's, article which problematizes the growing discourse on the relationship between biotechnology and Maori development. Despite using the ideological cloak of "development" and "progress" the deployment of biotechnology and subsequent claims to intellectual property rights (IPR) if not properly managed could be tantamount to "intellectual cultural piracy."

Paul Reynolds provides a detailed account of the opposition by the Ngati Wairere sub-tribe (hapu) in the central North Island of Aotearoa to AgResearch, a government research agency, which attempted to place copies of human genes into cows to produce a human-cow hybrid. The opposition was based on the concern about lack of consultation with local communities and the impact this type of research will have on whakapapa (genealogy). The case provided a platform for future consciousness raising on biotechnology amongst Maori.

The issue raised by Reynolds manifests a fundamental contradiction between reductionist scientific research and local indigenous discourses. Nevertheless, engaging research and activism in mutually engaging ways within the broader indigenous context could provide the way forward for indigenous empowerment as Linda Tuhiwai Smith argues. "Decolonizing methodologies" for indigenous research and how this can be used to reinforce indigenous activism and vice versa is one of the major challenges to enable indigenous communities to achieve cultural sustainability and self-realization in the face of globalization and cultural hegemony.

In the article on the Cook Islands, Te Tika Mataiapo-Dorice Reid asks the question which resonates throughout the book: "Are the lives of indigenous people less important than those of others?" This is in reaction to a case where the Cook Islands government "agreed in principle" in 2002 to allow Diatranz Ltd a New Zealand company to commence xenotransplantation [human and pig] experimentation in the Cook Islands without consultation and without the informed consent of the people. This is a classical example of how biotechnology can be used for ethically questionable practices.

The debate regarding the implications of biotechnology and bioprospecting on indigenous identity and cultures is taken up by Steven Ratuva in his assessment of the need to put in place legal mechanisms which recognizes indigenous Fijian knowledge and cosmology. Ratuva's analysis focuses largely on the holistic relationship between the environment, Fijian epistemology and cosmology and how the fine balance between these could be undermined by bioprospecting. The next chapter by Joeli Vakabua reinforces Ratuva's point further by arguing for the need for the embedment of intellectual property rights and ownership of resources in the hands of the landowners. Vakabua also argues for recognition of rights of other stakeholders such as farmers, breeders, designers and composers as crucial aspects of IPR.

The ethics of human genetic research is discussed in a comprehensive way by Lea' Malia Kanehe of Hawaii. The article is a critique of the National Geographic sponsored Genographic Project which attempted to collect and analyze 100,000 DNA samples to trace the origin and links between human groups. Kanehe's argument is that a genome map does little to inform indigenous peoples about themselves culturally because "we know who we are and where we come from".

The next article is a joint piece authored by Walter Ritte and Le'a Malia Kanehe on the contentious issue of genetic modification of taro in Hawaii. It looks at the circumstances surrounding the attempt by the University of Hawaii's College of Tropical Agriculture and Human Resources to genetically modify Hawaiian taro. One of the significant messages of the chapter is the need for scientists to have more respect and sensitivity for the sentiments of the indigenous people who have been guardians of local crops like taro for hundreds of years. Modifying and patenting Hawaiian taro tantamount to modification and commodification of the spirit of ancestors.

Alphonse Kambu provides an overview of some of the shortcomings associated to scientific research and development in Papua New Guinea, especially in relation to the Hagahai patent case which involved removal and patenting of genes belonging to the Hagahai people by Dr Carol Jenkins a US medical researcher. The case provides some important lessons for other Pacific communities to learn from especially in the areas of effective communication between stakeholders, lack of understanding of the benefits and inadequacy of the law. The case of the Hagahai is further elaborated on by Eric Kwa who explores the legal aspects of the case. While the legal system may have changed in response the Hagahai case, there are still ambiguities and lack of political commitment on the part of the government. A lot still need to be done to sort out the legal gaps and protect the PNG people from further genetic piracy.

Clark Peteru from Samoa provides two contributions. The first one is about the agreement between the Samoan government and the University of California at Berkely in relation to the mamala plant. Peteru puts the case forward that indigenous land-owners and Pacific governments need to take a critical and

long-term view to negotiating with foreign researchers. Access to genetic resources of plants, and the equitable sharing of benefits of the use of biodiversity and associated traditional knowledge is the subject of intense international debate. In the second section of the book, Clark also provides an annotated version of the Pacific Model Law on Traditional Biological Knowledge, Innovations and Practices.

Lopeti Senituli's article documents civil society responses to attempts at biopiracy from a regional activist's point of view. The first case relates to the attempt in 1995 by the University of the South Pacific to sign an agreement with Smith Kline-Beecham a pharmaceutical conglomerate to extract bio-diversity material from two locations in Fiji. The other case involves the Australian company Autogen Ltd which signed an agreement with Tonga's Ministry of Health to identify and extract Tongan genes for the purpose of identifying causes of common diseases such as diabetes. The other article on Tonga by Sister Keiti Ann Kanongata'a provides a theological view of the Autogen project, especially the relationship between bio-ethics, human values and human dignity.

The last article by Chief Viraleo Boborenvanua and Motarilova Hilda Lini provides an alternative framework for indigenous living in the face of globalization. The "Turaga Nation" is an attempt to re-capture traditional philosophy, governance and economics in an applied way as a means of maintaining social coherence and sustainability in the face of the dominant market economy and cultural values.

The chapters are deliberately organized to engage with each other in a dialogue, yet retain their own independent voices. Each has its own voice echoing across the Pacific space and conversing with each other without being restricted by any mechanical editorial template. This is one of the intended strengths of this volume. The authors articulate their own voices in ways which are specific to their own context. Some of these voices have been marginalized and have struggled to enter into scientific and legal discourse on biotechnology and bioethics.

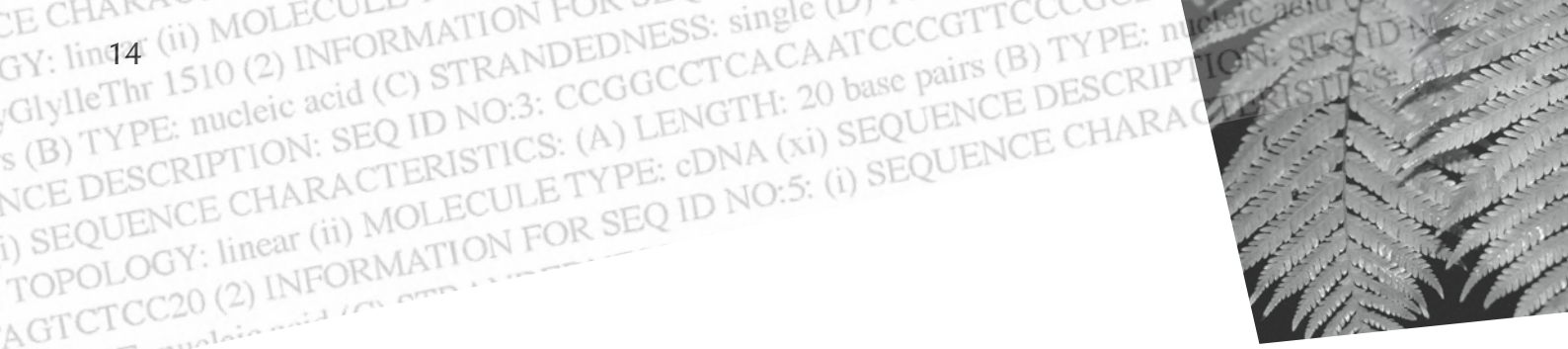
The dominant reductionist science separates components of life into isolated entities which can be manipulated and commodified, however, one has to be conscious of the fact that those isolated "entities" are still part of the human environment from which they are extracted. Respect for the human values and spirit must remain a paramount consideration both in symbolic and practical terms. The book represents - both in a symbolic and practical way - the need to contest dominant discourses in their own terms not as a mere intellectual, ideological or political exercise for its own sake but as a means of articulating subaltern voices and finding a respectable niche in the domain of global discourse. This is important for small Pacific communities who have historically been nothing more than objects of romantic image-making for novelists and tourist brochures. This is especially so as a form of empowerment and self-actualization for indigenous communities who have been at the receiving end of cultural hegemony and marginalization.

Hopefully this book will provide space and visibility for Pacific activists and communities to contribute to on-going national, regional and international discussions on the ethics of science, biotechnology and the commodification and ownership of life through intellectual property rights.

Aroha Te Pareake Mead

Steven Ratuva

Woman form the Pinai tribe, PNG (PNG Institute of Medical Research, Goroka)



# BIOGRAPHICAL DETAILS OF AUTHORS

1. Chief Viraleo Boborevanua
2. Jessica Hutchings
3. Alphonse Kambu
4. Le'a Malia Kanehe
5. Sister Keiti Ann Kanongata'a
6. Eric L Kwa
7. Motarilavoa Hilda Lini
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9. Clark Peteru
10. Steven Ratuva
11. Te Tika Mataiapo - Dorice Reid
12. Paul Reynolds
13. Walter Ritte
14. Lopeti Senituli
15. Linda Tuhiwai Smith
16. Joeli Vakabua

## Chief Viraleo Boborevanua (Vanuatu)
*Traditional Chief, Turaga Nation*

Chief Viraleo Boborenvanua is a highly respected leader with strong interests in natural philosophy, natural laws, indigenous wisdom and positive spirituality for peaceful and sustainable livelihoods.

For over 25 years he has been responsible for administering his own village community, Lavatmagemu, the home of the administrative headquarter of Turaga, the Tanbunia and Tanmarahi (indigenous bank and reserve bank of indigenous currencies), the Melanesian Institute of Philosophy and Technology, the Sarabalaleo (indigenous parliament), the Bule-Tabi Ginau Tahehei (food security and economic trade centre) and the venue of annual meetings/conferences of indigenous leaders.

Chief Viraleo is the Chief Executive Officer of Turaga Peace Model for Sustainable Livelihood, supervising 50 sustainable livelihood development programmes implemented at village, local, national and international level. He is also advisor to Liviniketu (a network of indigenous chiefs of Vanuaroroa/ Pentecost Island) and a national spokesperson for Tuvanutu Komiuniti (a network of indigenous communities throughout the Republic of Vanuatu).

Previously, he was special advisor at constituency level to the Late Vuhunanvanuatu Dr Fr. Walter Hadye Lini, first prime minister of the Republic of Vanuatu.

Chief Viraleo's first overseas trip was in 2000 to Canada where he had the opportunity to visit and meet with leaders of First Nations communities. Further missions abroad have also included Geneva (2000), Brussels (2001), Bangkok (2002) and Fiji (2005) for a range of topics including global politics, economics,

religious conflicts, environmental injustice, poverty, hunger and war. Chief Viraleo speaks through an interpreter.

Jessica Hutchings (Aotearoa/New Zealand)
*Resident Scholar, Massey University*

Dr Jessica Hutchings is from Aotearoa from the tribe of Ngai Tahu and Ngati Huirapa (Maori). She is also of Gujarati, Indian descent. Jessica has been working in the area of GE and new technologies for the last eight years and completed a PhD undertaking a Maori feminist analysis of GM. She has worked along side Maori communities in particular Maori women's groups in developing analyses and Maori focused frameworks for assessing new technologies. She continues to publish in the area of Maori, GM, nanotechnology and other new technologies. Her current research is focused on the impact other new and emerging technologies in particular Nanotechnology may have on Maori.

Jessica teaches Maori environmental and resource management in the Masters of Environmental Studies at Victoria University, Wellington as well as in gender and development. She is the current Resident Scholar at Te Mata o Te Tau at Massey University, Wellington where she is continuing her activism and research in this area.

In addition Jessica is also a biodynamic grower. She is currently converting 6ha of land in the North Island to Demeter certification and is developing the property along permaculture principles of self-sufficiency. She is working with local communities to grow traditional varieties of plants and is regenerating native bush with locally sourced plants.

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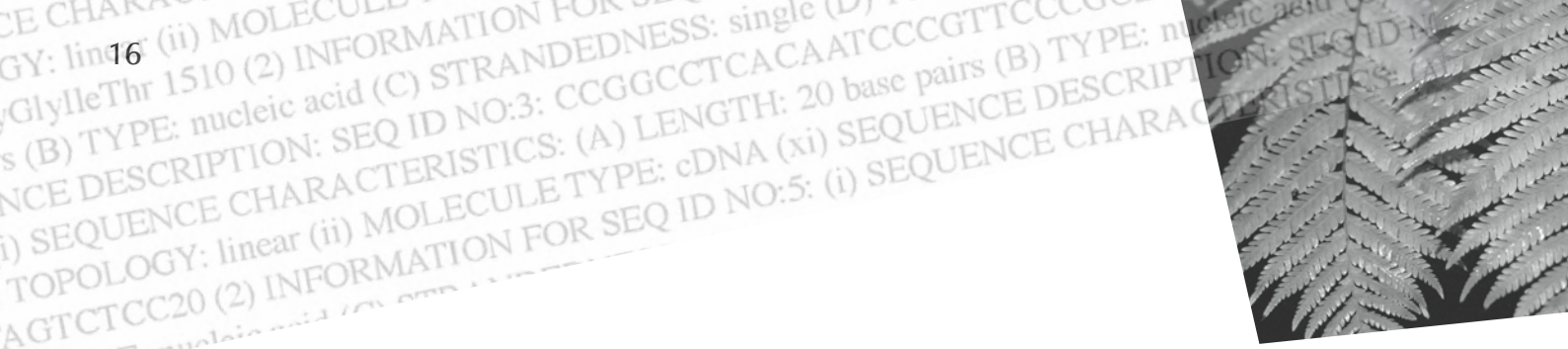
Alphonse Kambu (Papua New Guinea)
Director, Ishikawa International Cooperation Research Centre (IICRC)
*Alphonse Kambu, a Papua New Guinea citizen, holds a PhD from Chiba University, Japan, and specializes in environmental law. He is the Director of Ishikawa International Cooperation Research Centre (IICRC), a Special Programme of United Nations University Institute of Advanced Studies (UNU-IAS), based in Kanazawa, Japan. Prior to this post, he was a JSPS-UNU Postdoctoral Fellow at UNU-IAS in Tokyo and Yokohama and IUCN/Ford Foundation Policy Fellow at IUCN in Washington D.C.*

He has participated in various capacities at numerous international processes including the Kyoto Protocol, the Convention on Biological Diversity and the Inter-governmental Committee of the World Intellectual Property Organization on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

He is Lead Author and Contributing Author of the Typology of Responses and Biodiversity sections respectively of the Policy Responses Volume of the Millennium Ecosystem Assessment. He has also published on the legal protection of traditional knowledge and genetic resources, water regulation and



numerous topics within the environment and sustainable development agenda. His current work and research interests are in environmental law and policy, legal protection of traditional knowledge and genetic resources, sustainable management of ecosystems in Satoyama and enforcement of water pollution laws.

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### Le'a Malia Kanehe (Hawaii)
*Legal Analyst, Indigenous Peoples Council on Biocolonialism,*
*Call of The Earth Llamado de la Tierra Member*

Le'a Kanehe is a Kanaka Maoli (Native Hawaiian) lawyer from Honolulu, U.S.A. She is also a member of Call of the Earth Llamado de la Tierra. She is a legal analyst with the Indigenous Peoples Council on Biocolonialism based on the Pyramid Lake Paiute Reservation in Nevada, USA, where she works to address the impacts of genetic technologies on Indigenous peoples and their territories, natural resources and traditional knowledge. Her previous experience includes self-determination advocacy work and legal research with Kanaka Maoli community organizations and conducting legal research in the areas of indigenous peoples' and native Hawaiian rights. She has also participated in a number of international forums regarding Indigenous peoples' rights, with a particular focus on protection of indigenous knowledge, including at meetings of the Convention on Biological Diversity and the United Nations Permanent Forum on Indigenous Issues.

Le'a holds a Bachelor of Arts in Hawaiian studies (Honours) and Juris Doctor degree from the University of Hawaii (Honours) and a Masters of Law (LLM) from the University of California, and is a current member of the Bar of the State of Hawaii, Federal District Court for the District of Hawaii and the U.S. Court of Appeals for the Ninth Circuit.

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### Sister Keiti Ann Kanongata'a (Tonga)
*Director/Founder, Liloitafaanga Theological Institute*

Keiti Ann Kanongata'a is of Tongan descent and is a Catholic and member of the Religious Community of the Sisters of Our Lady of Nazareth (a local order of Sisters of the Pacific Islands, the members are all Island women). Keiti's educational qualification is a Doctoral of Missiology (Theology) which she gained from the Pontifical Urbaniana University in Rome, Italy.

For the last ten years she has been a resource person for the Pacific Islands in the local and international level mainly for the promotion of women, of Island Identity, ecumenical unity, and justice, peace and integrity of creation. Keiti was a former Professor of Missiology at the Catholic Pacific Regional Seminary (Suva, Fiji) of Christian Anthropology at Siatoutai Theological College in Tonga (a Wesleyan College), and of Doing Theology (Contextualization) to women and men groups in Tonga.

Currently Keiti is founding a new Theological Institute for the lay people of the Pacific Islands in Tonga.

Dr. Eric Lokai Kwa (Papu New Guinea)
*Head, Law Department, University of Papua New Guinea Law School,*
*Former Dean – UPNG Law School, University of Papua New Guinea*

Dr. Eric Lokai Kwa is the Chief of Mararamu Village, of the Kowai tribal group in Papua New Guinea and also the Chief of the Sal Clan. He has an LLM (Hon) Wollongong University, LLB (Hon) University of Papua New Guinea. He recently (2005) completed his PhD at the Auckland University. His thesis is entitled: "Traditionalizing Sustainable Development: The Law, Policy and Practice in Papua New Guinea."

His main areas of research interest are: sustainable development, environmental law and policy, natural resources management law and policy, constitutional and administrative law, traditional laws and knowledge, resources use and management in local communities.

Eric has presented papers at both international and national conferences and published papers on sustainable development, environmental law and policy, natural resources management law and policy, constitutional and administrative law, traditional laws and knowledge, and resources use and management in local communities.

He is the author of the legal text - Constitutional Law of Papua New Guinea (Sydney: Law Book Co, 2001) and the Editor of another legal text – Natural Resources Law of Papua New Guinea (Sydney: Law Book Co, 2001). He is also the lead editor of two legal texts - Judicial Scrutiny of the Electoral Process in a Developing Democratic State (New Delhi: UBSPD, 2002) and Development of Administrative Law in Papua New Guinea (New Delhi: UBSPD, 2000) and the joint editor of another legal text - Twenty Years of the Papua New Guinea Constitution (Sydney: Law Book Co, 2001).

Eric has worked as a consultant with AusAid, the Government of Papua New Guinea (PNG), Non Governmental Organisations, and for UN funded projects in PNG as an Environmental Law and Constitutional Law Consultant. Presently Eric is working with the Government of PNG (since 2004) to develop its National Biosafety Framework funded by UNEP and GEF and also with The Nature Conservancy (TNC) (since 2003) in developing a legal framework for the sustainable use and management of natural resources in indigenous and local communities in PNG.

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Motarilavoa Hilda Lini (Vanuatu)
*Executive Officer & International Spokesperson, Turaga Philosophy on Peace & Human Security and the Melanesian Institute of Philosophy Motarilavoa*

Hilda Lini is a member of the Tabi tribe within the Turaga indigenous nation of Vanuaroroa (Pentecost Island). She is a mother of two children and a chief in Raga women's chiefly society.

Hilda graduated as a journalist from the University of Papua New Guinea in 1979. Currently she is Executive Officer and International Spokesperson for four organizations: Turaga Philosophy on Peace & Human Security,

Tuvanutu Komiuniti, the Melanesian Institute of Philosophy and Technology and the Tanbunaiatanmarahi indigenous banking system. Previously she was the Director of Pacific Concerns Resource Centre, based in Fiji.

Hilda was a member of the Vanuatu Parliament from 1987 – 1998 where she held several portfolios including Minister responsible for Justice, Culture, Religion, Women's Affairs, Health, Rural Water Supply, Children, Population policy, Quarantine and Traditional Medicine. In 1982 she became the first Director of the Inter-Governmental Pacific Women's Resource Bureau of the South Pacific Commission. She was instrumental in Vanuatu's struggle for Independence as Editor of their newsletter and Coordinator of the Women's Wing. She is a graduate in Journalism from the University of Papua New Guinea.

Hilda is a founding member of the Vanuatu National Council of Women. She was very instrumental in the struggle for independence, first as the Editor of the New Heridean and Vanuaaku Viewpoints, as well as the Coordinator of the 'Women's Wing' of the liberation movement. Since 1995, she has continued to be an active advocate for peace, re-indigenisation, fundamental human rights, a nuclear free and independent Pacific, the global ban on nuclear and chemical weapons, bio-piracy and genetic engineering.

## Aroha Te Pareake Mead (Aotearoa/New Zealand)

*Aroha Te Pareake Mead is from the Ngati Awa and Ngati Porou tribes (Maori) of Aotearoa. She is a founding member and Co-Chair of Call of the Earth Llamado de la Tierra.*

Aroha has been involved in indigenous cultural and intellectual property and environmental issues for over 30 years at tribal, national, Pacific regional and international levels.

Aroha is currently a Senior Lecturer in Maori Business, Victoria Management School at Victoria University of Wellington and also teaches International Diplomacy for Te Whare Wananga o Awanuiarangi. She is a Senior Visiting Research Fellow at the Centre for Environmental Law, Macquarie University in Sydney, Australia and received one of two National Research Fellowships from Nga Pae O Te Maramatanga National Institute of Research Excellence for Maori Development & Advancement in 2006 to write a Guidebook for Kaupapa Maori Researchers for the protection and promotion of their research.

Previously, Aroha worked in Senior Policy positions within the NZ government for over twenty years. She has extensive experience in public policy, legislative development and reform, in a wide range of issues including: international treaty negotiations, obligations and reporting, Maori resource management, repatriation of ancestral remains, protection of Maori language, Treaty of Waitangi claims and settlement processes, reform of Trademarks, Copyright, Plant Variety Rights and Patent laws and sui generis mechanisms for Maori.

She is serving a second term on the Governing Council of the IUCN World Conservation Union and plays an active role in IUCN Commissions and programmes of special interest to indigenous peoples.

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Clark Peteru (Samoa)
*Environmental Legal Adviser,*
*Call of the Earth Llamado de la Tierra Steering Committee Member*

Clark Peteru is a founding member of the Call of the Earth and is on the Steering Committee. He is Environmental Legal Adviser at SPREP, the Secretariat of the Pacific Regional Environment Programme, an Inter-Governmental Organisation.

Previously he was a lawyer in private practice in Samoa where a large amount of his work focused on intellectual property, and access and benefit-sharing. From 1991-1994, Clark was the director of the Siosiomaga Society, a Samoan environmental NGO which at that time did worked largely on rainforest conservation. Clark became involved in intellectual property issues in 1995 when working for the Fiji-based Pacific Concerns Resource Centre (PCRC).

He helped organise the UNDP Pacific Regional Consultation on Indigenous Intellectual Property rights for the PCRC, and drafted the Treaty & Related Protocols for a Lifeforms Patent Free Pacific developed through the Pacific Consultation Meeting. Since then, Clark has attended many meetings and workshops on IP policy relating to genetic resources, access and benefit-sharing and traditional knowledge, particularly meetings of the Convention on Biological Diversity.

Clark helped draft Model Laws for the Protection of Expressions of Culture for Pacific Island Developing States, and has been very active within the Pacific region on intellectual property issues and genetic resources for food and agriculture, working with UNESCO, the Secretariat for the Pacific Community and the Pacific Islands Forum Secretariat.

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Steven Ratuva (Fiji)
*Senior Fellow, Governance, University of the South Pacific*

Dr Steven Ratuva is a political sociologist with a PhD from the Institute of Development Studies, University of Sussex, UK. He is a senior fellow in governance in the Pacific Institute of Advanced Studies in Development and Governance at the University of the South Pacific.

He recently worked as a fellow at the Research School of Pacific and Asia Studies, Australian National University (ANU) and continues as a visiting fellow at ANU. He was also a visiting fellow at the University of New South Wales and researcher and resource person for a number of institutions including the East West Center in Hawaii, Life and Peace Institute in Sweden and the International Working Group for Indigenous Affairs in Denmark. Dr Ratuva has carried out extensive consultancies for a number of international organizations including UNDP, ILO and Asian Development Bank. He has published widely in issues relating to affirmative action, political parties, ethnicity, identity, indigenous rights, security and conflict.

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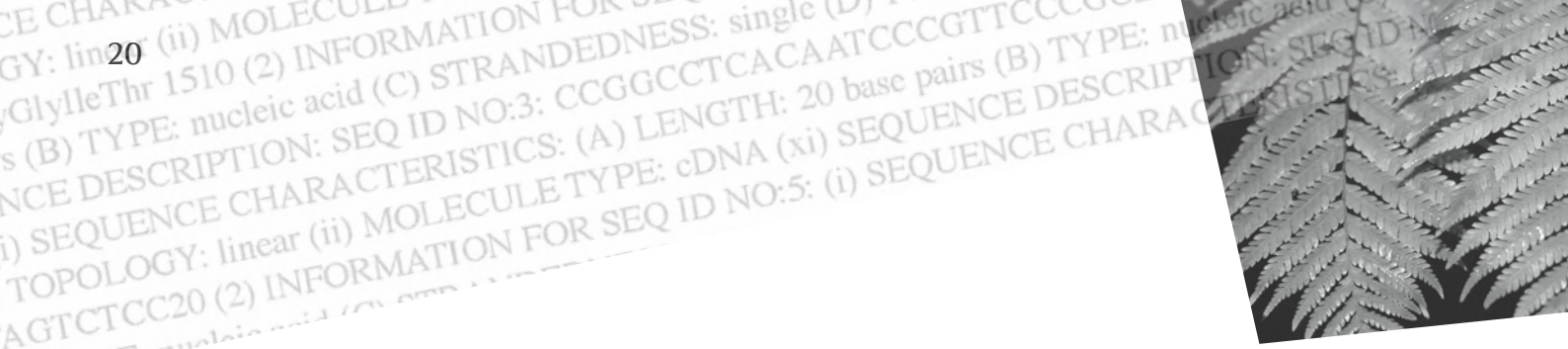

## Te Tika Mataiapo - Dorice Reid (Cook Islands)

*Traditional Chief, Call of the Earth Llamado de la Tierra Member*

Te Tika Mataiapo - Dorice Reid is a traditional Chief from the district of Takitumu on the island of Rarotonga. For nine years, she has served for 10 years as President of the Koutu Nui of the Cook Islands (a Council of Traditional Leaders). She was a member of the Cook Islands Maori Language Policy Committee which formalised the completion of the legislation for Parliament.

As Traditional Leaders, the Koutu Nui of the Cook Islands consider themselves to be custodians of the Land, from the mountain to the sea, environment, traditional knowledge and practice, customs, language, cultural heritage and to protect the welfare of the people. The Koutu Nui actively brought the various communities, stakeholders and private sector together to successfully re-establish the Raui system of traditional marine protection, which had not been practiced for over 50 years, in Rarotonga. The Koutu Nui of the Cook Islands with other NGO's and community stakeholders pressured Government to declare the island of Suwarrow (which was being considered for lease to an Australian company for pearl farming) as a Sanctuary for wild birdlife.

Te Tika has voyaged to Hawaii and return to Rarotonga on the Vaka "Te Au O Tonga", a double-hull ocean voyaging canoe. Vaka Voyaging is one of the purest forms of ancestral experience in Polynesia, confirming the global communion Polynesians have with their environment.

Te Tika represented the Koutu Nui of the Cook Islands at meetings held with the company Diatranz. (Diatranz was working to use advance experiments using pig cell implants as a cure for diabetes patients).

## Paul Reynolds (Aotearoa/New Zealand)

*Co-Director, Te Atawhai o Te Ao, Independent Maori Institute for Environment & Health*

Dr. Paul Reynolds is a whanau researcher from the Maori tribes of Ngati Tuwharetoa and Nga Puhi. He is currently the Co-Director for the community-based research institute, Te Atawhai o Te Ao: Independent Maori Institute for Environment & Health. From 2004 to 2006 he worked as a Post-Doctoral Fellow for Nga Pae o Te Maramatanga, a National Centre of Research Excellence hosted by the University of Auckland. In 2004 he completed his Ph.D. thesis on the impacts of genetic engineering on Maori and Indigenous peoples. His general research interests include Maori health and well-being, and the protection and retention of Maori and Indigenous knowledge.

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Walter Ritte (Hawaii)
*Key Organiser Against Genetic Engineering Kalo in Hawaii,*
*Co-ordinator, Hawaiian Learning Centre*

Walter Ritte (Kanaka Maoli) is 61 yrs old and married with four children and seven grand children from the island of Molokai, Hawaii. Walter is a hunter and Hawaiian Activist now working on the restoration of traditional fishponds and educational programs based Hawaiian culture.

Walter was involved in stopping the bombing by the US Navy of the Hawaiian Island of Kahoolawe, the last Hawaii Constitutional Convention establishing the recognition of Hawaiian Gathering Rights. He was also one of the first elected trustees to the Office of Hawaiian Affairs.

These days, Walter considers himself as a self appointed guardian of the island of Molokai from the onslaught of the American Dream, and the heath and other dangers of economic driven Genetic Modification of our biodiversity.

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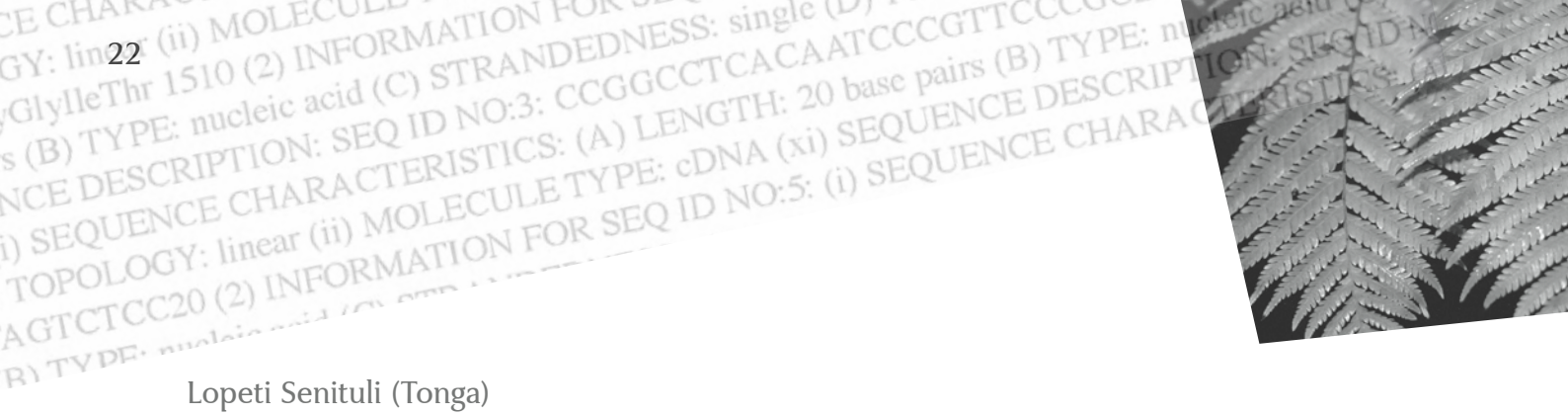
Linda Tuhiwai Smith (Aotearoa/New Zealand)
*Joint Director, Nga Pae o te Maramatanga*

Linda Tuhiwai Smith is a Professor of Education at the University of Auckland, New Zealand and is Joint Director of Nga Pae o te Maramatanga the National Institute of Research Excellence in Maori Development which is one of seven centres of research excellence in New Zealand.

She has an extensive background in the field of Maori education as a researcher and teacher and through her involvement in major policy initiatives. Professor Smith is known internationally as a public speaker on issues related to indigenous education, development and research methodology and for her critically acclaimed book "Decolonising Methodologies; Research and Indigenous Peoples." Professor Smith is also the co-editor with Judith Simon of A Civilising Mission? Perceptions and Representations of the New Zealand Native Schools System that was drawn from an oral history research project.

Linda has been a recipient of prestigious research grants from New Zealand's Marsden Fund for research on youth. In the area of policy development Professor Smith was a member of the Tertiary Education Advisory Commission that provided advice to the Minister of Tertiary Education on tertiary reform. She is Chair of the Maori Tertiary Reference Group for the Ministry of Education, is a member of the Advisory Group for the Best Evidence Synthesis Work of the Ministry of Education and is on the Council of Te Whare Wananga o Awanuiarangi a Maori institution of higher learning.

She is from Ngati Porou (Maori) on her mother's side and Ngati Awa (Maori) on her father's side. She was involved in the establishment of Kura Kaupapa Maori and has played an active role in advancing institutional change to enable greater achievement by Maori in education in ways that expand opportunities and build on the strengths of identity, language and culture.



Lopeti Senituli (Tonga)
*Press Secretary / Political Adviser to the Prime Minister of Tonga*

Lopeti Senituli's name is synonymous with political activism in the Pacific region. He is a former Director of Pacific Concerns Resource Centre in Suva and also founding Director of the Tonga Human Rights and Democracy Movement.

Lopeti is a native of Tongan and is currently Press Secretary / Political Adviser to the Prime Minister of Tonga. He is a former Deputy Chair of the Tonga Human Rights and Democracy Movement. He was a member of the World Council of Churches Committee of Eminent Persons to inquire into racism in the US and has worked with UN agencies as well as with international civil society organisations.

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Joeli Vakabua (Fiji)
*Director, Animal Health, Ministry of Agriculture, Sugar & Land Resettlement*

Joeli Vakabua is currently the Director of Animal Health, Ministry of Agriculture, Sugar & Land Resettlement in Fiji. He has degrees in Veterinary Biology and Veterinary Science from the University of Queensland, Australia and earned a Master of Science specialising in tropical veterinary science from the Royal (Dick) School of Veterinary Studies in Edinburgh, Scotland.

Joeli has had a long career with the Ministry of Agriculture first working in the dairy, beef, livestock and veterinary pathology sectors eventually working his way up to the position of Principal Veterinary Officer. It was during this time that he started participating in the development of Bilateral Trade Agreements with countries including Tonga, Papua New Guinea, Solomon Islands, Vanuatu, Niue, Kiribati and Guam.

This led to working on the creation of Fiji's Trade Development Committee, the formation of the Fiji World Trade Organization Unit and the Cairns Group negotiations in the capacity as Director for Crops Research of the Ministry of Agriculture. Intellectual property rights were also part of the areas of interest during these bilateral and multilateral talks which also stemmed a strong interest in patenting of intellectual properties of Fiji.

As a native Fijian and custodian of the flora and fauna of Fiji, Joeli has a keen interest in intellectual property rights of the Fijians, prior informed consent, access and benefit sharing, material transfer agreements, memorandums of understanding, sui generis systems, TRIPs 27.3b and the sustainable development of Fiji's agricultural resources.

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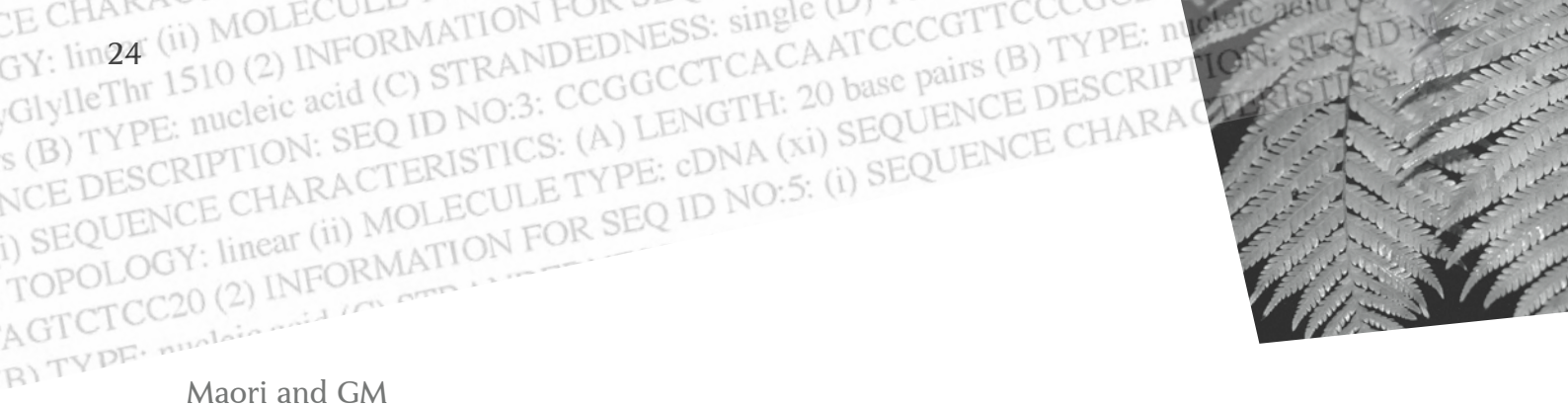
# IS BIOTECHNOLOGY AN APPROPRIATE DEVELOPMENT PATH FOR MAORI?

By Dr Jessica Hutchings
*Ngai Tahu, Ngati Huirapa and Gujarat descent.*

Global corporations and the biotechnology sector continue to secure profit from plundering the knowledge of others, also known as biopiracy. This intellectual and cultural piracy in which the cultural and intellectual heritage of communities and the countries are freely taken without recognition or permission, are used for claiming intellectual property rights (IPR) such as patents, trademarks and plant variety rights. The IPR system protects the profit for trans-national corporations (TNC) and biotechnology companies in the development of genetically modified organisms and products. Many groups including; consumers, farmers, non-governmental organisations (NGO's), Maori and other indigenous peoples have opposed biotechnology[1], in particular the biopiracy aspect associated with the technology. The concerns of these diverse groups include the possible adverse effects to; human health, the environment, biodiversity, intellectual and cultural property rights, traditional farming practices and the implications for ownership and sharing of benefits from genetic resources.

This chapter is being written at a time when several Maori are training as scientists in the areas of biotechnology and are proposing to Maori communities to participate in this technology. This paper looks at whether biotechnology is an appropriate development path for Maori? And explores how the profit from these technologies in particular genetic modification (GM), are protected through intellectual property law. To set the scene for this discussion an overview of Maori views pertaining to GM is presented.



## Maori and GM

Maori views on GM are well documented and there is an emerging academic discourse in this area. Furthermore a large number of individual Maori, iwi, Maori organisations and whanau based groups presented their views on GM to the Royal Commission on Genetic Modification (RCGM). The RCGM was established in 2001 to provide advice to the Government on:

1. the strategic options available to enable New Zealand to address, now and in the future, genetic modification, genetically modified organisms, and products and
2. any changes considered desirable to the current legislative, regulatory, policy, or institutional arrangements for addressing, in New Zealand, genetic modification, genetically modified organisms and products (RCGM, 2001).

Almost all of the Maori views to the RCGM presented concerns with regard to the technology and recommended caution with regard to GM proceeding (Hutchings, 2003). Furthermore the National Maori recommendations on GM adopted at the RCGM National Maori Hui in 2001 summarise the broad range of Maori concerns regarding GM.

National Maori Recommendations on GM

1. That the Crown honour Te Tiriti o Waitangi.
2. That a process for implementing constitutional change is negotiated between Maori and the Crown which includes a revision of all legislation inconsistent with Te Tiriti o Waitangi including the Hazardous Substances and New Organisms Act 1996.
3. That following such a process, any constitutional change implemented reflects a basis in tikanga Maori and acknowledges the following constitutional documents as the foundation for such process:
    - Declaration of Independence;
    - Te Tiriti o Waitangi;
    - Draft Declaration of Indigenous Peoples Rights; and
    - Mataatua Declaration.

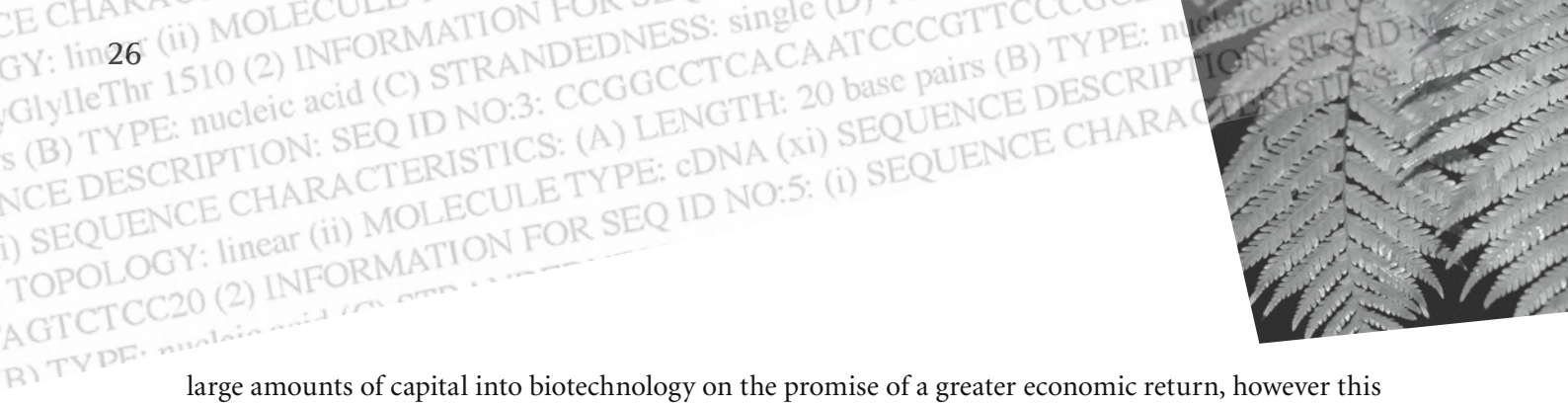
4. An Aotearoa (New Zealand) Constitution.
5. The Crown fund a parallel process which seeks Maori knowledge and opinions on genetic modification (GM) sourced from kaupapa Maori processes and contexts immediately.
6. That a moratorium be placed upon all activities related to GM and GMO's immediately.
7. That we outlaw the patenting of any life forms.
8. That an inventory on GMOs and GM activity in Aotearoa be completed by Maori and the Crown. Such an inventory must source all GMOs and GM research, outputs and activities to date.
9. That Maori in negotiation with the Crown commence immediately an environmental, spiritual and cultural GMO impact assessment, followed by a cultural, spiritual and environmental clean up.
10. That the Crown stops free-trade negotiations and stops biotechnology multinationals from entering Aotearoa to conduct GM experiments.
11. That Maori in negotiation with the Crown develop separate standards from the current ANZAF and other food standards that label GM foods.

12. That Maori in negotiation with the Crown label all GM foods.
13. That Maori in negotiation with the Crown half the import of GM foods for the future.
14. That the Crown fund sustainable organic agriculture practices and implements processes that will ensure that Aotearoa is an organic nation by 2020.
15. We declare Aotearoa should be an independent, nuclear and GE Free Nation.
16. That the Royal Commission include the resolutions form the National Maori Hui held 6-8 April 2001 in their final report, and to the New Zealand Government.

Image of a Tiki in a Jar by Theresa Reihana, Nga Puhi.
Image reproduced with artists permission

It is evident from the RCGM report that Maori expressed many concerns with regard to GM (Hutchings, 2003). Frequently raised were tikanga Maori concepts of whakapapa, mauri, tapu, noa, hara and ke, mana, ihi and wehi, whanau, hapu and iwi. All of these concepts were relevant to the Commission understanding the holistic ecological approach Maori have to the environment, but also to explaining why Maori prioritise an obligation to kaitiakitanga. Other imperative issues raised in the RCGM debate were environmental concerns and Te Tiriti o Waitangi. In addition to the views collected by the RCGM there is also an extensive Maori literature around GM, which further highlights the concerns Maori have with regard to this technology[2]. Despite the overwhelming opposition from Maori submitters and civil society to GM the RCGM's recommendation was that New Zealand preserve opportunities with regard to GM and proceed with caution. In turn this has meant that Maori concerns with regard to GM were not upheld. Lisa Reihana's image of a tiki a jar is a direct reference to the commodification and cultural offence GM has for her, she produced this artwork as a response to the RCGM debate.

One of the key issues that Maori raised at the Royal Commission process was the question of who will benefit from this technology? This question becomes increasingly pertinent as some Maori scientists enter into molecular science, working with Crown Research Institutes, or privately as we see on the horizon, the possible emergence of a Maori biotechnology company with a particular focus on ronoga Maori (traditional Maori medicinal plants). For many Maori this raises serious and urgent questions with regard to our tikanga and the protection of Maori cultural and intellectual property as well as the kaumatua mentoring and support for such an idea. To be expected, there seems to be a belief amongst some within our Maori science and business communities that if Maori engage with this technology we can reap the benefits and the rewards. The foremost benefit that the biotechnology sector offers those who are involved at the development end is profit. This profit is protected by intellectual property law and patents which has encouraged, multinational biotechnology companies and governments to invest



large amounts of capital into biotechnology on the promise of a greater economic return, however this has not always been the case. Although the commercialisation of science is big business and one that now dominates world economies the high returns experienced at the beginning of the biotechnology boom have not again been seen. The question to ask and answer in this paper is if Maori choose to participate in biotechnology what is the reality of Maori reaping these benefits given the protection that intellectual property laws accords biotechnology development?

## Biotechnology a Promised Land or Property Rights for Multinationals?

The majority of biotechnology companies are also TNC[3], and have been built on the promise of profit for shareholders. However publicly listed biotechnology corporations have experienced a sharp decline in share prices as the promised lands of biotechnology have continued to fail in delivering all that was promised; agriculturally, economically and socially.

An issue of great concern for many indigenous peoples and communities from developing countries with regard to biotechnology is the area of intellectual property. In particular the ability the biotechnology sector has in protecting their profit through patents.

## What Are Patents?

Patents are a limited property right that give the inventor a monopoly right to commercial exploitation of their invention for a period of time, usually 17-20 years. Patent law is what enables scientists to secure exclusive rights to the commercial benefits of their genetic research.

To be patentable, an invention must fulfil three basic requirements:

- Be inventive (ie: is not a discovery)
- Have novelty (i.e. is not obvious)
- Have industrial applicability.

Patents allow the patent holder to determine how and whether an invention can be used and by whom. A patent holder may exploit an invention, sell exclusive or non-exclusive licenses at a negotiated fee, or leave an invention unexploited. The primary motivation for such decisions will be how to maximise profits, the size of potential markets and the actions of competitors. Public interest is of little consequence in the decision making process (GeneWatch 2000).

Until 1980 patents were restricted to inanimate inventions such as new machineries, vacuum cleaners, drugs or processes for producing chemicals. The first patent on a living organism was awarded in 1980 in the USA for the creation of an oil-eating microbe. Since then the US patent and trademark office has granted numerous patents for newly created; micro-organisms, living animals, human tissues and genes.

A patent on a gene or a DNA sequence covers anything that is derived from it, and may extend to all plants, animals, mirco-organisms, drugs and diagnostic tests that have been developed with the aid of the patented gene (GeneWatch 2000).

Secretary Ron Brown on behalf of the US Department of Commerce filed patent claims on the human cell lines of indigenous peoples from the Solomon Islands. Private biotechnology companies are involved in large-scale sampling in the search for useful genes. DeCODE Genetics have successfully negotiated with the Icelandic Government for exclusive access to the medical histories and tissue banks of all 270,000 Icelanders (Lechmann, 1999). Furthermore, Hoffman La Roche have agreed to pay up to $200 million for DeCODES Icelandic data on genetic causes of twelve common illnesses.

## John Moore US Patent No. 4, 438, 032

John Moore US Patent No. 4, 438, 032 is the origin of the 'Mo' cell line. A patient of hairy cell leukaemia (a rare and potentially fatal type of cancer), John Moore's enlarged spleen was removed surgically by Dr David Golde of the University of California, Los Angela Medical Centre, who then went along with his colleague and the Regents of the University and patented the cell line claiming to be its inventor.

Thus following the historic decision of the Supreme Court of California in the John Moore case, all genetic material of the billions of human beings, especially the millions of indigenous peoples of the world, are raw material with the potential of being owned and exploited commercially.

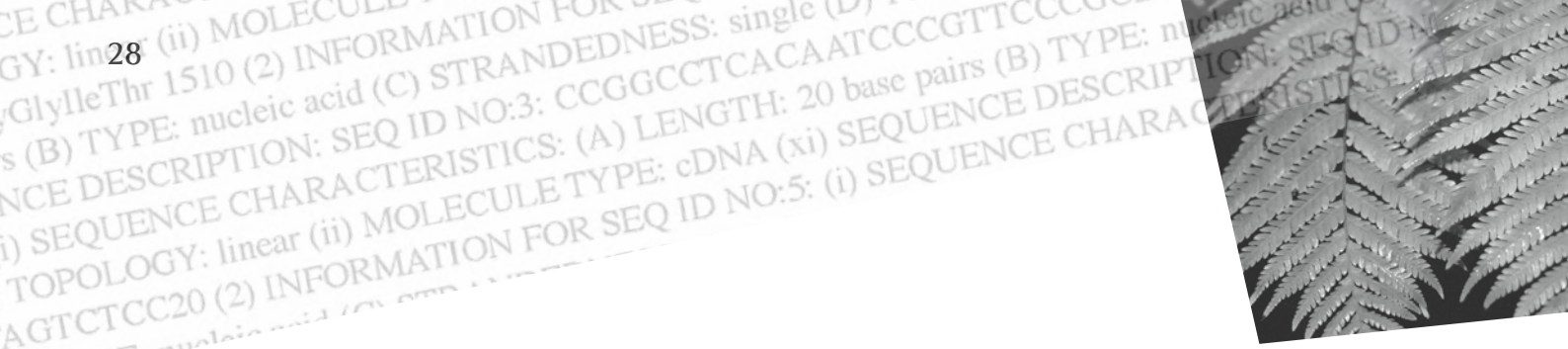
What is Wrong with Patenting Living Organisms?
There has been much discussion about the patenting of living organisms, some of the criticisms include the following:

- Genes exit in nature and cannot be considered to be inventions;
- Claiming to have invented genes and organisms is immoral,
- Allowing the control of genetic information and how it is used to fall into private hands is dangerous,
- The biotechnology sector (often situated in rich countries) is claiming patents through the piracy of other's wealth.

## Intellectual Property and the WTO

The race to secure patents to protect profit and to stake claim over knowledge and nature are the foremost method for capturing profit from biotechnology, in particular GM. These eurocentric notions of property and piracy according to Vandana Shiva (1998) are the bases on which intellectual property rights law, the WTO and biotechnology TNC have been framed. When the West first conquered and colonised, the ethic of 'discover and conquer' was predominant. Western science and the West continues to be impelled to: conquer, discover, own, dominate and posses everything in nature, in society and in communities. Furthermore the colonial tool of *terra nullius* and empty lands is now being extended through intellectual property laws to the areas of nature and seeds, being empty, and available for ownership and profit. Vandana Shiva (1998:10) states that;

> The same logic is now used to appropriate biodiversity from the original owners and innovators by defining their seeds, medicinal plants, and medical



> knowledge as nature, as non-science, and treating the tools of genetic engineering as the yardstick of 'improvement'. The definition of Christianity as the only religion, and all other beliefs and cosmologies as primitive, finds it parallel in defining commercialized Western science as the only science, and all other knowledge systems as primitive.

The WTO consider the property rights of the biotechnology sector and TNC as critical to the globalisation agenda and to free trade. However free trade does not mean that nation states, indigenous peoples and developing countries all have the ability to trade freely. In reality it has meant that the freedom of biotechnology corporations and TNC to trade and invest has been expanded. In truth free trade protects the economic interests of powerful TNC which already control 70% of the worlds trade.

## Indigenous peoples and intellectual property rights

For many indigenous peoples, biotechnology and GM poses a threat to the intellectual property rights they hold over generations of indigenous knowledge. This threat impacts upon indigenous peoples' spiritual and cultural practices. As a result, many indigenous peoples have taken a critical and strong position against biotechnologies in particular GM.

Writers such as Vandana Shiva and the Indigenous People's Council on Biocolonialism have referred to biotechnology as 'biopiracy'. They regard this as a further extension of colonialism as patents and biotechnology create new colonies. These writers state that the huge impacts on the global environment have perpetuated colonisation, erosion and pollution of the earth and peoples'. They argue that the Western world, rooted in capitalism and practices of maldevelopment[4], is looking for new colonies to invade and exploit for further accumulation of wealth. Vandana Shiva (1998:11) states that:

these new colonies are, in my view, the interior spaces of the bodies of women, plants, and animals. Resistance to biopiracy is a resistance to the ultimate colonisation of life itself - of the future of evolution as well as the future of non-Western traditions of relating to and knowing nature.

> Biopiracy threatens the core of indigenous communities' relationships with people and the environment because it fails to value both cultural and biological diversity. The ability to patent life through intellectual property laws is more than an issue of trade and profit it is an issue of ethical and ecological justice that is intimately related to the social injustice of biopiracy.

This global injustice is perpetrated because the intellectual knowledge and achievements of local and indigenous communities are not fully recognised and legally protected. Northern corporations, the trans-national life sciences, are taking the technologies, knowledge and biodiversity of local and indigenous communities as if they were their own. While the life science trans-nationals are determining the future of the genetic resources of the South, local farming communities and indigenous peoples continue lobbying for intellectual property laws that protect their innovations and inventions, as in the case of the neem tree. Carl Casale in a testimony to the House of Agriculture Committee in the United States talked about the: "absence of patent protection or the strict enforcement of national seed laws being unable to safeguard our [Monsanto's] investment and this will affect our ability to invest in new technology" (Monsanto, 2001).

Hence, the biotechnology sector and TNC are calling for an opening up of intellectual property laws to allow further plundering of the resources and countries in the South, local farming communities and indigenous peoples.

## Maori and IPR

Maori issues around intellectual property are not new. The WAI 262 Indigenous Flora and Fauna Claim, which concerns the ownership by Maori of genetic material from indigenous flora and fauna was registered with the Waitangi Tribunal in December 1991. Furthermore intellectual property issues were raised in the RCGM process by Maori submitters. These concerns included;

- Patentability of indigenous flora and fauna
- The WAI262 claim
- Western views and indigenous views on property ownership and
- International approaches to indigenous issues (RCGM A2).

The South Island tribe, Ngai Tahu expressed to the RCGM that the patenting of traditional knowledge was of particular concern; their submission to the RCGM stated:

> While traditional knowledge and use, including medicinal use of indigenous flora, could provide economic benefit for indigenous peoples, the fact of patenting a process, or slightly modifying an indigenous species so that it is a new organism, serves to steal these opportunities and ownership away from indigenous people (RCGM A2,2000:191).

In addition the WAI 262 submission to the RCGM summarised the problems concerning IPR as follows:

> The IPR system is concerned with private economic rights whilst those of indigenous peoples are collectively based and consider obligations to and respect for natural resources as important as the right to use those resources (RCGM H, 2000:286).

At the core of the intellectual property issue for indigenous peoples is the fundamental difference between the western ethic of private based ownership and communal basis of traditional ecological knowledge. This was outlined by Ngai Tahu in their submission to the RCGM:

> The intellectual property approach adopts the inappropriate application of the term property to traditional resources of indigenous communities. This concept of ownership and the ability to transfer ownership which are fundamentally common law notions of property and are foreign and incomprehensible to indigenous peoples such as iwi (RCGM A2:193).

The issue of IPR is a key concern for Maori and other indigenous peoples with regard to GE and biotechnology. Biotechnology companies continue to impose western intellectual property systems and

laws over Maori and other indigenous peoples in order to protect and secure profit. IPR laws undermine our traditional indigenous systems of collective ownership and knowledge protection and are being resisted by Maori in Aotearoa and other indigenous peoples internationally.

## A Maori Biotechnology Company ~ Rongoa Maori.com

How long before a Maori biotechnology company emerges. There are a handful of Maori scientists working in the area of biotechnology. Could we see the emergence of a Maori biotechnology company with a focus on rongoa Maori? What implications would this have for our collectively owned iwi/hapu/whanu/Maori knowledge with regard to rongoa?

Maori scientists engaging with or of thinking of engaging with this technology on the premise that Maori can share and reap benefits from this technology are kidding themselves. The structure of benefits maintained by the IPR system is not directed to indigenous peoples or communities, as is evident with the discussion on intellectual property rights. The WTO global order and the TRIPS system on intellectual property has created a system where trans-national corporate freedom is based on the ethic of profit and capitalism for the benefit of the corporations themselves not for the benefit of indigenous peoples.

TNC are not concerned with sharing the profits and benefits of their technologies and investments with indigenous peoples. The sector has and continues to thieve indigenous intellectual property through the patent system. There is very little incentive for the biotechnology sector direct benefits back to indigenous peoples. The benefits of biotechnology that this paper has focused on are the potential financial returns. Given the current IPR regime and the numerous cultural, ethical and environmental issues that Maori have expressed with regard to biotechnology and GM that and I believe biotechnology is an inappropriate development path for Maori and that our participation in the sector could seriously compromise Maori values and tikanga (cultural practices and ethics). Other reason why biotechnology is an inappropriate development path for Maori are listed below.

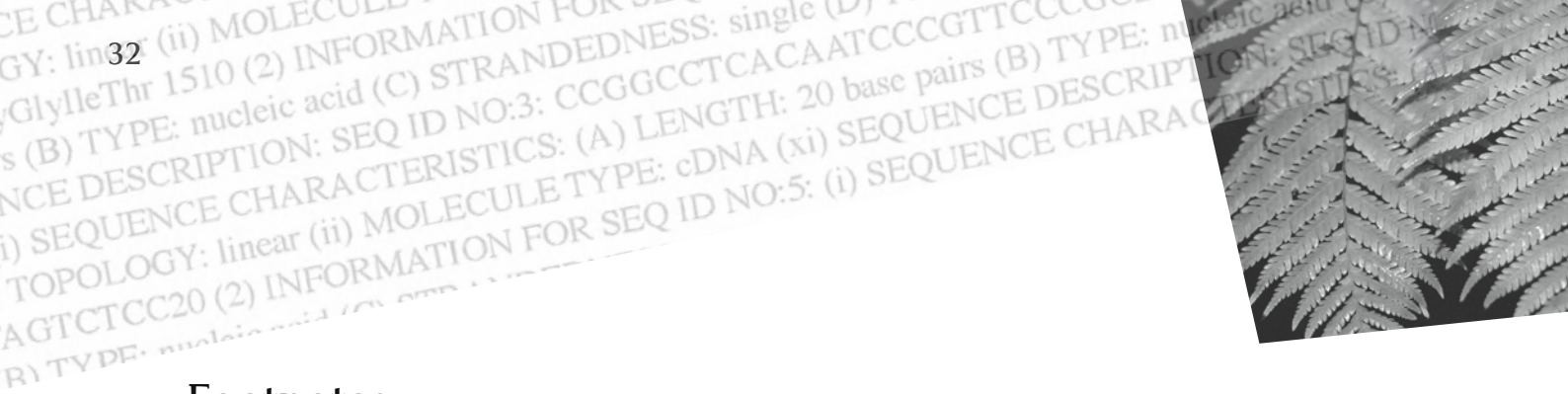
1. TNC are not concerned with sharing power and benefits with indigenous peoples from biotechnology?

    1) The current IPR does not allow for the protection of collectively owned indigenous knowledge (matauranga Maori).
    2) The patent system of profit compatible with Te Ao Maori ethics and tikanga?
    3) It is unclear how Maori will share in the benefits of biotechnology.
    4) There is no track record of the biotechnology sector sharing benefits and power with indigenous peoples.
    5) The engagement by Maori in biotechnolgoy does not have widespread support amongst Maori communities.

The promise of biotechnology to bring freedom, justice, democracy and empowerment may be producing

the opposite, centralisation rather than de-centralisation, global corporate concentration, economic globalisation and excessive commercialisation. Community rights, iwi/hapu/whanau rights are the countervailing force to IPR regimes emerging from corporate interest and have to form an intrinsic part of all IPR legislation, including patent laws, trademark laws and plant variety laws. These community iwi/hapu/whanau rights need to be the screen through which IPR regimes are evolved and IPR claims evaluated. These rights existed prior to and are more fundamental than IPRs, they must be accounted for to ensure that the knowledge and production systems on which livelihoods of our local communities remains.

In the era of biotechnology Maori, other indigenous peoples, farmers, environmentalists and communities are all claiming and protecting the value of biodiversity and nature. The interconnectedness of our ecological systems is becoming increasingly important to protect. Seeds are valued as life and not as profit, they are valued for their regenerative power and their ability to hold diversity and creativity. Traditional knowledge is held collectively and is not to be manipulated for individual or corporate profit by the biotechnology sector. It is clear that biotechnology is not an appropriate development path for Maori and that as maori and iwi, hapu and whanau we continue to protect our communities, our seeds and our cultural and intellectual property from manipulation and monopolisation from the biotechnology sector.



# Footnotes

1. Principle technologies falling with biotechnology include; gene amplification, DNA sequencing, DNA synthesis, diagnostics kits, DNA probes, protein synthesis, protein sequencing, protein crystallography, monoclonal antibodies, cell/tissue culture and engineering, purification/separation techniques, electrophoresis, transgenic plants and animals, gene therapy, gene antisense technology, biotransformation and enzyme engineering.

2. See the following writers for further literature around Maori and GM. Barr, 1999, Cram, 2000, Hutchings, 2001. 2001a, 2003, 2004, Jackson, 2001, Mead 1997, 1998, Nga Wahine Tiaki o Te Ao 2000, Reynolds 2004, RCGM V1,2,3,4.,

3. Biotech TNC include, Monsanto Aventis, Du Pont.

4. According to Vandana Shiva, maldevelopment is a form of development that assumes Western style progress equating it to Western economic categories. It is based in modern Western patriarchy's vision which is based on the exclusion of women and the exploitation and degradation of nature (Shiva, 1989:1).

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# THE POLYNESIAN 'EXCELLENCE' GENE & LIFE PATENT BOTTOM TRAWLING

Aroha Te Pareake Mead
*Ngati Awa, Ngati Porou*

***Scientific Breakthrough: Genetic clue in Polynesians to strive for excellence discovered in landmark DNA study.***

***After ten years of extensive research, Scientists in a pioneering study have discovered the Polynesian "excellence" gene. Archetypal study identifies a genetic variant or single nucleotide polymorphism (SNP) that inhibits poor or medium performance in Polynesians and impels outstanding performances in a range of actions.[1]***

## Introduction

Like many people in the Pacific of my generation, my early exposure to genetics and intellectual property assertions on life, occurred through awareness of, and activism against, the global mega-human population study *The Human Genome Diversity Project (HGDP)* and, through the US government patents on the DNA of indigenous individuals from the Hagahai tribe in Papua New Guinea and from the Solomon Islands in the early 1990's.

When news of the Hagahai and Solomons patents serviced[2], it seemed incomprehensible that a foreign government could patent DNA cells collected from Pacific indigenous people without the informed consent of the individuals, their communities or even their national governments. The Pacific patents were eventually challenged by the governments of Papua New Guinea and the Solomon Islands, but the US government rejected their concerns taking the view that the source of the DNA (and by implication the process in which they were collected) was of no consequence. According to former (and now

deceased) US Commerce Secretary Ron Brown , "*Under our (US) laws, as well as those of many countries, subject matter relating to human cells is patentable and there is no provision for considerations relating to the source of the cells that may be the subject of a patent application*"(Bereano, 1995).

These early experiences undoubtedly shaped my views and analysis of genetics and intellectual property assertions on life. Perhaps if my first exposure had been one of news about the discovery of a 'Polynesian Excellence Gene', or some other study of a culturally affirming nature, I might be more conducive to the promises and claims made by genetics and biotechnology. What if the science had been used to answer a question that plagues millions of the world's indigenous peoples - is there a 'racism gene'? and if so, can it be removed or bred out?

Far from being isolated incidences confined to the past, the same partnership between genetics and intellectual property rights that produced the Hagahai and Solomons DNA patents, continues to this day in a bottom-trawling approach[3] to the commodification and ownership of life.

Indigenous peoples of the Pacific have prominence world wide in terms of the critiquing of genetic research and intellectual property rights, and for good reason. This is because many of the world's best examples of bad practice originate from this region, for example *inter alia*; the Hagahai and Solomon Island DNA patents, the failed Autogen/Tongan gene bank and Diatranz/Cook Island trials of pig/human insulin, the Auckland's Green Lane Hospital baby organ bank (of children's organs taken without their parents consent), and New Zealand's AgResearch transgenic (human genes into sheep) project.

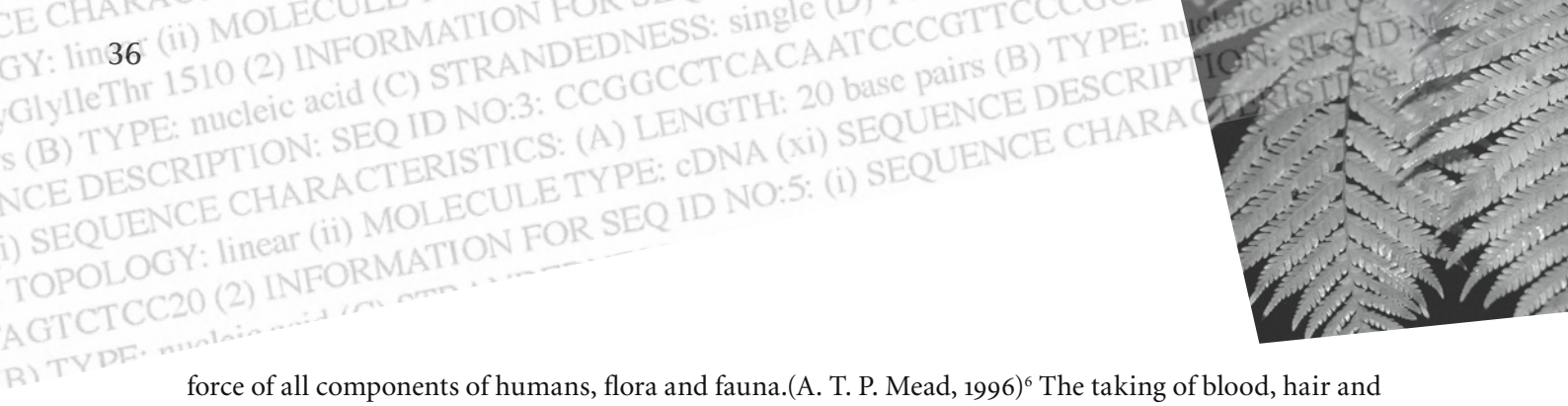
In fact, the Pacific has the dubious honour of providing to the world's policy analysts, legislators, students and researchers in ethnobotany, bio-ethics and indigenous intellectual property policy and law, some of the very best examples of unethical practice. The mistakes made in the Pacific Region, have become the flagship case studies used in bioethics, genetics and law texts all around the world.[4]

This paper takes the view that the Pacific has a greater purpose than to educate the world in bad practice in genetics and intellectual property. The direct experiences and responses of the Pacific can serve to highlight gaps and provide valuable guidance in developing best practice in national, regional and international policies and legislation, and in ethical codes of conduct for researchers.

This paper also offers the view that Pacific States do not yet take seriously enough the direct threat that life patents present to national sovereignty, sustainable development, and continued access to the traditional foods, medicines and natural resources that are so vital to cultural integrity and survival.

## 1. Biotechnology and Patents on Life-forms are Value Systems

Biotechnology is not a neutral value-free science. It is a reductionist science and technology that uses living things to make commercial products.[5] Biotechnology is a value system as it requires one to agree to locate, isolate, modify and commodify the DNA of humans, plants and animals. For most indigenous cultures, and for many others, this objective is the antithesis of their core beliefs. Central to indigenous cultures is a profound respect and understanding of sacredness and the inherent integrity of the life



force of all components of humans, flora and fauna.(A. T. P. Mead, 1996)[6] The taking of blood, hair and tissue samples is an affront to the religious beliefs, cultural values and sensitivities of many indigenous peoples..." (National Congress of American Indians, Resolution No. NV-93-118). "We believe that exclusive monopoly and control of genes and gene products will frustrate or prevent innovation and the exchange of information, and well increase the cost of medical care or health care… To allow this to happen to human genes or genetic material is much worse than being colonized."(Liloqula, 1996)

As biotechnology is mostly concerned with commercial activity, the use of patents and other intellectual property mechanisms to protect research outcomes and products, is part and parcel of the science. Patents are not a tool of humanitarian research. They are a tool of commerce and exclusive property rights and serve to give signals to others "stay away, they're mine. I own them'. (A. T. P. Mead, 1996) The dominant theory of patents is that they are essential incentives to inventors to be inventive confident that their work will be protected from commercial exploitation by unauthorised persons. Mgbeoji argues that no scholarly work of merit or repute on the issue has yet demonstrated any empirical basis for the alleged direct, causal or organic relationship between patents and inventiveness. He points out that neither the ancient Chinese, Pharaonic Egypt, nor the great Arab advances in mathematics, medicine, astronomy and other sciences owe any debts to the patent system.(Mgbeoji, 2001)

That being said, the use of Patents for man made technological inventions is not being questioned in this paper. For example, patents such as the MP-3 player 'Zen' patent (US 6,928,433), Phone answering machine (US 4,371,752), Microwave Oven (US 2,495,429) or the Mobile Cell Phone (US03906166) fulfill the Patent requirements for human invention and discovery. The problem arises when patents are applied to physical natural life forms, traditional food crops, medicines and knowledge that have existed for centuries, and when individuals are accorded legal rights as 'inventors' and owners of life forms and traditional knowledge and practices enabling them to restrict access and usage to these same resources by others and/or to charge fees.

## 2. The Promises of Biotechnology

Many promises have been made about the benefits of biotechnology and human population genetics such as eradication of poverty, curing of diseases, increasing food production and crop productivity, but very few, if any, of these so-called 'benefits' have eventuated as positive contributions in the lives and livelihoods of Pacific indigenous communities.

The pioneers of genetics have not sought to highlight the advantages of cultural diversity or the particular strengths of various cultures, or make bold assertions such as the genetic predisposition of Polynesians to strive for excellence, or to do well in specific fields and health conditions. But, there have been continued pronouncements of research citing Polynesian genetic predispositions to a range of negative socio-economic conditions ranging from alcoholism, obesity, smoking, drug abuse, diabetes to under-achievement at schools and high rates of teenage pregnancies. Even when something looks like it might be positive, such as research on a presupposed Maori "Warrior gene", named so because 'historically Maori were extremely adventurous risk takers and fearsome warriors'(Rod Lea, 2006), it transpires that the motive for the research is not to focus on risk-taking and achievement, but rather to make a

connection in terms of" "*understanding the evolution of the MAO gene will also be useful for studies of human* ***behavioural disorders*** *such as alcohol and tobacco dependence.*"(Rod Lea, 2006).

The fundamental issues facing the Pacific Region are not going to be solved through biotechnology. Climate change, waste management, regional security, over-fishing through illegal fishing and bottom-trawling, continue to threaten the Region's resources. The Pacific has the highest number of endemic birds at risk of extinction than any other region in the world. These threats are well recognised in regional plans, including the South Pacific Forum's blueprint 'The Pacific Plan.' What is not included in the consciousness of Pacific planners is the actual threat to Pacific resources and well-being posed by the continued misappropriation of Pacific cultural and natural heritage through life patents.

## 3. Life Patent Bottom Trawling

Life patents are increasing at a phenomenal rate. I use the term '***Life Patent bottom-trawling***' to describe the large scale biopropsecting[7] and patent assertions on life-forms that is occurring in a hit-and-miss approach to harvesting genetic resources by simply gathering and taking ownership over almost everything in a researcher's path whether or not they have certainty of the future value of the genetic materials or not.

For instance, in 1999 Celera Genomics Group through its President Craig Venter, filed preliminary patents on 6,5000 whole or partial genes in spite of making a promise at hearings before the US Congress that Celera would not seek to patent more than 100 to 300 genes. A commentator noted that Celera was one of several companies competing to map or sequence the human genome, and while many are doing it painstakingly, Celera was using a "shot-gun" approach, sequencing random bits of genes in the belief they will all fit together when they are done. (Lovgren, 2005)

There are a growing number of other terms used in the discourse of biotechnology and patents to describe the greedier seedier side of the industry, for instance *biopiracy*, which refers to the appropriation, generally by means of patents, of indigenous biomedical knowledge by foreign entities (including corporations, universities and governments) without compensatory payment.[8]

Patent lawyers have coined the term *patent trolls* to describe companies that register or buy patents but have no plans to make any product based on the patent. Opponents say their sole purpose is to collect money from companies that have developed a technology, process or design covered under the patent and are successfully selling products or may do so.(Wisconsin State Journal, 2006)

All three terms describe quite specific actions, but each indicates a level of greed and wastefulness as well as the highly speculative nature of life patents. This is not hard, well-established, well-researched public good humanitarian science. This is about greed and power using the genetic resources of life for the commercial benefit of a very few.

In 1995 the 'Treaty for a Life-Forms Patent Free Pacific' was drafted as a regional attempt to carve out Pacific resources, human and physical, tangible and intangible, from the insatiable world of life patents.

*"Treaty for a Life-Forms Patent-Free Pacific and Related Protocols", 1995*

"Believing in the sanctity and integrity of life even in its smallest form;
Aware that prospecting for biological materials is occurring throughout the Pacific;
Aware that collection and research into human genetic materials of Pacific indigenous peoples is occurring;

Aware also that patents are being granted on living organisms including microbial, plant, animal and human genetic material;

Gravely concerned that these activities are occurring in a policy vacuum and without the full knowledge or consent of those affected;

Affronted by the use of intellectual property rights systems and western science and technology to control and exploit the lands, territories, resources and integrity of indigenous peoples;

Concerned that the heritage of future descendants will be diminished through the commercialization of the biological resources of the Pacific;

Article 3 - Principles[9]
(n) The conversion of life forms, their molecules or parts, into corporate property through patent monopolies is counter-productive to the interests of the peoples of the Pacific
(q) All forms of the heritage of the indigenous peoples of the Pacific, that has been or will be taken without their full and informed consent, should be returned or joint mechanisms established to ensure the equitable sharing of any benefits.

Since the 1995 Life-Forms Patent Free Treaty, the frequency of life patents and Pacific-focussed genetic research has actually intensified. Life patents have become part of the currency of the Pacific, not as the owners or primary beneficiaries of patents, but as the source countries of origin of the genetic resources (flora, fauna, and human) accessed, used and developed by others.

A recent Ernst & Young Report claims that the Asia-Pacific region has the highest growth rate in the world with a ''scorching 46% increase in revenues and significant programmes".(Ernst & Young, 2006) But according to a 2005 report prepared for the Pacific Islands Forum Secretariat, very few patents are actually issued in Pacific Island countries, and of the few that are, the majority are from overseas applicants. In at least three countries (Samoa, Tonga and PNG) the screening of Patent applications isn't undertaken within the country, rather, applications are outsourced to the Australian Intellectual Property Office. The ultimate decision about what is being patented and by whom, isn't being made by Pacific countries.

*Table One: Annual Pacific Intellectual Property Application Activity (Farquhar, 2005)*[10]

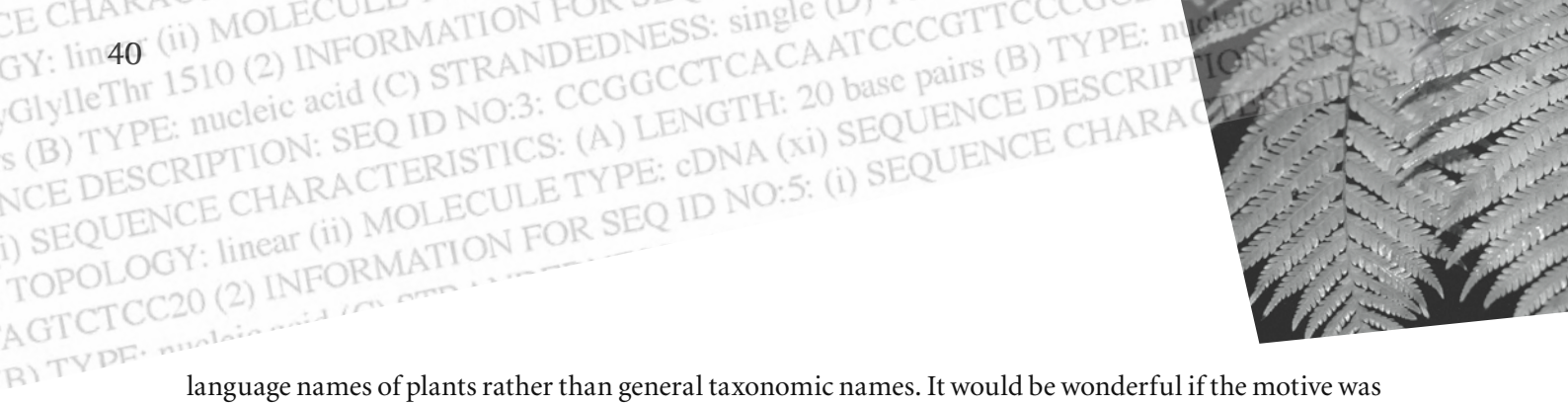
| Country | Trademarks | Patents | Industrial Designs |
|---|---|---|---|
| Fiji Islands | 600 | 2 | - |
| Samoa | 150 | 5 | - |
| Tonga | 60 | 5 | - |
| Papua New Guinea | 800 | 6* | 5 |
| **Total** | **1610** | **18** | **5** |

Farquhar's report highlights the low number of Patents registered through Pacific national laws. A search through the US Patent Office database shows a very different picture. Bearing in mind the inherent difficulties in searching a patent data base and interpreting the results[11], nevertheless one can conclude that more Patent activity involving Pacific countries and resources is occurring outside the region, than inside the Region.

*Table Two: US Patent Data Search using fields 'DNA' and Pacific identifiers (Mead, 2006)*

| Search Fields: Country/ Island/Grouping & DNA[12] | Number of Patents |
|---|---|
| Easter Island | 3 |
| Fiji | 51 |
| Hawaii | 376 |
| Nauru | 17 |
| New Caledonia | 5 |
| Papua New Guinea | 45 |
| Rarotonga (Cooks) | 4 |
| Solomon Islands | 4 |
| Tonga | 22 |
| Micronesia | 2 |
| Melanesia | 4 |
| Polynesia | 8 |

I suspect that in the future, keeping track of patents will become increasingly difficult as patent applicants become more sophisticated in their descriptions of invention and source. Already, a country/ patent analysis can be unreliable as there are many ways in which an applicant can identify their patent components. For example, in the above chart, four patents were identified for Rarotonga and yet a search under Cook Islands did not reveal any entries. Applicants have also started using indigenous



language names of plants rather than general taxonomic names. It would be wonderful if the motive was one of supporting Pacific linguistic diversity, but the more probable reason is to disguise the origin of resources. This trend is likely to intensify and is something that requires attention at the policy level.

## 4. The Owners of Life

The grabbing of genetic resources and life patents is widespread and not limited to one particular sector. Pharmaceutical and agricultural seed companies lead patent bottom-trawling, as one would expect, but patents are also fast becoming an expected standard of achievement not only in the commercial sector but also in universities and at an individual researcher's level. The lines between government funded 'public' research and private commercial enterprise are becoming more and more clouded as government research institutions join the spectrum of life patent holders.

Universities in fact compete amongst each other for ranking on the basis of the highest number of patents. In 2001, U.S Universities were granted more than 3000 patents. "University of Wisconsin-Madison with 77 patents in 2005 moved up three notches in the rankings of universities or university systems with the most intellectual property activity. In 2004 - UW-M ranked 8th with 64 patents."[13] New Zealand's Auckland University's UniServices recently announced it held 180 technology patents, and The University of Melbourne hailed its patent performance, "Melbourne leads Australian universities in patents. (Press Release, 2000)

But by far, the leaders of patent bottom-trawling are the pharmaceutical and agricultural companies. In these sectors, patent activity is significant but limited to a very small number of multi-national companies who are systematically using patents as a means to control the world's food supply and to force small farmers into a cycle of dependency of products from these same companies. Recent research has shown that three quarters of patents on plant genes are held by the private sector, and almost half of the 601 patents on plant DNA were filed by just 14 multinational companies.

- Five companies control 90% of the world's grain trade (Action Aid 2006)
- Three companies control 85% of the world's tea market (Action Aid 2006)
- Two companies handle 50% of the world's trade in bananas (Action Aid (2006)
- Five companies (AstraZeneca, DuPont, Monsanto, Novartis and Aventis) account for 60% of the global pesticide market, 23% of the commercial seed market and virtually 100% of the transgenic seed market.

## 5. What is being Patented?

Everything you can possibly think of, and more, is being patented. Biotech firms say that if they couldn't patent genes it wouldn't be worth their while developing lifesaving drugs and therapies. The market for Gene sequences is estimated to be worth $767 billion. The following list is not exhaustive but has been developed to provide an indicative 'snapshot' of recent patent activity.

*A. Patents based on harvesting and using essential human life elements*

- **Human genes**
  In a study reported in the journal Science more than 4,000 genes, or 20 percent (1/5th) of the almost 24,000 human genes, had been claimed in U.S. patents. About 63 percent were assigned to private firms and 28 percent assigned to universities. (Lovgren, 2005) In the late 19080's Dr Malcolm Simmon patented 95% of the DNA of most living creatures. Refered to as 'junk DNA' the patent is now owned by Australian firm Genetic Technologies, and is being legally enforced worldwide. The Executive chairman of Genetic Technologies said his company was building a database that now had 2000 names of groups believed to be infringing the patent. About $5 million had been charged in licence fees in the past 12 months.(Noble, 2003)
- **Human placenta**, International Patent WO 00/49892 A3, Dietetic supplement from human placenta, US 4,696,813 whitening skin cosmetic containing human placenta.
- **Human urine (and placenta)**, the process for purification of proteins from medically terminated pregnancy (placental tissue) and urine has been filed for patent (Anand K. Kondapi)
- **Human breast milk**, Presently, there are about 635 patents in the US Patent Office that involve human milk.(Valerie W. McClain, 2004)
- **Human organs**, there is a wide range of patents on human organs ranging from parts of the brain, heart, kidneys, lungs, mammary glands, salivary glands, skeletal muscle, spleen, stomach and uterus. Companies who patent organs do so in order to gain income from researchers who pay fees to access cloned organs for their own research.

The number of patents on human life elements is considerable. Indigenous Pacific peoples are active contributors to this whether they realise it or not. It is too early to draw a conclusive assessment about the inter-relationship between Pacific indigenous DNA that is gathered for medical research reasons and patents, but I suspect the link is well entrenched.

*Refer to Annex I for a 'product list' from one company of cloned human organs available for purchase through the internet for research purposes.*

*B. Patents on traditional crops used by Pacific peoples*

- **Canarium Nut Oil, C. *indicum***, US6,395,313,28 with a statement of intent to pursue the patent in a total of 127 countries. The patent identifies three source Pacific countries, Vanuatu (nangai), PNG (galip) and the Solomon Islands (ngali).(McGowan, 2003)
- **Cassava, *maninot esculenta***, The two cassava patents cover a natural disease resistance gene and a gene which affects the type of starch produced.
- **Coconut**, US6,699,847, Anti-parasitic formulation includes fractionated coconut oil 20-75%. Calgene has been granted a US patent for the thioesterase gene, which covers the expression of the gene in rapeseed and other annual oilseed crops, including coconut oil.
  A Solomon Islands company is also "vigorously pursing to patent the copra bio-fuel as a diesel fuel substitute to be widely used in the Pacific region. (Pacific Islands Energy Policy and Strategic Action Planning, 2005)
- **Kava, *piper methysticum***, Kava patents include; US2,495,429 Kavalactone product, US6,312,736

herbal composition to relive pain, US5,976,550 dietary food supplement, US20030099756 Method of producing a processed kava, EP1284745 Use of kava extracts for alcohol dependence

- **Mamala**, ***Homolanthus acuminatus***, EP531413, US5,599,839, WO9118595 claims ownership of the prostratin compound found in the mamala belongs to the US Department of Health & Human Services, US Army and Brigham Young University
- **Papaya**, ***Carica papaya***, Greenpeace International lists eleven Papaya patents and reports that the Hawaii Papaya Industry Association (HPIA) having offered free GE Papaya seeds to encourage farmers to move away from organic to GE crops has now instigated charges for transgenic papaya seeds.(Greenpeace International, 2003)
- **Rapa Nui soil extracts**, US5,322,722, 5,093,338 and 5,091,381
- **Sandalwood**, according to Marinova the US Patent office issued 1371 sandalwood patents 1976-2005 (Marinova, 2005)
- **Tamanu Oil**, there are several patented products using tamanu oil, and many more tamanu products at patent application stage (Wellnes Directory of Minnesota, 2005)
- **Taro, *Colocasia esculenta***, US Patents PP12,342, PP12,361 and PP12,772 for Hawaiian varieties of Taro were recently abandoned after strenuous protests from native Hawaiians, but other taro patens remain.

In an astonishing press release, Melbourne biotechnology company Dia-B Tech Chief Executive, Ken Smith, boasted that it had located a natural alternative to insulin in the bark of plant found in Tonga, but would not disclose the name of the vine until the company had a provisional patent over its use. Smith candidly revealed "But what I can tell you is that plant has been used by traditional healers in Tonga to heal Type Two Diabetes and obesity over hundreds of years." (McLean, 2006) This statement demonstrates that as recently as June 2006, researchers and companies are still largely ignorant of the high level international agreements and discussions about misappropriation of traditional knowledge and resources.

### *C. Patents on marine resources*

- **Beche-de-Mer (Sea cucumber)**, US Patents 5,047,957, 5,492,938 and 4,599,152
- **Coral** US Patent 6,808,650, water improver of coral algae, shell and ascorbate salt, US Patent 4,463,031 and 4,540,584, coral calcium, EP04102643 coral propagation techniques
- **Marine algae**, US5,091,368, Biologically active compounds from blue-green algae. Also patented in France, Germany, Great Britain, Italy, Spain, Switzerland
- **Marine sponges**, US4,302,470, anti-tumour agent derived from sponges
- **Seaweed**, red collected from four sites in Fiji (Georgia Tech has filed a provisional patent to protect the discovery of structures and small variations within the seaweed varieties.
- **Seaweed**, brown US,2543,220 for pure brown seaweed extract.

There are also patents on aquaculture and growing marine fish in freshwater (US6,854,422). Pacific countries are prime targets for approaches from bioprospecting companies interested in exploration and ultimately extraction of undersea minerals, and other substances, within their respective Exclusive Economic Zones. London-based Neptune Minerals Group has been granted two licences to explore up to 10,000 square miles of submerged 'lands' in New Zealand. Neptune has also applied to undertake

a similar exploration in the Northern Marianas. If the agreement proceeds it is estimated that the revenue payable to the CNMI would only be $14,000 a year for an exploration area of 8,000 square miles. (Cumming, 2005) The NZ annual rental is of a similar low value, $2.25 per square mile. In the classic economic analysis of 'provision of raw resources' and 'added value", such agreements are not going to generate substantial income in the country of origin. "If Neptune strikes gold in the form of economically viable concentrations of minerals it could fetch between US$400 and $1000 a tonne and Government would only receive a 1% royalty.[14]

### *D. Patents on many of the world's primary food resources*

There are almost one thousand patents on rice, wheat, maize, soybean and sorghum--the five staple crops that constitute 70% of the world's food supply. Six major agrochemical corporations--Aventis, Dow, DuPont, Mitsui, Monsanto and Syngenta--own 30% of the global seed market and 98% of the global market for genetically engineered crops. By modifying genes of plants or cross-breeding varieties and "allowing patents on plants that are clearly not 'inventions,' the current patent system is giving agrochemical corporations unprecedented control over the food chain," ActionAid commented. (PANNA, 2002)

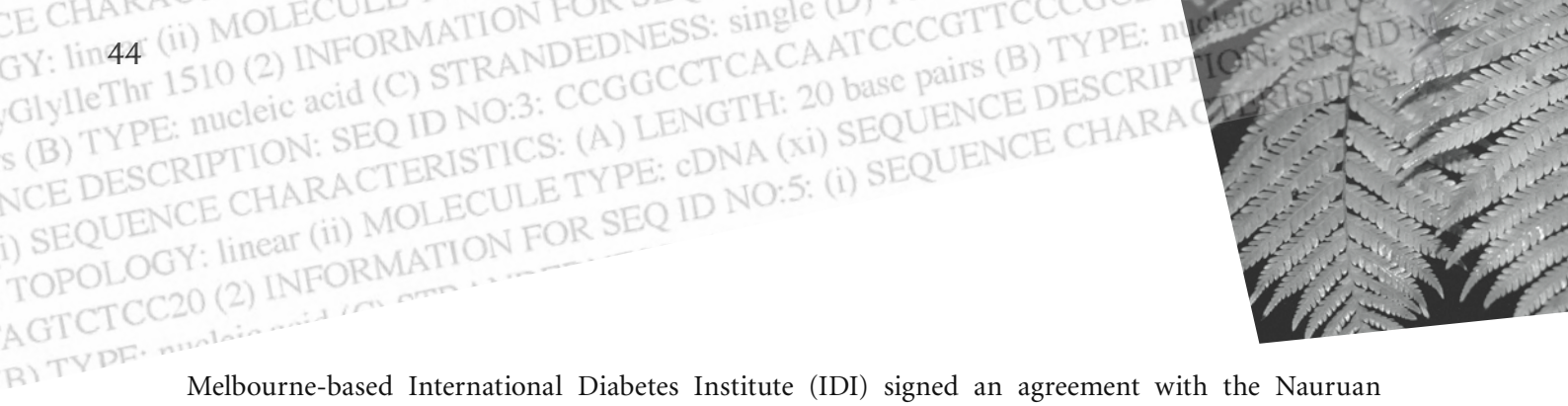
Devinder Sharma cites an article in The Guardian indicating 152 patents have been applied on rice. Sharma also writes that there are 25 patents on pineapple, 25 on raspberries, 21 on grapes, 6 on kiwifruit, 11 on oranges, 9 on apples, 8 on pawpaw, four an strawberries and cherries, two on grapefruit, one each on tamarind and peach. (Sharma, 2005)

The European Patent Office granted a patent to Calgene (bought by Monsanto) includes fruits such as tomatoes, grapes, blueberry, cranberry, currant, eggplant, cherry, plum, apricot, peach, nectarine, avocado, raspberry, blackberry, oranges and citrus, peas, green beans and soybeans.

### *E. Patents on specific health conditions*

Health condition patents have been asserted on a wide range of conditions[15] under the premise that once a genetic pre-disposition to a condition is established, an 'inventor' can then develop a commercial product to test the predisposition of others. For many conditions this is still theoretical and has yet to stand the generational test of time. The patents themselves are just one component of the research that has taken place in order to reach that level of property assertion by the researcher. Health condition patents require a sizeable database of population samples.

In 2002 Autogen, the same company that attempted to gain exclusive access to the Tongan gene pool, was granted an Australian patent (742,651) for the "obesity" gene. Prof. Greg Collier, CEO of Autogen (now renamed ChemGenex Pharmaceuticals) indicated that patent applications had been filed for over 40 diabetes and obesity related genes.



Melbourne-based International Diabetes Institute (IDI) signed an agreement with the Nauruan government in 1997 for a 10-year diabetes genetic screening programme. The stated interest of the IDI is to identify genes for a predisposition to Type 2 diabetes. Under the terms of the agreement, Nauru is to receive a 50/50 share in any profits resulting from the research. This is where the issue of derivatives takes on primary importance (refer Section 7 of this paper).

ChemGenex (Autogen) and IDI have more in common than both being Australian biotech companies. Paul Zimmet is a Board Member of both organisations and has been collecting Pacific Island genetic samples from 12 different islands including, Cook Islands Fiji, Kiribati, Nauru, New Caledonia, Papua New Guinea, and Samoa for over 30 years. The Pacific samples were licensed to Autogen. Zimmet was instrumental in the IDI Nauru agreement. Together with the other samples that Autogen collected independently, there are now over 47,000 in the database at their Toorak facility (Bioshares, 2002) The unique databases of population samples are a valuable commercial asset and their contribution to the company's share values are reported on quarterly.

Like the words of the Disneyworld song classic 'It's a small world after all', the inter-connections between those carrying out health condition genetic-based research in the Pacific are well entrenched.

## 6. The zealot promotion of Biotechnology

The biotechnology sector is in some ways its own worst enemy. Biotechnology and intellectual property proponents take on the qualities of neo-liberal zealots, boasting about the speculative nature of the industry, inciting competition to such a degree that scientists claim to have "discovered' new techniques when in fact they have fabricated results or compromised research ethics in the rush to be acknowledged as 'the first",[16] asserting discovery and ownership claims over food crops and indigenous land and marine management techniques and resources when they've been part of the cultural expression and heritage of peoples for hundred or thousands of years, and dismissing those who critique their activities as being uninformed, ignorant and anti-development.

The Australian APEC Study Centre at Monash University for instance, claims "there are virtually no cases of biopiracy" (which they define as forcible and illegal removal of property) and argues that if foreign transfer of genetic resources is 'biopiracy' so is international trade.(The Australian APEC Study Centre, 2006) To ignore the role of biotechnology in commodifying and systematically privatising and owning through intellectual property rights the world's food supplies, flora and fauna, and human DNA is indefensible.

Seed company Monsanto's Director of Corporate Communications was quoted in Time Magazine as saying "Monsanto should not have to vouchsafe the safety of biotech food. Our interest is in selling as much of it as possible. Assuring it's safety is the FDA's job.' (Time Magazine, 1998)

*Genetic Use Restricted Technology: Terminator Seeds*

The product that most blatantly shows the raw hard commercial edge to biotechnology, is genetic use restricted technology, more commonly known as "terminator seeds".

Terminator technology is the genetic modification of plants to make them produce sterile seeds. It is being developed my multinational agribusiness companies to prevent farmers from saving seeds to replant from one harvest to the next. If farmers have no choice but to buy new seeds every year, the companies are guaranteed large profits. (UK Working Group on Terminator Technology, 2006) Terminator seeds threaten biological diversity, erode traditional food and medicinal crop and knowledge, force farmers into a cycle of dependency and further marginalise Pacific women's knowledge in those societies where women are the main food crop growers.

There already exists a numbers of patents utilising terminator technology , e.g. M.J. Oliver et al., "Control of plant gene expression," US Patent Number 5,723,765, March 3, 1998 [now owned by Monsanto]. Syngenta, Dupont and BASF also have terminator patents.

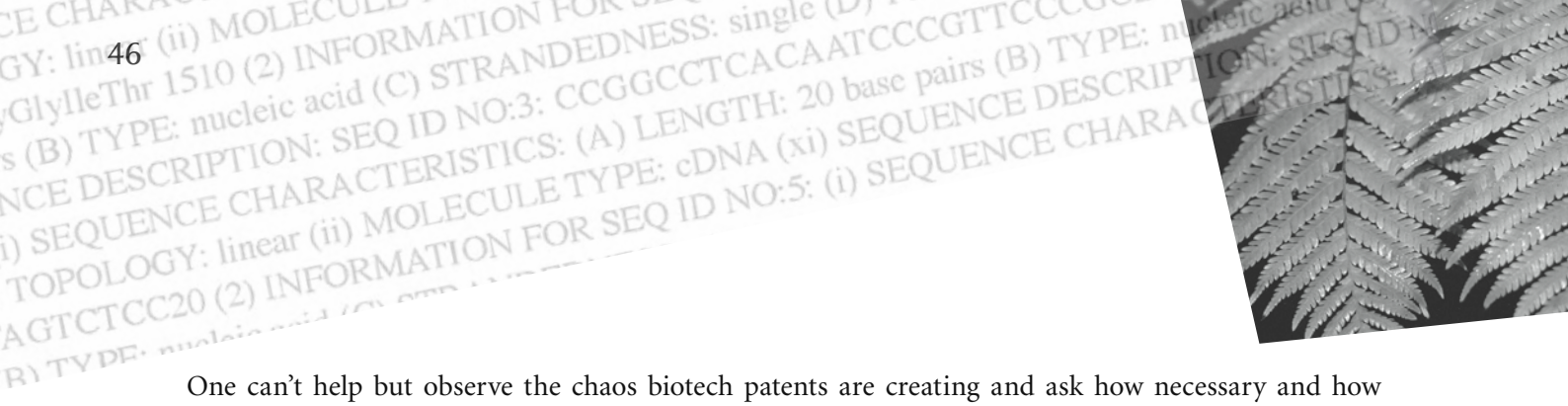
In 2000, The Convention on Biological Diversity placed a de-facto moratorium on this technology due to the speculative and high-risk nature of the technology. At the 8th CBD Conference of the Parties held in Curitiba, Brazil, US, Canada, together with Australia and New Zealand failed in their attempts to have the moratorium lifted. Civil society celebrated the decision, on behalf of the 1.4 million people world-wide who depend on saved seeds. According to Fransisca Rodriguez of Via Campesena, a world wide network of subsistence farmers, "Terminator seeds are a weapon of mass destruction and an assault on our food sovereignty."

The position Pacific Islands states have on Terminator technology is relatively unknown, as few Pacific countries articulate positions in relevant CBD discussions.

According to Ravicher executive director of the Public Patent Foundation, the patent system is "absolutely failing". There is a point where you can benefit patentees and it actually harms the public. ... We are past that point."

In a recent US Supreme Court decision *Laboratory Corp. of America Holdings v. Metabolite Laboratories*, Inc., Justice Breyer wrote that sometimes patents can discourage research because they impede the free exchange of information, they may force doctors to spend unnecessary time and energy to enter into license agreements; divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations and in so doing raise the cost of healthcare. (Breyer Judge, 2006)

If there are failings in the patent system causing harm to the public – the system is also failing companies. The US Patent Office is overwhelmed by biotech applications "USPTO Biotech Backlog: Bad, Getting Worse, NoEnd in Sight". (Young, 2006)



One can't help but observe the chaos biotech patents are creating and ask how necessary and how sustainable is this practice? Should some forms of research, e.g. public health, traditional knowledge, publicly funded and food security research be exempt from patents?

## 7. Indigenous Critiques of Biotechnology & Life Patents

Indigenous criticism of biotechnology and life patents has long been characterised as 'uninformed' and anti-development. It was this way 15-20 years ago and is still typecast as such today.

Pacific, and other indigenous critiques of the Hagahai and Solomon Island patents centered on five themes. Life patents were; (1) unethical; (2) contravened deeply valued cultural beliefs about the sanctity of life; (3) breached human rights standards, including prior informed consent; (4) encroached on local community and national sovereignty over cultural heritage; and, (5) typified bad practice in science and law

At the time indigenous analysis was ridiculed as being; primitive-like superstition; anti-development and anti-science; ignorant of the complexities of the science and patent law; naïve to the promises of biotechnology; and disrespectful of intellectual property as a purported essential mechanism to achieve all of the aforementioned. Indigenous concerns weren't misplaced then, are still are not now. They stem from direct responses to actual situations of bad practice and gross abuses of trust by external scientific and medical researchers and governments.

Over the years, indigenous critiques have become more technical and detailed but still encompass these core themes. Ironically, each and every one of the indigenous critical themes has since become the focus of intensive international, regional and national standard-setting initiatives, spawning new policies, legislation, institutions, disciplines and treaties in cultural rights, bioethics, scientific and corporate responsibility, rights-based approaches to research and resources, derivatives, and the application of the principle of informed consent.[17]

For instance, Henry Greely, a member of the Ethics Committee of the Human Genome Project, and legal advisor to Carol Jenkins in the later stages of the controversy over the Hagahai PNG-1 patent, attempted to ridicule opponents by dismissing their concerns as being 'technically naive', "*activists failed to grasp the simple distinction between a cell line and the materials from which it was derived.*" *(Pottage, 1998)*

Acknowledgement of the source materials from which derivatives originate, requires researchers and governments to be reminded of the human rights, food sovereignty and territorial integrity of donor communities. Such acknowledgement is a cornerstone of the numerous ethics statements and policies that have been developed over the past sixty years, dating back to The Nuremberg Code of 1949 and the 1964 Declaration of Helsinki, from where the principle of 'informed consent' was first established as an essential standard in medical research. Acknowledgement of 'source' requires a discussion, a negotiation and informed consent between a research and the 'donor(s)'. Those who argue that derivatives are synthetic do so because in their minds, it removes the human and ethical considerations from their research.

The UK Report on the Ethics of Genetic Modification and Food Use concluded that "because a number of steps had been taken in vitro to purify and replicate the donor gene, for all practical purposes, the inserted material is not human, in the sense that it contains DNA derived directly from a human donor.[18]

The question of derivatives is also now one of the most contentious issues in the negotiations for the elements to be included in a new international mechanism to regulate the access, utilisation and sharing of benefits of genetic resources and associated traditional knowledge under the Convention on Biological Diversity. Developing countries insist that derivatives (such as extracts of genetic resources or chemical compounds derived from such resources) should be included, but this is opposed by many developed countries.

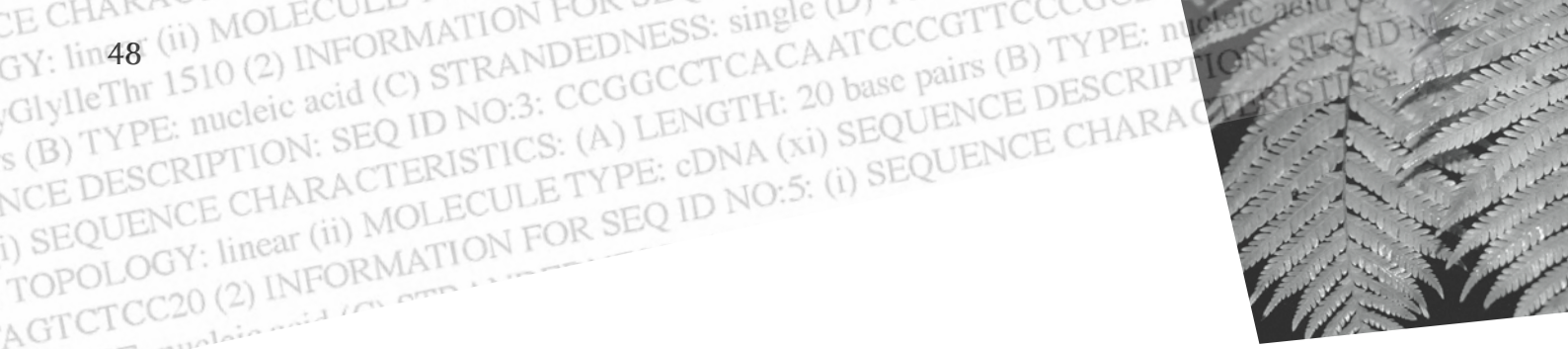
The Mataatua Declaration on the Cultural and Intellectual Property Rights of Indigenous Peoples makes clear that indigenous peoples are willing to share their knowledge with humanity provided their fundamental rights to define and control their knowledge is respected.(Mataatua Declaration, 1993) Indigenous peoples are not anti-science or anti-development, but they do want the integrity of life and cultural knowledge to be respected.

## 8. The research behind a patent - how many others are involved?

Research doesn't appear out of a vacuum of nothingness. It emerges from an idea and goes through several manifestations before a researcher ever sets foot in a community and/or before a 'subject'. There is good research that empowers communities and there is bad research that takes more than what is received and causes offence, harm and distress to those being researched. Pacific cultures have protocols and intrinsic understandings of what is good practice and in the same token, what is 'bad practice'. Greater understanding of the key values and principles behind custom and customary law[19] can offer guidance to future generations in issues as complex as the commodfication and ownership of life, and/or as detailed and practical as assessing research proposals and outcomes.

Before anything can be patented, a considerable body of research has already taken place. Even the most rigorous patent application processes can't prevent inappropriate research or regulate ethical conduct between a researcher and those they research.

People need to understand the nature of research. Indigenous individuals, families, communities, tribes need to acquire a greater capacity to critically assess research proposals that seek their consent to access and utilise genetic resources (human, flora, fauna, marine, microbial) as well as to be able to negotiate benefit-sharing agreements, when appropriate. Governments and policy makers need to better understand the nature of research because they are developing policies and laws, and contributing to international standard-setting negotiations (such as those underway through the WIPO, CBD and the WTO) in ignorance about research standards. Researchers also need to be reminded of the existing and emerging codes of conduct expected of them – ethics being one code of many, but perhaps it is the code that is most misunderstood and abused. Patent owners and those aspiring to be patent owners need to know that they also have a duty to observe codes and protocols.



US patent 5,369,867 involved the cell line of one specific Hagahai man, but the research behind the patent required a much larger 'donor community' before the precise properties of the patent could be isolated. Consider these three examples of genetic population research conducted on Pacific donors, as described by the researchers.

Example One – PNG:

> A serologic survey for human T lymphotropic virus type I (HTLV-I) infection was conducted on nearly half of the entire 260-member Hagahai population, a hunter-horticulturist group occupying the northern banks of the Yuat River Gorge in Madang Province of Papua New Guinea. For comparison, sera from two neighboring groups, the Pinai and Haruai, were tested. (exact number of those tested from the Pinai and Haruai wasn't revealed)
> (J. C. Yanagihara R, Alexander SS, Mora CA, Garruto RM., 1990)

Example Two – Solomons:

> To ascertain the prevalence of human T-lymphotropic virus type I (HTLV-I) infection and the occurrence of diseases caused by HTLV-I in the Solomon Islands, we tested 1141 sera from 851 patients (317 females and 534 males), who were hospitalized at the Central Hospital in Honiara between Feb. 1984 and Nov. 1988, for antibodies to HTLV-I using an enzyme-linked immunosorbent assay
> *(ELISA).(A. A. Yanagihara R, Garruto RM, Sharlow ER, Wu XY, Alemaena O, Sale H, Alexander SS, Gajudusek DC., 1991)*

Example Three – Vanuatu:

> In February 2002, we recruited 391 women during a clinical survey for sexually transmitted diseases in various remote rural communities of western Ambae Island in the Penama Province of the Vanuatu Archipelago The women participating in this survey were offered a complete clinical examination, with Papanicolaou test analysis for all women >25 years of age.
> *(A Gessian)*

All three examples eventuated into patents. Example one highlights that a minimum of 130 people were sampled. The exact number is more likely to be over 200 people. Example two required 851 'donors', and Example three involved 391 had donated their samples for a sexually-transmitted disease study and had these samples used for research that was additional to and went beyond the initial study they had consented to. Such significant numbers of 'donors' should not be invisible or under the radar of policy and legislation. Their rights to be fully informed about the implications of the research, and where applicable, to benefit from the research should be accommodated.

In my 2006 paper 'It All Begins With The Research', I provide a detailed critical analysis of the research methodology applied to the PNG research that resulted in the Hagahai patent. I also advocate for Pro-Pacific Indigenous research which I describe as "research that has at its core, the best interests of Pacific indigenous individuals, their families, communities, resources and cultural heritage respectful of and consistent with custom and customary law that is correct and genuine. Best interest is guided by a balance between any immediate research problem or question and the long term well-being of Pacific indigenous individuals, their families, communities, resources and cultural heritage. Correct and

genuine means that the custom being cited is not a false construct redefined through a post-colonization or religious reinterpretation. Correct and genuine also refers to customs that might have been practiced in the past but do not meet today's standards of best interest and well being, particularly in relation to women and children.

Dr. Hirini Mead from whom I have borrowed the prescription of 'correct' or tika, and 'genuine' or pono, writes that "processes, procedures and consultation need to be correct so that in the end everyone who is connected with the research project is enriched, empowered, enlightened and glad to have been part of it.(H. M. Mead, 2003) Mead makes no distinctions about who experiences these effects but infers that if research is tika then everyone – participants, their whanau (families), the researchers, the community – will be left in a better place because of the research project. *(Pipi, 2003)*

Customary protocols such as tika and pono take on particular relevance for communities being asked to consent to research or to patents when they may not fully understand the implications of their consent. This is particularly so when communities are told by researchers that research is being carried out for humanitarian purposes without explaining at the same time the corresponding commercial drivers inherent in any research outcome. Assessing research on the basis of customary laws and practices can provide practical guidance in sorting out that which is correct and genuine from that which is not.

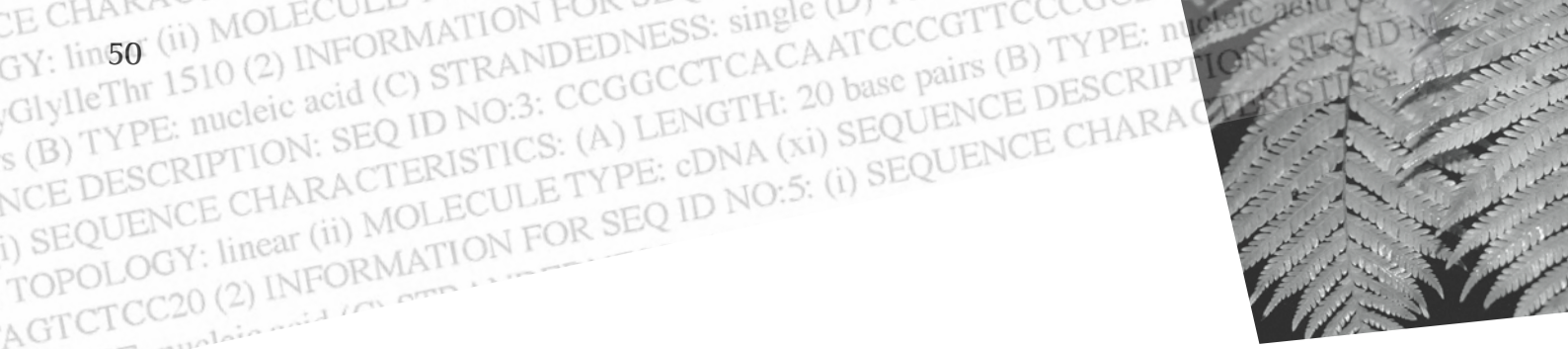
When undertaking research, either across cultures or within a minority culture, it is critical that researchers recognize the power dynamic which is embedded in the relationship with their subjects. (Linda Tuhiwai Smith, 1999)

## 9. Pacific Responses to the Commodification & Ownership of Life

There has been a consistent record of responses to life patent issues from Pacific communities and NGOs over the past 15 years. Pacific governments, including Australia and New Zealand have been less forthcoming in regulating inappropriate intellectual property assertions, and in taking action against 'at risk' genetic research proposals, in spite of the scale of the situation and the many innovative responses that hail from the Pacific region. Some proposals have found currency at a Regional level amongst Pacific countries, but progress in implementing news laws and policies has been slow.

Some of the Pacific responses include:

- Mataatua Declaration on the Cultural and Intellectual Property Issues of Indigenous Peoples (Aotearoa, June, 1993)
- The Julayinbul Statement on Indigenous Intellectual Property Rights (Australia, November, 1993)
- Final Statement from the PCRC/UNDP Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights (Fiji, 1995)
- Treaty for a Life-Forms Patent Free Pacific, and Associated Protocols (Fiji, 1995)
- Statement from the Inaugural Indigenous Peoples of the Pacific Workshop on the United Nations Draft Declaration on the Rights of the Indigenous Peoples (Fiji, September, 1996)
- Model Law on Traditional Biological Knowledge, Innovations and Practices (Forum Secretariat, 2000)



- Final Statement of the Bioethics Consultation in the Pacific (Tonga, 2001)
- Resolutions of the 7th Conference on Nature Conservation in the Pacific Islands Region (Rarotonga, 2002)
- The Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture (Secretariat of the Pacific Community, 2002)
- Paoakalani Declaration (Hawaii, 2003)
- Recommendations of the 1st Pacific Consultation on the UN Permanent Forum on Indigenous Issues (Fiji, 2004)
- Submissions from Pacific Concerns Resource Centre and Call of the Earth Llamado de la Tierra, on the Pacific (2004 and 2005)

The 1993 Mataatua Declaration stated that indigenous peoples are the guardians of their customary knowledge and have the right to protect and control dissemination of that knowledge. The 2001 Statement of Bioethics Statement from Tonga listed eighteen principles including; (m) the conversion of life-forms, their molecules or parts, into corporate property through patent monopolies is counter-productive to the interests of the Pacific, and ,(r)confirm our stand against the unauthorized collection and commercialisation of genetic resources from the Pacific. The 2003 Paoakalani Declaration notes that 'Although biological and genetic samples have been transferred, sold, patented or licensed, Kanaka Maoli never relinquished our rights to our biological and genetic materials and, therefore, call for the rightful repatriation of such samples and due compensation, and then goes on to declare that ' Kanaka Maoli human genetic material is sacred and inalienable. Therefore, we support a moratorium on patenting, licensing, sale or transfer of our human genetic material.

This level and consistency of Pacific community response should indicate to governments that the issues warrant serious concerted action sooner rather than later.

## 10. A Pacific Regional Intellectual Property Office

The proposal to establish a Pacific Regional Intellectual Property Office has been the topic of discussion ever since the African region broke the ground in 1976 and developed the Lusaka Agreement establishing the African Regional Industrial Property Organisation (ARIPO) for the 15 English-speaking African states. ARIPO considers applications for patents and registered trademarks in its member states who are parties to two African regional protocols (Harare – patents) and Banjul (marks).

Through the Pacific Plan, Forum countries have committed to a vision that pronounces, "We treasure the diversity of the Pacific and seek a future in which its cultures, traditions and religious beliefs are valued, honoured and developed. (Pacific Island Forum Leaders, 2004).[20] The Communique of the 36th Pacific Islands Forum reconfirmed the four pillars of the Pacific Plan[21]. One of the pillars, Good Governance, has as its key objective "to support a safe, enabling, inclusive and sustainable environment for economic growth and personal development and human rights." The Plan also pledges to support the maintenance of strong Pacific cultural identities and the protection of traditional knowledge and intellectual property rights.

Forum leaders indicated their support in principle to establish a regional Pacific IP office. At the June

2006 meeting of Forum Trade Ministers, this initiative was progressed further by seeking additional meetings with relevant stakeholders. No timeframe has yet been set for when a firm decision will be made to proceed with or reject this proposal.

The Pacific could move relatively quickly to develop a Regional intellectual property office that could carry out patent and trademark application assessments, informed by Pacific model laws and responses (similar to how ARIPO operates). A regional office could enable patent application assessments to be carried out in a more critical and pro-Pacific cultural heritage manner than at present.

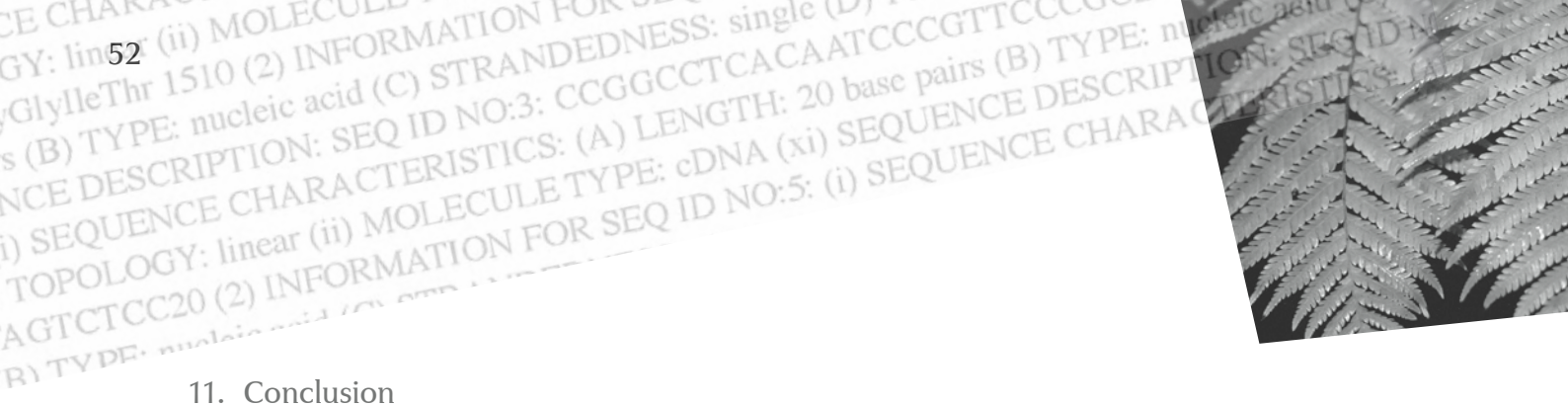
It will be important however, for Pacific states to decide on the form and function of patent laws in this Region. There is a window of opportunity for Pacific states to enact patent laws that either prevent entirely or significantly reduce "patents on life", particularly on human life and in relation to traditional genetic resources of cultural significance. This could be achieved through explicit exclusions in the patent law and/or according a high technical weight within the application assessment process for applicants to demonstrate prior informed consent of communities of origin and analysis of other source communities that might have an interest.

Should Pacific States takes this path, it would not be easy, as the international system would resist any such move, and likely argue such an approach contravenes at least one international agreement (Article 27 of the TRIPS), but as is evidenced through the earlier section of this paper, patents are out of control and a growing number of sectors of society are indicating that limits do need to be drawn. Furthermore it is evident, that patent bottom trawlers will not self-regulate. Boundaries and limitations set through an open policy process that holds at the very core of the exercise the integrity of Pacific indigenous values and cultural resources would greatly assist in stemming the problem of misappropriation.

A regional approach could require and assess evidence from applicants for a range of requisites that would make it more difficult for misappropriation to continue to occur, for example, prior informed consent, community certificates of origin and inclusion of derivatives.

A Regional Pacific Intellectual Property Office would be a constructive way forward on the proviso that any regional patent laws/protocols include best practice in terms of carving out exceptions for not granting patents, and in championing community collective rights. A regional office would also enable better leverage and capacity for Pacific states in relevant international processes.

The establishment of a Pacific regional intellectual property office is a constructive and necessary step forward but it is one small part of the solution to a much larger dilemma. An 'IP' office would be the 'last step' in the process of commodification and ownership of life, as it's function would be to receive, assess, approve or reject intellectual property applications, including patents. In carrying out this work, it would be guided by patent laws or protocols that could require specific actions and processes of applicants with regard to acknowledging the source of patented resources. What is also required is the elaboration and promotion of Pro-Pacific Indigenous Research to ensure that communities are not faced with the added burden and stress of being asked to give consent to proposals that don't originate from within, for which they can see no clear benefit for themselves, that in some cases they may not fully understand or agree with.



## 11. Conclusion

As stated at the beginning of this paper, everything that can be patented is being patented. While there are an increasing number of institutions and sectors engaged in life patenting, the situation remains that the vast majority of life patents are owned by a very small number of multinational bio-agricultural, pharmaceutical and human genome companies. The activity of life patents surpasses societal consciousness or comfort of both indigenous and non-indigenous sectors of society.

This activity is not restricted to every region in the world except the Pacific. It is happening at the very core of Pacific communities as source communities and countries of origin of biological genetic resources and associated traditional knowledge.

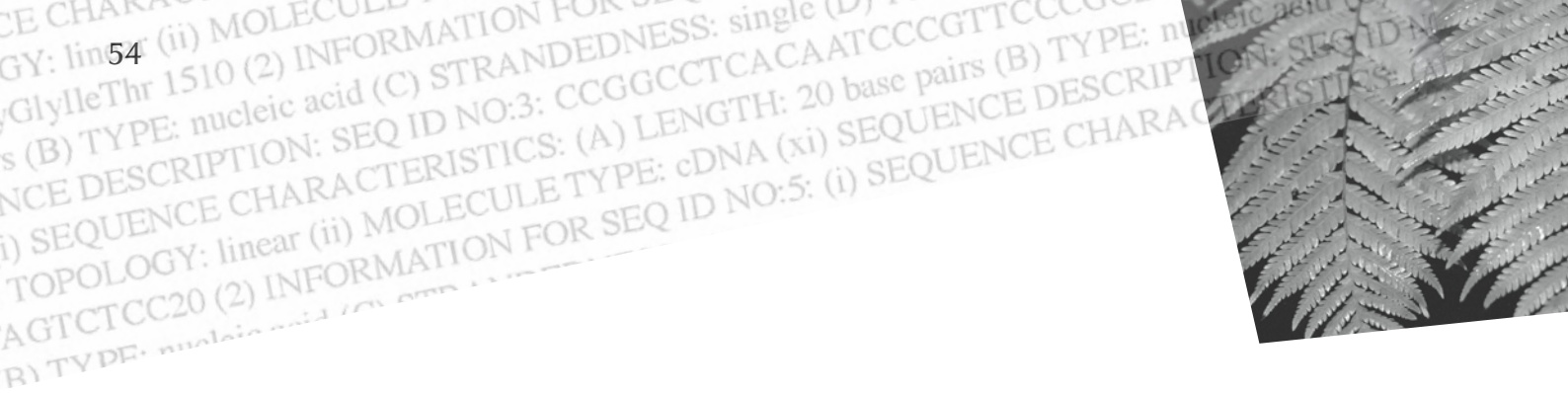
Policies and laws enacted by Pacific governments nationally and regionally to date are not sufficient to prevent cultural misappropriation as most Pacific States do not provide a clear statement on their agreement or disagreement with the principle of commodification and ownership of life and life forms. Nor do they elaborate clear guidance on the rights of Pacific indigenous contributors to research ('subjects'), as the source of life form resources and/or associated traditional knowledge, as individuals, genealogical kinship groups or as peoples, or regulations relating to access by external researchers.

I am of the view that the only viable option to halt the misappropriation, commodification and ownership of Pacific genes, cultural resources and knowledge is through a pluralist approach. An approach that comprises a radical reform of formal intellectual property laws, policies and practices, at national, regional and international levels alongside an equally radical transformation of customary laws, policies and practices that have been rendered invisible or marginalized through colonization, to be brought forward and allowed to take their rightful place in policy. The establishment of a Pacific Regional Intellectual Property Office to administer regional protocols for patents consistent with Pacific customary laws and values, together with a comprehensive Pro-Pacific Indigenous Research agenda would place the region in a much stronger position than at present.

Finally, in answer to my opening comment about whether I would have a different reaction to biotechnology had my first experiences been more culturally affirming, such as the discovery of the Polynesian excellence gene, well the remark is in some ways redundant. This technology was never designed for affirmation of cultural diversity. It is underpinned with ideologies of colonization, globalization and ownership over the very elements that make life sacred and meaningful to the bulk of the world's population. Furthermore, I don't think Polynesians need geneticists is tell us we're excellent. If my extended family and friends are any measure of Polynesian well-being, then I can confidently say, we're already well aware of that.

# Footnotes

1. The title and descriptor is hypothetical and based on a variation of introductory comments made by the author in a Keynote presentation at the Talking Biotechnology Conference 'Reflecting on Science in Society', Wellington 2005, in which the concept of a 'Maori Excellence Gene' was used to introduce an indigenous experience and analysis of biotechnology.
2. Canadian-based RAFI, now re-formed as the ETC Group, was responsible for breaking the news worldwide about the Hagahai and Solomon Islands patents. RAFI made direct contact with Pacific indigenous organisations and worked collaboratively to contest the Patents. This paper is deliberately Pacific-centric but it would be remiss to not acknowledge the leadership role of NGO's such as RAFI, GRAIN, IWGIA, the Third World Network as well as a sizeable group of dedicated organisations and individuals supportive of Pacific indigenous issues.
3. Bottom Trawling (known in the scientific community as Benthic trawling) is a fishing technique involving dragging heavy nets across the sea floor to catch bottom-dwelling fish. It results in severe changes to the sea floor and a high rate of by-catch because it harvests anything and everything in its path. Bottom trawling and drift net fishing are still widely used fishing techniques in the Pacific even though they are deemed overtly destructive to fish stocks and the marine environment.
4. Examples include: (i) Genebanks: A Comparison of Eight Proposed International Genetic Databases, Austin,Harding,McElroy, Community Genetics 2003, (ii) Transaction and Creations: Property Debates and the Stimulus of Melanesia, Ed.Hirsh & Strathern 2004, (iii) Human Tissue and Global Ethics, Dickenson, Genomics, Society & Policy(2005); (iv) God, Adam & Eve Theology and Science in the Genome Age, Course Text, Chicago Theological Seminary and University of Chicago
5. This definition of biotechnology is provided by: ehrweb.aaas.org/ehr/books/glossary.html
6. Maori tribes collectively have shared values about that which is tapu (sacred) and that which is noa (common). Hair, blood, mucus, the main sources used by westerners to collect DNA, are all tapu. In past times, touching the hair or even the hair comb of a Chief was punishable by death, a custom common to many other formal occasions today, Tihei Mauriora! literally translates as the sneeze (of mucus) of life. It isn't coincidental that my culture and most other indigenous cultures regard hair, blood, and mucus as being sacred. We may not have had traditional terms for DNA or genes, but we know the importance of protecting those things which could render us vulnerable. (A. T. P. Mead, 1996)
7. There are numerous definitions of the term 'bioprospecting', and no one single term is considered definitive. According to a UN University study, a basic definition of bioprospecting is: 'the exploration of biodiversity for commercial valuable genetic and biochemical resources and the process of gathering information from the biosphere on the molecular composition of genetic resources for the development of new commercials products." (Salvatore Arico and Charlotte Salpin, 2005)
8. Refer to http://en.wikipedia.org/wiki/Biopiracy for a full definition of bio-piracy.
9. At a meeting in Tahiti in 1999, the Treaty was re-named the Hagahai Treaty. I'm assuming the decision was made in line with international precedence for naming a significant document after the place that hosted the meeting. As one who contributed to the drafting of this Treaty, I query the wisdom behind the re-naming. [Clark Peteru was the lead drafter, Jean Christie , Aroha Mead and others provided advice on terminology, scope and other issues]. The meeting was not hosted by the Hagahai, or held in PNG, consent was not sought from the Hagahai, or all those involved in drafting the Treaty, and many prominent groups had already signed the 1995 Treaty [e.g. National Maori Congress and Ka Lahui Hawai'I. The Treaty had been created as a response to the wide ranging issues facing all Pacific peoples. My own preference would be for the Treaty to revert to its original title.
10. Farquhar's study was conducted in four Pacific Island Forum Island countries as part of a series of scoping studies undertaken in the context of 'The Pacific Plan'. Farquhar explained that the figures cited in this Table are approximate based on her research. It was also noted that as PNG is a member of the Patent Co-Operation Treaty, it has received 940 notifications since 2002 of which only four have entered the national phase.
11. Searching the databases of the US or European Patent Offices is a specialized activity that requires attention to detail in reading any patents identified through an initial search. This chart only reflects a cursory search of



the US data-base and does not include European (EP) or international (WO) patents. Patent searching can be complicated by a number of factors including; (i) a country name could identify the origin of the actual source material, or a reference or a location of the inventor or some other matter not related to DNA or country of origin.

12. The same USPTO database search revealed that Australia had 1816 patents and NZ, 2823. Those countries showing a "0' result include, Niue, Tuvalu and Tokelau
13. Listed ahead of UW-Madison were the 10 campuses of the University of California System with 390 patents; the Massachusetts Institute of Technology, with 136 patents; the California Institute of Technology, with 101 patents; and Stanford University and the University of Texas which tied for fourth with 90 patents each. (Wisconsin State Journal 2006)
14. Ibid, Cumming, 2005
15. For example, High Blood Pressure gene (US5,589,584), Osteoporosis gene (US5,501,969), Melanoma gene (US5,501,969), Blindness gene (US5,705,380) and the Alzheimer's gene (US5,508,167). Researchers also claim to have discovered a 'depression gene' and a 'poverty gene'.
16. The most high profile example is that of South Korean scientist Dr Hwang Woo Suk. Dr. Hwang was hailed as a global stem cell pioneer and treated as a national hero until investigations showed that he had fabricated key data in two papers published in the journal Science. He was subsequently indicted on embezzlement and bioethics law violations linked to faked stem cell research. (The Associated Press, 2006) Dr Hwang is by no means the only scientist in the world who fabricated results in an attempt to be hailed as an inventor. There are a large number of so-called inventors who have either fabricated results or stolen information and resources from others, particularly indigenous peoples, without any recognition of the original source.
17. For example,inter alia, the Universal Declaration on the Human Genome and Human rights (UNESCO, 1997), International Declaration on Human Genetic Data (UNESCO, 2003), Universal Declaration on Bioethics & Human Rights (2005) , World Intellectual Property Rights –WIPO- Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, and the Convention on Biological Diversity Ad-Hoc Working Groups on Access & Benefit Sharing of Genetic Resources, and Article 8(j) Traditional Knowledge. Innovations & Practices of Indigenous & Local Communities.
18. Ibid, Mead:47
19. The NZ Law Commission provides a useful elaboration of the term 'customary law'. "We use custom law to describe the indigenous law, including its current practice within communities, its codification and its application by Courts…It is perceived as law by the people whose law it is, and, it is that to which they habitually subscribe or that which they profess to be proper."
20. The 16-member Pacific Islands Forum represents the heads of government of all independent and self-governing Pacific Island countries, Australia and New Zealand. The 14 other member countries are Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Nauru, Niue, Palau, Papua New Guinea, Marshall Islands, Samoa, Solomon Islands, Tonga, Tuvalu and Vanuatu.
21. The Pacific Plan is built on four pillars that are geared towards enhancing: Economic Growth, Sustainable Development, Good Governance and Security for the Pacific through regionalism http://www.forumsec.org.fj/

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# ANNEX 1

## QUICK-Clone™ cDNA October 2005

Product List

QUICK-Clone™ cDNAs are double-stranded cDNA generated from Premium Poly A+ RNA from specific tissues, ready for use in PCR.

### Human

| RNA Source | Size | Cat. No. |
|---|---|---|
| Human Universal pooled from more than 30 QUICK-Clone cDNAs from normal human tissues | 2 x 10 rxns | 637260 |
| Human Adrenal Gland pooled from 67 male/female Caucasians, ages 17–72 | 2 x 10 rxns | 637211 |
| Human Aorta thoracic, pooled from 19 male/female Caucasians, ages 21–75 | 2 x 10 rxns | 637219 |
| Human Bone Marrow pooled from 51 male/female Caucasians, ages 22–70 | 2 x 10 rxns | 637239 |
| Human Brain whole; pooled from 2 male Caucasians, ages 43 & 55 | 2 x 10 rxns | 637242 |
| Human Brain, amygdala pooled from 76 male/female Caucasians, ages 16–75 | 2 x 10 rxns | 637244 |
| Human Brain, cerebellum pooled from 11 male/female Caucasians, ages 16–70 | 2 x 10 rxns | 637212 |
| Human Brain, cerebral cortex 66-yr-old male Caucasian | 2 x 10 rxns | 637202 |
| Human Brain, hippocampus pooled from 25 male/female Caucasians, ages 16–70 | 2 x 10 rxns | 637228 |
| Human Brain, substantia nigra pooled from 69 male/female Caucasians, ages 22–70 | 2 x 10 rxns | 637245 |
| Human Brain, thalamus pooled from 76 male/female Caucasians, ages 16–75 | 2 x 10 rxns | 637243 |
| Human Colorectal Carcinoma SW480 cell line, ATCC No.CCL228 | 2 x 10 rxns | 637224 |
| Human Fat Cell whole epiploon; pooled from 11 male/female Caucasians, ages 19–57 | 2 x 10 rxns | 637220 |
| Human Fetal Brain pooled from 10 male/female Caucasian fetuses, ages 21–30 weeks | 2 x 10 rxns | 637221 |
| Human Fetal Heart pooled from 14 male/female Caucasian fetuses, ages 20–25 weeks | 2 x 10 rxns | 637227 |
| Human Fetal Kidney pooled from 9 male/female Caucasian fetuses, ages 19–36 weeks | 2 x 10 rxns | 637229 |
| Human Fetal Liver pooled from 2 female Caucasian fetuses, ages 22 & 26 weeks | 2 x 10 rxns | 637230 |
| Human Fetal Lung pooled from 9 male/female Caucasian fetuses, ages 20–25 weeks | 2 x 10 rxns | 637238 |
| Human Heart pooled from 7 male/female Caucasians, ages 20–78 | 2 x 10 rxns | 637213 |
| Human HeLa S3; ATCC No.CCL2.2 | 2 x 10 rxns | 637203 |
| Human Kidney pooled from 6 male/female Caucasians, ages 28–52 | 2 x 10 rxns | 637204 |
| Human Leukemia, lymphoblastic MOLT-4 cell line; ATCC No.CRL1582 | 2 x 10 rxns | 637225 |
| Human Leukocyte pooled from 550 male/female Caucasians, ages 18–40; all donors tested negative for HIV-I, HIV-II, hepatitis B & syphilis | 2 x 10 rxns | 637240 |
| Human Liver pooled from 2 male/female Caucasians, ages 44 & 45 | 2 x 10 rxns | 637205 |
| Human Lung pooled from 2 female Caucasians, ages 24 & 32 | 2 x 10 rxns | 637206 |
| Human Lymph Node pooled from 34 male/female Caucasians, ages 14–70 | 2 x 10 rxns | 637223 |
| Human Lymphoma, Burkitt's (Raji) ATCC No.CCL86 | 2 x 10 rxns | 637226 |
| Human Mammary Gland pooled from 7 Caucasians, ages 15–46 | 2 x 10 rxns | 637231 |
| Human Ovary pooled from 15 Caucasians, ages 15–77 | 2 x 10 rxns | 637214 |
| Human Pancreas pooled from 9 male/female Caucasians, ages 19–75 | 2 x 10 rxns | 637207 |
| Human Pituitary Gland pooled from 87 male/female Caucasians, ages 15–75 | 2 x 10 rxns | 637232 |
| Human Placenta pooled from 11 Caucasians, ages 22–41 2 x 10 rxns 637208 | | |
| Human Prostate pooled from 20 Caucasians, ages 20–58 2 x 10 rxns 637215 | | |
| Human Retina pooled from 76 male/female Caucasians, ages 16–75 | 2 x 10 rxns | 637216 |
| Human Salivary Gland submaxillary, pooled from 26 male/female Caucasians, ages 10–70 | 2 x 10 rxns | 637233 |
| Human Skeletal Muscle quadriceps, iliopsus & pectoralis major; pooled from 11 male/female Caucasians, ages 12–52 | 2 x 10 rxns | 637234 |
| Human Small Intestine pooled from 2 male/female Caucasians, ages 25 & 30 | 2 x 10 rxns | 637235 |
| Human Smooth Muscle small intestine; pooled from 11 male/female Caucasians, ages 15–60 | 2 x 10 rxns | 637241 |
| Human Spinal Cord pooled from 69 male/female Caucasians, ages 22–70 | 2 x 10 rxns | 637222 |
| Human Spleen pooled from 5 male/female Caucasians, ages 44–70 | 2 x 10 rxns | 637217 |

The RNA source may vary from lot to lot. Please refer to the Product Analysis Certificate accompanying each Universal cDNA for the most current information.

| | | |
|---|---|---|
| Human Stomach pooled from 10 male/female Caucasians, ages 25–53 | 2 x 10 rxns | 637218 |
| Human Testis pooled from 25 Caucasians, ages 28–64 | 2 x 10 rxns | 637209 |
| Human Thymus pooled from 7 male/female Caucasians, ages 17–40 | 2 x 10 rxns | 637210 |
| Human Thyroid Gland pooled from 41 male/female Caucasians, ages 17–61 | 2 x 10 rxns | 637236 |
| Human Uterus pooled from 10 Caucasians, ages 17–49 | 2 x 10 rxns | 637237 |
| Human XG Burkitt's Lymphoma (Daudi)* derived from ATCC No.CRL-213 | 2 x 10 rxns | 637254 |
| Human XG Glioblastoma (SF-295)* derived from cell line | 2 x 10 rxns | 637257 |
| Human XG Lung Carcinoma (LX-1)* derived from metastasis of poorly differentiated lung carcinoma | 2 x 10 rxns | 637248 |
| Human XG Malignant Melanoma (A375)* derived from ATCC No.CRL-1619 | 2 x 10 rxns | 637258 |
| Human XG Prostatic Adenocarcinoma (MRI-H-1579)* derived from surgical explant | 2 x 10 rxns | 637259 |
| Human XG Prostatic Adenocarcinoma (PC-3)* derived from ATCC No.CRL-1435 | 2 x 10 rxns | 637251 |
| Human XG Renal Carcinoma (MRI-H-121)* derived from surgical explant of a metastasis | 2 x 10 rxns | 637256 |

## Mouse

| RNA Source | Size | Cat. No. |
|---|---|---|
| Mouse Brain pooled from 300 BALB/c males, ages 8–12 weeks | 2 x 10 rxns | 637301 |
| Mouse 7-day Embryo Swiss-Webster/NIH | 2 x 10 rxns | 637308 |
| Mouse 11-day Embryo Swiss-Webster/NIH | 2 x 10 rxns | 637309 |
| Mouse 15-day Embryo Swiss-Webster/NIH | 2 x 10 rxns | 637310 |
| Mouse 17-day Embryo Swiss-Webster/NIH | 2 x 10 rxns | 637311 |
| Mouse Heart adult BALB/c male | 2 x 10 rxns | 637304 |
| Mouse Kidney adult BALB/c male | 2 x 10 rxns | 637306 |
| Mouse Liver pooled from 200 BALB/c males, ages 8–12 weeks | 2 x 10 rxns | 637302 |
| Mouse Smooth Muscle adult BALB/c male | 2 x 10 rxns | 637307 |
| Mouse Spleen adult BALB/c male | 2 x 10 rxns | 637305 |
| Mouse Testis adult BALB/c male | 2 x 10 rxns | 637303 |

The RNA source may vary from lot to lot. Please refer to the Product Analysis Certificate accompanying each Universal cDNA for the most current information.

## Rat

| RNA Source | Size | Cat. No. |
|---|---|---|
| Rat Brain adult Sprague-Dawley male | 2 x 10 rxns | 637312 |
| Rat Heart adult Sprague-Dawley male | 2 x 10 rxns | 637314 |
| Rat Kidney adult Sprague-Dawley male | 2 x 10 rxns | 637317 |
| Rat Liver pooled from 200 Sprague-Dawley males, ages 8–12 weeks | 2 x 10 rxns | 637313 |
| Rat Pancreas adult Sprague-Dawley male | 2 x 10 rxns | 637318 |
| Rat Spleen adult Sprague-Dawley male | 2 x 10 rxns | 637315 |
| Rat Testis adult Sprague-Dawley male | 2 x 10 rxns | 637316 |

The RNA source may vary from lot to lot. Please refer to the Product Analysis Certificate accompanying each Universal cDNA for the most current information.

**Notice to Purchaser**
**PCR**

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# THE SANCTITY AND RESPECT FOR WHAKAPAPA: THE CASE OF NGATI WAIRERE & AGRESEARCH

Paul Reynolds
*(Nga Puhi & Ngati Tuwharetoa)*

***One of the loudest arguments against genetics and biotechnology is coming from our own Kaumatua [elders], who are saying very clearly that no one should corrupt or interfere with whakapapa [genealogy]. The sanctity and respect for whakapapa is to be maintained. Both mauri (life principle) and wairua (spirit) of living things are sacred. The responsibility falls on us to protect the legacy of our future generations and this includes the guardianship [kaitiakitanga] of whakapapa.***[1]

## Introduction

Ngati Wairere is a small hapu (sub-tribe) within the rohe (region) of Tainui, an iwi (tribe) made up of over 30 hapu located in the central north island of Aotearoa, New Zealand. Ngati Wairere have kaitiakitanga (guardianship) over the land that is occupied by the University of Waikato and AgResearch, a Crown Research Agency at the Ruakura Research Centre in Hamilton. Ngati Wairere has been vociferously opposing research that AgResearch has been conducting within their rohe. Ngati Wairere's opposition to research relates to the placing of copies of human genes into cows in order to produce a human-cow hybrid, or transgenic cow. The scientific justification for the research is based on the hope of producing therapeutic proteins in the transgenic cows' milk that may lead to a treatment for multiple sclerosis. Ngati Wairere is concerned with the impact that this type of research will have on whakapapa (genealogy).

Presented in this paper is a case study of Maori engagement with Western reductionist science. Ngati Wairere was put in the unenviable position of being the face of opposition to Western reductionist science in the form of genetic research that would impact on the whakapapa of a species and produce

transgenic offspring. In opposition to Maori and Indigenous worldviews of holistic conceptions of the world where the parts are seen as indivisible from the whole, Western reductionist science generally views the parts as autonomous. This view of science gives rise to the possibility for Western reductionist scientists to manipulate and modify the parts, for example research involving the modification of genes, in order to influence the whole. This reductionist conception operates on the mechanistic notion that by replacing or changing a part, the whole will be "fixed." However, Western reductionist scientists are not fully prepared for unintended consequences resulting from the manipulation of the parts to influence the whole. This case is an example of how one Maori community had to respond to a scientific process that on international face-value would seem to be cutting-edge. It provides a powerful and poignant 'snap-shot' of the difficulties our communities face.

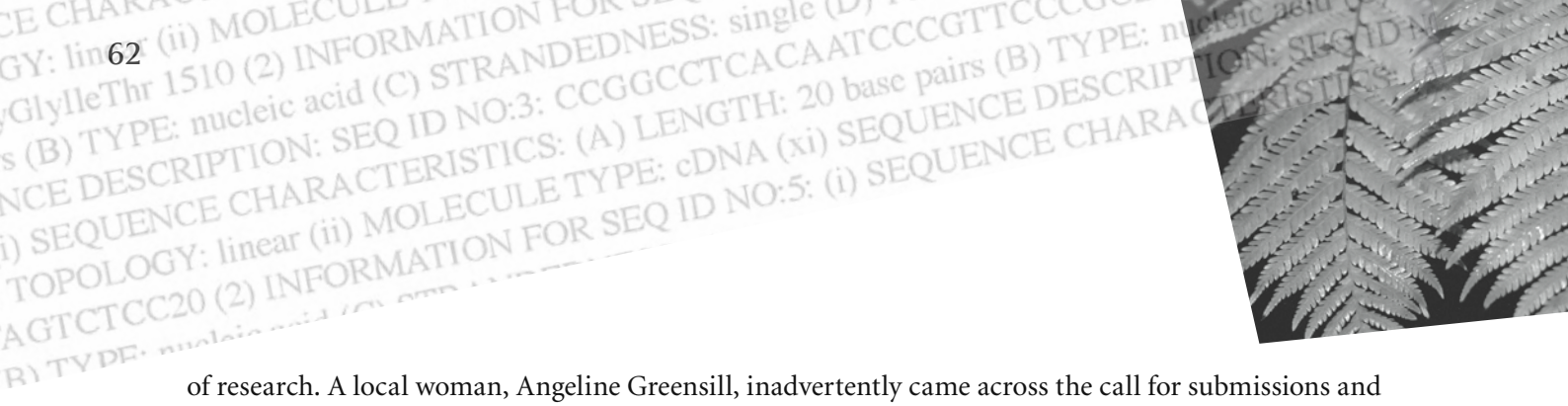
Specifically, this paper will provide an historical overview of the Ngati Wairere case. The primary focus for this paper is to highlight the decision-making processes that Ngati Wairere had to engage with in order to voice their concerns and opposition to this type of reductionist science. For this reason, the body of the paper describes the government submission process for opposing research and the presentation of Ngati Wairere's submission to this decision-making body. As much as possible prominence has been given to the voices of the people who were central in presenting this case on behalf of Ngati Wairere. The paper will conclude with a brief update of the current situation in Ngati Wairere and provide a brief overview of the lessons learnt.

## History of the case

In New Zealand the area of genetic engineering and modification is highly visible, as has been the resistance by Maori. Maori have been one of the groups at the forefront of a broad-based opposition. Since 1998 major political contestations have emerged around the issue of genetic engineering and modification, particularly leading up to and after the 2000 New Zealand Royal Commission on Genetic Modification. The de-legitimising of Indigenous ways of knowing and the privileging of Western reductionist science underpin these contestations. In response to these challenges, government interests and biotechnology industry groups have been legitimising the industry through processes of "consultation" and the establishment of organisations such as the Environmental Risk Management Authority (ERMA) and Institutional Biological Safety Committees, which are mandated to assess and provide approval for scientific research.

The most visible and controversial genetic research for Maori, and indeed the New Zealand public in general, relates to transgenic cow research being conducted by AgResearch, a Crown Research Institute based at Ruakura in Hamilton. AgResearch made two separate research applications, one in 1998 and one in 2002, which was an extension of the first. In 2002 blanket approval was given by ERMA to undertake GE research and trials to create calf embryos using synthetic human genes and genes from mice, deer, goats, or sheep. AgResearch hoped to produce therapeutic proteins in the transgenic animals' milk for treatment of diseases such as multiple sclerosis.

For Ngati Wairere, this case started in 1998 when AgResearch first made an application to ERMA, the government appointed decision-making body invested with providing approval to conduct this type



of research. A local woman, Angeline Greensill, inadvertently came across the call for submissions and hurriedly submitted an application on behalf of Ngati Wairere to be heard at the public hearing for the application. Since that first hearing, Angeline and people from the hapu of Ngati Wairere were engaged in a process that was hostile to a Maori worldview and hospitable to a science that is seen as cutting-edge and promising significant health benefits.

## The case details

In December 1998, AgResearch first submitted an application to ERMA for approval to insert copies of human genes into cows. In August 1999 ERMA heard submissions by the public on the AgResearch application, of which Ngati Wairere was a submitter, albeit last minute.[2] In July 2000 AgResearch was given approval to proceed with their research by ERMA. Papers were filed by Ngati Wairere and other concerned citizens in the High Court in August 2000 to challenge the approval given by ERMA. In May 2001 the High Court overturned the research approval given by ERMA citing some concerns with the application process and security and safety measures surrounding the research. ERMA announced in May 2001 that a "special committee" would be established to conduct a rehearing, in private, to address the High Court's concerns with the application process, and the "special committee" would not hear any new submissions. Later in May 2001 ERMA reconfirmed the AgResearch research approval, after AgResearch and ERMA addressed the concerns of the High Court related to procedure and security for a high-level containment research facility.[3] During this research application process, sixty cows were pregnant with transgenic offspring. In December 2000 only six transgenic calves were born from the sixty pregnant cows. The six transgenic calves were New Zealand's first genetically modified dairy cattle.

AgResearch made a second submission to ERMA in May 2002 to insert genes from humans, goats, pigs, deer, sheep, mice and other genetic sequences into cows. In August 2002 ERMA held a hearing into the AgResearch application and in September 2002 approved the research application. AgResearch was given ERMA approval to experiment on cows using genes from humans and other mammals as well as move from the laboratory to an outdoor containment facility, which basically consisted of a high-security fence and electronic tagging of the transgenic cows.[4]

Bevan Tipene-Matua, who was at the time ERMA's Senior Policy Advisor on Maori Issues, states that this case represented a list of firsts.

> This was the first application to be opposed by an iwi, the first public submission received from a Maori, and the first time an application (or at least the human gene aspect) was deferred for six months. More importantly, the AgResearch proposal to produce a herd of GM cattle raised stakes considerably in determining the nature and extent of the impact on Maori of GMOs. Te Kotuku Whenua, an environmental group representing Hamilton-based hapu Ngati Wairere, consistently argued that the production of GM cattle on their ancestral lands would cause a spiritual imbalance within that community and result in serious adverse psychological impacts on the Ngati Wairere. This claim raised the ante on the impacts of GMOs on Maori. One participant at a hui we held at the time exclaimed, "Is it an animan or manimal?"[5]

Ngati Wairere, along with other submitters from around the country, opposed the research. Key figures in the case against the AgResearch application were Jacqui Amohanga, Angeline Greensill and Maree Pene. In their own words, they reveal and unravel the AgResearch and ERMA processes from an insider's perspective.

## Submission heard by ERMA relating to AgResearch application #1

Jacqui Amohanga pays tribute to Angeline Greensill for instigating opening up the process for Maori.

> *The first time the AgResearch application that was undertaken in regard to the issues of human DNA and cow DNA came to us, there was only one Maori submission. That was Angeline Greensill. What Angeline effectively did was ensure that the Authority came out to the local hapu, which ended up being my people. There were two applications going at the same time. That other application, which had nothing to do with human DNA, was manipulating the DNA structure of sheep. Now, as a result of that, those two applications, Maori promptly became really, really interested in actually what was happening in the scientific area.*[6]

Angeline Greensill describes what happened when she first found out in mid-1999 about the AgResearch application to create transgenic cows.

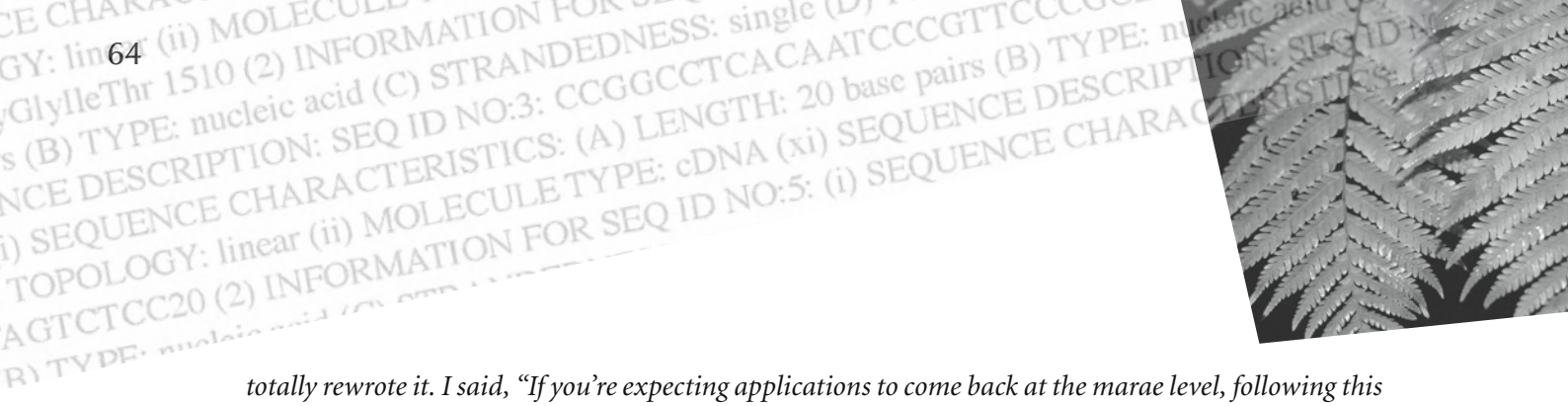
> *What really happened when they first started this thing, I found out the day the submissions closed that the application was happening at AgResearch, and I rang Jacqui. I said, "Hey, there's this big thing about cows and humans happening down there. Let Wairere know." Because I thought, geezzus, two hours to go and I slapped this submission in, which was a doorway in, which meant that they had to go back and try and talk to the people whose land this thing was happening on. And Wairere ended up having to be chucked in at the backend on this issue that they had never, ever, been consulted on. And this was after the submissions had closed.*[7]

What was surprising was that there was no public announcement or call for submissions in the local media.[8]

> *They never advertised anything in the local media. The advertisements were in Otago, in Auckland, and there was nothing in the Hamilton papers. And even today, when they have hui's around the country, often, it is advertised in other centres, except Hamilton where the research takes place. They're keeping the people of this town ignorant. So it's a deliberate move to exclude the public from knowing what is happening in their backyard.*[9]

Another hurdle for submission was the language and terminology used in the application forms for making a submission.

> *Both me [Jacqui Amohanga] and Angeline [Greensill], we've got really good analytical minds eh. And like it took us awhile to figure out what they were trying to get at in regards to their processes for Maori risk assessments. And so Angeline was asked to go down there. So we went down there and we just*



*totally rewrote it. I said, "If you're expecting applications to come back at the marae level, following this formula, you won't get a response."*[10]

They're not fulfilling their responsibility under the treaty to make the parties well informed by creating academic, scientific terminology that people can't understand. And they wonder why previously they didn't have many people submitting in opposition to the application. Because they couldn't understand them!

## Presentation of Ngati Wairere submission to ERMA

### *opposing AgResearch application #1*

The process for the Ngati Wairere submission involved extensive consultation with the hapu, as Jacqui Amohanga, Maree Pene, and Angeline Greensill explained.

*Jacqui Amohanga – What our process was, basically, we listened to the korero [discussion/talk] that happened from the people, and then what we do is we go back to the office and then we identify what we think could be possible issues for Ngati Wairere, and then that discussion paper gets circulated around Ngati Wairere for them to add comments to, to throw out whatever's not relevant or to alter. So that's the way we did it. The initial research was actually done by me, in identifying the key points associated with Maori values in general. And then once you've gone through the Ngati Wairere process, then that's when it actually came down to the actual Ngati Wairere perspective.*

*Maree Pene – I didn't have a clue what to do about it in the beginning. I was just a normal housewife.*

*Angeline Greensill – Like most of us. I mean I looked at it, and I thought it was unbelievable. When they tell you this stuff and when I read up, they can't do this. You know, it's just strange.*[11]

Jacqui Amohanga, working as part of Te Kotuku Whenua Consultants, the Ngati Wairere Environmental Agency, helped Ngati Wairere formulate a submission. *"ERMA and AgResearch tried to sidetrack Ngati Wairere right at the beginning. And one of the things that we were told is that, 'oh, we don't need such a long report from Ngati Wairere, we just want to use your name.'"*[12] The most important thing for AgResearch was to report to ERMA that the local hapu, Ngati Wairere, were consulted. As part of the ERMA process, research applicants are required to consult with local hapu and iwi. However, consultation does not mean that those consulted will be listened to. Consultation is just another box to be ticked off in the application process. Alongside these token efforts of consultation are the hostile submission and consultation environments. The whole submission process was hostile to tikanga Maori processes.

*And then we had to, this is all the rarurarau [trouble] that we had to go through, just to go through the Ngati Wairere informative process, before a decision could be made by Ngati Wairere. So, here's a small group of us trying really hard to applicate with AgResearch, and we can't, our small crew can't make a decision just on our own. We have to collate the information, and then we have a method of actually circulating that information back down to the people as a whole. And they couldn't understand that, and their timeframes didn't allow that to happen.*

*What we wanted all the time was to have a hui with the people. We didn't have enough time to actually speak, to contact certain representatives from different whanau groups, which is not the right process for Maori to go through. You have a hui. To make a decision you have a hui that's advertised to everybody that belongs there. But for convenience sake, you select certain individuals from different families to kick the process off to advocate for a hui of the people. And also to identify some issues. It got to the actual hearing stage where the Authority made a decision on it without that hui. And then the Maori representatives basically had to argue strongly that a hui of Ngati Wairere take place. So we did end up having that hui.*[13]

The ERMA review process reveals the inconvenience of a democratic process that allows adequate time for consultation and review by the various publics. This "quick and nasty" ERMA submission style is counter to a tikanga Maori process, but it is also inadequate for all citizens of New Zealand. Not only were tikanga Maori processes undervalued, but Jacqui Amohanga also explains how Ngati Wairere were basically sidelined as having spiritual concerns only in the hearing process.

*Now, when it got to the hearing stage, what they did was categorize Ngati Wairere as only interested in spiritual values. They took no notice of the physical values and the psychological values.*

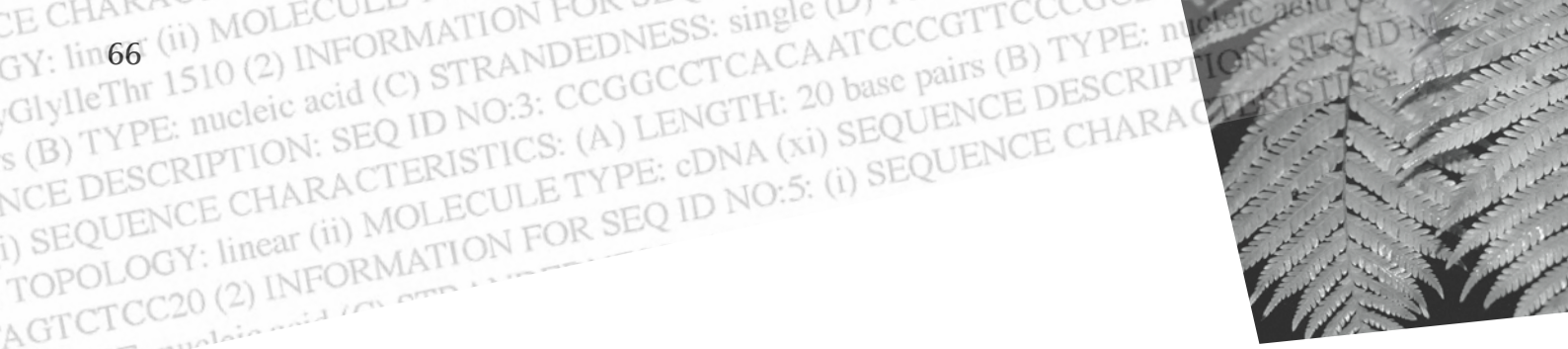
*So some of the physical things that we addressed were the intergenerational problems, which is a physical thing. The impact on the underground water table and the potential for organisms to regenerate themselves in the soils and also in the underground water tables with the effluent from the genetically modified cattle. So all those physical things, they didn't address. The physical values that we had a concern with, they didn't address. They turned the whole hearing, the whole argument around, and this is the media portrayal that we came out with too, they turned it into a public perception that Ngati Wairere were only interested in the spiritual things.*

*The thing is, if they focussed on just the spiritual, it means that they can ignore the physical things. They sidetracked everything to the spiritual side, even through the whole court process.*

*The psychological things in regards to, you know, Aotearoa and their clean, green image, that's a psychological effect. But the fact was that Ngati Wairere were having these types of experiments in their rohe, and for the status of their mana, as perceived from other people, if Ngati Wairere didn't stand up and do something about it? You know, these all go to psychological things.*[14]

Moana Jackson would perceive Ngati Wairere as treated as providing a Maori "perspective" that can be "noted" but swiftly ignored because the scientific and economic arguments are more compelling in the quantifiable ERMA research application approval environment.[15] AgResearch and ERMA considered anything else apart from reductionist science of less importance, such as the tikanga Maori knowledge issues addressed by Ngati Wairere.

What was important for Ngati Wairere was to exercise their rights and responsibilities of self-government, with the authority to monitor what happens in their own rohe (region/territory). This Ngati Wairere case highlighted for Maori around the country the presence of transgenic research being conducted in New Zealand.



*Maree Pene – One thing I will say, with all that's going on, it's certainly alerted Maori throughout New Zealand, if not probably the world, because of this case…it made other Maori people aware of what was happening out here, right in our rohe [region/territory], you know. And we had people wanting to know what Ngati Wairere was doing about it. Then you get other hapu's and iwi's wanting to come and support you and they all want to go off and do their thing. It certainly made Maori aware in some areas what was happening with our genes.*

*Angeline Greensill – Yea, I felt sorry for Wairere, the load that they carried in terms of being in the limelight on the issue.*[16]

Scientists were quick to imply the "public good" aspect of the research to the public, as in a cure for multiple sclerosis, but officially the scientific argument was couched in terms that highlighted the benefit to scientific knowledge.

*The argument that was always used by scientists is that this is for the public good, that this particular case was going to help multiple sclerosis, without any fact or rationale behind it. They promised things and then when it came to the actual case, it was quite evident that they were not promising any medical benefit. They were saying that this experiment was for scientific knowledge itself. No benefit to the public. But the media stance was all the way through, and continues to be, GE is good for you because of the benefits that are going to accrue to all you sick people who are diabetics, who are mainly Maori, who are such and such, and such and such. And it's that emotional blackmail.*

*When they put their case to the High Court [where AgResearch's research approval from ERMA was challenged], there was no talk about the benefits to medicine; it was about the scientific knowledge, that's all, because they can't prove anything.*[17]

AgResearch's lawyer asked the question, "How do you quantify Maori spiritual risk?" Jacqui Amohanga, Maree Pene, and Angeline Greensill explained this incredulously.

*Jacqui Amohanga – Who's defining, you know, like at the hearing AgResearch's lawyer questioned me on, "how do you quantify Maori spiritual risk?" And I said "Well, haven't I said this all the way, I said this in my evidence, that there's no way you can quantify spiritual, risk associated with spiritual values. You've got so many Pakeha religious representatives out there, going blessing all over the place. Do you expect them to go and actually count how many times they go and do a blessing and act with people in areas, and you're expecting or wanting us to do the same?" And another thing is, a lot of people will do a karakia [prayer] in the morning, or because of occasions or issues, how can you count that? The karakia is actually part of the process, the spiritual process of protecting yourselves. Ok, how do you quantify that?*

*Angeline Greensill – And why should you have to?*

*Maree Pene – Yea, it's a ridiculous question asked.*

*Angeline Greensill – Yea, they're not quantifying anything.*

*Maree Pene – We asked them several times to put in writing what are the risks of this experiment? We asked them "what are the risks? Do you know of any risks?" They said the question was irrelevant.*[18]

*Angeline Greensill – And this is the Environmental Risk Management Authority. Their job is to manage risk. If you don't know what the risks are, how can you manage the risk?*

*Jacqui Amohanga – I can't understand how that application could go ahead without them actually looking at the soil, without them looking at the water table.*

*Angeline Greensill – And those are all things that you can test.*

*Jacqui Amohanga – Containment, disposal, there's those two things as well.*[19]

AgResearch publicly advertises that they have a "fail safe" containment system.[20] Jacqui Amohanga and Angeline Greensill discuss with me how absurd this position is, as highlighted by Malibu Hamilton, another Maori who worked on the Ngati Wairere submission opposing the AgResearch application. He also works with Jacqui at Te Kotuku Whenua Consultants, the Ngati Wairere Environmental Agency. They also express how shocked they are about some aspects of the research.

*Jacqui Amohanga - But it's even like dealing with some of the AgResearch issues using humor, like Malibu's [Hamilton] saying that, you know, part of their containment systems that they actually have, part of the containment process for security was for them to ring…*

*Angeline Greensill – 111 or ring the police*

*Jacqui Amohanga – the police. Ring the police. But how much experience do the police have in herding cattle? And then another one was, and as for the security firms, ok, because Malibu [Hamilton] runs a cleaning business, the alarms accidentally are set off sometimes by some of his workers, and the security firms don't even turn up. And even if they do turn up, they come about half an hour, an hour, later.*

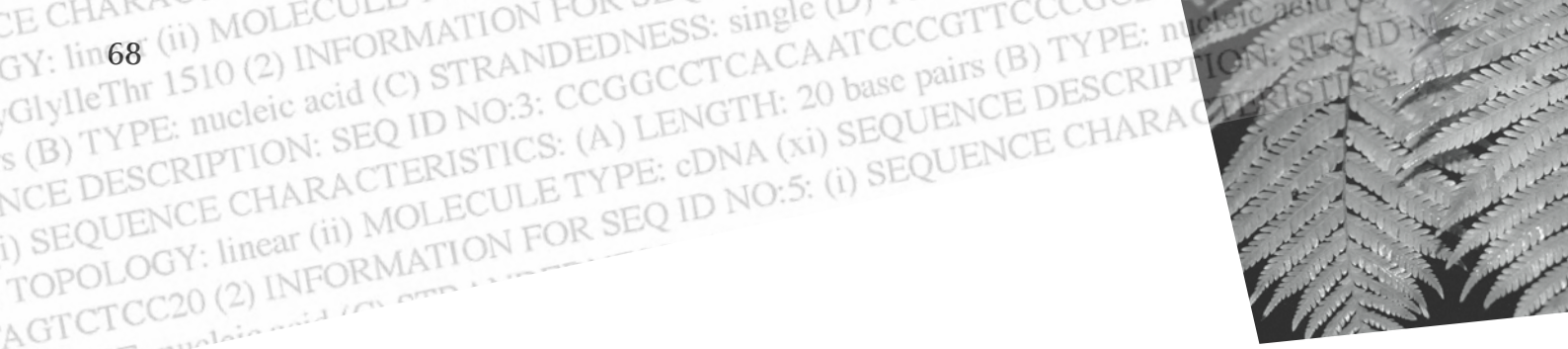
*Angeline Greensill – You can get in and out of there very quick.*

*Jacqui Amohanga – The other humorous things that Malibu [Hamilton] said was, if you allow this to go ahead, the reputation of the Waikato will be that you could go up to anywhere on the paddock and say "kia ora" [hello] and they'll say "kia ora" back. And then they'll also say, "pull the left teet for milk, and the right one for medicine."*

*Paul Reynolds - That's biopharming or something like that.*

*Angeline Greensill – Yea, it's shocking. They're treating the cows as factories eh. Living factories.*[21]

*Jacqui Amohanga – But the thing with that, with that first application, is that usually you get a ninety-five percent success rate in a cow producing calves. This one…*



*Angeline Greensill – There's three living out of sixty. Yea. Three living out of sixty! That's bad science. Why bother, I don't understand it.*

*Jacqui Amohanga – Yea. They should've had fifty-five.*

*Paul Reynolds - That's nature telling them, telling them something, right away.*

*Angeline Greensill – Why are they even doing it?*

*Jacqui Amohanga – Now, we're consistently asking, Ngati Wairere's consistently asking, we want the reports on why the calves have died or why the calves have been aborted. They have never given us it.*[22]

## AgResearch application #2

A second AgResearch submission to extend the already existing research was made in May 2002. AgResearch was seeking to extend their therapeutic protein research by conducting trials for a genetically modified enzyme replacement therapy to treat Pompe disease. Pompe disease is the result of an enzyme deficiency in cells, which can cause respiratory problems in newborn babies or heart failure.[23] The second submission sought approval to create calf embryos using genes from humans, mice, deer, goats, sheep or cattle. It won blanket approval to undertake genetic engineering research and trials using human material and other mammals. Some of the reasons why AgResearch wanted to make such a generic research application were to refine the technology that produces transgenic animals and to avoid the cost and delays of having to gain approval from ERMA for each new GM organism.[24] ERMA approved the AgResearch application in the face of eight hundred and fifty-six objections and just seven submissions in support.[25] Even though the number of objections may seem astounding, when a government, such as New Zealand, has a heavy investment in a new technology, manifest in the promotion of publicly funded research in genetic engineering and in a regulatory body that evaluates an application primarily on its economic potential, then objections to a research application become irrelevant.

The total eight hundred and sixty-three submissions were made by a variety of people and groups, including the Green Party and other organizations opposed to genetic research, such as MAdGE (Mothers Against Genetic Engineering) and Greenpeace, and concerned members of the public, and those for genetic research, such as the Life Sciences Network, Fonterra (representing the national dairy industry), Federated Farmers (representative of the national farming industry), and the New Zealand Organisation for Rare Disorders.[26] The spectrum of objections ranged from questioning the legal and jurisdictional capacity of the ERMA to make a decision on such a generic application, to adequacy of containment facilities, to assessment of significant risks of the organism, to concerns of the risks to Maori economic, social and cultural well-being. The sheer number of objections is heartening to Maori who are also concerned about the applications of this new technology. However, as discussed earlier, working collaboratively with some of these groups is problematic for Maori because of the differences in worldview. The variety of groups concerned with these new technologies nevertheless make visible

the different issues surrounding genetic engineering technology for the New Zealand publics and make space for the engagement between applicants, ERMA and the public in the decision-making process. In order for the government and its agencies to be perceived by the general public to be operating in a fair and democratic way, concerns need to be seen to be heard, but not necessarily listened to.

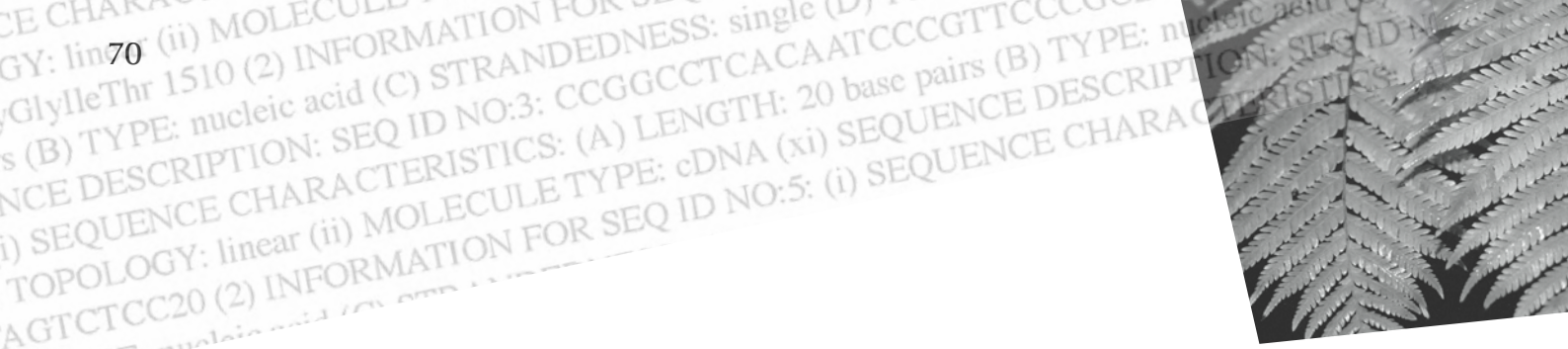
Prior to the December 1998 AgResearch application to ERMA, Ngati Wairere, the local hapu in whose rohe the research was to be conducted, was not consulted. In a similar genetic research case in 1994, Pharmaceutical Proteins Limited (PPL) Therapeutics (Scotland-based company that produced Dolly) and Selbourne Biological Services (based in Tauranga, New Zealand) were able to say that they had consulted with local Maori by convincing one member of the local iwi that the genetic engineering research seeking a cure for cystic fibrosis and other such diseases that they were going to do was for the benefit of all of humankind. The only reason Ngati Wairere were alerted to the 1998 research application was because Angeline Greensill discovered on the last day that ERMA was receiving submissions from the public for this application and concluded that she needed to hastily submit something so that the Maori view could be heard by the ERMA committee. Since this first AgResearch application, Ngati Wairere has made sure they were fully aware of the research AgResearch was conducting in their rohe. As a result, AgResearch needed to find ways to "consult" with Ngati Wairere as part of the ERMA application process and as part of its own internal research processes.

AgResearch, since the first application, has been instrumental in developing consultation processes with different Maori groups, after taking advice from PHP Consulting Ltd, legal advisors Russel McVeagh, ERMA and others. In fact PHP Consulting Ltd prepared a consultation and relationship-building planning document that was written by Paora Ammunson.[28] AgResearch has brought Ngati Wairere on board in their decision making of new applications and projects by giving them membership in: the Ruakura governance structure; the Ruakura Institutional Biological Safety Committee (IBSC); key project monitoring groups; and stakeholder consultations in applications.[29] AgResearch also intends to consult more widely with other hapu and iwi in the Waikato area in its future research applications.

## Implications of research

You might ask, "Why is medical research being conducted in an agricultural research environment?" A possible answer to this innocent, yet often overlooked, question may be found in a small paragraph embedded in the "Strategic Directions" section of the November 1999 "Medical and Health Industries Strategic Portfolio Outline," (SPO) which is used by the Foundation for Research, Science and Technology (FRST) to guide investment decisions in research, science and technology.

> The interchange between the medical and health industries and the food and fibre sectors is important to the success of this SPO. Much of the technology can find a testing ground in the food and fibre sector where competitive product entry is often less regulatory intensive than the human healthcare market. Conversely, many of the biomedical tools offer new sophistication for novel approaches in the food and fibre areas.[30]



Astounding as this sounds, it is entirely logical for genetic researchers to find the path of least resistance, the "less regulatory intensive" food and fibre sector. It would seem that the Foundation for Research, Science and Technology, in its position as one of the largest public funding agencies for research, helps researchers find the path of least resistance by influencing the direction of research. Biomedical research is seen as a vital area of growth in New Zealand. As this case illustrates, AgResearch is seen as a big player in this development.

This case illustrates the significance of biomedical research in New Zealand. Dr Mere Roberts believes ERMA's decision in approving AgResearch's application for research to create transgenic cows was swayed because genetic research, including transgenic research, is widely pursued throughout the world and is well established in New Zealand particularly in agricultural research. They consider that "if the Committee were to decline the present application because of Ngati Wairere's concerns, all transgenic research – in universities, hospitals, research institutes, and whether in the laboratory or under field test conditions – might have to be terminated."[31]

As a new technology that is being sanctioned and publicly funded through the implementation of neo-liberal government policies, genetic research will of course be widely pursued by researchers. However, the black and white scenario painted here by Dr Roberts of ERMA's decision-making process makes it very easy for a decision that recommends, "Proceed with caution." Because there is no visible "middle-ground" for ERMA when assessing the merits of genetic research, where the choice was to grant approval or terminate all transgenic research across the country, the decision will more often than not fall on the side of the genetic engineers regardless of what Maori or the general New Zealand public think. The result of this thinking by ERMA is that Maori concerns about genetic modification are listened to with "exquisite politeness" and then overridden. As Dr Mere Roberts states, "In the absence of any known cultural, spiritual or psychological effects of genetic modification, particularly that involving transgenic organisms, the ERMA has increasingly sought to place the 'burden of proof' on affected hapu/iwi by requiring them to provide evidence of any adverse effects."[32]

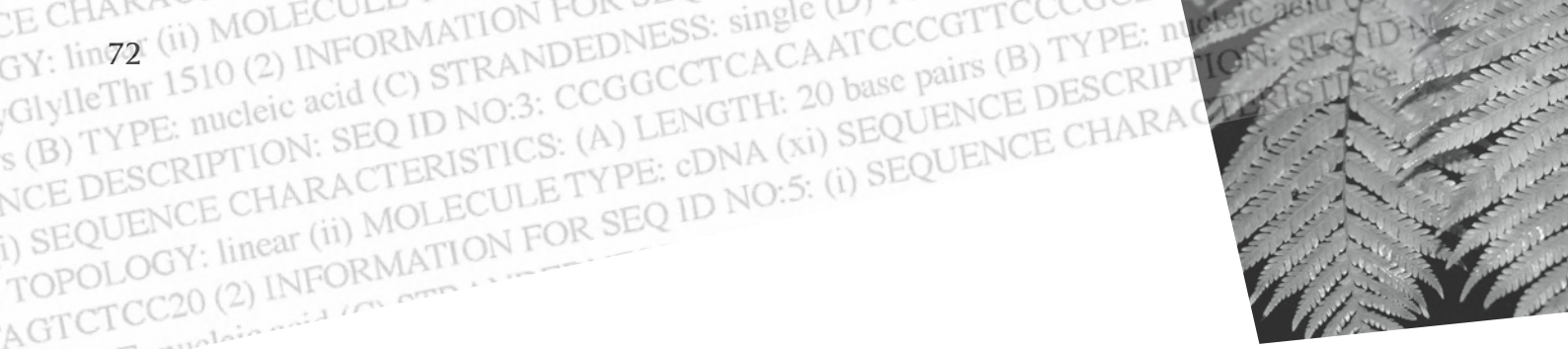
## Lessons Learnt

For Maori around the country this case highlighted the possibility that, through the rise in prominence of research that tampers and interferes with genes, the sanctity and respect for whakapapa would be violated. This violation of whakapapa is sanctioned by industry, government, and bodies set up to ensure a relatively smooth path toward research approval. This type of research is seen by some as the way forward for ensuring New Zealand's economic sustainability. The large majority of Maori expressing views on this type of research in various fora have quite clearly declared their opposition to research that violates the sanctity and respect for whakapapa.[33]

With all the consultation occurring with Maori since AgResearch's first application in 1998 and the consistent opposition by Maori, the research projects nevertheless continue and are extended. This sends a strong message to Maori generally, as stated by Angeline Greensill in her Statement of Evidence to ERMA for the first AgResearch application, "The approving of this application will serve as a permanent reminder to our people that our cultural and spiritual values and beliefs are still considered

insignificant in matters which have the potential to adversely affect us, our future generations and our relationship with our environment."[34]

Ngati Wairere has, however, achieved tremendous ground for Maori in interrupting this undemocratic and irresponsible decision-making process. Ngati Wairere have first of all conscientised Maori communities and made them more aware of the importance of monitoring what happens in their own rohe (region/territory). We all have a responsibility to care for our environment and our whakapapa relationship to all things. This responsibility starts at home in our own local communities. Second, Ngati Wairere has forced a space in the ERMA decision-making process for Maori communities to participate and be consulted. It is now mandatory for researchers to consult with local hapu and iwi before approval for research is given. As in the case of Ngati Wairere, research organisations such as AgResearch now have local hapu and iwi representatives on some decision-making boards. However, we must also be vigilant in ensuring that our participation is not just tokenistic. Third, Ngati Wairere has re-engaged Maori communities in utilising our own Maori knowledge perspectives and frameworks in the process of analysing research applications. Te Kotuku Whenua Consultants, the Ngati Wairere risk assessment environmental body, was set up to evaluate and assess the impacts of proposed research in their community using Maori knowledge perspectives and frameworks. Community engagement with Maori knowledge perspectives as an analytical tool has perhaps lain dormant because some communities have seen that it has not been given legitimacy in processes such as the ERMA submission and approval process. With the continued use of Maori knowledge worldviews by Maori communities in forums such as the ERMA process, Maori knowledge becomes even more visible as an alternate and legitimate worldview to Western reductionist science. Finally, this case has highlighted for Maori across the country the impacts of Western reductionist science research on the sanctity and respect for whakapapa. Although much attention has been given to Treaty of Waitangi and land-based struggles, which are extremely important, this case also highlights that we have many other struggles that we need to monitor at the same time as they significantly impact on our kaitiaki relationship we have for all our relations.



# Footnotes

1. Reynolds, P., & Smith, C., Maori, Genes and Genetics: What Maori Should Know About the New Biotechnology, (Whanganui, New Zealand: Whanganui Iwi Law Centre, 1999), 3.
2. Angeline Greensill, who made a submission on behalf of local Maori, Ngati Wairere, accidentally heard about the submission process the day the call for submissions closed.
3. Waikato Times, "$3000 fine for man who sold stolen Ruakura meat," 27 June 2001. It is interesting to note that this incident of a local man convicted for selling uninspected meat from the AgResearch site occurred after AgResearch had assured the New Zealand public that security at AgResearch was more than adequate for high-level containment research.
4. Source: New Zealand Herald news articles.
5. Matua-Tipene, B., "A Maori response to the biogenetic age." In Prebble, R., (ed.) Designer genes: The New Zealand guide to the issues, facts and theories about genetic engineering. (Wellington, New Zealand: Dark Horse Publishing Ltd, 2000), 106.
6. Jacqui Amohanga, research interview with the author, Hamilton, 9 March 2002.
7. Angeline Greensill, research interview with the author, Hamilton, 9 March 2002.
8. In GE tamarillo trials conducted in Kerikeri, there was also insufficient notification. Organic farmer and activist Marty Robinson says, "They [ERMA] say notify apparently in three places, which turned out to be the Herald [national paper based in Auckland], the Dominion [Wellington based newspaper] and the Christchurch Press or Star [Christchurch based]. And that's not very relevant to Northland." Marty Robinson, research interview with the author, Kerikeri, 6 March 2002.
9. Angeline Greensill, research interview with the author, Hamilton, 9 March 2002.
10. Jacqui Amohanga, research interview with the author, Hamilton, 9 March 2002.
11. Angeline Greensill, Jacqui Amohanga, Maree Pene, research interview with the author, Hamilton, 9 March 2002.
12. Jacqui Amohanga, research interview with the author, Hamilton, 9 March 2002.
13. Ibid.
14. Ibid.
15. Jackson, M. An exquisite politeness: The Royal Commission on Genetic Modification and the redefining of the Treaty of Waitangi. (Unpublished paper, 2001).
16. Angeline Greensill, Jacqui Amohanga, Maree Pene, research interview with the author, Hamilton, 9 March 2002.
17. Angeline Greensill, research interview with the author, Hamilton, 9 March 2002.
18. When I attended a closed meeting on 24 September 2003 between a group made up predominantly of scientists and Minister for the Environment Marian Hobbs, held at the University of Waikato, I heard a similar comment from an AgResearch scientist saying that the risk of horizontal gene transfer is so minimal that you can forget it. Prior to this, Marian Hobbs asked the scientists present whether or not horizontal gene transfer can occur through cow excrement, where GM DNA leaches into the soil, as that very question had been asked of her by a member of the public. Another AgResearch scientist commented that there is a likelihood of this occurring but the risk was seen as low/minimal. What the scientist was more concerned about was the impact of mosquito's because in a lab or closed containment you could discover the effects, but it is unlikely you would discover the effects of mosquito's in a field experiment. The concern about mosquito's is that they might transfer genes or viral vectors or naked DNA from transgenic cows to other hosts including humans.

19. Genetic engineering is a specifically designed technology that allows the transfer of genes horizontally between species that do not interbreed, such as the research conducted by AgResearch to create transgenic calves. Horizontal gene transfer is defined as "the transfer of genes to unrelated species by infection through viruses, through pieces of genetic material, DNA, by being taken up into cells from the environment, or by unusual mating taking place between unrelated species." Ho, M.-W., Genetic engineering - Dream or nightmare? The brave new world of bad science and big business. (Bath, UK: Gateway Books, 1998), 13.
20. Angeline Greensill, Jacqui Amohanga, Maree Pene, research interview with the author, Hamilton, 9 March 2002.
21. Suzuki & Knudtson believe "However carefully lab tests are performed, those studies must eventually be replicated outside if engineered plants or animals are designed for external use. Accidental escapes in the lab or field are inevitable and the ecological consequences cannot be predicted beforehand" Suzuki, D., & Knudtson, P., Genethics: The ethics of engineering life. (Toronto: Stoddart Publishing Co. Limited., 1990), 299.
22. "Bioreactors," "biopharming" and "pharming" are terms used by the research scientists and genetic engineers to describe the use of animals as production houses for the purpose of secreting drugs in the animals milk. Dr Mae-Wan Ho, Dr Ruth Hubbard and Jeremy Rifkin are examples of people who have critically discussed this development.
23. Angeline Greensill, Jacqui Amohanga, Maree Pene, research interview with the author, Hamilton, 9 March 2002.
24. BIOTENZ News Update, 19 September 2003. To date there has been a dismal record of gene therapy experiments.
25. NZ Herald, "'Floodgates' warning for ERMA," 14 August 2002.
26. NZ Herald, "Gene plan meets fierce opposition," 12 August 2002.
27. Environmental Risk Management Authority Decision: Application GMD02028, 30 September 2002.
28. ERMA had previously only made decisions on specific descriptions of the organism and not made decisions on applications that were generic in their description of the organism used. AgResearch had also described its application as the "development" of a genetically modified organism in containment (which has less regulatory controls), but some submitters contended that the application was actually a field test, which would require tougher regulatory controls.
29. Application No. GMD01194, Form 3, Application for approval to develop in containment any genetically modified organism under section 40 of the Hazardous Substances and New Organisms Act 1996. ERMA generic application submitted 20 December 2001 by AgResearch Limited. (p. 38).
30. Ibid., 57.
31. Medical and Health Industries Strategic Portfolio Outline, (November 1999). Foundation for Research, Science and Technology (FRST). Obtainable on FRST website at: http://www.frst.govt.nz/about/spo/medical.pdf, accessed on 8 September 2003. Strategic Portfolio Outlines (SPO) are used as investment strategies that set out the Foundation's investment priorities in order to achieve government outcomes. FRST is one of the main government research funding bodies.
32. Roberts, 2000: 19.
33. Ibid., 27.
34. For a more in-depth look at Maori concerns with this type of technology, see: Reynolds, P. (2004). Nga Puni Whakapiri: Indigenous Struggle and Genetic Engineering. Unpublished PhD Thesis, Simon Fraser University, Vancouver, Canada.
35. ERMA Hearing: Application GMF98009 (AgResearch, Cattle), 25 August 1999, Wellington District Courts, Wellington.

# GETTING THE STORY RIGHT – TELLING THE STORY WELL
## Indigenous activism – Indigenous research

Linda Tuhiwai Smith
*Ngati Awa, Ngati Porou*

There is no easy or natural relationship between activism and research. Although some activists are also researchers, and have to undertake their own research, and researchers may also be activists, the roles are very different. Research and activism exist as different activities, undertaken by different kinds of people employing different tools for different kinds of ends. Certainly, at the most abstract level activists and researchers share some kind of belief that they are acting to improve the world and to make it a better place for human beings. Beauty contestants espouse similar ideals, as do many tyrants and despots. Researchers and activists also suffer to some degree with a problem of discourse; they are reviled in some quarters, held in suspicion in others, respected reluctantly, revered only when they have reached their used-by-date and are yet regarded as necessary constituents of robust societies. Within many indigenous communities there is a deep conservatism and an unwillingness to upset the status quo and in these environments any agents of change whether educators, researchers or activists are regarded as suspect. This is not just a feature of indigenous communities as former British Prime Minister Margaret Thatcher disliked sociologists as a collective group of scholars and tried to get rid of them all by attacking their credibility.

The basis of this paper is to relate the more generic question about why we do what we do either as researchers and/or activists to questions about the potential ways in which indigenous activists and indigenous researchers can collaborate to advance indigenous interests at local, national and international levels. While this paper addresses the specific relationship between indigenous research and indigenous activism it is not my intention to rule out engagement of activists and researchers with wider non-indigenous alliances as indeed such engagements are often unavoidable and are tactically necessary to get the work done. It is also not my assumption that all indigenous projects at local, national or international level are supported by all indigenous peoples around the world. Some projects and some major international initiatives have been worked on collaboratively for decades and do have

support in principle from a majority of indigenous nations. There are also shared discourses, visions and aspirations that resonate across many indigenous contexts – cultural and linguistic survival, self-determination and the right to remain indigenous are some examples of the shared discourse that has been the platform for indigenous activism.

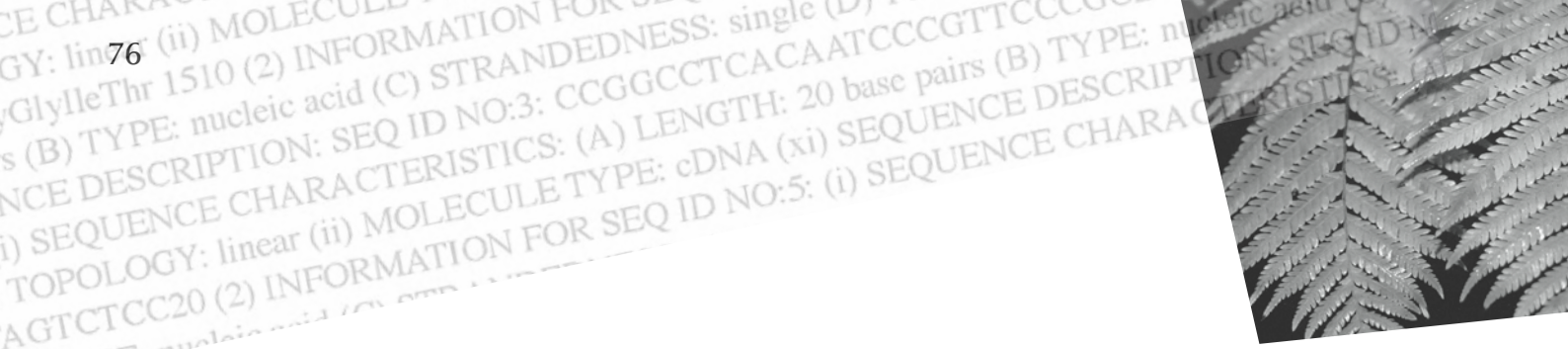
## Aligning the agenda for indigenous research and indigenous activism

In my book *Decolonizing Methodologies: Research and Indigenous Peoples* (1998) I set out what I referred to as "the indigenous peoples project" and made some suggestions about how an indigenous research agenda could be formulated in relation to the indigenous peoples' project. This approach contextualised research in an explicitly decolonizing, political and international framework and attempted to draw the attention of researchers away from their traditionally western disciplines towards indigenous visions, aspirations and aims. One chapter in the book set out twenty five 'projects' that I had identified as work in progress by indigenous researchers I had observed, read and talked to over the years. Another chapter discussed such issues as training indigenous researchers and developing indigenous research entities that could build the capability needed to sustain the indigenous peoples' project. In attempting to bring together indigenous researchers within an indigenous peoples' research agenda I was arguing primarily that indigenous researchers needed to make more of an effort to connect with the wider indigenous peoples project. I suggested that researchers needed to understand that the institution of research by its nature would alienate them from their own communities and aspirations and would perpetuate the colonising structures that many aspired to overcome and that as a response researchers needed to me more conscious about decolonising the academy.

In the last two decades the issues for indigenous activists and indigenous researchers have changed dramatically; the world has been and is in the process of being reconfigured in ways that simultaneously impact on indigenous peoples. These changes require further conversations about how research assists or hinders indigenous activism, how indigenous activism can undertake and employ more research in activist arguments, how the two activities of research and activism connect with the visions, aspirations and needs of indigenous communities and how the activities of research and activism assist indigenous communities to live as indigenous communities that experience cultural sustainability as well as social, economic and political well-being.

## Globalisation, the marketplace and indigenous peoples

In the 21st Century indigenous communities are among those communities that have been excluded from the world - in some cases quite literally excluded to the margins of societies. They represent a portion of peoples whose languages and cultures have been obliterated, assimilated or at best hybridised into some other culture. Today, somewhere around the world indigenous peoples are meeting in small groups or large gatherings to discuss local and/or global issues. Also meeting and interacting somewhere in the world are 'world leaders' whom we can assume are the leaders of less than a dozen countries. Both sets of gatherings represent something interesting about globalisation; the first set of gatherings brings together descendants of peoples who were for the most part were not expected to survive into the 21st century. They are potentially what Boaventura de Souza Santos (Dale and Robertson, 2004)



calls a "*transnational interaction from below, that is, from the victims, the exploited, the excluded and their allies…..*" The second set of gatherings brings together those who presume to govern and set the world's agenda for peace, for democracy, for market reform, for alleviating poverty, for 'regime change', for dealing with terrorism. Of course, nothing is quite so neat or binary so on the edges of both gatherings are other kinds of meetings with other combinations of peoples and interests, some of which intersect in complex ways but mostly the agendas compete with each other for attention and priority.

Neo liberal economic theory informs one aspect of globalisation (Olssen, 1996). It is best known in developing countries through the application of structural adjustment programmes administered by agencies such as the World Bank. Neo liberal economic theory is also understood in the indigenous world for such things as free trade agreements and the World Trade Organisation because of the implications of these agreements on traditional knowledge. In New Zealand, neo liberal economic theory has driven two decades of reform. At one level Maori people have not had any reason to support government economic policies that predated the neo liberal reform programme because the impact of decades of government legislation and policies on Maori has been continuing economic marginalisation and cultural assimilation. Neo liberalism for some Maori represented a possibility for Maori to engage more proactively in the economy. Other Maori saw more dangers in the reforms especially in the way competition and individualism were fostered at the expense of collaboration and collective identity. After more than two decades it is certain that for younger generations of indigenous and non indigenous people neo-liberalism is the status quo, the taken for granted knowledge that underpins society.

Neo liberalism has also become the dominant economic theory for how the world should function as a global community. The key site for the economy is the market place – in other words the world is a market place – and the role, some argue the only role, of states and governments is to ensure the free operations of the marketplace so that commodities can be bought and sold at market prices. Indigenous peoples are situated at an interesting part of the market. They are considered potential market players because they offer unique commodities such as traditional knowledge. But, they are not quite market-ready because their unique commodities have not been made market ready, that is they have not yet been 'discovered' in the research sense nor have they been commercialised in terms of intellectual property.

From indigenous perspectives some of their unique knowledge is on the verge of extinction and ought never to be commercialised while other aspects of the culture may in fact be commercial but there is no regime for ensuring benefits flow to the communities who created or have possessed such knowledge. The issue of indigenous knowledge is pivotal for the work of activists and researchers at this moment because it is the term or concept that currently embodies most of what remains of indigenous cultures. Traditional indigenous knowledge is regarded also as a potential avenue for indigenous communities to enter the market place with items to sell while at the same time it lies at the heart of identities, histories, legacies and responsibilities for generations that have been here before and those to come. Selling that legacy is viewed by many activists as tantamount to destroying the culture.

The topic of biotechnology and the patenting of human life forms is significant because it brings into very sharp focus what the extreme implications of a market economy are about; indigenous bodies and their cell lines. This seems scarier than the exploitation of images and art forms but it is part of the same

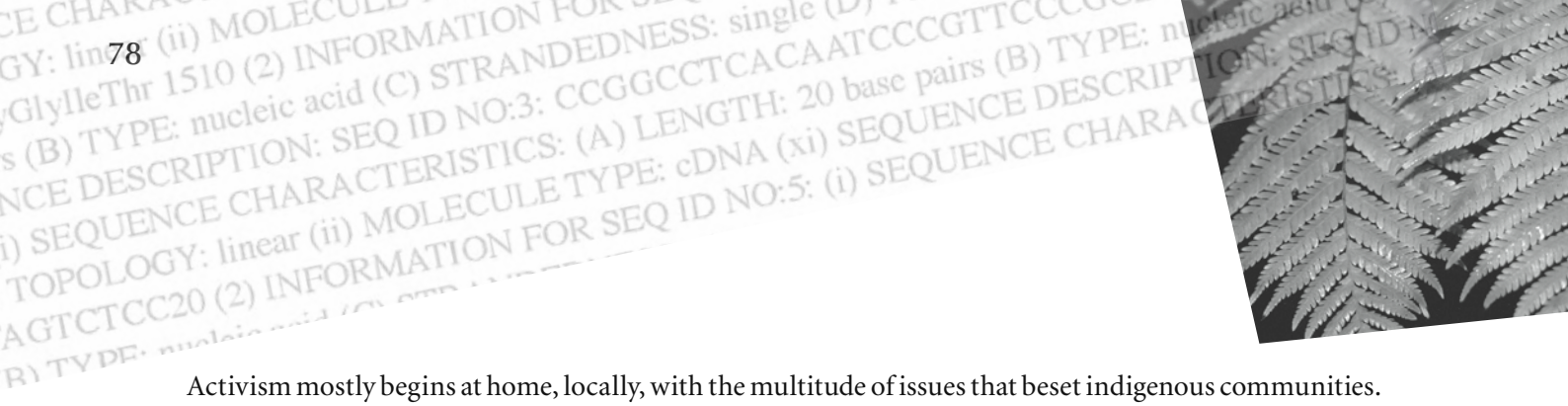
process of commodification of traditional indigenous knowledge because it literally commodifies our biology in ways that attack the very existence of indigenous peoples. This is not about all things being equal and that every one's cell lines are up for study – this is about the powerlessness of groups and communities around the world whose bodies are viewed as potential commodities.

## Traditional indigenous knowledge – the work of activists

In the last twenty years indigenous activists have had a hugely significant role in educating the community about globalisation and neo liberal economic policies and practices. They have often acted as the critic and conscience of societies much to the displeasure of governments and powerful business voices. Some indigenous activists have been accused of treason because they were seen as putting the economy at risk and more recently others have been accused of terrorism for engaging in political acts against their governments.

Indigenous activists working in the international domain have identified the extent to which many states and governments have been prepared to sacrifice traditional indigenous knowledge and peoples, treaties, and other historic agreements and understandings to the market economy. Major free trade agreements have been signed with no consultation with the indigenous communities or indeed even other communities about the nature of their undertakings and the implications for the future. Multinational companies have been given trans-national freedoms that enable them ultimately to move labour across borders, that is to import and export people for the labour market, to foster an intellectual property regime that has few ethical limits, to shape national laws and values at the expense of national identities, to develop themselves in competition with governments. In this environment activists have had to cover and document activities that are happening locally, nationally and globally and demonstrate the links and the logic between rhetoric and global discussions with material and environmental changes in the lives of local indigenous communities.

One of the battlegrounds in the international arena for indigenous activists has been around concepts of *traditional knowledge*. This is a shift of tactics in terms of earlier battles over the word self-determination or the struggle to have the 's' recognised in terms of describing indigenous communities as *peoples* that marked early activist strategies and writings. The issue is partly about the best term to use in international instruments and documents but the more significant matters concern the existence, protection, ownership, and right to development of indigenous environments, indigenous bodies, stem cell lines, and identities, historical and contemporary practices, lores, laws, values and belief systems, knowledge frameworks, ways of thinking and knowing, products and creations, concepts, designs and materials, images and representations, songs and performance, visual arts and all the other diverse parts of whole living cultures. The activist struggle is to defend, protect, enable and facilitate the self determination of indigenous peoples over themselves in states and in the global arena where they have little power. Activists in this area of international work have to develop arguments that will be heard in a political environment where indigenous people don't matter, are plain irritating or viewed as downright dangerous.



Activism mostly begins at home, locally, with the multitude of issues that beset indigenous communities. Most of these issues are also international issues as activists usually discover for themselves when they start talking to others and mobilising support. Locally grown activism and activism that is supported or 'mandated' by local communities (however they may define themselves) is seen as a badge of legitimacy and evidence of flax roots credibility. Communities have expectations that activists know their needs because they have experienced those needs at a very personal level. Over the years of indigenous activism the activist community has developed its own protocols or codes of conduct and networks for local activists are global activists – they form part of a global network of indigenous activism.

One of the skills that many front line indigenous activists have in abundance is the ability to communicate. Indigenous activists have that added ability of communicating across linguistic, cultural and literacy divides. Another skill they possess is the ability to ignite others, to move them to take action. Other activists however do their work behind the scenes, in quite hostile environments where they are either alone or are collectively marginalised with other indigenous and minority and special interest groups. No one really sees their achievements when they manage to influence the text of an international charter, no one quite understands the significance of their work. Activism takes different forms and one of those forms is the kind of activism that is deeply knowledgeable about the struggle, where it has come from, what is at stake and what tactics are required now.

## Traditional indigenous knowledge – the work of researchers

While communities and activists assert claims to traditional indigenous knowledge the work of researchers has some other dimensions. Remember for example that colonial processes such as religion and education actively set out to destroy the existence of indigenous knowledge or systems for knowing – there were many ways this occurred from beating children at school, to isolating the leaders and healers, burning places of significance and to the use of ridicule and cartoon characters. The attack on traditional ways of knowing was often carried out under the guise that tradition impedes progress and access to literacy, medical health and economic development. The academy played a very significant role in upholding western intellectual superiority – the disciplines of western knowledge were used as a platform for dismissing or denying the existence of indigenous knowledge – that view still exists in some parts of the academy today. So, the first task of many researchers is to survive and do exceedingly well in an education system that denies the existence of knowledge of their own peoples. This does not always mean that they were necessarily successful in the system in terms of credentials but that they were able to decode, demystify the system in order to learn and be educated without being damaged. Academic researchers have had to perform well if not better than their peers to get through the system and reach its higher levels. In many if not most academic disciplines one's indigenous identity has to be masked, hidden from view as a pre-condition of success. Few have actually succeeded and very few in the sciences which highlights another challenge for activists who can not easily identify researchers with understandings of the science and with the empathy and knowledge of the values and knowledge of indigenous communities to mount powerful counter arguments in areas such as bio-technology.

In the field of traditional indigenous knowledge researchers have their own arguments to make, sometimes inside their own heads as they must debate it at a personal psychological level, but most times

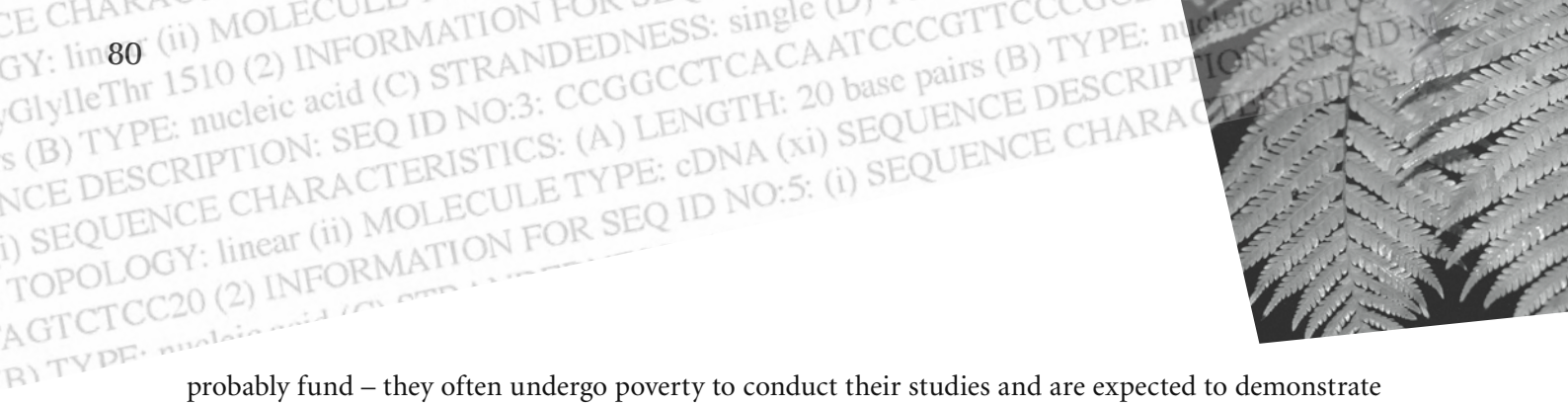
within the very institutions of knowledge in which they have been trained. One of the most difficult academic arguments for indigenous scholars has been to argue the existence of indigenous knowledge as a unique body of world knowledge that has a contribution to make in contemporary disciplines and institutions let alone for indigenous peoples themselves. The arguments are not necessarily framed as knowledge questions as they are more likely to be about political issues of access to institutions, equity and equality of opportunity, physical spaces, designated staff positions and course content. In many cases if there are in fact indigenous academic staff members the first issues are about surviving in a culturally hostile environment. Many writers such as Vandana Shiva have noted the monoculturalism of western European institutions of knowledge and how much a barrier this culture of monoculturalism is to other possibilities for knowing and understanding the world differently. In what he calls a *sociology of absences* legal sociologist Boaventura de Sousa Santos (2004) argues that through the epistemological and social monocultures of Europe there has been a "gigantic mode of production of silences, unpronounced-abilities and absences' that has had a devastating impact on developing countries. Santos talks about global cognitive justice being an important part of global social justice.

Indigenous academic researchers who work in the area of traditional knowledge have to work at a philosophical or epistemological (theory of knowledge) level to muster their arguments as well as at very practical levels such as the provision of support for indigenous students or the design of a course. In the academic environment they are assessed by their peers through such things as publications in international refereed journals of high standing. So, yet another challenge is to find an international refereed journal of high standing that publishes papers on traditional indigenous knowledge. The difficulty in identifying such publishing outlets is indicative of the way the academic environment works to legitimate certain kinds of knowledge. Activist academic researchers who understand this challenge have attempted to create forums for indigenous scholarship and programmes for supporting indigenous knowledge and ways of knowing but these attempts are for the most part still in the margins.

Field based, science researchers have different challenges as they often work for very large research organisations or companies such as the United States National Institutes of health or in New Zealand the Crown Research Institutes. The imperatives of these organisations are to solve problems and to turn a profit while they do this. Profit for the organisation is a major driver for the way they undertake research. In these systems indigenous researchers often bring capacities to the organisation that it needs such as networks with indigenous communities and understandings about how communities work but they also work in a difficult environment where their culture is seen as potential intellectual property.

## Traditional indigenous knowledge – where the work of activists and research come together.

The NGO sector provides one potential bridge for activists to gain access to the kinds of research specifically relevant to their needs. Academic researchers and community based researchers however do produce research that is also extremely powerful. Academic researchers are trained to provide in depth analyses and have the freedom to conduct research that is out on the edge of knowledge. Academic researchers, and often these are graduate students, do get to study issues in depth that no one else would



probably fund – they often undergo poverty to conduct their studies and are expected to demonstrate a certain intellectual dedication to their task. The point is that it is often graduate students who are doing substantial original research and they represent a potential pool of researchers who could work in collaboration with activism. There are some risks in such a collaboration but they can also be managed of planned for ahead of time.

Community based researchers offer something quite different because they are so well placed within a community to document what is happening at a local level over long periods of time. They have an advantage and a disadvantage of being eye witnesses to events and the aftermath, they lend a different kind of evidentiary authority because of the immediacy of their context. A major problem for both indigenous researchers and activists is the lack of a good internationally networked clearinghouse and archives that can locate, co-ordinate, analyse and disseminate research and evidentiary documentation. There are very good electronic indigenous networks and some great websites where information can be downloaded but most information is stored within individual's memories and in specific networks of activists. A large part of the research stories that need to be told are small stories from local communities across time and space, in other words the stories that map devastation across generations and across landscapes or the stories of transformation and hope that can also be tracked across time and space.

A significant point to make here is that not all indigenous thought about indigenous knowledge is going to be useful for activists rather, the very existence of a community that can study and research traditional indigenous knowledge, is something that activism has actually created and must also protect – in other words it is a measure of the success of activism but can not be successful unless the knowledge scholars do the work they have to do to protect, defend, expand, apply and pass on to others. As an example, in the Maori arena, scholarship in terms of indigenous knowledge seems to be flourishing especially within Maori institutions but also across a range of quite diverse areas such as science, health, architecture, education, visual and performing arts as well as Maori Studies. Conceptual work and other research in relation to Maori knowledge or what is known as matauranga Maori has been the subject of student dissertations, research programmes and funded science programmes. There are debates about what it is and how it is to be taught and learned. There are Masters level courses in Maori educational institutions of higher learning known as Wananga that focus specifically on Matauranga Maori. This level of activity and institutionalisation has not come without activism that has stretched back over several decades. The types of activism required over each generation to protect and nurture indigenous knowledge has varied from direct political action and protests to defend the Maori language, court action, land occupation, claims to the Waitangi Tribunal, through to the implementation of programmes that would nurture the knowledge in public institutions. Traditional indigenous knowledge is re-generating in spaces created by activism.

## Getting the story right – telling the story well

Let's now return to the ideas of improving the world, world peace and saving 'mankind'. Most research is produced on the basis that it will contribute to something greater than itself and that it adds value to society for the future. Most countries that invest heavily in research are investing in developing tools for change or technologies and insights that will take a country into the future. The research ideal of

benefiting society is an important ideal. Interestingly it is a very activist notion because it implies that societies will change, that they will be improved and lives will get better. Research is expected to lead to social transformation. The critical question for indigenous communities is that research has never really demonstrated that it can benefit communities because the benefits never reach indigenous peoples or the benefit is used as a ploy or tactic to coerce indigenous communities into sacrificing their cultural values, to leave their homes, to give up their languages and to give up control over basic decision making over their own lives.

In other words research exists within a system of power. What this means for indigenous researchers as well as indigenous activists and their communities is that indigenous work has to 'talk back to' or 'talk up to' power. There are no neutral spaces for the kind of work required to ensure that traditional indigenous knowledge flourishes, remains connected intimately to indigenous people as a way of thinking, knowing and being, is sustained and actually grows over future generations. The title of this paper is ambiguous for a reason, getting the story right and telling the story well are tasks that indigenous activists and researchers must both perform. As in the case of the authors in this publication, there are few people on the ground and one person must perform many roles; activist, researcher, family member, community leader plus their day job. The nexus, or coming together of activism and research, occurs at the level of a single individual in many circumstances. An activist must get the story right as well as tell the story well, so must a researcher. In a world where indigenous peoples wield some political and economic power activists would be able to call up their Think Tank which has a head office near the other institutions of power and ask for research on any given topic. Researchers would be trained to provide it in multiple forms. In an ideal world there are some issues that activists and researchers would not ever have to address.

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# Pig cell 'guinea pigs' - an experience of 'xenotourism': the proposed Diatranz Experiment in the Cook Islands

Te Tika Mataiapo - Dorice Reid

Are the lives of indigenous people less important than those of others? This is the question I asked myself when reading articles from the *Cook Islands News* and watching footage from Cook Islands Television News on a proposal by a biotechnology company, Diatranz Ltd., to commence xenotransplant experimentation in the Cook Islands. (Xenotransplantation is the transplantation of live cells, tissues or organs from animals into humans.) The company proposed to conduct clinical trials on 24 Cook Islanders to find a possible cure for Type 2 diabetes, quoting the high incidence of the disease among Pacific Islanders as part of its justification.

In March 2002, without prior consultation, the Cook Islands government agreed "in principle" for the New Zealand based company to commence the surgical insertion of insulin-producing pig cells into diabetes patients in order to restore insulin production and remove the need for daily insulin injection.

Diatranz's interest in locating its research in the Cook Islands followed a decision by the New Zealand government, in December 2001, to amend the Medicine Act 1981 to constrain future use of xenotransplantation and genetic engineering of human embryos until June 2003, with a provision to extend this to June 2005 (RSNZ News, 20 Dec. 2001). As a consequence, xenotransplantation experiments had to meet strict criteria and undergo scrutiny by the Health Research Council's Gene Technology Advisory Committee (GTAC).

Three applications from Diatranz to conduct xenotransplantation experiments in New Zealand had been rejected by GTAC, most recently in July 2001. On that occasion, the New Zealand Director-General of Health, Dr. Karen Poutasi noted that the Heatlh Research Council could not dismiss the possibility that

the procedures proposed by Diatranz could cause transmission of the Porcine Endogenous Retrovirus (PERV) to human populations. Dr. Poutasi invoked the 'precautionary principle' requiring that regulatory authorities give the balance of doubt to protecting the community, where there is uncertainty about the evidence of risk or benefit. (New Zealand Ministry of Health, 2001; Williams, 2002)

## Diatranz reaction

Following the New Zealand government's decision in 2001, Diatranz was reported as saying, "We can't continue to exist here [New Zealand]. We have been legislated out of the country. We have been delivered a vital blow, but it won't stop xenotransplantation. It's happening *elsewhere*. The risks are now that it's going to be come *unregulated*." (Taylor, 2002)

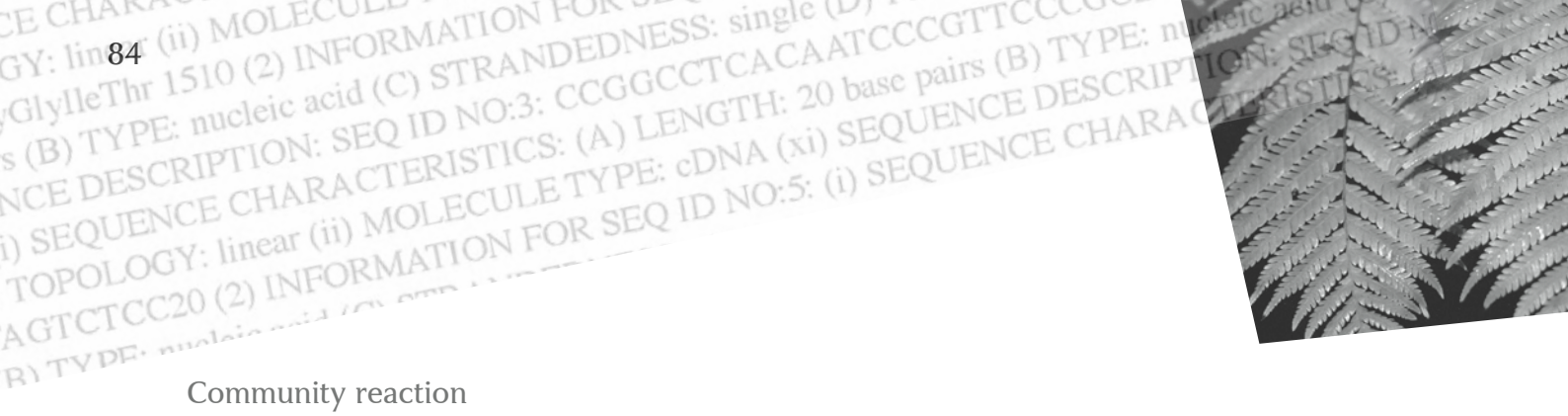
Diatranz's 'unregulated elsewhere' was the Cook Islands. Diatranz planned to take advantage of the Cook Islands 'free association' with New Zealand by experimenting on non-insulin dependent Cook Islanders living in New Zealand but visiting the Cook Islands. Following surgical insertion of the pig cells in the Cook Islands, the patients would then be sent back to New Zealand for further monitoring and testing.

When news of the proposed relocation of the banned experiments became public, the New Zealand Ministry of Health took the unusual step of issuing a 'Xenotransplantation Research Warning" (7 March 2003) relaying expert opinion from Professor Tony d'Apice of the International Xenotransplantation Association, an association of eminent doctors and scientists working in the field. Professor d'Apice expressed serious concerns at the proposed the Cook Islands trials noting that -

- "Xenotransplantation of pig cells, tissues or organs to humans presents risks of infection from the pig spreading into the human population …It is our opinion that the studies of possible benefits are inadequate and do not counterbalance the potential risks involved."
- The Cook Islands [does not] have the sophisticated virology facilities needed for monitoring for pig viruses, bacteria, etc which might affect humans";
- "Jurisdictions like Mexico[1] and the Cook Islands do not have the appropriate regulatory authorities to develop appropriate guidelines to safeguard the patients and their contacts. One suspects that the reason that trials are conducted in such countries is precisely because they do not have such safeguards." (New Zealand Ministry of Health, 2002)

The New Zealand government also expressed its concerns about the potential flow of disease between the two countries due to the constant exchange of people (RSNZ News, 5 March 2002).

The MP representing Cook Islanders resident overseas, in the Cook Islands Parliament, Dr. Joe Williams, responded to the New Zealand Government's intervention, claiming that, "New Zealand has absolutely no right to interfere in an internal Cook Islands' matter." The Cook Islands government subsequently sought to opt out of further controversy by stating that it would leave it to the individual Cook Islands diabetic to decide whether they wanted to take part in the pig-cell implant trials. They then instructed the Health Department to seek the views of Cook Islanders though public consultations.



## Community reaction

Traditional leaders in the Cook Islands were outraged that the Government should even consider using our people as "guinea pigs" for the Diatranz experiment. The implantation of live pig cells into human beings is considered a desecration of the sacredness and spirituality of the human body. Traditional practice is based on sacredness, respect and spirituality. The Religious Advisory Council were similarly unhappy with the prospect of xenotransplantation experiments taking place in the country. The issue also created great concern within the Cook Islands Chamber of Commerce which argued that the Cook Islands was being fast-tracked into a controversial medical project for which insufficient technical and professional advice was available. There were no borders for bio-risks, the Chamber argued. The matter was not simply an internal Cook Islands matter, as Dr. Williams had suggested, but required endorsement from the international medical community. To proceed against international opinion carried the risk of bringing the Cook Islands into serious disrepute. The country possessed no scientific community nor a competent regulatory authority to properly evaluate the experiment. The prior endorsement of the World Health Organization was a non-negotiable pre-requisite. It was unacceptable, the Chamber continued, for the Cook Islands to be seen as a medical "jurisdiction of convenience", where New Zealand residents could receive treatments deemed illegal by New Zealand medical authorities. If the research was to proceed, it should proceed in the USA or another jurisdiction where competent regulatory authorities could exercise appropriate oversight. The Cook Islands would be following a dangerous path, the Chamber concluded, if the trial was allowed to proceed in the absence of impartial and comprehensive scientific advice, without a competent impact assessment and without the endorsement of the international scientific community.

## International reaction

The Chamber of Commerce's warnings turned out to be prescient. In Washington, decisions being taken by the Cook Islands government were causing considerable agitation among members of the U.S. Secretary of Health and Human Services' Advisory Committee on Xenotransplantation.

"What we really want to make clear is that this is just not another medical technology that's being done outside our borders with no regulation. We want to be very specific of the serious nature of the infectious disease risk of xenotransplantation technologies, and we want to be absolutely clear about that….. This is putting our folks at risk, and it's putting others at risk, there's a potential international risk, and that's the heads up." (U.S. Department of Health and Human Services, transcript, 2002)

The Committee was particularly concerned at the prospect of US citizens traveling to countries like the Cook Islands and Mexico to participate in xenotransplantation trials in the hope of obtaining remission from disease ("xenotourism"), returning home as possible carriers of a dangerous retrovirus. More broadly, committee members were concerned not just with "our citizens who are directly involved as potential consumers, but the broader issue of whether the actions taken, for example, in the Cook Islands …still have the indirect impact of potentially creating infectious risk to which citizens of this country and other countries are all at risk. So our country… has an interest in what goes on there in the same way we have an interest in … what happens to our environment when another country pollutes

their local air space or water or whatever." (U.S. Department of Health and Human Services, transcript, 2002)

In the event that the trials proceeded, members of the Committee were considering how to advise the US Government "what do you do when they [the Cook Islands government] don't want to co-operate. Well, the one thing we can control is travel into the country, and if Cook Islands wants to do pig xeno transplants with no infectious disease monitoring, then we can refuse admission to the country from people from the Cook Islands." (U.S. Department of Health and Human Services, transcript, 2002)

The Committee broadly concluded "that the main issue here is that … there has been an agreement in every developed country on both sides of the Atlantic that this is something that can't be taken lightly and deserves an overarching regulatory environment for a well-designed trial that involves issues on the animal side and on the ethics and on the monitoring of the patients, and that we have concerns that that kind of a regulatory framework doesn't exist in Mexico [and the Cook Islands] … That's what we are worried about, period." (U.S. Department of Health and Human Services, transcript, 2002)

There was the remote possibility that the Cook Islands might, in a moment of negative spin, come to be regarded as a 'rogue nation' in the eyes of American regulatory authorities.[2]

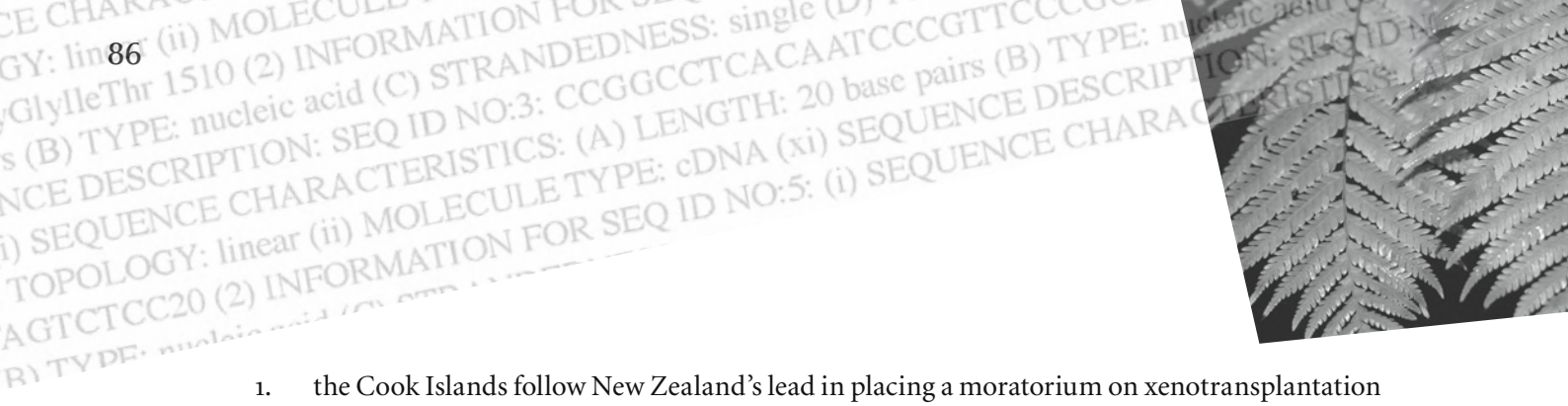
## Further community response

Although no-one in the Cook Islands was aware of these US Government deliberations, local community reaction reiterated US concerns about the absence of a regulatory framework and competent medical advice, the absence of appropriate infrastructure within the Cook Islands Health Department to monitor and evaluate complex research projects such as that proposed by Diatranz, and the failure by government to disclose its total proposed involvement which, according to Diatranz, included royalty payments if the trials were successful.

At public meetings held in Rarotonga[3] by Diatranz, less than a dozen Cook Islands diabetes sufferers indicated their willingness to undergo the experimental treatment. In all cases, their lives were so filled with the pain and discomfort of daily injections that they were willing to participate, even with the risks still unknown.

A talk-back on Radio Cook Islands confirmed overwhelming public condemnation of the proposed medical trials. One caller, however, felt the experiment would be acceptable if participation was confined to volunteers past the age of child bearing, where the individuals involved had no other possible cure available to them.[4]

In the event, following sustained public protest, the Cook Islands government decided against proceeding with the trial (Thomson, 2002), opting instead to seek further advice from the New Zealand Health Research Council (HRC). The Council subsequently recommended that -



1. the Cook Islands follow New Zealand's lead in placing a moratorium on xenotransplantation studies in humans pending the outcome of future pre clinical research;
2. the government ask the HRC directly or via the New Zealand Ministry of Health to review the proposal submitted by Diatranz; and
3. a third party country be asked to conduct the scientific review of the proposed trial. *(reference?)*

## Diabetes

The main justification for xenotransplantation is to find alternatives to human organ transplants and in the case of diabetes lessen the need for insulin, which controls blood sugar level. Although many human transplant operations are highly successful, there is always a severe shortage of suitable donated organs and tissues. In public presentations in the Cook Islands, Diatranz drew attention to the high incidence of diabetes among the local population. Indeed diabetes and related illnesses such as hypertension are among the biggest killers in the Cook Islands. Type 1 (insulin dependent) diabetes is usually found in young children whose pancreas has been partially or completely damaged and cannot produce insulin. Type 2 (non-insulin dependent) diabetes - which was the subject of the proposed Diatranz experiments - is particularly common among Cook Islands adults and is brought on by lifestyle factors such as eating the wrong food, lack of exercise, or excessive alcohol consumption.

According to a WHO consultancy in 2001, the prevalence of diabetes in the Cook Islands is 11.8% for males and 3.8% for females (not including patients with well-controlled pre-existing diabetes). The prevalence of obesity is 48.4% for males and 36.2% for females. The hypertension rate is 55.3% for males and 24.5% for females. According to hospital records, almost 70% of patients were reported to have acquired hypertension disease, 14.2% having both hypertension and diabetes and 15.9% having only diabetes from 1980 to 2001. Of all the reported hypertension cases, 64.3% were in Rarotonga and 35.7% in the outer islands. For cases of diabetes, 50.4% were in Rarotonga and 49.6% in the outer islands (WHO Regional Office for the South Pacific). Given the high incidence of the disease across the Pacific region, any 'magic bullet' for the disease might have considerable public appeal. However, many people argue that the millions spent on speculative research for 'techno-fixes' might be better spent on preventative measures such as public health programs to encourage proper diet, and regular exercise.

In the event, Diatranz moved on to Australia in the hope of finding a more sympathetic regulatory environment. New Zealand, according to company founder Professor Bob Elliott, had "missed out by bureaucratic delays and pusillanimous political leadership. It's the Rugby World Cup all over again."[5] When last heard of, Diatranz was negotiating a trial with 10 patients at a Sydney clinic (Collins, 2002). Meanwhile, the New Zealand Government maintained its earlier stance with the then Health Minister Annette King arguing that there was no guarantee that Diatranz would get approval for clinical trials in Australia even if the Australian Government approved animal/human transplants in principle, because of the risk of a retrovirus from pigs infecting the human population. We have heard no more of Diatranz in the Cook Islands since.[6]

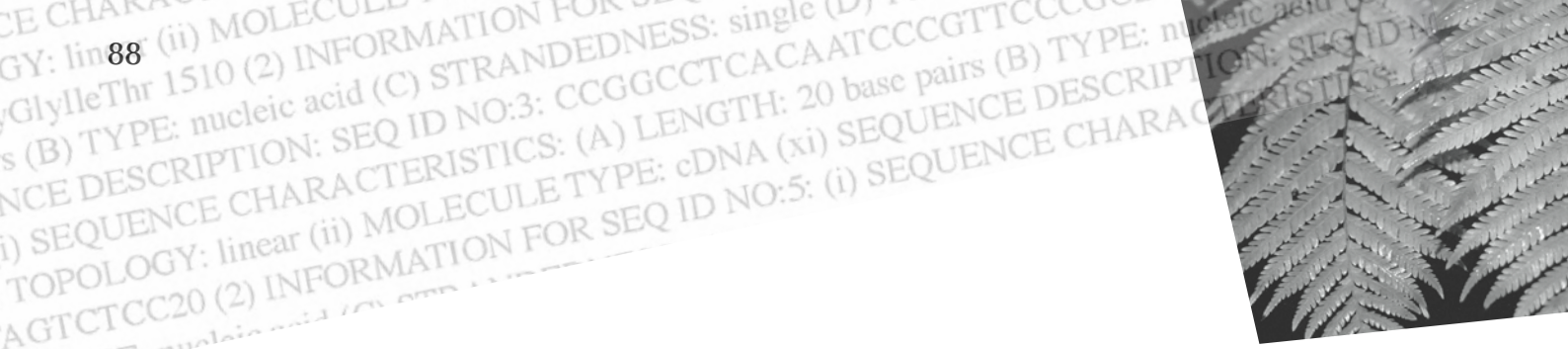
## Lessons from the Diatranz episode in the Cook Islands

The Diatranz episode is one of an increasing number of biotechnological ingresses into the Pacific region. As Roughlan notes, these have included (a) attempts by the US Department of Commerce to patent human cell lines containing novel virus variants derived from blood cells sampled from indigenous Solomon Islanders and Papua New Guineans, and (b) island governments granting exclusive rights to genetic screening programs in Nauru and Tonga, raising issues about informed consent, the fate of genetic information, its potential commercial value and the loss of this value to island peoples (Roughlan, 2002).

Genes are a key resource of the new world bio-economy and our isolation and diversity makes the Pacific Islands particularly attractive. We urgently need to act to protect our genetic resources from theft, misuse, piracy and pollution, in the same way as we previously struggled to regain sovereignty over and protect our nations' other key resources. If the capacity to review, monitor and evaluate research and experimentation is currently beyond the limited means of most individual small island governments it can be tackled collectively through regional and international organizations such as the secretariat of the Pacific Community (SPC), the World Health Organization (WHO) and NGOs such as Call of the Earth (COE). A development in this direction is the establishment of the Pacific Health Research Council (PHRC) based at the Fiji School of Medicine.[7]

Developments in biotechnology are also outstripping our island nations' abilities to develop informed understandings and appropriate legislation addressing the social, legal ethical and other implications of the new technology. As Diatranz has clearly shown, some companies are willing to take advantage of this lack of capacity and absence of regulation. The use of indigenous peoples in unregulated and less litigious countries as the subject of experimentation is part of the general 'export of risk' to less regulated environments - one of the negative impacts of globalization. But as the US response to the proposed Diatranz experiments in the Cook Islands has demonstrated, bio-risks recognize no national boundaries. It is in the common interest of all governments and peoples that adequate regulatory environments are established globally.

Returning to my original question - are the lives of indigenous peoples' of less value than others? The answer may well be yes unless we ready ourselves to take control of these new biotechnological ingresses. In addition to vigilant island governments, there is, I believe, a burden on indigenous leaders to familiarize themselves fully with the issues. Xenotransplantation, like genetic engineering, raises philosophical questions relating to the breaching of species boundaries and cultural, spiritual and ethical considerations concerning the integrity of human beings and the incorporation of animal parts or material. Xenotransplantation also raises issues about the rights of individuals and the common good of all members of society. Traditional leaders are, in my opinion, uniquely positioned to provide informed leadership on these philosophical, ethical and moral issues. They can also provide a useful check and balance on government decision-making. It was, after all, community not government action that averted Diatranz's xenotransplantation experiments in the Cook Islands.



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# Footnotes

1. Diatranz had also conducted clinical trials on 12 children with Type 1 diabetes in Mexico during 2001/2.
2. "DR. MICHAELS: We recommend the Secretary of Health and Human Services to encourage investigators to work within guidelines of -- I don't know what the correct word is here, if someone could fill in the blank -- of countries that have reviewed guidelines and discourage rogue -- but rogue isn't the right word either. I'm trying to put a positive spin. To encourage countries to work within guidelines that have been set forward by international committees, by national and international committees, and discourage individuals working without guidelines." (U.S. Department of Health and Human Services, transcript, March 2002)
3. capital of the Cook Islands
4. The caller's comments reflected then current advice from the NZ Department of Health that, "Until more is known about the risks associated with xenotransplantation, international guidelines for participants in such research require that they: not be of childbearing age and not have children after participation in the trial; notify health authorities of any sexual partners they have; practice safe sex ; permit health authorities to closely monitor their families and any sexual contacts they may have for the rest of their lives; and not give blood or donate any organs or tissue.
5. A reference to the bureaucratic failures that resulted in New Zealand losing its opportunity to jointly host the Rugby World Cup with Australia
6. A notice of the appointment of liquidators for Diatranz Limited appeared in The New Zealand Gazette, Wellington. Thursday, 8 January 2004
7. The specific objectives of PHRC are to • promote and strengthen health research by Pacific people as a vital developmental tool for healthcare improvements,• develop Pacific people capacity to exert more control and ownership of data and information generated through research, • develop and support a network of Pacific researchers and institutions, and • assist Pacific governments in the development of focused, integrated national health research agendas. (Pryor, et.al., 2000

# Na kilaka vaka-Viti ni veikabula
# Indigenous knowledge and the Fijian cosmos: Implications on bio-prospecting

Steven Ratuva

## Introduction

The discussions on bio-prospecting on indigenous land usually centre around economic, political, legal and ethical discourses and often the ethnographic aspects, especially in relation to the local people's knowledge of their cosmology, sense of being and the importance of bio-diversity to their lives are portrayed with generalized emotional assumptions or at worst relegated to footnotes. Nonetheless, highlighting the importance of the natural habitat and the resources within to the indigenous people's daily lives is important to provide credence to the ethical and economic arguments relating to regulation of bio-prospecting. Fore thousands of years indigenous peoples have interacted with their environment in complex ways and in the process developed cultural systems and constructed group identities specific to the local context and cosmology. Modernity often imposes itself, modifies, reconfigures and in many cases undermines the local community's socio-cultural identity and relationship with nature and the cosmos. One of the manifestations of "modernity" is bio-prospecting by pharmaceutical companies and other corporate institutions whose interest is to commodify indigenous resources for profit.

This chapter is not about bio-prospecting as such but an attempt to put it within the broader ethnographic context of Fijian indigenous culture and identity. Its primary focus is to identify and examine the complex interplay between Fijian knowledge of nature, cosmology and land and how these could be the basis for understanding the potential impact of unregulated bio-prospecting on local communities, especially in terms of loss of resources, reconfiguring of identity and loss of control over their future. The implicit questions are: What are the relationships between the Fijian sense of self, nature and the cosmology? In what ways could bio-prospecting interfere with these relationships? How can legislation on bio-prospecting take the socio-cultural factors into consideration?

This chapter is divided into six parts. The first examines the nature of Fijian knowledge of natural resources, focusing on various aspects of local epistemology and how the world is defined. The second examines the Fijian cyclic view of the world and its relationship to the cosmological order. The third discusses the relationship between land and Fijian identity, especially how one shapes the other. The fourth looks at some inherent weaknesses in early attempts in the past to legislate traditional ownership and use of land and resources and the implications on Fijian relationship with the land. The fifth part briefly discusses the need for legislation on protection of indigenous genetic material.

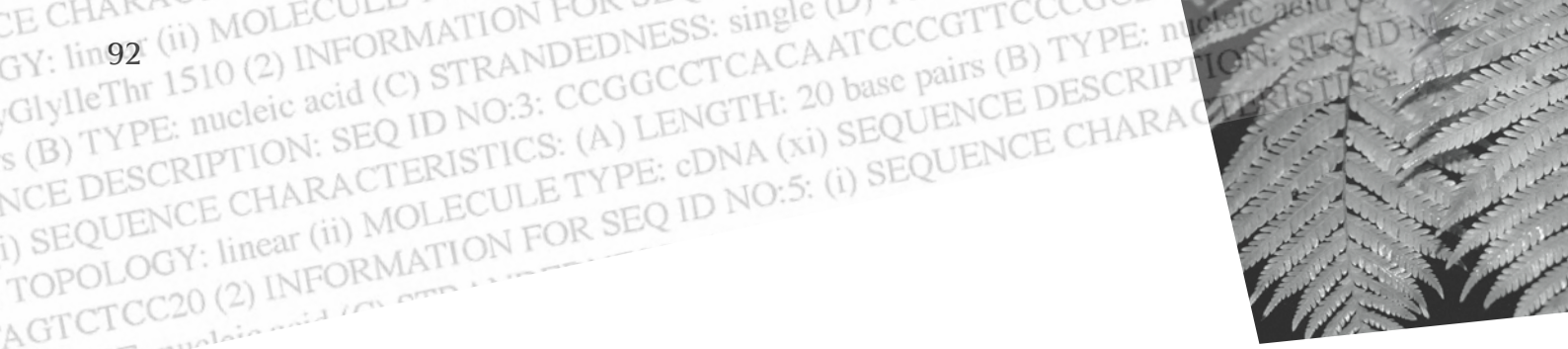
## Fijian knowledge of their socio-cultural habitat

The term *kilaka vaka-Viti* (Fijian knowledge) refers to a complex system of relationship which links together individuals, social kinship groups, land, environment and the greater cosmological order.[1] The cosmological order here refers to the socio-spiritual-ancestral realm not as an isolated form of existence on its own but as an integral part of the dynamics of everyday social relationship (*bula ni veisiga*). The cosmological realm is considered part of the integrated system of observing, doing, encoding, organizing, thinking and reflection. Knowledge is social and is derived from a living and transforming set of multiple relationships between humans, the environment and the cosmological realm. Knowledge is constructed, reproduced and institutionalized in various ways. It defines and sustains people's relationship with each other, with their culture, with the environment and with the broader cosmos.[2]

Within the local village context, knowledge of the world can be understood at three levels of perception. The first refers to knowledge of the empirical world (*kila ni vuravura*). The second refers to knowledge of the social order and socio-cultural relationships (*kila ni bula vakaveiwekani kei naitovo*). The third refers to knowledge of the cosmos (*kila ni bula vakayalo*). These levels exist side by side and relate to each other in an independent and sometimes syncretic manner.[3] For instance the empirical world is not seen as existing in an independent physical realm but is categorized, valued and given life by the social and cosmological dimensions. The social order needs the cosmological realm for spiritual validation (*veivakadeitaki vakayalo*). This syncretic triangular relationship defines Fijian understanding of things such as land (*vanua*), death (*mate)*, birth (*sucu*), culture (*i tovo*), and even mundane activities such as fishing (*qoli*), planting (*teitei*) and hunting (*vakasasa*).

Changes brought about by Christianity, colonialism and globalization have added new dimensions to Fijian knowledge and world view, especially in relation to land ownership and notions of the cosmos.[4] Contrary to popular perception, one of the fundamental thrusts of British colonialism was to "preserve" the Fijian community, not as an expression of humanity but as part of the paternalistic social Darwinian thinking that "inferior" races had to be saved from total demise and must be nurtured along the path towards "civilization." For Fijians the nurturing process included a social engineering program which included deployment of very rigid legislation to keep them within the bounds of subsistence life in villages under the tutelage of chiefs and colonial officials.[5]

However, despite the socio-economic transformation during the 19th and 20th century resulting from the commodification, alienation and change in the stewardship of the *vanua* (land) and resources, Fijians by and large still see their roots embedded in the *vanua*. Paradoxically while the British colonial "native policy" aimed to "preserve" Fijian culture, it also transformed it in various ways. For instance the British



attempted to establish a unified and codified Fijian landowning system as well as restructure the Fijian society by introducing a rigid form of communalism.[6] While the mechanics of landownership changed, Fijian perception of the *vanua* and its link to the cosmos to a great extent remains unchanged.

## Cyclic view of life and the cosmology

The view of the world and cosmology as a cyclic process is the key to understanding Fijian knowledge of the environment.[7] Time (*gauna*) is conceptualized as a cyclical process which repeats, reproduces and refreshes itself in an endless and boundless fashion. The spirits of the dead do not fade away but live on within the community (but in the realm of the cosmos) as guardians of plants, animals, fish, as well as of living humans. This is in contrast to the dominant modernizationist theory which conceives of life as a unilinear process with a beginning and an end.

The cyclic view is important in terms of understanding Fijian knowledge of their surrounding resources, especially in relation to plants and animals. While western empiricist science conceives of humans and the environment as being separate entities as part of the lineal evolutionary process, local Fijian knowledge conceives them as part of the same interacting being (not entity) located within the same circle. The human being lives within the same cosmological world as the plants and animals. Fijians develop their indigenous calendar in accordance with the cycle of growth of fish and plants. For instance, *vula i se na balabala* or month for the flowering of ferns falls in May. *Vula i nuqa levu* or month for the breeding of the *nuqa* fish falls in January. Every month is associated with harvesting of a root crop, flowering of a plant or breeding of a particular fish species.[8] The chronological space between two similar events (such as the harvesting of yams) constitutes a full cycle rather than a space between two linear events. The bio-environmental cycle also becomes the cycle of human transformation and life since they are dependent on each other. In essence, this interlocking process synthesises the human, plant and animal worlds into a single cosmological embrace.

To destroy plants or animals means extricating them from the cosmological circle thus causing an imbalance and possible tragedy for the community. For communities which rely substantively on plants and animals for survival, this could have long term consequences. The genetic materials which make up the plants and animals are considered part of the circle of life and as such are sacrosanct. This is one of the strong ethical points for protection of indigenous genetic materials. The social and spiritual inter-connectedness between indigenous Fijian culture and the immediate environment makes this reinforces this argument.

This circle of relationship between humans, plants and animals take place within the broader ambit of the *vanua*. What is the *vanua* and what are the constituent elements which make it sacrosanct?[9]

## *Vanua* and Fijian identity

The notion of *vanua* has three inter-related dimensions which engage in a state of perpetual oscillation with each other. These are the territorial sphere or *qele*, social kinship (*veiwekani*) and the cosmological

dimension (*yavutu*). These three aspects define the extent and boundaries of the cultural space as well as the sacredness of and ownership of knowledge associated with these.

## *"Qele" and bio-diversity*

Although a physical entity, the *qele*, which also refers to soil, also has association with fertility and productivity not only in the physical sense, also in the social and spiritual sense. A child's umbilical cord is often buried in a designated place, usually with a tree planted on the spot, as a sign of perpetuity and connectivity between the environment and the person. This connection is endless, boundless and interactive thus to hurt the living environment (*veikabula*) tantamount to hurting the human being (*tamata*).[10]

The *qele* also provides sustenance (*kanakana*) for the community. Trees, plants, animals, birds and insects constitute a symphony of land-based life (*bula ena qele*) and are considered innately bound to the human spirit and the spirit of the *qele*. This makes them indispensable components of the cosmos. The cosmos thus is seen to constitute the interconnectedness between the physical environment and the socio-spiritual realm.

*Qele* is perceived as both permanent in the sense of relationship to human spirit and temporal in the sense that social groups to which a piece of land (*tiki ni qele*) is associated would change due to various reasons. For instance the *tiki ni qele* may be given to another closely aligned group as part of peace-making, reciprocity or consolidating everlasting relationship.

Interestingly, the colonial land—ownership framework had a number of implications on the relationship between the *qele* and the resources. Firstly it transformed the dynamic process of land use and exchange into a static system which was guided by British legal framework. Secondly, the codification of land and imposition of the colonial land legislation compartmentalized commonly owned land and thus restricted the local community's access to plants and animals. Thirdly, jurisdiction over land resources came under the colonial administration through laws relating to environmental protection, agriculture, logging, mining and customary fishing areas or *qoliqoli*.[11]

The introduction of British law did not totally undermine the cosmological essence of the *qele*. Instead, it retained the physical-cosmology relationship and to some extent gave it a new configuration. While the new law restricted the physical boundaries and transferability of the *qele* it did not totally eradicate the Fijian belief in the inseparable connection between land and the cosmological order of the ancestors.

## *Knowledge of resources and sacredness*

Knowledge of resources is often shared within the community, despite the land boundaries. For instance medicinal plants are often picked from other tribe's land without having to ask permission from the owners. Medicinal plants (*wainimate*) are considered "common property" available to everyone. This principle of sharing is based on the assumption that life and sustenance of life are shared responsibilities,

unhindered by legal or political restrictions. The community healers (*vuniwai*) are assured of unrestricted access to people's land to collect *wainimate* for the sick. The vuniwai normally has specialist knowledge of the *wainimate* plants which others would not have. The *vuniwai* has three major functions. Firstly he or she is the healer, bearer of life and an agent of socio-biological reproduction. Secondly, the *vuniwai* is the living repository of local knowledge of medicinal plants. Thirdly, he or she is the focal point that links the cosmology and the community.

The knowledge of the *vuniwai* is usually passed down through the family or in certain cases through specially anointed individuals. The preservation of specialist knowledge is important in the sense that it ensures protection of medicinal intellectual property from being lost as well as ensuring that it is accorded a sense of importance and *tabu* or sacredness.

The existence of a widely sought after medicinal plant in a certain locality often provides the place with a sense of communal importance and sacredness. For the owners of the piece of land this brings about social prestige as people come to respect their sense of generosity in sharing the healing resources of their land.

The reproductive and life-giving capacity of the land also extends to the sea. The sea, unlike the land, is less restricted in terms of boundary and represents mobility, boundlessness and uncertainty. It's seen as the bridge between islands rather than a barrier to mobility. The sea has shaped peoples' skills and consciousness over centuries and it is now seen as an extension of people's life world. Almost every coastal Fijian village has a fish totem which they consider sacred and representative of their ancestral being. Often these fish are not eaten or disturbed because these are believed to invoke the wrath of the gods. Certain birds and plants are also considered sacred and must not be *vakacacani* (destroyed or violated) or *vakacudrui* (angered) because this tantamount to destruction of the human spirit itself.

The totem birds, fish and plants are seen not as mere biological entities but extensions of the human spirit and human life. They provide the link between humans and the environmental cosmos (*vuravura bula*). The environmental cosmos too has a sprit and a personality which engages humans in a dynamic symbiotic embrace. The environmental cosmos and human life (*bula vakatamata*) constitute a unitary whole rather than a dualistic relationship as empiricist natural science would suggest.

Social norms such as the practice of *vakatabui* (socio-cultural restrictions) are carried out to keep certain places *tabu* or sacred. For instance when a chief dies, fishing in certain designated areas are prohibited because they have been declared *tabu*. After a hundred nights the *tabu* is lifted and fishing resumes. One of the effects of this is that dwindling fish stocks and other marine species are allowed to reproduce and grow thus helping to sustain bio-diversity.

Some places as are also regarded as *vanua tabu* (sacred places) because of their association with ancestral gods and ancestral spirits. Plants which grow within the vicinity are also regarded as *tabu* and must not be cut down or used for any purposes which may undermine the *tabu*. The designated *tabu* places may include the ancestral *yavu* (old house foundation), burial place or other places of socio-cultural significance.

The term *yavu* does not only refer to house foundation, at the more phenomenological dimension it refers to one's origin and ancestral roots. It is the most basic circle of identity for a Fijian. Reference to one's *yavu* is reference to one's human essence, story of generational evolution, social being and central identity.

Fijians have a number of spheres of identity which may be represented in the form a number of concentric circles. The outermost circle would be the *matanitu* (confederacy) identity, followed by the *vanua, yavusa, mataqali, tokatoka, vuvale* and *yavu* identities in that order. The most central of identities is the *yavu*. In fact the yavu transcends all the other forms of identities. A Fijian without a *yavu* has "no ground to stand and sit on" and no sense of belonging. The *yavu* signifies both the beginning and the end of one's journey in life, it is the legitimizing framework which defines one's sense of "Fijianess". A Fijian who travels away from home will always return to visit the *yavu* as a form of pilgrimage and as a form of self-reassurance, refreshing one's identity and re-provisioning for one's journey in life. Migrating Fijians continue to make references to their *yavu* when asked about their place of origin and often make it a point to go back to Fiji every now and then to revisit their *yavu* roots.

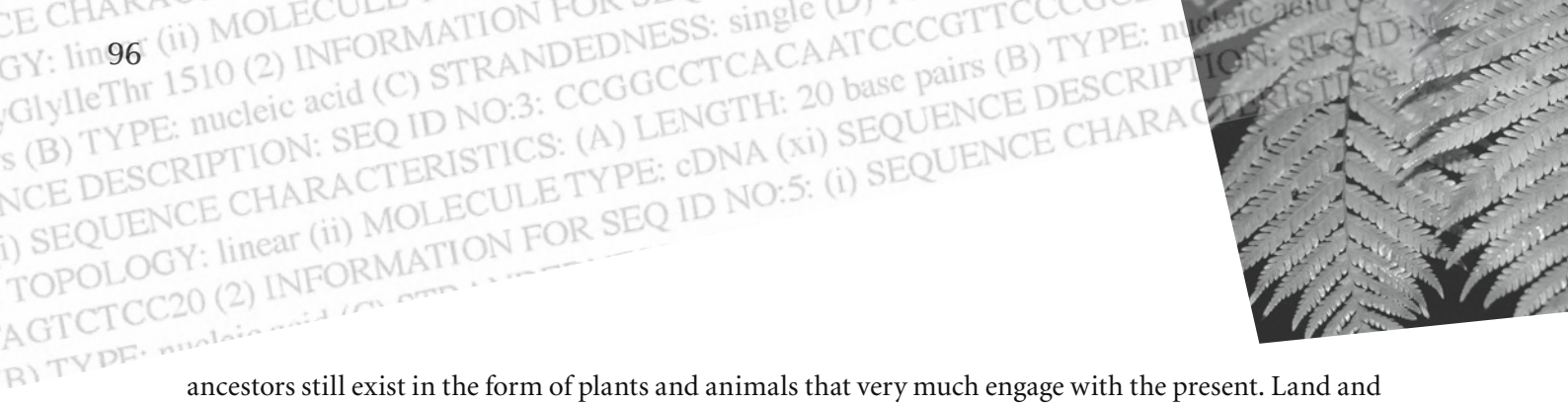
The *yavu* thus is a socio-cultural entity which continues to define Fijian sense of identity. The *yavu* does not have a fixed form and size. It varies in geo-cultural and socio-cultural configuration depending on the context. A *tokatoka* may have its own *yavu*, a mataqali may have its own *yavu* and even a *vanua* may have its own *yavu*. A group of smaller *yavus* may constitute a bigger and encompassing one.

Several *yavus* may be connected by genealogical links and there is a sense of spiritual oscillation between them. The *yavu* belonging to the eldest or patriarch within the kin-network is usually accorded the highest status as it is seen as the *vuna* or ultimate root. The *yavu* is the arena of convergence where social identity, environmental cosmos and the ancestral world meet and engage in an interconnecting and perpetual rhythm of cosmological reproduction. It is where the world of mythology and socio-cultural reality intersect and define each other. It is precisely this interaction between the social, cosmological and spiritual which gives it the *tabu* status. Because the the *yavu* envelopes the surrounding territories, the resources within are also defined within its socio-spiritual jurisdiction.

Fijian cosmology does not make any distinction between knowledge of the social world and knowledge of the physical environment. The social world and the world of the physical environment are integrated into a whole. For instance, every known plant species has a specific use or social significance. Coconut is regarded as a "source of life." The term *vinaka vaka niu* (as useful as a coconut) refers to wholeness of life, being useful in every respect and life-sustaining. Fijians use all parts of the coconut-roots, trunk, leaves, nuts etc.

Likewise the kava plant is associated with community socialization, ceremonies and sacredness. A further example is the parallel between seasonal cycles and socio-cultural cycles. Traditional Fijian calendar is based on the seasonal harvesting cycle of root crops and fish.

The Fijian cyclic view of the world is important to discuss here because it defines the relationship between the past, present and future. The past, present and future are not distinctive slots on a chronological continuum but simultaneously exist in a common cosmological space. For instance, the spirits of past



ancestors still exist in the form of plants and animals that very much engage with the present. Land and living things represent the continuity between the past and present, the bridge between the past (*gauna makawa*) and present (*gauna qo*). It is this relationship which shapes Fijian philosophy, perception of and attitude to land and the species of plants and animals within.

## Denial of sacred knowledge through legislation?

Attempts to legislate land and resources have not really taken into consideration the importance of the link between Fijian identity, cosmology and knowledge of their natural resources discussed above. To date there has not been any attempt to put in place legislation to protect the bodies of Fijian traditional knowledge of genetic materials, especially from bio-prospectors. The closest protective legislation initiated by the British colonial administration dealt primarily with land alienation and not protection of indigenous knowledge in relation to land-based resources. One such act is the Native Lands Act of 1907 which makes two contradictory declarations. The first is that native lands "shall be held by native Fijians according to native customs as evidenced by usage and tradition". In the next sentence it puts forward a fundamental condition: "and subject to any regulations made by the Fijian Affairs Board…"[12]

Thus on one hand is acknowledgement and endorsement of "customs" and "tradition" and on the other hand is subservience to hegemony by the Fijian Affairs Board, a British created institution. This contradiction has been a cause of misunderstanding amongst Fijians over the years. Administration and guardianship of Fijian land was later transferred to the Native Land Trust Board (NLTB), set up in 1940 by Ratu Sir Lala Sukuna, a prominent Oxford-educated Fijian chief and colonial administrator. Since inception, the NLTB was meant to administer Fijian land and help protect Fijian culture.[13] The role of the NLTB was established by the Native Land Trust Act of 1940 which decreed that the control of "all native land shall be vested in the Board and all such land shall be administered by the Board for the benefit of the Fijian owners."[14]

The institutionalization of Fijian land had a number of significant implications on the relationship between Fijians and their resources. The fluidity which characterized the earlier relationships were legislated and codified to define specific jurisdiction of the landowners. The legislation, in effect, also attempted to re-categorize and codify the cosmological world. To some extent this worked, in as far as it provided a codified system of kinship succession recorded in the *volanikawabula* or register of Fijian genealogy established by the Land Commission, set up under the Native Lands Act.[15] At the formal level, Fijians began to define their identity and being in relation to the paradigms designed by the legislation. It was assumed that formal land boundaries also coincided with one's cosmological jurisdiction.

Under the rigid rules of the Native Affairs Act, Fijians were locked into their village subsistence economy under the tutelage of chiefs. This system of forced communalism and the impact of Christianity began to challenge the relationship between Fijians and the land. Nevertheless, this did not totally undermine the underlying dynamics between the Fijian community and the cosmological world, described earlier. In fact the legal and the socio-cultural paradigms have managed to co-exist in a syncretic type relationship over the years (the term syncretic here refers to the simultaneous existence of contradiction and accommodation). At one level the two paradigms seem to negate each other and at another level,

they engage in mutual accommodation. Fijians as agencies for transformation adopt either one to suit relevant circumstances. This utilitarian situation has nurtured the Fijian perception of their relationship with the land and their cosmology over the years.

It is also of interest to note that while colonial legislations codified Fijian rights to land, there was also an attempt to control and regulate its usage. For instance the Land Conservation and Improvement Act of 1953 attempted to prohibit, regulate and control the cultivation, clearing and burning of land and the need for compensation.[16] The Native Land Trust Act also reinforces this by stating thus: "No person shall, on native land (a) fell, cut, ring, lop, tap or injure by fire or otherwise any tree; (b) cut, convert, manufacture or burn to charcoal any timber; or (c) cut, collect or remove any forest produce."[17]

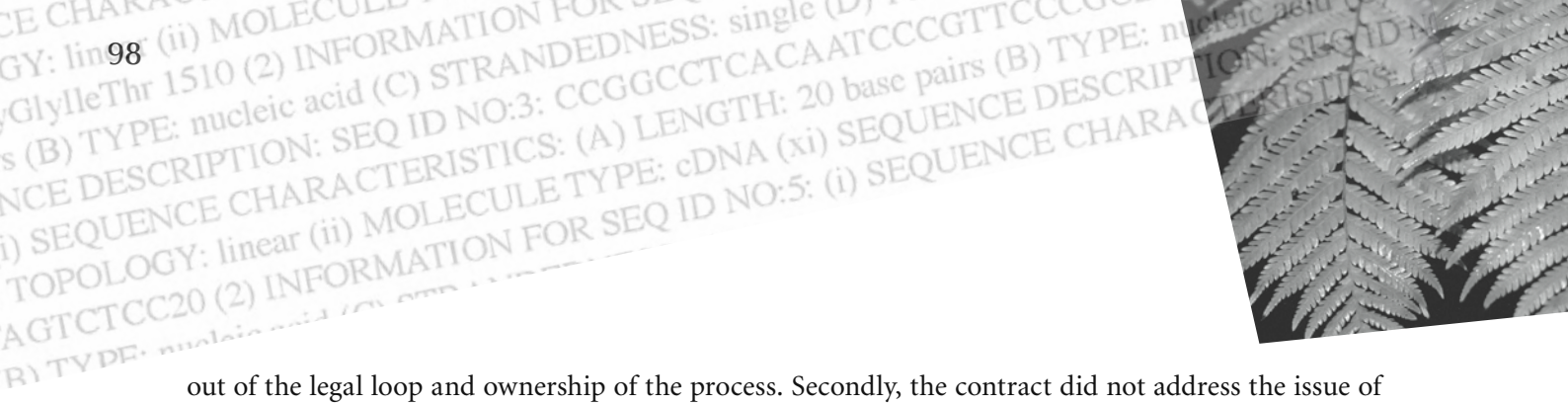
While these provisions were meant to protect Fijian land, they were still silent on acknowledgement and protection of Fijian knowledge of biodiversity, let alone intellectual property. This has been one of the biggest shortcomings of the numerous Fijian "protective" legislations over the years.

## Need for legal protection of knowledge of genetic material and intellectual property rights

The preservation of native trees and plant species under the Land Conservation and Improvement Act of 1953 was to address the problem of slash and burn farming method, which was prevalent amongst the Fijian communities and to guard against unscrupulous exploitation of the forest. It was an attempt to regulate socio-economic activities rather than a conscious policy direction to preserve Fijian traditional knowledge of bio-diversity and genetic material. Even up to now, there has been no legislation relating to protection of genetic material. A recent legislation on intellectual property rights only covered issues relating to music and arts copyrights and those who were involved left out bio-prospecting because it was deemed too complex and time-consuming to deal with. The issue of music and art copyright was considered more urgent given the high level of music piracy, especially on Fijian music, which had become a major public issue in Fiji. Nevertheless, appropriate legislation is still important to protect indigenous knowledge from bio-piracy, especially at a time when there is a rush for bio-prospecting projects by pharmaceutical companies.

Perhaps the biggest bio-prospecting project in Fiji to date project is in Verata, on the main island of Vitilevu, carried out by Glasgow's Strathclyde Institute of Drug Research (SIDR) as the "collector", the Verata community as resource owners and the University of the South Pacific (USP) as the intermediary. The contract was for SIDR to buy dried raw materials from USP which collected these from the Verata area. The money collected was deposited in a trust fund belonging to the Verata people. The project included bio-conservation to boost bio-diversity which would provide abundant materials for USP scientists to collect raw materials from. One hundred grams of dried material sold by USP to SIDR cost FJD$200. This amounted to about FJD$100,000 after 5 years.[18]

However, there were two questionable aspects to the project. Firstly, the contract was only between USP and SIDR and did not include the Verata community. SIDR claimed that the Verata community was not a "legal" entity and could not engage in any contractual arrangement with it. This kept the Verata people



out of the legal loop and ownership of the process. Secondly, the contract did not address the issue of intellectual property rights (IPRs) associated with ethno-biological knowledge because it was claimed that "there was no reliance on traditional knowledge of marine species."[19] This claim ignores the fact that local knowledge of seasonal cycles and marine species may have provided background information for the successful operation project. The fact that locals were directly engaged in the project meant that their knowledge of the area and existing bio-diversity were deemed important.

In commending the success of the Verata project, the International Development Research Center argues that:

> Traditional knowledge and IPRs [Intellectual Property Rights] are not necessarily vital components of successful agreements for access and benefit sharing. While this may seem like good news for fishing communities without a history of medicinal uses of aquatic genetic resources, problems are bound to arise. In the first place, the agreement with Verata was only possible because the national government had recognized indigenous ownership over lands and marine resources. Communities that have neither ownership rights nor relevant traditional knowledge may not have the opportunity to negotiate benefits unless national legislation permits it.[20]

The argument that "IPRs are not necessarily vital components of successful agreements for access and benefit sharing" is highly contested because it does not recognize the issue of "ownership" of the local knowledge being utilized. At the outset, this lack of recognition puts the local partner in a disadvantaged position. This is one of the reasons why a legislation covering IPR relating to bio-diversity bio-prospecting is needed to protect resources owners.

Also although there may be a certain degree of truth in the claim that "recognized indigenous ownership over land" is sufficient condition for "successful" agreements in relation to bio-prospecting, this still does not address the question of local knowledge. Land legislation does not cover the issues of ownership, intellectual property and benefit sharing. Specific legislation to this effect is needed.

## Conclusion

Thus far this chapter has outlined the cultural significance of the land and associated resources to the indigenous Fijian community. Fijian cultural identity, land, resources and the cosmology are intertwined in a continuous cycle. Various legislations dealing with land rationalization and "protection" over the years have to some degree transformed the ownership and landuse patterns but have not changed the social and spiritual significance and relationship with the land and the resources within.

Any legislation on bio-prospecting and IPRs relating to bio-diversity should at the outset establish the recognition of the inseparable link between indigenous Fijian culture, land, resources and the cosmological world of the spirit. Plants and animals are not seen as mere physical or biological entities but also as embodiment of the ancestral spirits. Recognition of the local people's world view, no matter if they appear absurd to "outsiders" is an important part of the process of empowerment, mutual participation and understanding. The issue of ownership, IPR and informed consent should also be

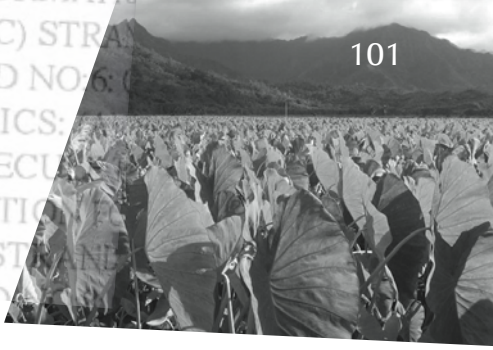
clearly spelt out in any legislation to make sure that resource owners are protected and they are in a position to negotiate the terms of the bio-prospecting agreement which are beneficial to them without being exploited.

Any future legislation in question should not just be a "protective" mechanism to ensure the survival and perpetuation of the indigenous knowledge of the world, beyond that it must be used to actively transform the people's lives to enable them to come to terms with the rigors of the modern world.

Kava Welcoming Ceremony, Fiji, 2005 (Brent Stirton, WWF-SPP-Fiji)

# Footnotes

1. A number of studies have been carried out on indigenous epistemology in the Pacific. For instance see Smith, Tuhiwai Linda. 2003. *Decolonizing Methodologies: Research and Indigenous Peoples*. New York: Zed Books; Gegeo, David and Gegeo Karen. 2001. "How we know: Kwara'ae rural villagers doing indigenous epistemology." *The Contemporary Pacific*, Volume 13, Number 1; Huffer, Elise and Qalo, Ropate. 2004. "Have we been thinking upside down? The contemporary emergence of Pacific theoretical thought." *The Contemporary Pacific*, Volume 16, Number 1; Baba, Unaisi. *Knowing and Learning: A Fijian Approach to Education*. Suva: Institute of Pacific Studies (Forthcoming).
2. For a comprehensive exposition on epistemology, see Dancy, Jonathan. 2006. *An Introduction to Contemporary Epistemology*. London: Blackwell Publishers.
3. By syncretic in this case, I refer to how these different levels of epistemological engagements shape each other - sometimes they may conflict each other and sometimes they may accommodate each other. For an application of the syncretic discourse in Pacific societies, see Ratuva, Steven. 2005. "Reconceptualizing Contemporary Pacific Island States: Towards a Syncretic Approach." *The New Pacific Review*, Volume 2, Number 1.
4. See Newland, Lynda. 2004. "Turning Spirits into Witchcraft: Penticostalism in Fijian Villages." *Oceania*. Vol 75.
5. See Ratuva, Steven.1999. "Ethnic Politics, Communalism and Affirmative Action." PhD Thesis, Institute of Development Studies, University of Sussex.
6. Ratuva, 1999.
7. Most other Pacific societies and other groups in many parts of the world have the same cyclic view of cosmology.
8. The indigenous Fijian calendar is still very much in use today by fishermen, farmers and those involved in subsistence life as way of determining planting and harvesting seasons.
9. The term *vanua* has resonance al around the Pacific. Ni-Vanuatu also describe their world in terms of the *vanua* and in other parts of Polynesia it *is fanua, fenua* etc. and they all refer to the relationship between people and land.
10. The *tamata* consist of three inter-related components: the *yago* (body), *i tovo* (norms and values) and *yalo* (soul or spirit).
11. Fishing customary rights has always been a contentious issue in Fiji. Currently the *qoliqoli* areas come under state jurisdiction and recently the government has been in the process of putting together a parliamentary bill to facilitate control of the qoliqoli by indigenous landowners.
12. Native Lands Act, Cap 133, No.3, 1907, p4
13. Sukuna, like his British colonial superiors, was a great believer in the Social Darwinian orthodoxy which assumed that Fijians were a dying "lower" race which had to be protected from the "superior" western culture and through cultural progression, they would eventually become mature and self-reliant. When this happens, there will no longer be a need for the NLTB. See Scarr, Deryk. 1983. *The Three-legged Stool: Selected Writtings of Ratu Sir Lala Sukuna*. London: Macmillan.
14. See Native Land Trust Act, Cap 134, No.4 [1] 1940
15. Cap 133, No3, 1912; p4
16. Land Conservation and Improvement Act, Cap 141, 10 July 1953: pp5-6
17. NALTA, Cap 134, No.3: S-2.
18. Personal communication with Marika Tuiwawa, Curator, Herbarium, University of the South Pacific and one of the major participants in the Verata project.
19. See International Development Research Center-http://www.idrc.ca/en/ev-67677-201-1-DO_TOPIC.html.
20. See International Development Research Center; p 3.



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# A Fijian's Perspective on the uses and ownership of Intellectual Property

by Joeli N. Vakabua

## Introduction

Globalization poses a serious challenge to the communities of the Pacific as they try to maintain control over their destinies, intellectual properties and natural resources. Globalization, driven by colonialism and imperialism in the 18th and 19th century, incorporated Pacific communities into the global system in a way which has rendered them marginal and powerless in the face of global corporate hegemony. Part of the challenge in responding to this situation of marginality is how to address the question of bio-piracy and intellectual property rights (IPR) relating to gene ownership. There are complex legal and ethical questions which underpin these issues.

This paper examines some of the indigenous Fijian perceptions and sentiments relating to the issues of gene ownership, IPR, *custodian rights,* farmers' rights, breeders' rights and a "*sui generis*" Act. It will also discuss the issues of prior informed consent (PIC) and Material Transfer Agreements (MTA) as means of accessing fair benefit sharing of our resources.

## IPR ownership

Rights over indigenous intellectual property should be sacrosanct as they are inherent in our cultures. Every community possesses various forms of cultural capital which help define their identity. Every society has collective right to intellectual property, irrespective of their type of civilization. However, the only difference is that in some societies, intellectual property is protected by law while in some there is no legal protection whatsoever thus opening the doors to property rights abuse. It needs emphasizing that apart from IPR, there are also other associated forms of rights such as indigenous rights, *custodian rights*, farmers' rights, breeders' rights, designers' rights, composers' rights, to name a few.

Rights associated with Fiji's flora and fauna are directly linked to land landownership and land rights. Indigenous Fijians through tribal land rights control about 83% of the land and by implication this also extends to rights over flora and fauna. However, the dramatic transformation of Fijian community as a result of colonialism has changed the relationship between Fijians and their traditional culture and land. A significant amount of land, largely consisting of the most arable, was alienated by Europeans and later a much larger portion was leased out to Indo-Fijian cane farmers.

To a certain degree, loss of Fijian land also had implications on indigenous intellectual property.

## International instruments and indigenous IPR: A mismatch?

The World Trade Organization (WTO) provides for an agreement on the Trade-related Aspect of Intellectual Property Rights (TRIPS). Article 27.3b of TRIPS allows for the patenting of plant varieties of commercial plant breeders but does not provide for a protective mechanism for native plant & animal *custodians* and farmers whose cultures have developed or kept alive native flora & fauna over several civilizations. At the same time Article 27 of TRIPS raises contentious issues centering on the use of patents as a device for securing ownership (Peteru, 1997).

In the case of Fiji we are only becoming aware of IPR for plants and animals. While Fiji may have unique plants, TRIPS does not allow patents to be taken out on plants, however, it offers the development of a *sui generis* with or without the patent system. While we have an extensive range of plant varieties their protection has not been very successful. A classical example is kava or the yaqona plant ( *Piper methysticum* ).

Furthermore, the World Intellectual Property Organization (WIPO) which theoretically overseas IPR issues in the global context has done things which are not exactly empowering for indigenous people. For instance it created the International Union for the Protection of New Plant Varieties (UPOV) which protects large multinational companies involved in commercial plant breeding but not farmers and native plant *custodians*.

At one stage of its metamorphosis UPOV had a clause on Farmers' Rights but this has been downgraded to farmers' privilege and it would not be a surprise that this has been further diluted not to have any protective measures for farmers now. The UPOV Act of 1978 did have some protection of farmer's rights but this was removed at the insistence of professional breeders by the UPOV Act of 1991. Encouraged by UPOV commercial plant breeders have not only bred but also genetically modified plants whose seeds are infertile, forcing farmers to continue to depend on these companies for their seeds. This raises the issue of food security. In addition there have also been incidences of genetically modified plants transferring their infertility clocks to native plants and in other cases natural weeds have developed chemical weedicide resistant characteristics.

These are just a couple of examples of how WIPO through UPOV has undermined small players in the global intellectual property rights field. Thus the idea of WTO creating a level playing field is but a fictitious reality, especially in terms of indigenous animal and plant *custodians*' and farmers' rights.

## 1999 *sui generis*: Where are we?

Fiji and other Pacific Islands Forum member countries were required by WTO to produce a *sui generis* by 1999. Due to lack of resources and capacity this has not been achieved. When efforts were made in this direction, it seemed that there was inclination towards the WIPO/UPOV position. This was problematic in Fiji's case because Fiji has no official commercial plant breeder, only farmers and native *custodians.*

Frustratingly, some people involved in the process, including desk scientists, economists, government and agricultural officials have tended to favour the UPOV position when they did not have much understanding of intellectual property issues or they themselves do not have land, native plants, farms nor their own crops to protect.

India, Bangladesh, the Organization of African Unity (J.A.Ekpere, 2000) and some other countries have developed *sui generis* laws and this could also be endeavored for Fiji. The main template for Fiji could be something along the lines and principles outlined in Annex 1.

## Customary relationship, totemism with the environment

Fijian communities relate to their immediate environment through in complex ways. For instance every agnate unit, village or social group has an oral tradition and/or documented plant, animal or fish as a totem. The totems symbolize *custodianship* and link between the community and the environment. These are recorded in the annals of the Native Lands Commission (NLC) of Fiji.

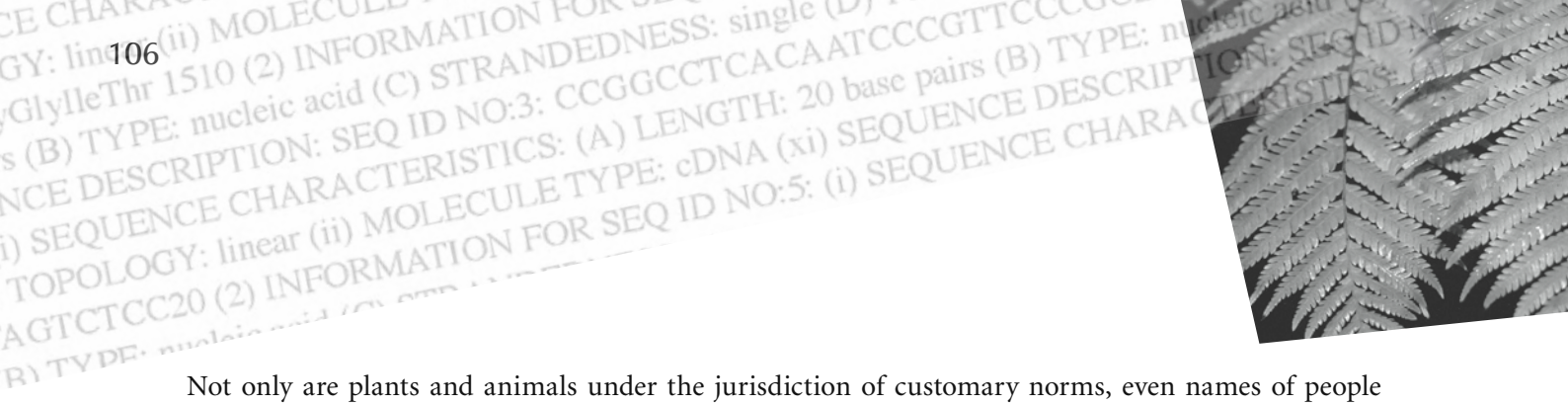
The flower of the Tagimoucia plant is found only in Fiji in the island of Taveuni (J Vakabua)

Some examples of this native totems and custodianship appear in the table below.

Some examples Fijian totem plants and custodianship

| | Province | District | Island | Village | Tribe | Plant totem |
|---|---|---|---|---|---|---|
| 1 | Lau | Lau | Lakeba | Waciwaci | Lomanikoro | Vuga |
| 2 | Lau | Lomaloma | Vanuabalavu | Levukana | Namasi | Uci |
| 3 | Lau | Mualevu | | Mualevu | Yaro | Yaro |
| 4 | Vanua Levu | Laucala | Laucala | Togo | Qaraniyaku | Nokonoko |
| 5 | Vanua Levu | Vuna | Taveuni | Nakorovou | Vuna | Salato |
| 6 | Kadavu | Tavuki | Kadavu | Nukunuku | Matavura | Vesi |
| 7 | Kadavu | Naceva | Kadavu | Nakoro-i-soso | Kese | Mocelutu |
| 8 | Yasawa | Viwa | Viwa | Natia | Natia | Niu |
| 9 | Yasawa | Waya | Waya | Namara | Sabutoyatoya | Vadra |
| 10 | Vanua Levu | Dreketi | Vanua Levu | Nasigasiga | Nabuna | Sakiki |
| 11 | Macuata | Namuka | Vanua Levu | Gevo | Navua | Tatagia |
| 12 | Macuata | Sasa | Vanua Levu | Korotubu | Korotubu | Ivi |
| 13 | Nadroga | Malolo | Viti Levu | Solevu | Taubere | Yabia |
| 14 | Nadroga Navosa | | Vatulele | Ekubu | Ekubu | Vudi |
| 15 | Namosi | Veivatuloa | Vitilevu | Veivatuloa | Nabukelevu | Mako |
| 16 | Bua | Bua | Vanua Levu | Koroinasolo | Rukuruku | Buabua |
| 17 | Bua | Navakasiga | Vanua Levu | Naviqiri | Navakasiga | Yasi |

Source: Native Land Commission, Fiji 1999. (Pers. Comm.) * *Flora Vitiensis*



Not only are plants and animals under the jurisdiction of customary norms, even names of people are bound by such customs. The name of an individual is protected under the Fijian customary laws. For example, one needs permission for usage of a name belonging to a different social unit. Names are protected under a customary form of intellectual property system and this has been in place years before colonialism/colonization and the introduction of new IPR and patent systems. One of the causes of unease has been the inability of the European system to recognize the legitimacy of the old system of intellectual property.

## Transfer of genetic material: The material transfer agreements related to Fiji

The material transfer agreement (MTA) between Fiji and its neighbors, Samoa and Tonga on the Fiji Fantastic breed of sheep is a good example of how sharing of genetic materials can enhance regional corporation. This practice should be encouraged and given support, but a number of important factors need to be taken into consideration.

From 1980 onwards Fiji began a sheep genetic breeding program which culminated in the development of the Fiji Fantastic breed of sheep, which is unique to Fiji and found nowhere else in the world.

This sheep was sold to Samoa for the first time in 2004 and to Tonga in 2005. The sheep exported to Samoa and Tonga were selected on the basis of their good condition and the fact that they were free from diseases. Care was taken to ensure that the individual genetic lines were distant from each other to minimize the possibility of inbreeding. The price of each sheep was lower than most unique pedigree sheep on the international market. An example of the Material Transfer Agreement between Samoa & Fiji appears in Annex 2.

Given the above, there are a number of important issues relating to transfer of material. The first issue is prior informed consent. While prior informed consent (PIC) is a concept that has been incorporated into material transfer agreements, the vast gap between the bio-prospector and the resource owner is such that it is never beneficial to the latter. Often the community is informed that bio-prospecting is contributing to research for the good of humanity. However, in cases where modification and manipulation of raw material take place, often people are not fully informed of the implications. A case in point is the consent given by resource owners for Fiji's Hydroelectric Project, who were not fully informed of the process of hydro-electrification. They were originally told that they would be amongst the first to have access to electricity but this was scientifically impossible because the electricity had to go through the transformer many miles away in Suva city the capital. The landowners were without electricity for more than two decades while the rest of Fiji was enjoying electric power. All the flora & fauna, and biodiversity taken over by the watery dam has been unaccounted for & lost forever. What kind of compensation will return those lost entities to the native custodians or resource owners? None, I guess.

Another example was the kava. Although kava had been cultivated and used in the Pacific for centuries, it was patented in the USA and Germany without the consent of Pacific peoples. The issue of prior informed consent is in important one and this must be included in a comprehensive intellectual property legislation which at the moment still does not exist.

The second issue deals with benefit sharing. Land and resource owners have always been short-changed in Fiji. The new legislation should make benefit sharing from bio-diversity extraction much more empowering and transparent. Mostly, the economic benefit to the resource owner is around 5% with 95% kept by the non-resource owner.

The third issue is Intellectual Property Rights which in Fiji at the moment is only legislated for songs and compositions via the Copyright Act. There are Trademark Acts also. However, legislation for biological resources, traditional knowledge etc is non-existent. Though a *sui generic* Act was required of Fiji by 1999 under WTO rules, there does not seem to be one in existence. Having looked at some of the models of IPR laws there are examples that Fiji can learn from - countries like the Philippines, Bangladesh, India, some South American countries and countries from the continent of Africa.

The fourth issue deals with custodian rights. The new legislation needs to incorporate this but there is expected to be still opposition from non-Fijians. At the moment the land legislations are not comprehensive enough to facilitate and strengthen the custodian rights of Fijians.

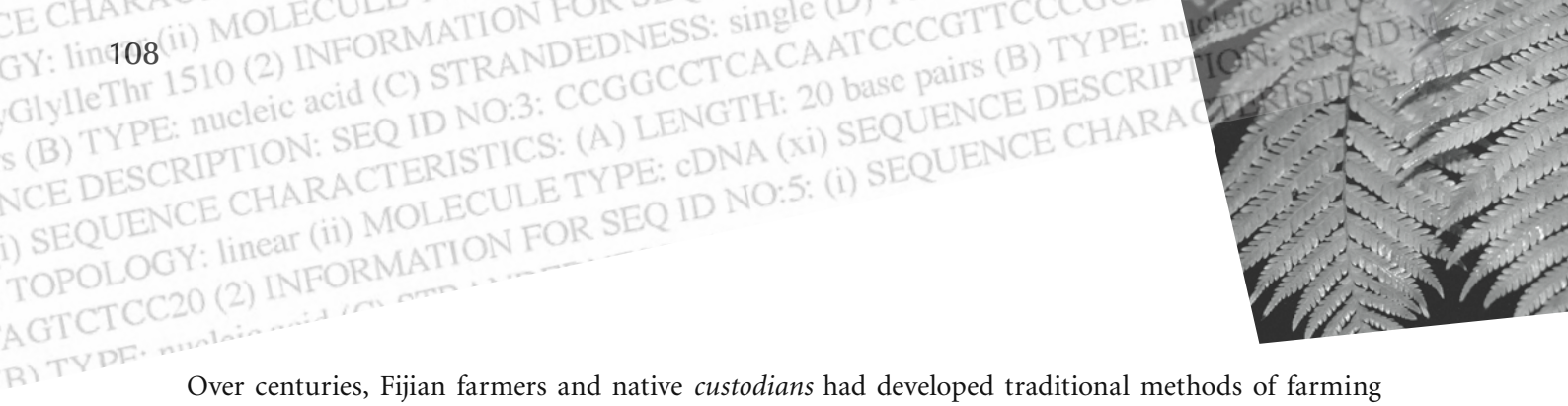
It must be noted that this "*sui generis*" Act proposed for Fiji will also cover the non-indigenous resource owners rights, farmers' rights, plant breeders' rights and so on. It therefore caters for all the peoples of Fiji, irrespective of race, religion, creed or color.

The fifth issue deals with farmers' rights. It has been suggested that the Convention on Biological Diversity (CBD) in the Food & Agriculture (FAO) Program provides the instrument for farmers' rights. The FAO is endeavoring to define "farmers' rights" and recognize the work of domestication and improvement of local varieties by successive generations of farmers. This concept, which seeks to identify an intellectual property right for resources, is more fragile than the other internationally recognized systems of protection (patents, brands, copyright).

Indeed, it was initially conceived as a counterpart to the plant breeders' right. The FAO is attempting to concretize the concept via national legal provisions, though such provisions will remain limited as they grant no exclusivity to farmers.

In this regards, Andersen R. (2005) states:

> "In 2001 the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was adopted, and it entered into force on 29 June 2004. The Treaty includes provisions on farmers' rights, and explicitly states that the responsibility for implementing these provisions rests with the national governments. The governments are free to choose the measures they deem appropriate, according to their needs and priorities. Certain measures to protect and promote farmers' rights are suggested. The preamble of the ITGRFA highlights the necessity of promoting farmers' rights at the national as well as international levels. There is as yet no common understanding of how this can be done. Such an understanding is of great importance for making progress in the realization of farmers' rights".



Over centuries, Fijian farmers and native *custodians* had developed traditional methods of farming which sustained them to this day. These also need to be protected for future sustainability.

The sixth issue is the breeders' rights. In relation to this, protection of breeders' rights is important in Fiji, especially in the example of the development of about 70 different varieties of taro by the Ministry of Agriculture, Sugar & Land Resettlement (MASLR). As a breeder, the Fiji government needs protection by the new legislation.

The seventh issue is the lack of definition of "custodian" and "custodian rights". In this regard Fiji's case of intellectual property rights is much more complex and complicated then for countries in the western civilization. Even the definition of "farmers' rights" is still being debated, argued and synthesized by the western world. However, they do not have the understanding, conception and conceptualization of who a "custodian" is, what a "custodian's right" is, let alone attach a definition to these communities. Therefore, Fiji needs to come up with a legal definition of these and negotiate with the international community to accept the terms and definitions. This will be a significant challenge for resource owners and native custodians of Fiji in the future. A suggested definition of custodians' rights is as follows –

*Custodians' rights consist of the customary rights that indigenous, aboriginal, native, custodians have had as stewards of biodiversity, inclusive of agro-biodiversity since the dawn of native custodianship of its flora and fauna, including agriculture to save, grow, share, develop and maintain plant varieties, of their legitimate right to be rewarded for their contribution to the global pool of genetic resources as well as to the development of commercial varieties of plants, and to participate in decision making on issues that may affect these rights.*

The final issue relates to royalties from land exploitation of Fijian natural resources. It is time now for Fiji and those investing in Fiji while taking advantage of all its biological, environmental and physical resources to be more serious about benefit sharing. At the moment the 6% lease for Unimproved Capital Value (UCV) tantamount to exploitation of the indigenous resources owners. A 25-35% benefit sharing scheme is a more acceptable figure for the resource owners who have been custodians of Fiji's natural resources for thousands of years. In relation to this is the issue of "third country utilization" where those who provide animal species, especially endemic ones, such as crested iguana, falcon, Kadavu/Taveuni parrots etc, for zoos need to be properly compensated (See Annexes 3-4 below).

## Conclusion

It is now appropriate for Fiji to develop a *sui generis* act for the protection of the rights of local indigenous and non-indigenous communities, farmers and breeders, and for the regulation of access to biological resources. According to WTO rules this was due by the end of 1999 and therefore it is already late and overdue. Model acts from other countries can be used as basis for this.

Around 80% of the biological, environmental, ecological, terrestrial, land, sea and water resources of Fiji are owned by the indigenous Fijians. It would be appropriate therefore that they are empowered to be directly responsible for the development of legal protective measures with regards to their bio-

diversity. Fiji is not very advanced in terms of protective legislations relating to intellectual property and effort should be made to ensure that a comprehensive framework is put in place to protect indigenous rights to intellectual materials.

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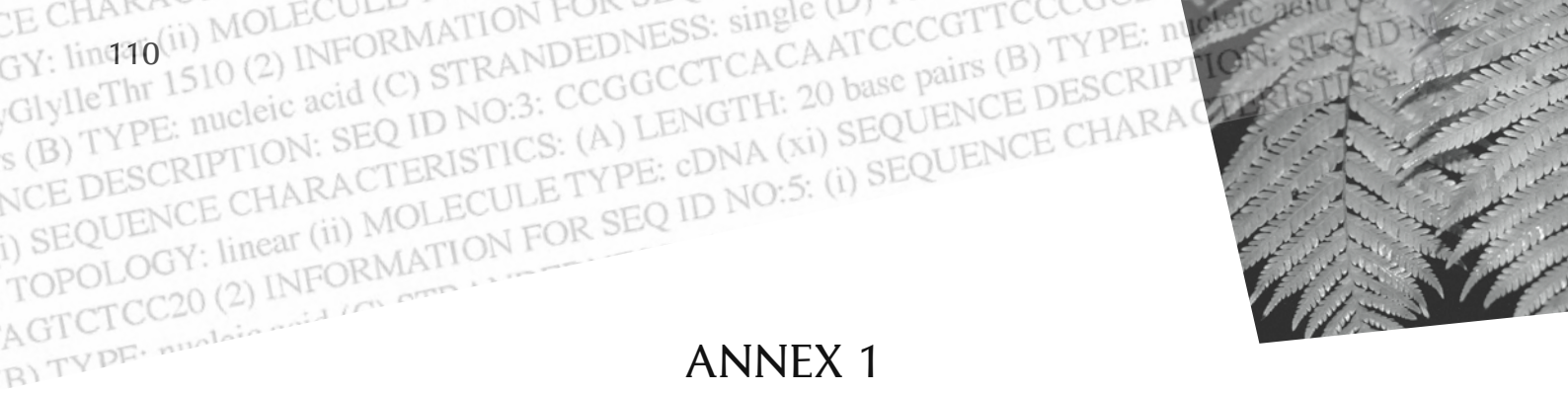


# ANNEX 1

## GUIDING PRINCIPLES FOR FIJI'S SUI GENERIS LAW

Fiji has sovereignty rights over its own native flora and fauna and derivatives of these both locally and third countries.

Fiji's indigenous and custodian rights from the past, present and future contributions in conserving, improving and making flora and faunal genetic resources available need to be internationally recognized. This is in order to allow indigenous native custodians and owners, their respective communities and countries in all regions of the world to participate fully in the benefits derived at present and in the future, from the improved use of floral and faunal genetic resources, through plant and animal breeding or other scientific methods.

Fiji farmers' rights arising from the past, present and future contributions of farmers in conserving, improving and making plant and animal genetic resources available are also recognized internationally. Once again this recognition is needed in order to allow farmers, their communities and countries in all regions of the world to participate fully in the benefits derived at present and in the future, from the improved use of the plants and animal resources, through breeding and other scientific procedures.

Fiji's biological diversity, including genetic diversity, shall be conserved, enhanced and used in a sustainable manner. Patents and other IPR shall be supportive of and not run counter to this objective.

Access to Fiji plant and animal genetic resources by a third country or party in a third country shall be subject to Prior Informed Consent (PIC). Where granted, access shall be on mutually agreed terms.

Benefits arising from the commercial and other utilization of Fiji plants and animal genetic resources both locally or in a third country shall be shared in a fair and equitable way upon mutually agreed terms, multilaterally or on a bilateral basis.

The results of research and development arising from the utilization of Fiji plants and animal genetic resources, as well as the technology using such resources, shall be shared with Fiji in a fair and equitable way on terms mutually agreed upon. Transfer of technologies relevant to the conservation of biological diversity, and access to the sustainable of its components, and to technologies that make use of these plants and animal genetic resources shall be provided and/or facilitated to Fiji under fair and most favourable conditions.

Fiji's *custodian*, indigenous and farming communities' knowledge, innovation and practices related to plants and animal genetic resources shall be protected and encouraged. Special measures shall be taken to ensure this, including mechanisms of free and prior informed consent.

The utilization of Fiji's plants and animal genetic resources whether locally or in a third country shall be in a manner that is sustainable to the environment and beneficial to the indigenous native owners.

# ANNEX 2

## AN EXAMPLE
## MATERIAL TRANSFER AGREEMENT (MTA)
## SALE OF THE FIJI FANTASTIC BREED OF SHEEP OF FIJI ORIGIN FROM FIJI TO SAMOA

The parties, the Government of Samoa and the Government of the Republic of the Fiji Islands

Re-affirming that
- the conservation of animal genetic resources is a common concern of humankind;
- nations have sovereignty right of its animal genetic resources in and outside of their territories;
- animal genetic resources should be made available for animal breeding and other scientific purposes of human benefit;

Noting that
- the best way to guarantee the maintenance of animal genetic resources is to ensure their effective and beneficial utilization, in all countries
- the farmers of the world over the millennia, domesticated, conserved, nurtured, improved, and made available animal genetic resources, and continue to do so today ;

Recognizing
- the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on animal and plant genetic resources;

Adopts
- the voluntary Code of Conduct for Animal Germplasm Collecting and Transfer the overriding purpose of which is to contribute within the context of the Global System of Animal and Plant Genetic Resources, to the conservation and rational use of animal genetic resources for sustainable development by providing broad guidelines for animal germplasm collection and transfer.

The Government of Samoa and the Government of the Republic of Fiji, bearing in mind the preceding clauses, agree:

1. The Intellectual Property Rights (IPR) and this Material Transfer Agreement (MTA) is accepted by both the Government of Samoa [the recipient] and the Government of Fiji [ the provider]

2. To safeguard the rights of Fiji in developing the breed over the years

3. The sale of Fiji Fantastic Sheep, their offspring and derivatives within Samoa only and to registered bone fide farmers is allowed without encumbrance to either Party for the next 10 years, except that
   3.1 This sale and provision excludes and does not apply for or to the University of the South Pacific or any other international organization in Samoa

3.2 In the case of the University of the South Pacific or any other international organization in Samoa, separate and independent Material Transfer Agreements [MTA] by these respective organizations will have to be negotiated with the Ministry of Agriculture, Sugar and Land Resettlement of Fiji

4. Samoa may carry out Research & Development on the Fiji Fantastic Sheep, their offspring and derivatives within Samoa only, on Samoan Government Research Stations and by Samoan Government Ministry of Agriculture scientists and officials only

5. With regards to consultancies, technical cooperation etc on the Fiji Fantastic Breed of Sheep in Samoa, Fiji reserves the right to provide this at a negotiated price with Samoa, while Samoa agrees to this reservation of professional and technical expertise by Fiji except when-

5.1 Fiji cannot provide such consultancy and technical expertise, then Samoa may source these from outside with full participation be Fiji counterpart/s together with all costs borne by Samoa

6. That Samoa will not sell or make available (free or otherwise) Fiji Fantastic rams and ewes, and any genetic material from the Fiji Fantastic breed of sheep to a third country/party/buyer outside of Samoa for the next 10 years

7. That the recipient will not patent or apply for patent any of the Fiji Fantastic Breed of Sheep or its derivatives, micro-manipulated or otherwise, or any of the processes from which the Fiji Fantastic Breed of sheep was created and/or bred for the next 10 years without the Prior Informed Consent (PIC) of Fiji.

8. Any sale to a Third country/party/buyer outside of Samoa will require -

8.1 the prior informed consent and approval of the Fiji Government,
8.2 that each animal shall be sold at no less than F$4000.00,
8.3 any genetic material or derivatives thereof shall be sold at a price approved by the Fiji Government
8.4 the third country/party/buyer shall pay a 20% royalty to Fiji on all sales of Fiji Fantastic sheep or any derivatives thereof for the next 10 years.
8.5 the third country/ party/buyer shall use the animals and/or genetic material for breeding, research & development only for the next 10 years before it could sell the progenies or any offspring commercially, unless the animals are being culled for age or disease
8.6 the naturally derived or micro-manipulated offspring of all Fiji Fantastic sheep shall remain the property of the Fiji government for the next 10 years.
8.7 the genetic offspring of all the Fiji Fantastic sheep sold to Samoa shall be the property of the Fiji government for the next 10 years.
8.8 After the 10th Year all the genetic offspring and material of the Fiji Fantastic sheep sold to Samoa may be freely sold and exchanged by the Government of Samoa without encumbrances and with no royalty or obligations due to Fiji

9. The Sale Price of the ewes to be sold to the Government of Samoa by the Government of the Republic of Fiji shall be F$3000.00 each.

10. The sale price of the rams to be sold to the Government of Samoa by the Government of the Republic of Fiji shall be F$4000.00 each

11. All other costs like shipping, freight, etc will be met by the Government of Samoa.

12. Fiji shall insure the 42 sheep and replace them should any losses occur during shipping from Fiji to Samoa.

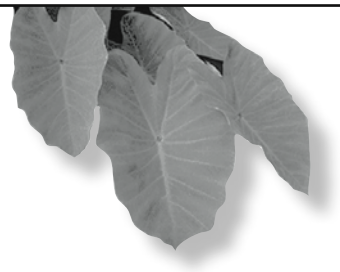
13. This Material Transfer Agreement may be reviewed within the first 3 years of inception, a third year review must be carried out within 6 months of the end of the third year, and then 3-year reviews thereafter.

Signed in Suva, Fiji this …… the ….. th of June 2004

CEO for Agriculture, Sugar and Land & Resettlement, FIJI

Signed in Apia, Samoa this ……..the …..th of June 2004

CEO for Agriculture, Forests,Fisheries Meteorology,SAMOA



# FROM KUMULIPO: I KNOW WHERE I COME FROM- AN INDIGENOUS PACIFIC CRITIQUE OF THE GENOGRAPHIC PROJECT

Le`a Malia Kanehe, Esq. (Kanaka Maoli/Hawai`i)[1]

## Introduction

*"There is nothing that a map of our genome would tell us about ourselves culturally; we know who we are and where we come from."*

I made the above statement in 2004 in response to a human genetic researcher's claim that "a map of the Hawaiian genome will be a cultural icon for the Hawaiian people regarding their migration through the Pacific." Dr. Charles Boyd was responding to an Indigenous community-based organization resolution calling for a cease to his proposed project, the Hawaiian Genome Project, or any other patenting or licensing of genetic material of the Hawaiian peoples.[2]

This resistance by Kanaka Maoli is consistent with the position that many Indigenous peoples worldwide are taking to oppose human population genetic research, especially where such research has ancient human migration theories as an objective of the project. This article will provide a Pacific Indigenous critique of human population genetic research primarily by exploring the different kinds of genetic research being conducted on Indigenous peoples, particularly in the Pacific. There will be a particular focus on anthropological based migration research, especially in light of the new global Genographic Project launched by National Geographic and IBM Corporation proposing to map human migration via collection and analysis of 100,000 DNA samples from Indigenous peoples around the world. Although not unique in its objectives, this project poses new risks to Pacific Indigenous peoples. The article will examine how Pacific Indigenous peoples are making decisions based on their own cultural values and principles about whether to participate in genetic research, including the Genographic Project.

## I. Human Genetic Research on Pacific Indigenous Peoples

Pacific Indigenous peoples are subjects of curiosity to genetic researchers because we are considered "isolates of historic interest." They assert that we have been geographically isolated for a long time and, therefore, we have homogenous genomes unlike urban populations. For medical reasons, scientists want to study any unique genes that cause either immunities or susceptibilities to certain diseases that are different from other populations. For example, when Autogen Ltd. proposed studying Tongan DNA, the Tongan people were characterized as a "unique population resource."

Often researchers assert that Indigenous peoples should participate in this kind of genetic research because it will aide all humankind. For example, in 1993, the United States Department of Health and Human Services applied for a patent on the human T-Cell lines of 24 Hagahai people from Papua New Guinea taken in 1989. The patent claimed usefulness in treating and diagnosing individuals infected with human T-lyphotropic virus type 1 (HTLV-1), which is associated with adult leukemia and with a chronic degenerative neurologic disease.[3] The novel cell line was seen as a potential value in understanding the enhancement or suppression of immune system response to this virus.[4]

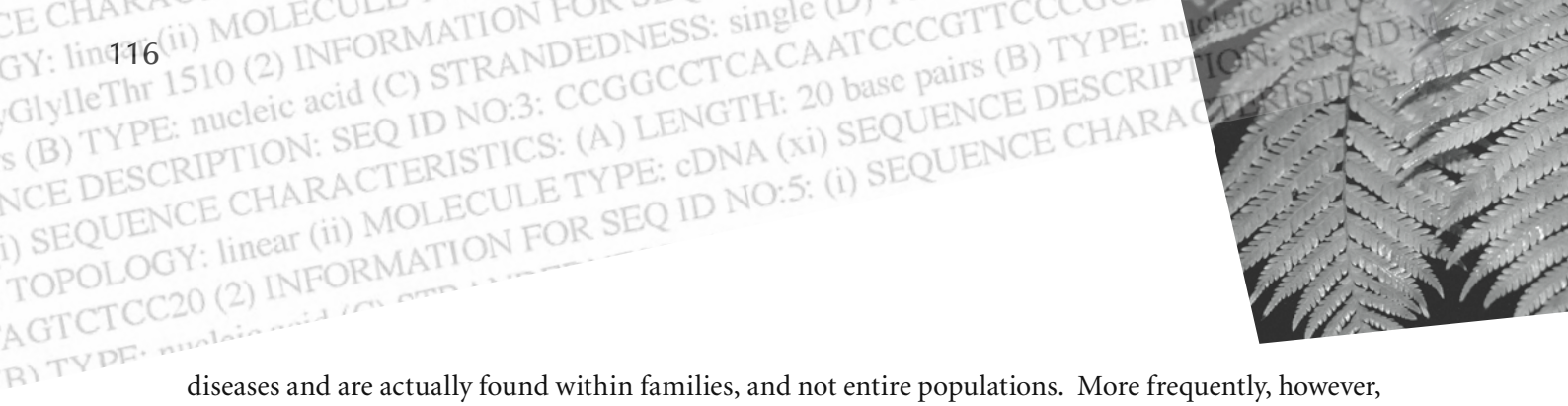
Not all genetic research, however, has medical objectives. Often times the different types of genetic research and their agendas are blurred. Research projects that have been touted as health-related often end up being used to achieve other goals. There is a pervasive, negative history of widespread secondary uses of samples given for one purpose, but used without consent for other types of research. For example, in the Hagahai case, the donors did give informed consent for blood to be taken for diagnosis, but did not consent for those samples to be taken out of the country for further research.[5] Once the Papua New Guinea government protested the U.S. move to patent the Hagahai T-cell line, the application was withdrawn in 1999, however, the Hagahai cell line was still available to the public at the American Type Culture Collection as ATCC Number CRL-10528 Organism: Homo Sapiens for $216.[6] Because of this experience, the Hagahai people have suggested that they will not trust researchers again.[7]

### Different Types of Human Population Genetic Research

Human population genetic research can be understood in four basic categories:
1) health-related genetics,
2) behavioral genetics,
3) genetic mapping, and
4) anthropological genetics.

Indigenous peoples of the Pacific have been the subjects of pervasive genetic research in all of these areas.

Health-related genetics deals with researching genetic bases for various diseases. For example, in the 1980's, in Hawai'i, a project was conducted to find the "breast cancer gene" in Kanaka Maoli women. Although some health-related research may be useful when it is conducted to identify single-gene mutations (such as pseudoxanthoma elasticum (PXE), a rare connective tissue disease), those are much more rare types of



diseases and are actually found within families, and not entire populations. More frequently, however, Indigenous peoples are studied for complex diseases such as diabetes, hypertension, or breast cancer. For example, in 2000, the Australian company Autogen Ltd. proposed to identify genes for diabetes in the people of Tonga.[8] Similarly, the Hawaiian Genome Project proposed to find a genetic source for the high rate of obesity, diabetes, renal disease and hypertension in Kanaka Maoli.[9] These types of diseases have multiple factors that contribute to afflict many Indigenous peoples. Socio-economic and environmental factors such as poor diets, lack of exercise, smoking, stress and environmental pollution cause these diseases, not any inherent genetic defect within Indigenous peoples.

Behavioral genetic research involves searching for genetic reasons for human behavior, especially behavior that is seen as undesirable or responsible for leading to disease. For example, some research has been conducted proposing that there is a smoking gene in Maori that contributes to the high rate of smokers among the Indigenous peoples of Aotearoa (New Zealand).[10] This type of research should be looked at with a discerning eye because behavioral "defects" such as smoking or drinking are learned behaviors often induced by socio-economic factors, rather than a genetic predisposition to be smokers or alcoholics.

Genetic mapping research generally deals with researching the structure and identification of genes on the forty-six human chromosomes. The Human Genome Project (HGP) sequenced 3 billion bases in humans to arrive at a prototype or "generic" or "average" genome.[11] Other scientists are studying variations among populations, which is the area of genetic research in which Indigenous peoples DNA is of particular interest.[12] Research on the variations in genes was the aim of the Human Genome Diversity Project (HGDP), which sought samples from over 700 different Indigenous peoples. There is perceived value among scientists to study people whom they believe have a high degree of variation within their genetic makeup. "The result is a new 'gold rush' where universities, governments, corporations, and private researchers are all seeking to identify human genetic variation" by studying Indigenous peoples around the world.[13]

A Pacific example of genome mapping of such "unique" genetic populations is embodied in the proposed Hawaiian Genome Project. Dr. Boyd was seeking 150 samples of the most "pure bred" native Hawaiians for a five to ten million dollar project that would propose to produce an annotated map of the entire genetic makeup of the Hawaiian peoples. In a letter explaining his intentions with that proposed project, Dr. Boyd states, "There are many communities now with their own unique genetic history imprinted into their genomes and these include Asians, Europeans and the peoples of Oceania. The Hawaiian genome represents an important example of one of these communities of the Oceania people."[14]

Anthropological genetics studies the history of populations, their relationships with others and often theorizes about ancient human migrations. Often this type of research involves taking biological material from our deceased ancestors, which often includes smashing, scrapping and other desecrating acts on the ancient ones. Dr. Boyd's proposition beginning this paper that the Hawaiian Genome Project would be an icon for Kanaka Maoli because it would tell us about our migratory history through the Pacific is an example of anthropological genetic research in the Pacific region. Anthropological genetic research, including proposing new theories about the peopling of the Pacific islands and Australia, is also at the heart of the new Genographic Project, which is detailed in the next section.

## II. The Genographic Project

On April 13, 2005, The National Geographic Society and the IBM Corporation announced the launch of the "Genographic Project," which purports to help people better understand their ancient history. The privately funded project, sourced by Gateway Computers' charitable arm, the Waitt Family Foundation, expects to collect 100,000 DNA samples from Indigenous peoples around the world.[15] The taking of blood and other biological samples, as well as oral histories, will be coordinated and maintained by ten regional research centers around the world.

With centers in Australia, Brazil, North America and Southeast Asia, Sub-Sahara and South Africa, this project is certain to affect many Indigenous peoples around the world. Nevertheless, the stated goal of the project is not invited or designed by Indigenous peoples. The Genographic Project Fact Sheet states that, "[t]he goal . . . is to help people better understand their own history, learn about ancient migratory paths our ancestors took to populate the planet, and discover how, in spite of our diverse appearances, we are all part of the same family tree and share common origins."[16]

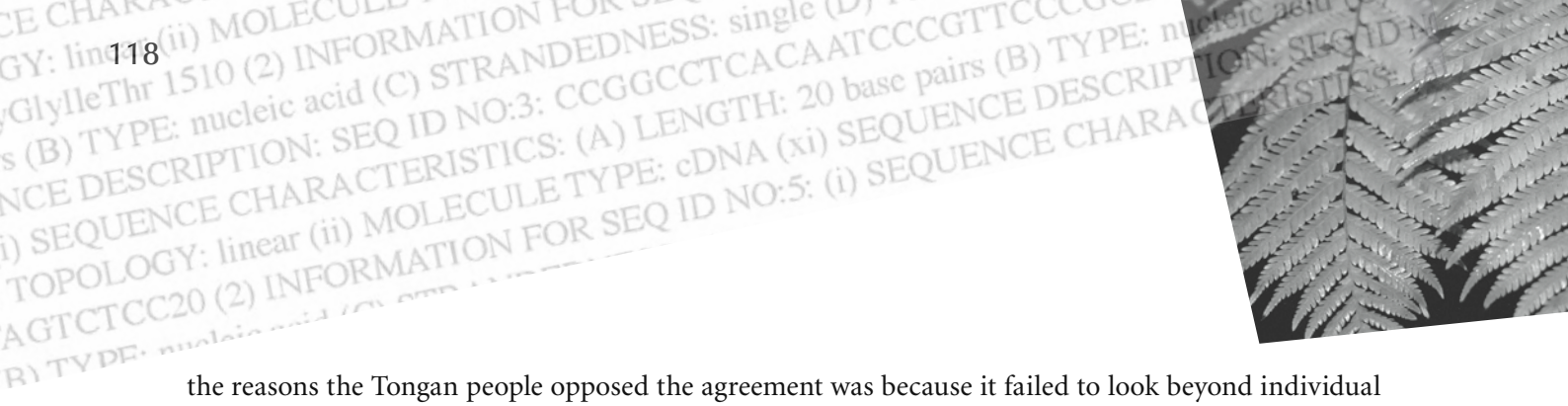
Indigenous peoples around the world are very concerned about being exploited by this new project based on previous experiences. In the 1990s, Indigenous peoples strongly opposed a similar project known as the Human Genome Diversity Project (HGDP), which targeted approximately 700 different Indigenous peoples for blood samples, earning it the nickname, "The Vampire Project," because it was more interested in collecting the blood of Indigenous peoples than in their well-being.[17]

The HGDP was so fraught with ethical and scientific problems that it failed to get endorsement from UNESCO, and even the United States' National Science Foundation. The new Genographic Project is essentially the same project as the HGDP and Indigenous peoples are similarly opposing this new effort to take Indigenous genetic material. For example, Prue Odachao a community leader of the Karen Indigenous peoples in Thailand, says, "[w]e did not want to be exploited then, and we don't want to be exploited now,"[18] referring to the HGDP and the Genographic Project respectively.

### Ethical Concerns: Free Prior Informed Consent

All of the standard ethical issues that arose with the HGDP come to bear in The Genographic Project. First, there must be guarantees that ensure strict adherence to free, prior informed consent (FPIC), not only of the individuals involved but also of the Indigenous nations impacted or potentially impacted by this project. Although prior informed consent has become the accepted standard for human subject research,[19] it is much easier ensured and verifiable when applied to individual subjects, yet, FPIC is much more difficult to apply to whole populations.

How is group consent ensured? Individual members of tribe or other Indigenous group cannot consent for the entire population. Nevertheless, with past human population genetic research, very few samples have been taken from individuals, who may or may not have consented, yet the outcomes of the research are attributed to the entire Indigenous group of which they are a part. Therefore, the data derived from the samples are often labeled with a tribal name. In the Tonga situation with Autogen Ltd., one of



the reasons the Tongan people opposed the agreement was because it failed to look beyond individual informed consent. Lopeti Senituli, a Tongan political activist and former director of the Tonga Human Rights and Democracy Movement, notes that, "[t]he Tongan extended family, the bedrock of Tongan society, would have no say even though the genetic material donated by individual members would reflect the entire family's genetic make-up."[20]

Although Dr. Spencer Wells, the Genographic Project's overall principal investigator, has promised that the Project will seek consent from tribal authorities as well as from individual DNA sample donors, that consent may still not suffice. In Tonga, for example, although the agreement would have been between Autogen Ltd. and the government of the Kingdom of Tonga via the Ministry of Health, the Tongan people themselves did not consent. The Project seems to base its ethics solely on the notion of individual informed consent. However, individual informed consent was insufficient in the case of the HGDP, as the National Academy of Science Committee noted:

> Consent alone cannot justify research on populations that will not be able to benefit from it because such research violates basic principles of social justice and equality. Research subjects can make a gift to researchers or humanity, but the validity of such a gift in the context of studying genetic diversity, especially of isolate populations, is too problematic to provide the sole justification for the research.[21]

The conclusion is that unless the risk-benefit ratio is in favor of the populations to be studied, the research protocol is not ready for institutional review board (IRB) (or any other) ethical review.[22] Regardless, the University of Pennsylvania Social and Behavioral Sciences IRB has approved the research protocol for the Genographic Project to begin in North America.

## Ethical Concerns: Do the Benefits Outweigh the Risks?

Another standard ethical requirement in human research is that the benefits must outweigh the risks. The consent form provided to would-be donors states that one admitted risk of the project is that, "it is possible that some findings that result from this study may contradict an oral, written or other tradition held by you or by members of your group."[23] Several of the proposed research questions reveal the Project's interest in answering questions such as "Could Europeans have migrated to the Americas thousands of years ago?", "Who were the aboriginal inhabitants of North Africa, and are the Berbers their direct descendants?" and "Who were the aboriginal inhabitants of Indonesia?"[24]

The Genographic Project poses a risk that there could be serious political implications that result from a so-called "scientific" assertion that Indigenous peoples are not "Indigenous" to their territories, but instead are recent migrants from some other place. This cuts at the heart of the rights of Indigenous peoples, which are based, in part, on being the original inhabitants of a certain territory or region.[25]

Although Dr. Wells, an anthropological geneticist, proposes that the project will support Indigenous peoples, other anthropologists, such as Dr. Pinkaew Luangaramsri from Thailand, counter that "the

quest for human origins is only to satisfy those white men, especially Americans, who don't really know their roots."[26] Wells maintains that the project aims to show that humans are all related, having common ancestral roots in Africa. But Pinkaew questions, "I want to know how this knowledge will help the Karen. Will the knowledge that the Karen and white man share a common ancestry improve their marginalized status? Definitely not."[27]

Maori attorney, Moana Jackson, aptly explains many Indigenous peoples' underlying concern with the risks of the Project. "I'm sure part of [the Genographic Project] will be to try to strengthen some of the existing theories about the arrival of indigenous peoples in various countries, and that has a sordid history because it has been used to diminish indigenous rights."[28] Indigenous peoples of Australia are similarly concerned that "results of the research are open to political manipulation" because "lawyers may use the genetic results to argue Aboriginal people have not always been in Australia and therefore do not have any special rights to the land, known in Australia as native title."[29] A Karen rights activist explains that, "[w]e already have our own creation story, and if the scientists show otherwise, the government may finally have what they need to evict us from our land."[30]

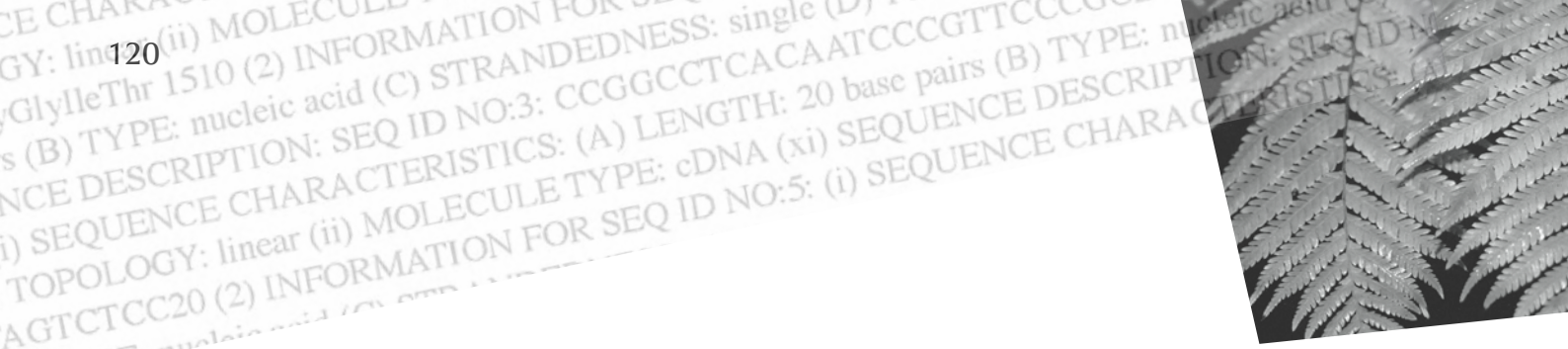
Cultural Survival Quaterly recently published a tripartite of views on the Genographic Project, including a piece from the co-chairs of the Cultural Survival Program Council, made of Indigenous and non-indigenous experts. Stella Tamang (Tamang, Nepal) and Dr. Richard Grounds (Euchee, Oklahoma) question the impacts of the Project in regards to Indigenous peoples own creation stories:

> Since Indigenous Peoples have their own cosmovision, ceremonies, songs and stories that provide satisfactory explanations of their past origins and migrations, why not trust and respect Indigenous knowledge and wisdom? Are not the findings likely to create a clash with traditional understandings and traditional beliefs? Is it acceptable to inject western constructions of descent, migration, and inheritance into Indigenous communities?[31]

The Project is promising some minimal benefit-sharing in the form of monetary compensation to be used for cultural preservation.[32] There is a huge disconnect, however, between genetic research and cultural preservation. Dr. Cherryl Smith, a Maori activist and researcher, states that, "[i]f they really want to help promote Indigenous peoples cultures, there are more productive ways and methods for doing so."[33] There is no price that can be offered to purchase the sacred genealogy of our ancestors that lives within our veins.

## Ancient DNA Research: Desecrating the Ancestors

The Genographic Project also proposes to do studies on so-called "ancient DNA", which involves crushing and scraping the bones of our ancestors to obtain viable genetic material to study. Aboriginal researcher Steven Kinnane of the Australian Institute of Aboriginal and Torres Strait Islander Studies, says "[t]here's not necessarily a great historical relationship with the scientific community."[34] Kinnane notes that, "scientific knowledge has in the past been used to the detriment of Aboriginal people, for example to support the idea that they are inferior."[35] The ancestral remains of Aboriginals of Australia, have been studied extensively in the past, particularly to advance theories that smaller cranial size correlates with inferior intelligence. The Ancient DNA center based in Adelaide, Australia under the



direction of Dr. Alan Cooper from the University of Adelaide, will focus on DNA collected from ancient samples.

Certainly, the individuals whose bones would be studied cannot provide free prior informed consent. When questioned on this point, Dr. Wells said that the Genographic Project would seek the consent of the tribe with whom the remains are affiliated.[36] Yet, in order to determine cultural affiliation with a particular tribe, especially when it concerns bones of antiquity (i.e, the most ancient remains), it is often difficult to prove such affiliation. Therefore, they are often subject to more and more desecrating research in the quest to prove or disprove relationship with present day tribes. Under federal law in the United States known as the Native American Grave Protection and Repatriation Act (NAGPRA), these ancestors are classified as "culturally unidentifiable."[37] This preference in favor of the scientific community has impeded Native American tribes in the United States trying to repatriate remains found at Kennewick, Washington (i.e, "Kennewick Man") and Spirit Cave and Wizard Beach in Nevada.[38]

Therefore, in regards to the Genographic Project, it is likely that the scientists will try to justify the need for genetic testing in order to verify whether a particular tribe is related to a given set of remains and, therefore, determine whether or not they have the right to consent or prohibit inclusion of genetic material from those remains within the Genographic Project's collections. Despite their insistence to the contrary, we must remember that DNA analysis cannot be used to conclusively determine whether an individual from whom DNA is obtained is a member of a particular group like a tribe.[39]

Dr. Stuart Newman, Professor of Cell Biology and Anatomy at New York Medical College, has very clearly explained that the ability of genetics to provide conclusive proof of ancestry is very limited:

> DNA evidence can only be used in an absolute sense to say that two samples are different. This can exonerate criminal suspects. But it can't be used to absolutely say that two samples are the same, since that would require sequencing the entire genome of both samples, which is unfeasible in the extreme. So any identification of individuals' samples can only be statistical. Trying to relate an individual to group DNA is even more tenuous - all groups are heterogeneous, so even if the sample resembles the average member of the group, it doesn't mean the individual was part of the group. And if the sample doesn't resemble the average member of the group, it doesn't mean that the individual was not part of the group.[40]

Thus, we cannot stand by while our ancestors are desecrated in the name of scientific curiosity, especially when such science is merely speculative.

## International and United Nations Opposition

For many of the reasons explained above, Indigenous peoples internationally have opposed the Genographic Project. On May 20, 2006 several Indigenous leaders convened to meet with representatives of the Genographic Project and National Geographic Society officials to express their overwhelming opposition to the project. The Indigenous Peoples Council on Biocolonialism (IPCB) presented a petition to Dr. Wells bearing the names of more than 850 Indigenous nations, organizations, individuals, and supporters calling on the National Geographic Society to stop the Project. Prior to and during the

meeting over thirty protestors rallied outside of the meeting at the United Nations Millennium Plaza and voiced their concerns about the project's exploitation of Indigenous peoples. Rally speeches called for a boycott of National Geographic products and supported meeting participants' call for an immediate halt of the Genographic Project. Although Wells and top National Geographic officials failed to agree to this demand, Indigenous peoples lobbied the United Nations Permanent Forum on Indigenous Issues (UNPFII), which was meeting for its fifth session during the same time period.[41]

On May 26, 2006, the UNPFII recommended that "the World Health Organization and the Human Rights Commission investigates the objectives of the Genographic Project" and request "that the Genographic Project be immediately suspended and report to the Indigenous peoples on the free, prior and informed consent of all the communities where activities are conducted or planned."[42] This UN recommendation from a panel of Indigenous rights experts should cause National Geographic to more seriously consider Indigenous peoples demands to discontinue the Project. IPCB's Director, Debra Harry notes that, "when UNESCO's International Bioethics Committee denied support to the HDGP, it wasn't much longer that the project came to an end."[43]

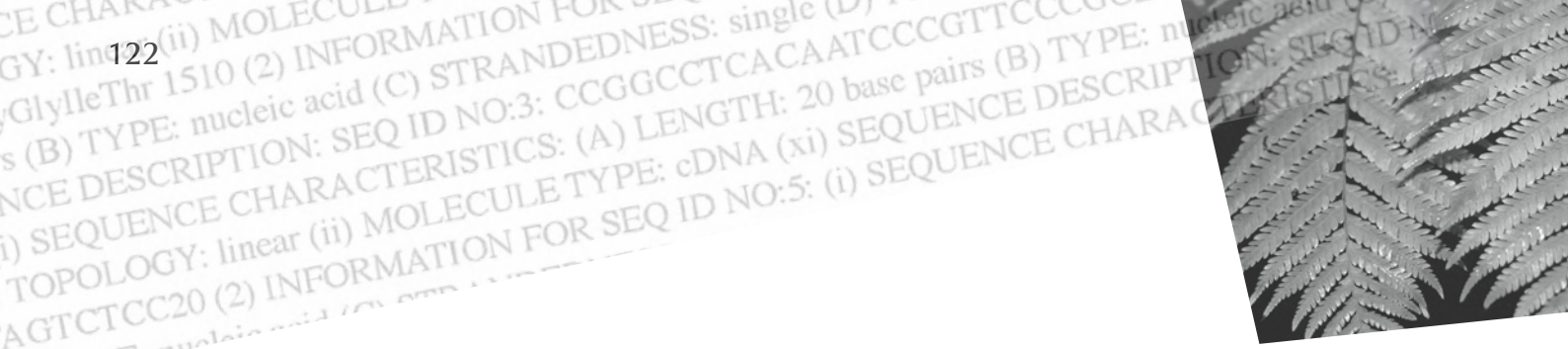
It is also important to note that the Pacific's Representative on the UNPFII, Mick Dodson, a well respected aboriginal rights scholar from Australia, cleared up misconceptions that his writings on ethical standards for research with Indigenous peoples were being used to promote the Genographic Project. During the closing session of the UNPFII, Dodson said, "A document has been circulated [by National Geographic] that implies that I support the Genographic Project. I don't. I oppose it."[44]

## III. Opposing the Genographic Project in the Pacific

Pacific Indigenous peoples have very clearly opposed intrusive genetic research in the past and should continue to do so, especially to resist the new Genographic Project's objectives in the region. Dr. Robert John Mitchell from La Trobe University in Melbourne Australia, who is responsible for the Pacific research center of the Project, very clearly explains the intentions of the Genographic Project. "I'm sure we will show that Aboriginals have descended from the common ancestor of us all back in Africa and that at some point, quite early on, Aboriginals hived off the main tree and arrived in Australia 50,000 years ago or so."[45] Dr. Mitchell says that "he hopes to track the migratory route taken by the ancestors of early Australians, possibly via India and Southeast Asia, and try to determine if any of their genes are left in India today."[46]

Pacific region-specific research questions contained in the overall project protocol and National Geographic media include:

- Were there any migrations to South America from the Pacific?
- Who were the aboriginal inhabitants of Indonesia, and was there much genetic exchange with Australia?
- How do the genetic patterns in Australia correlate with Aboriginal song lines – their own oral histories?
- Can we use genetics to trace the spread of the Polynesians and Micronesians from island to island in the Pacific?



- What impact did migratory bottlenecks/colonialism/disease/etc. have on the genetic patterns in the Pacific?[47]
- How the first modern humans reached Australia and Papua New Guinea?[48]
- Also, how did the ancestors of the Maori reach New Zealand?[49]

The Genographic Project will undoubtedly assert to answer these questions, but these are not research questions driven by Indigenous peoples of the Pacific. We know our creation stories and we know who our ancestors are. The following section will briefly summarize opposition in the Pacific by Indigenous peoples to genetic research that should provide a basis for continued opposition.

## Solomon Islands

In 1990, blood samples were taken in the Solomon Islands from a woman from the Marovo Lagoon in the Western Province and a man from Guadalcanal Province. The US Department of Commerce filed for a patent on the human T-cell line of Solomon Islanders because their T-cell lines were potentially useful in producing vaccines and/or diagnosing human T-lymphotropic virus type 1. The Solomon Islands' government officially protested and eventually the patent application were withdrawn in 1999.[50]

## Treaty for a Lifeforms Patent-Free Pacific

In April 1997, the Pacific Region completed the Treaty for a Lifeforms Patent-Free Pacific, also known as the Hagahai Treaty, which drew on the negative experiences of both the Hagahai and Solomon Islanders grew out of the 1995 Pacific Indigenous Peoples' Knowledge and Intellectual Property Rights Consultation in Fiji. In the Protocol on Human Genetic Research, the parties declare that there should be no patenting allowed on any specimen – or anything derived from the specimen – taken from any person.[51]

## Tonga

One of the outcomes of the Tongan opposition to the Autogen proposal was a Pacific Regional Bioethics Consultation held in March 2001 in Nuku`alofa and sponsored by the Pacific Council of Churches and World Council of Churches. The resulting Pacific Regional Bioethics Statement demanded "an end to bioprospecting and commercialisation of genetic resources in the region, full disclosure of all aspects of any genetic research projects in the region, and for the establishment of human rights protection in the region."[52] This event was the first time such a statement was issued by churches in the region.

## Hawai`i

Despite Dr. Boyd's proposal to patent and license the Hawaiian genome as the intellectual property of the Hawaiian people, Kanaka Maoli rejected any proposal to patent or commercialize their genetic makeup. Boyd proposed that by agreeing to patent discoveries from research on our DNA, we could stand to make significant profits. Although Boyd alluded to potential payoffs such as the $200 million

paid by Roche pharmaceutical company for right to the Icelandic genome, Kanaka Maoli clearly stated that their DNA was not for sale.[53]

In 2001, the Association of Hawaiian Civic Clubs passed a resolution urging the University of Hawai`i to cease development of the Hawaiian Genome Project. The resolution went further to call for a stop to all patenting or licensing of Native Hawaiian genetic material until such time as the Native Hawaiian people have been consulted and given their full, prior and informed consent to such project. The resolution clearly states that, "the Hawaiian genome represents the genetic heritage of our ancestors and is the collective property of the Native Hawaiian people."[54] As a result of this resolution, Kanaka Maoli were able to get the support of the University of Hawai''s Dean of the School of Medicine[55] that the Hawaiian Genome Project should not be pursued and, further, to get the Chancellor of the University of Hawai'i at Manoa to place a moratorium on the project.

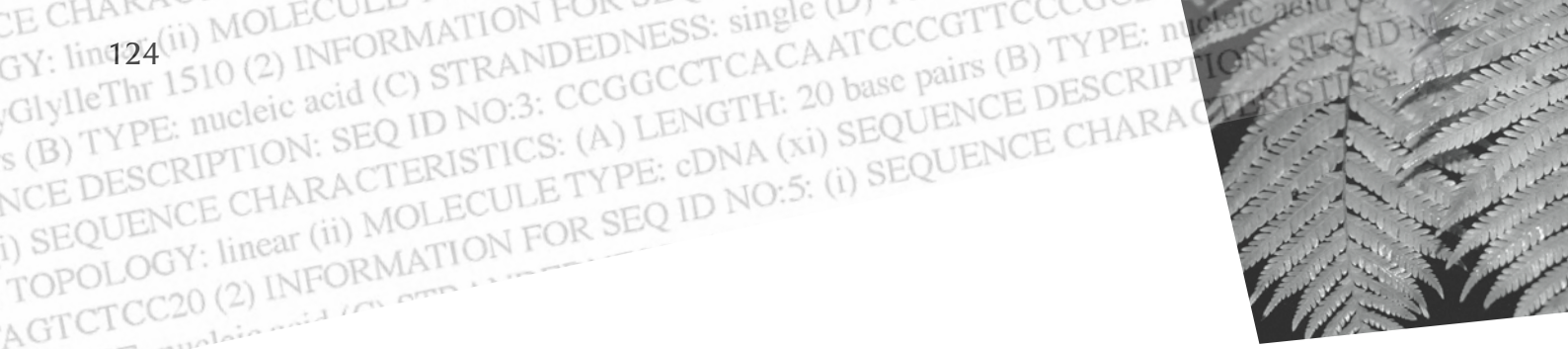
Furthermore, in 2002, `Ilioulaokalani Coalition, an organization comprised of Kanaka Maoli cultural practitioners, convened Ka `Aha Pono – Native Hawaiian Intellectual Property Conference, a conference/ gathering of Kanaka Maoli to discuss protection of traditional knowledge and prevent biopiracy in Hawai'i. As a result, the 'Aha issued the Paoakalani Declaration, which states, in part: "Kanaka Maoli human genetic material is sacred and inalienable. Therefore, we support a moratorium on patenting, licensing, sale or transfer of our human genetic material."[56]

## Human Right of Self-Determination

In 1997, UNESCO adopted the Universal Declaration on the Human Genome and Human Rights, which declares, in part, that, "no research or research applications concerning the human genome . . . should prevail over respect for human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people."[57] The basic human right of peoples is the right of self-determination as embodied in The International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights. Article 1(1) of both of these fundamental human rights documents states that, "All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development."[58] Therefore, by virtue of our right of self-determination, Indigenous peoples have the right to determine whether genetic research may proceed on our peoples. The corresponding right of free prior informed consent (FPIC) provides a process by which this right can be actualized and implemented. FPIC includes the option of withholding consent.[59] But, FPIC does not provide Indigenous peoples with the answer of whether to participate or not in genetic research. We must find those answers within our own cultures and traditional knowledge and values.

## Culturally-Based Decision Making

Indigenous peoples would be wise to utilize their own frameworks for evaluating the usefulness, potential, and appropriateness of ventures that affect their knowledge, resources, and culture. One such framework, a five point test utilizing a tikanga Maori framework, has been articulated by Hirini Moko Mead (Ngati Awa, Ngati Tuwharetoa, Tuourangi) of Aotearoa (New Zealand). The tikanga framework



facilitates decision-making on contemporary issues based upon the ethics inherent in Maori principles and philosophies.

Mead takes "the position that tikanga is the set of beliefs associated with practices and procedures to be followed in conducting the affairs of a group or an individual. These procedures are established by precedents through time, are held to be ritually correct, are validated by usually more than one generation and are always subject to what a group or an individual is able to do."[60] He further explains that, "They help us to differentiate between right and wrong, in everything we do and in all of the activities that we engage in. There is a right and proper way to conduct one's self."[61]

Thus, critical questions are filtered through a five-point test. If an issue fails to withstand this kind of evaluation, then it is determined that the question at hand violates the tikanga or the cultural, ethical standards of Maori. Mead says, "A culture that sets aside its pool of tikanga is depriving itself of a valuable segment of knowledge and is limiting its cultural options."[62] Maori in Aotearoa (New Zealand) have opposed both human and non-human genetic research based on their understanding that body parts are tapu (sacred), that all life has mauri (life force), and wairua (spirit) that should not be tampered with.[63]

All Indigenous peoples have their own cultural frameworks and worldviews to draw upon in making such judgments. For example, Lopeti Senituli, former director of the Tongan Human Rights and Democracy Movement, articulated the Tongan concept of "NGEIA," which means "awe inspiring, inspiring fear or wonder by its size or magnificence" and "dignity." NGEIA was central to the Tongan people's opposition to an Australian company's proposal to collect tissue samples and health data from individual consenting Tongans in the hope of identifying genes that cause diseases such as diabetes.[64] In exchange for the samples, the company, Autogen Ltd., had offered a benefit sharing arrangement that would have provided annual research funding to Tonga's Ministry of Health, paid royalties on revenues generated from any discoveries that might later be commercialized, and given whatever new therapies might be developed from the research to the Tongans free of charge.[65] As a result of the Tongan community's opposition to Autogen's proposal - an opposition based on the community's understanding of NGEIA and corresponding belief that "the human person should not be treated as a commodity" - the project did not proceed.[66]

Similar to the Tongan belief in ngeia, Kanaka Maoli in Hawai`i have opposed genetic research because it is not pono and is not consistent with the principle of malama `aina. The Paoakalani Declaration sets forth the principles of pono (to act appropriately; righteousness) and malama `aina (to care for the land) in the context of kuleana (the right and responsibility) to act in concert with pono.

7.1 Pono governs the cosmos, guiding and informing the behavior among the Akua, the `aina, and the kanaka, and their interaction at and between the microcosmic and macrocosmic levels, ensuring proper maintenance and development of our society, our culture, and our existence in all forms and in all dimensions.

7.2 Malama `Aina is the operating cultural principle that maintains pono. The people and the land are of the same integrated ancestral lineage, the `aina and all of her life forms, our ancestor, and the Hawaiian people, the younger.

7.3 Each aspect of the trilogy of the Akua, the `aina, and the kanaka share familial, interdependent, and reciprocal responsibilities to each other expressed in kuleana. Kuleana encompasses both the rights and corresponding sacred responsibility with accountability to maintain, conserve, and protect the Akua, the `aina, and the kanaka in perpetuity.[67]

Therefore, it is within the rights and responsibilities of Indigenous peoples of the Pacific to make decisions about whether to participate in genetic research, and to what extent, and under what conditions. Furthermore, as an exercise of sovereignty, Independent Pacific Island states should enact legislation consistent with customary law that protects their Indigenous peoples from intrusive and exploitative genetic research.

With regards to the Genographic Project, Pacific Indigenous peoples are clearly saying no to participation. Perhaps most important among the reasons for this opposition is the understanding that our creation stories and languages carry information about our genealogy and ancestors. Therefore, we do not need genetic testing to tell us where we come from.[68] Dr. Paul Reynolds of Nga Pae o te Maramatanga, a Maori research center at Auckland University, says that "we already have our stories about our origins, so we don't need a scientific rationale to justify our origins."[69] Maori researcher Aroha Te Pareake Mead from Victoria University in Wellington also notes that, "[t]he human story might be written in genes from a scientific point of view but the human story from a cultural point of view is actually written in our culture, it's in our language, it's in our art, it's in our dance, it's in our tradition."[70]

At some level, the Genographic Project understands that there is wealth in the traditional knowledge that Indigenous peoples have about our origins. Therefore, in addition to blood or other genetic samples, the researchers will also seek oral histories, linguistic information and artifacts from Indigenous peoples.[71] Wells says that oral histories will be stored in digests available to the public. When questioned about intellectual property issues, such as copyright, around the traditional knowledge shared, Wells did not have an answer.[72]

## Conclusion

Although the Genographic Project needs us, we do not need, nor should we want the project to proceed in our region. Pacific Indigenous peoples have consistently exercised their right of self-determination to oppose genetic research, especially anthropological genetic research that often undermines our own understandings of creation, our origins, and our ancestors. We have strong traditions of navigation throughout the Pacific, which indicates that we were not isolated islanders with homogenous genomes, rather genetic add-mixture undoubtedly occurred in the region. We also have oral histories and strong similarities in our native languages, cultural and spiritual beliefs that inform our understanding that we are indeed related. Therefore, we do not need genetics to tell us what we already know. I know where I come from: Mai Kumulipo (the source in deep darkness), Mai Ka Pae ʻAina o Hawai`i (from the Hawaiian Archipelago).

O ke au i kahuli wela ka honua
O ke au i kahuli lole ka lani
O ke au i kuka`iaka ka lani
E ho`omalamalama i ka malama
O ke au o Makali`i ka po
O ka walewale ho`okumu honua ia
O ke kumu o ka lipo, i lipo ai
O ke kumu o ka Po, i po ai
O ka lipolipo, o ka lipolipo
O ka lipo o ka la, o ka lipo o ka po
Po wale ho`i
Hanau ka po
Hanau Kumulipo i ka po, he kane
Hanau Po`ele i ka po, he wahine

At the time when the earth became hot
At the time when the heavens turned about
At the time when the sun was darkened
To cause the moon to shine
The time of the rise of the Pleides
The slime, this was the source of the earth
The source of the darkness that made darkness
The source of the night that made night
The intense darkness, the deep darkness
Darkness of the sun, darkness of the night
Nothing but night
The night gave birth
Born was Kumulipo in the night, a male
Born was Po`ele in the night, a female[73]

# Footnotes

1. Le`a Malia Kanehe is a Kanaka Maoli (Native Hawaiian) attorney from Honolulu, Hawai`i currently working as a Legal Analyst for the Indigenous Peoples Council on Biocolonialism (IPCB) in Nevada, USA (www.ipcb.org).
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4. Lopeti Senituli, *Biopolicy and Biopolitics in the Pacific Islands*, The Edmonds Institute 2003, p.
5. Debra Harry and Jonathan Marks, *Human Population Genetics versus the HGDP*, POLITICS AND THE LIFE SCIENCES, September 1999, p. 304.
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7. *Ibid.* Dr. Pauline Lane from the faculty of Science and Health of the University of East London did interviews with Hagahai to find out about their impressions of being subjects of a genetic patent. Lane reported that there were no long term benefits to the community and since Carole Jenkins, the medical anthropologist that took the blood samples and co-patent holder on the Hagahai T-cell line, left, there have been no additional medical services or supplies provided to the Hagahai. With regard to community understanding, Lane said "The community members I spoke to were confused. They feel that Jenkins had helped their community, but they also felt that maybe they had been cheated out of some money for their blood. They did give informed consent for blood to be taken for diagnosis but NOT to be taken out of the country for research. They suggested they would NOT trust researchers again." *Ibid.*
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73. These are the first fourteen lines of the Kumulipo, the cosmogonic genealogy of the Kanaka Maoli people, which details our origins beginning in deep darkness (Kumulipo) and provides an account over 2100 lines about our relationship to all the creatures in the sea and on land. See Kalakaua Text *in* THE KUMULIPO: A HAWAIIAN CREATION CHANT (MARTHA WARREN BECKWITH, ED, Appendix I, 187 (The University Press of Hawaii 1972). The Kumulipo embodies Kanaka Maoli traditional knowledge about our origins in Ka Pae `Aina o Hawai`i, the Hawaiian Archipelago.

# KULEANA NO HALOA (RESPONSIBILITY FOR TARO): PROTECTING THE SACRED ANCESTOR FROM OWNERSHIP AND GENETIC MODIFICATION

by Walter Ritte, Jr. and Le`a Malia Kanehe

## Kamali'i o Ka Po

Chant by Frank Kawaikapuokalani Hewett

Auhea wale 'oe kamali'i o ka po
Eia ho'i au kamali'i o ke ao
Wakea ka lani, Papa ka honua
No ka luna ko luna
No ka lalo ko lalo
He kuleana keia

Auhea wale 'oe kamali'i o ka po
Eia ho'i au kamali'i o ke ao
Ho'ohokulani ka wahine
Haloa ke kalo, Haloa ke kanaka
He kuleana keia

Where are you, oh child of darkness
Here I am, child of light
The sky above, the earth below
What is above belongs above
What is below belongs below
This is our responsibility.

Where are you, oh child of darkness
Here I am, child of light
Ho'ohokulani, the woman
Haloa the taro, Haloa the man
This is our responsibility

Genealogy ties the Hawaiian people to the land, nature and each other. Genealogy allows Hawaiians to trace our beginnings, to our original parents, and our firstborn. In our oral traditions, genealogical chants identifying family names would last for hours.

The gods, Wakea, sky father, and Ho'ohokukalani, star mother, gave birth to Haloa, the first born. Haloa was stillborn and placed in the earth outside of the front door. Haloa grew into kalo, the first taro plant. The second born of Wakea and Ho'ohokukalani was man, whose kuleana (responsibility) was to care for Haloa, the elder brother. Haloa, the kalo, became the staple food crop for the Hawaiian people.

This genealogy ties the Hawaiians directly to nature and places a spiritual obligation to malama (take care of and protect) their eldest brother. Haloa is also a metaphor for all living things in Hawai`i, as survival on little dots of land in the middle of the largest ocean mass, the Pacific Ocean, demanded an intimate and reverent spiritual relationship with nature. Understanding and knowing our mo`oku`auhau (genealogy) informs us of where we come from; who our kupuna (ancestors) are, including gods, all life of the sea and land, including humans; our place in the world; and who we are in that context and what our kuleana (responsibilities) are for our kupuna (ancestors) and mo`opuna (grandchildren/generations yet to come). All of these traditional Hawaiian concepts have played a significant role in guiding our work in response to research at the University of Hawai`i to both genetically modify Haloa and to claim patents/ownership over him.

## Genetic Engineering: What does it mean to genetically alter the ancestors?

In general, the Hawaiian community was not concerned about genetic manipulation and biotechnology until word spread in early 2005 that the University of Hawaii (UH) tried to genetically modify Haloa, our sacred taro. The Hawaiians immediately demanded the University of Hawai`i sign a moratorium against any genetic engineering of Hawaiian kalo. In May 2005, the University of Hawai`i's College of Tropical Agriculture and Human Resources (CTAHR), who did the genetic modification, signed a memorandum of understanding (MOU) in which the University agreed to a moratorium on genetically modifying Hawaiian varieties of kalo. The University has already genetically engineered Chinese varieties of taro and reserved the right to continue to do so in the MOU. The University has other non-Hawaiian varieties in its collection, which include other Pacific varieties, which are not covered by the moratorium MOU, and therefore, susceptible to genetic engineering.

UH needs to show more respect for native Hawaiian culture. Hawaiians would never dream of patenting or genetically manipulating kalo. Kalo is a gift handed down to us by our ancestors. We have a Kuleana or responsibility to honor, respect and protect Haloa, so he in turn will sustain us.

On the island of Moloka`i, Hawaiians have expressed their deep concern about genetic engineering, by referring to this technology as "mana mahele." It is the way we have described owning and selling of our mana or life force. Mana is the spiritual force Hawaiians have which comes from their knowledge and intricate relationship with nature. Part of mana is what the westerners call "biodiversity." In traditional Hawaiian thinking, land comes from the gods and was traditionally managed by the Ali'i (chiefs) for the collective benefit of all the people. In 1848, the foreign concept of owning land was introduced by

western business interests wanting to secure land title in Hawai`i. The time when the traditional land tenure system was supplanted for private land ownership was called "the Mahele." This Mahele severed the Hawaiians from their lands. Today lands in Hawai`i can only be bought by the very rich.

The genetic modification and patenting of our kalo, Haloa, has become the symbol of the second Mahele, now called the "Mana Mahele." The Biotechnology Industry now starting in Hawaii cannot succeed without the manipulation and ownership of our Mana or biodiversity and related traditional, Indigenous knowledge. They have taken our lands and now they come to take our Mana, our very soul.

Hawaiian concerns and activism around this issue was captured on Hawai`i's television news stations and in major newspapers. This began to wake up the Hawaiian people to the broader issues of bioprospecting, biopiracy and biotechnology. Although there was a growing movement against genetic engineering among haole (Caucasian) environmentalists and organic growers, it had not significantly included Hawaiians. Furthermore, although bills to regulate bioprospecting in Hawai`i were introduced in the Hawai`i State Legislature since 2003 and lobbied by some Hawaiian organizations, strong participation amongst Hawaiians did not ignite until more Hawaiians understood that Haloa, our first ancestor, was in harms way.

We have also worked with legislators to introduce a bill in the 2006 session of the state legislature to ban any genetic engineering of taro.[1] If passed, Senate Bill 2749 would prohibit genetic engineering of Hawaiian varieties of taro, but permits testing of an existing genetically modified non-Hawaiian variety of taro for a five year period, provided that adequate safeguards exist to prevent pollen from being released.[2] This is an important condition because we do realize that horizontal gene transfer can occur between the GE taro and non-GE Hawaiian varieties, thereby contaminating the natural stocks.

## Plant Patents on Kalo: What does it mean to own the ancestors?

Later in 2005, it came to light that the UH took out three U.S. plant patents on varieties derived from the Hawaiian variety, Maui Lehua. Hawaiians asked the question, "Who gave the University the right to patent a hybridized taro plant several years ago?"

Maui Lehua is one of 300 Hawaiian varieties that has been developed over centuries by extensive breeding by Hawaiians to suit differing microenvironmental and cultivation conditions, for special qualities of color and taste, and for different cultural, social, medicinal, and ceremonial purposes.[3] "Native cultivation of taro in Hawaii had created a greater number of varieties adaptable to varying conditions of locale, soil and water than are to be found anywhere else in Polynesia or, we believe, in the world."[4] The three patented lines carrying within them the traits that Hawaiians and other Pacific islanders have breed for over millennia. Palehua, Pa`akala and Pauakea, were hybridized by cross-pollinating the Micronesian male Ngeruuch variety from Palau, which is resistant to taro leaf blight disease (TLB), with the Hawaiian female Maui Lehua, which is known for its desirable agronomic properties (such as taste), but also highly susceptible to leaf blight.[5]

In 1999, the University applied for three separate plant patents claiming invention of Pauakea, Pa`akala, and Pa`lehua. All three are substantially similar, except corm colors are white, pink and purple, respectively, as indicated in the Hawaiian names attached to these hybrids ("kea" = white; "`akala" = pink; "lehua" refers to the famous Maui Lehua which has a purple corm) For example, the Pauakea plant patent claims invention for "a new and distinct variety of taro plant . . . that is characterized by resistance to taro leaf blight caused by Phytophthora colocasiae, resistance to root rot caused by Pythium spp., vigorous growth, large mother corm size, and white corm of very good flour quality and good eating quality." In 2002, the USPTO issued plant patent, PP12,342 for Pauakea (January 8, 2002), PP12,361for Pa`lehua (January 22, 2002), and PP12,772 for Pa`akala (July 16, 2002), all with named "inventor" Eduardo E. Trujillo, a UH researcher, and "assignee" University of Hawai`i.[7] The University has also sought world-wide patent rights.[8]

Some university researchers have claimed that what UH is doing regarding hybridizing kalo is the same as what Hawaiians have always done by doing selective cross-breeding of kalo varieties. But. Hawaiians have never claimed an exclusive, monopolistic ownership over kalo through patenting. Respected native activist, Alapa`i Hanapi, aptly explains that "ownership of taro is 'like slavery . . . it is as if someone owns your relatives."[9] Kalo was not invented by the University of Hawai`i, and they have no right to "own" or "license" it. If anyone owns the kalo, we do collectively as Hawaiians, and as Hawaiians, we have demanded the UH give up its taro patents and return these varieties to Hawaiians. Hawaiians are the appropriate stewards to care for the kalo. We are the custodians who have guided the appropriate use of kalo for millennia as a benefit for all people of Hawai`i. Given that the male parent for these hybrids is a Palauan variety, the indigenous peoples of Palau who are responsible for the Ngeruuch variety, should also be involved with the rightful repatriation and stewardship and custodianship of these new varieties. In any case, UH does not have a right to claim ownership.

Another concern related to these patents on kalo relates to the mandatory licensing agreement that taro farmers must agree to before they are permitted to grow the patented hybrid varieties. A taro farmer from Hanalei on the island of Kaua`i, Chris Kobayashi, has strongly stated,

> As a farmer, I strongly object to patents on taro or any other crop. Why should farmers have to pay for huli? Our taxes have helped to fund UH. Some of us have been cooperators with UH on different taro research programs including breeding, cultivation and diseases. More importantly, how can anyone claim ownership of plants that have evolved and been selected or bred by farmers for specific environmental conditions and desirable properties over generations?[10]

In the patent withdrawal demand letter sent to the Dean of the College of Tropical Agriculture and Human Resources, Andrew Hashimoto, we stated that,

> we object to several aspects of the licensing agreement that farmers must sign in order to obtain the patented cultivars, such as the collection of a 2% royalty on gross sales of corm. The collection of royalties from farmers whose taxes already support the University's

operations, including taro breeding activities, is abhorrent. It represents a superfluous and unjust levy on Hawaiian taro farmers.

The licensing agreement also prohibits Hawaiian farmers from selling, breeding or conducting research on the licensed plants. Such provisions can only stifle creative breeding and research on the part of Hawaiian farmers, which UH, as an institution charged with serving the public good, should encourage rather than prohibit.

Finally, the licensing agreement requires farmers to grant UH unrestricted access to their property to inspect, evaluate or retrieve samples of the plants. Such provisions invest UH with police-like powers to conduct intrusive inspections of farmers' private property, powers unbefitting a publicly-funded institition whose mission is to serve rather than police Hawaiian citizens, including its farmers.[11]

The Hawaiian people have now demanded the University drop their patents on Pa`akala (US Patent No. PP12,772), Pa`lehua (US Patent No. PP12,361) and Pauakea (US Patent No. PP12,342) or face a lawsuit. Although the cultural violations are of primary concern, we have preliminarily identified at least two legal means to challenge these patents based on prior art and failure to validate claimed properties. Our letter to Dean Hashimoto also briefly explains the basis for our legal challenge:

1) Prior art:

According to the patents, the female parent of all three patented varieties is "Maui Lehua," an unpatented cultivar that "belongs to the Group Lehua of Hawaiian-Polynesian taros." As you know, Hawaiian-Polynesian taros derive from a few varieties first introduced to Hawaii in the 4th to 5th century A.D. by the Islands' earliest settlers. From these few varieties, Hawaiians conducted extensive breeding over centuries to generate over 300 types of taro suited to differing microenvironmental and cultivation conditions. These varieties of taro were developed for food as well as ceremonial and medicinal uses.[12] Roughly 63 varieties, including Maui Lehua, are extant. Therefore, the qualities of the patented varieties derive to a considerable extent from Maui Lehua, whose properties are the result of many centuries of breeding efforts by native Hawaiians. Thus, the patent claims for the three patented varieties are invalidated by considerations of prior art.

2) Failure to validate claimed properties:

Irrespective of prior art considerations, the patents are invalid due to the failure of the "inventor" to properly validate claimed properties of the patented varieties. In a bulletin of the College of Tropical Agriculture and Human Resources released in August of 2002, soon *after* the third patent was issued on July 16, 2002 (for Pauakea), the "inventor" and his colleagues candidly admit that:

> "To date, only preliminary observations are available on the soil and nutrient requirements, *disease susceptibility*, crop duration, and *yield* of the three new cultivars [i.e. the three just-patented varieties]. No controlled experiments have yet been done to confirm the preliminary observations mentioned here." (emphasis added)[13]

> In each of the patents, "resistance to leaf blight caused by *Phytophthora colocasiae*," "(high) tolerance to root rot caused by *Pythium spp.*" and "(extra-)large mother corm size" are explicitly cited as claimed properties of the patented varieties. The first two claimed properties fall under the head of "disease susceptibility," while the latter claimed property is the primary determinant of "yield." Thus, the patents were granted on the basis of putative properties that were ascribed on the flimsy basis of "preliminary observations" that had not been confirmed by controlled experiments.[14]

In the first half of 2006, Hawaiians, including taro farmers, Hawaiian Studies students and faculty, Hawaiian culture-based charter school students, and supporters held several protests, demanding that the University withdraw the patents.[15] The protestors overwhelming political message of no patents on kalo was uniquely brought to life through cultural means, including erecting an ahu (altar) and dancing hula and offering chants in honor of Haloa. University officials responded that faculty contracts require them to protect the intellectual property rights of its scientists. The University eventually offered to assign the patents to a Hawaiian organization, but Hawaiians rejected the offer and made clear that we object to anyone patenting kalo, even ourselves.[16] As a result of protests, discussions and negotiations, however, the UH finally agreed to terminate the plant patents.[17] The University filed legal documents with the US Patent Office that disclaimed all proprietary interests in hybridized kalo effective June 16, 2006 and on June 20, 2006, Hawaiians celebrated their victory with a ceremony and by tearing up the three patent documents.[18]

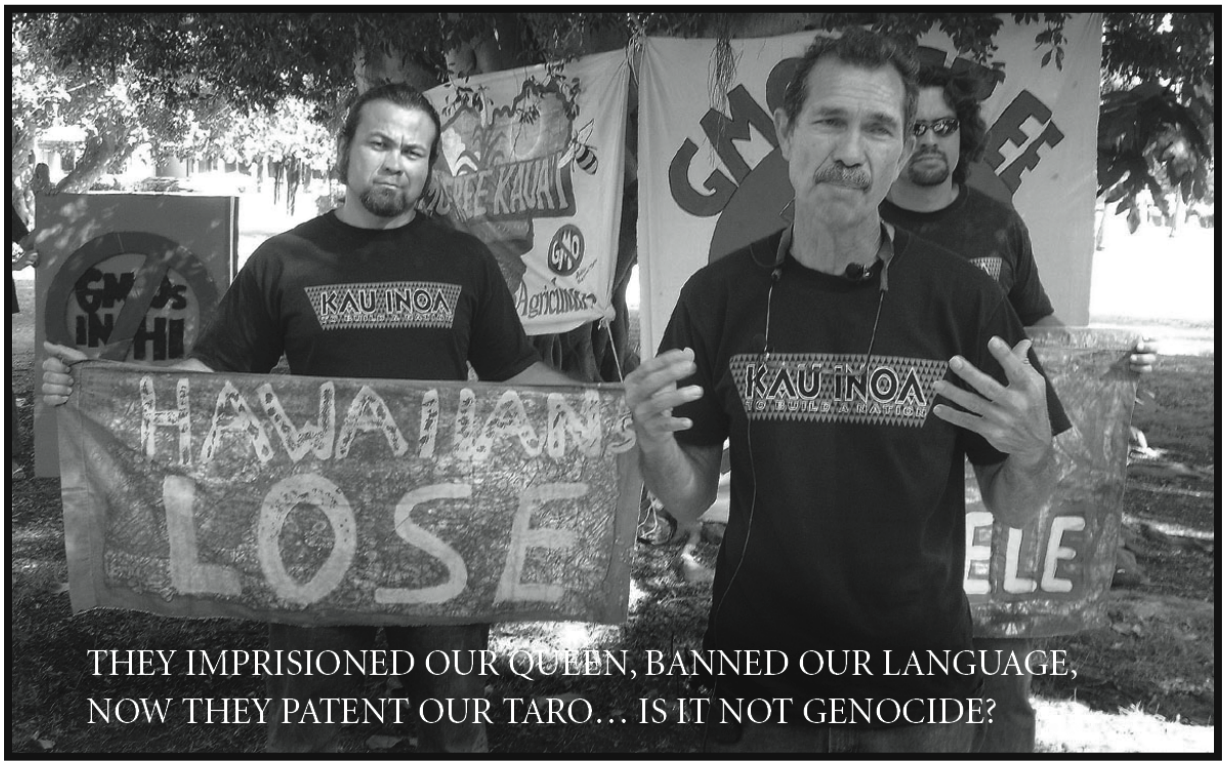
## Concluding thoughts

The treatment of Haloa, the kalo, by the University has become the window through which Hawaiians can view their future with biotechnology. It has become painfully clear that unacceptable manipulation and ownership of nature, the biodiversity that has sustained Hawaiians for thousands of years, is a major foundation for the economic success of biotechnology in Hawai`i. Although the kalo patents no longer exist, we know that much more of Hawai`i's biodiversity remains in jeopardy of manipulation and patenting. Accordingly, while appreciating the University willingness to cooperate with our demands regarding kalo, we have also requested that in the future, "UH consult with the Native Hawaiian community before claiming or obtaining intellectual property rights over living organisms of these Islands."[19]

The spiritual relationship of the Hawaiians to the biodiversity of Hawai`i as represented by the genealogy of Haloa, the firstborn, has been ignored by the State of Hawai`i. Haloa, the kalo, has now become the focal point and rallying point of efforts to control or stop the advancement of biotechnology in Hawai`i. It is becoming clear that unless the concerns of the native Hawaiians are met, the future of biotechnology is dubious at best. This uncertainty will keep away the capital investment that this new industry desires.

Through our experience with protecting Haloa and kalo, it appears that a fundamental conflict of interest exists between the biotechnology industry and Hawaiians. The biotech industry demands manipulation and ownership of sacred things. Meanwhile, the Hawaiian people continue to assert the rights and responsibilities inherent in our understanding of kuleana over Hawai`i. We respect our

genealogy, gifts of nature and traditional knowledge that our ancestors have passed down to us over generations, and for which we have kuleana to maintain and protect for the benefit of future generations, na mamo o Haloa.  E ola mau no Haloa (Haloa will live on.)




Taro Patent Protests, Hawaii, 2005 (Walter Ritte)

# Footnotes

1. There were also two bills (SB2751 and HB3219) introduced to provide a 10-year moratorium on testing, propagating, cultivating, growing, and raising genetically engineered coffee and taro, but neither bill has succeeded this session. Unlike kalo, coffee does not have any traditional cultural relationship with Hawaiians or Hawai`i.
2. Status of SB2749 can be checked at http://www.capitol.hawaii.gov/site1/docs/getstatus2.asp?billno=sb2749.
3. Press Release, University of Hawaii Told to Give Up Taro Patents: UH's Right to "Own" Sacred Taro Challenged, January 12, 2006. Contact Walter Ritte (rittew@hotmail.com) or Chris Kobayashi (waioli2@verizon.net).
4. E.S. CRAIGHILL HANDY AND ELIZABETH GREEN HANDY WITH COLLABORATION OF MARY KAWENA PUKUI, NATIVE PLANTERS IN OLD HAWAII: THEIR LIFE, LORE, & ENVIRONMENT, 71, (Bishop Museum Press, 1991).
5. PP12,342, Taro cultivar named 'Pauakea,' January 8, 2002, Inventor: Trujillo; Eduardo E., Assignee: University of Hawaii, Appl. No. 426393, filed Oct. 22, 1999. All three plant patents are available at the United States Patent and Trade Mark Office website, http://patft.uspto.gov/netahtml/srchnum.htm.
6. *Ibid.*
7. *Ibid.*
8. Press Release, *supra* note 3.
9. Craig Gima, "Protestors block medical school," HONOLULU STAR-BULLETIN, May 19, 2006, http://www.starbulletin.com/2006/05/19/news/story06.html.
10. PP12,342, *supra* note 5. "Huli" refers the cutting used for replanting which is cut from the crown of the corm to about six to nine inches up the stalk. E.S. CRAIGHILL HANDY AND ELIZABETH GREEN HANDY WITH COLLABORATION OF MARY KAWENA PUKUI, NATIVE PLANTERS IN OLD HAWAII: THEIR LIFE, LORE, & ENVIRONMENT, 71, (Bishop Museum Press, 1991). Interestingly, the plant patent for Pauakea describes this traditional farming practice as "huli reproduction" and claims that, "a large number of plants of the new variety have been reproduced by this method and the resulting plants have exhibited the distinguishing characteristics of the original plant which was used for asexual propagation, indicating that the new 'Pauakea' cultivar is established." PP12,342, *supra* note 4. Therefore, although not in a legal sense, but in a practical sense, this traditional farming practice and the traditional knowledge inherent within it, is also claimed in this patent.
11. Letter from Walter Ritte and Chris Kobayashi, to Dean Andrew Hashimoto, University of Hawai`i College of Tropical Agriculture and Human Resources, 2 (date?) (on file with author).
12. Cho, John J. "Breeding Hawaiian Taros for the Future." Dr. Cho is a professor at UH's Dept. of Plant and Envrionmental Plant Sciences, Maui Agricultural Research Center.
13. Trujillo, Eduardo E. et al. "Promising New Cultivars with Resistance to Taro Leaf Blight: 'Pa'lehua', 'Pa'akala', and 'Pauakea'," Cooperative Extension Service, College of Tropical Agriculture and Human Resources, University of Hawai'i at Manoa, August 2002.
14. Letter from Walter Ritte and Chris Kobayashi, *supra* note 10, 1-2.
15. Craig Gima, "Protestors block medical school," HONOLULU STAR-BULLETIN, May 19, 2006, http://www.starbulletin.com/2006/05/19/news/story06.html.
16. Alexandre Da Silva, "Lab work on taro opposed," HONOLULU STAR-BULLETIN, June 6, 2006, http://www.starbulletin.com/2006/06/06/news/story09.html.
17. Susan Essoyan, "Activists tear up 3 UH patents for taro," HONOLULU STAR-BULLETIN, June 21, 2006, http://www.starbulletin.com/2006/06/21/news/story03.html
18. *Ibid.*
19. Jan TenBruggencate, "UH expected to abandon controversial taro patents," THE HONOLULU ADVERTISER, June 20, 2006, http://www.the.honolulu advertiser.com/article/2006/Jun/20/ln/FP606200342.html/?print=on.

# Lessons from Omissions in the *Hagahai* Patent Case

Alphonse Kambu[1]

## Introduction

Indigenous and local communities around the world have long experienced historical, social and economic inequalities. Sometimes, there are not enough laws that protect these communities and if there are, they take the form of biased, destructive and ill-defined rules, policies and laws. To exacerbate this condition, several past and current institutions and other actors have, albeit at times inadvertently, contributed to the inequalities in this already uneven field by their established rules and mechanisms, as well as in their enforcement. This trend has been evident in the fields ranging from management of natural resources to education, culture, language, and to other tangible and intangible property. The biased and destructive policies have been partially responsible for displacing indigenous and local communities from their lands,[2] confiscating their rights to natural resources, encouraging misappropriation and misuse of their community intellectual property rights,[3] threatening their language and cultural diversity.

A recent trend that directly bears on the rights of indigenous peoples concerns the patenting of genes and DNA or of materials that have been derived from the tissues of indigenous and local communities. One celebrated example is the *Hagahai* patent case (hereafter referred to as the *Hagahai* case) of Papua New Guinea (PNG).[4] The long history of scientific research and development (R&D) in PNG, which dates back to the colonial era, has gained credit for foreign researchers. One notable case has been the discovery of a variant form of Cretzfeldt-Jacob Disease or *kuru*, which earned Carlton Gajdusek a Nobel Prize.[5] This involved the Fore people of the Eastern Highlands Province of PNG. The *Hagahai* case followed suit where the patent listed Dr. Carol Jenkins and her colleagues in the US as right holders.

Many observers throughout the world have wondered what has become of the *Hagahai* case in PNG since the US government withdrew the patent associated with the genes of the *Hagahai* tribesmen following both domestic and global resentment. After approximately 10 years of silence and apathy, PNG has

ultimately made some progress in developing some basic guidelines, policies and legislation to address R&D and the patenting of genes. However, this is not to say that all issues covering R&D and gene patenting have been settled, as there are still gaps in law and policy that constantly need strengthening. A thorough examination of the laws, norms, principles and practices existing in PNG at that time and today could provide some answers for precaution to be taken in the gene patenting exercise so as to avoid controversy. This paper will identify the major omissions inured in the Hagahai case, specifically in the conduct of its scientific R&D, in considering the laws and policies on patenting human genes as well as customary laws and practices; and its violation of the prevailing ethical and religious milieu in PNG. It will conclude with lessons learned from the analysis of these aspects.

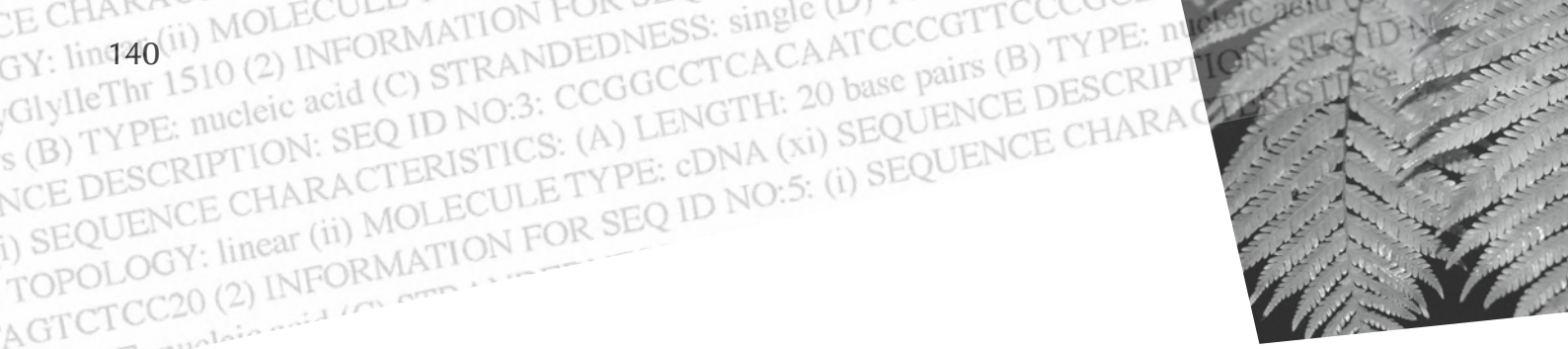
## 1. Omissions in the Conduct of Scientific Research and Development

Central to the process of the *Hagahai* case is the conduct of the scientific R&D. R&D has multiple purposes and intentions, including the sharing of results, ideas and information, and the use of its results for academic or educational purposes.[6] It is also used for finding solutions to medical problems and improving human health conditions. Scientific R&D can be a powerful tool for achieving sustainable development especially in developing countries if and when appropriate policies are in place to guide and enhance it. There is no question about the scientific role played by R&D in drug discovery and its contribution to curbing chronic diseases including HIV/AIDS, malaria and other serious ailments.[7] The research involving the *Hagahai* people per se probably had good intentions of curbing diseases and contributing to improved health care. Hence, given such virtues of scientific R&D, it should not be hindered, and the freedom to engage in R&D must be allowed to continue. On the other hand, R&D may involve sensitive issues that require very careful treatment of a step-by-step process in order to avoid criticisms that could lead to obstacles.

But the *Hagahai* case illustrates that there were failures in conduct of scientific R&D specifically, in the limited communication conducted among stakeholders, in the lack of realistic understanding of the direct benefits of gene patenting on drug benefits for the majority and in the exploitation of the seeming silence or ambiguity of PNG laws on human gene patenting.

### *a) Limited communication of issues among stakeholders*

The process of communication between and among not only the subjects of research but also the broader stakeholders to ensure the unbounded flow of adequate and clear information is crucial in R&D to ensure understanding among stakeholders and avoid unanticipated risks. It is the duty of the researcher(s) to make available such information to the subjects and various stakeholders through consultations, discussions and dialogue. In an extremely sensitive case such as the *Hagahai* case the communication factor is of utmost priority. It is the right of the subjects and the broader stakeholders to know and be informed of the process and as such, the researcher(s) are duty bound to provide appropriate information. The provision of information by the researcher(s) should not be viewed as a burden, but must be perceived as a positive duty that would educate others about oneself, the significance of the research and its pros and cons, which would then bring all stakeholders to a level of an informed



understanding that would enable them to decide on an issue. The exchange of information may help to clarify doubts and secure trust from a broader audience. This exercise could be done through following proper channels such as the prior informed consent (PIC) procedures.

In the *Hagahai* case, the researcher(s) claimed that PIC was established between the donors and the researcher(s). While some communication may have indeed occurred between the donors and the stakeholders, the fact that the opponents of the incident believed that PIC was insufficient, already signifies that the *Hagahai* tribesmen may not have fully understood the patent system.[8] This gives emphasis to the need for the purpose and process of PIC to be clear, simple and understandable to those involved.

### *b) Lack of a realistic understanding of the direct benefits of gene patenting on drug benefits for the majority*

One must not be easily misled by the idea that research and patenting of information and products from biomedical research will solve the serious ailments through drug discovery. This is, perhaps, too simplistic as the actual situation on the ground now has proven the contrary. Drugs on the market today are prohibitively priced due to the time, capital and technology invested in the drug discovery process and consequently making it overly expensive for the majority of consumers to afford. One can imagine only the top 25 per cent of the world's population being able to afford the basic essential drugs while the other 75 per cent will continue to be deprived of the benefits of products utilizing public goods and services.[9] The HIV/AIDS epidemic clearly illustrates this kind of situation where there are drugs to control the disease, but 40 million people in the world continue to live with the disease[10] and cannot afford the drugs. This is because only a few companies or individuals own the patents to such drugs.

When considering the patent system[11] and the high price for drugs, one could question whether the *Hagahai* patent would be beneficial to the poor majority of the world in general and PNG in particular. Some people would perhaps benefit if they were lucky enough to afford the price of the drug or if they were registered patent holders.[12] For the majority of the people, including the 85 per cent of the population in rural areas of PNG, this is perhaps something far from reality. The majority of the people in PNG are already unable to afford other essential drugs for common and prevalent ailments such as malaria, typhoid and pneumonia. In addition, the government cannot afford drugs and medical supplies, forcing health centers and its outposts to shut down.[13] Given these circumstances, it is questionable as to whether an additional patent on a new drug would improve the situation in PNG and elsewhere.

### *c) Exploitation of the silence or ambiguity of PNG laws on human gene patenting*

The *Hagahai* case evolved under a vague policy and legal framework in PNG. The laws establishing the Institute of Medical Research and public health issues, especially the sections referring to research, are broad and are silent on these issues. They failed to provide any clear or detailed directions as to how cases such as the *Hagahai* case were to be handled in PNG.

PNG has been encouraging scientific R&D in numerous fields through the establishment of policy and legislation that establishes various research and academic institutions. The Institute of Medical Research

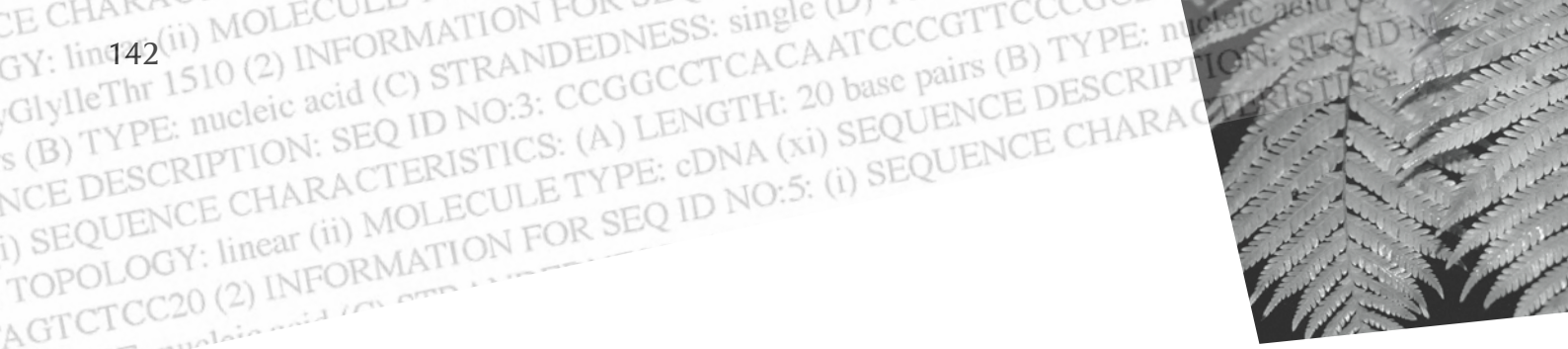
Act 1967 is of much relevance to research relating to human genes, especially in the *Hagahai* case. This pre-independence legislation, which was later consolidated in 1998, allows for the Institute to conduct research on any field of medical science or biology, anthropological and sociological aspects of health and ill-health, and public health in general. These objectives form the basis of research by the Institute, either independently or in collaboration with other local and international collaborators for educational, drug discovery purposes or otherwise.[14] The research involving the *Hagahai* is one such outcome of the research activity in the country engaging international collaborators intended for finding solutions to the "human t-lymphotropic virus (HTLV-I)." In the process of conducting biomedical R&D one crucial factor is the issue of information strategy. However, the aforementioned PNG legislation is silent on this crucial requirement of information dissemination and coverage. In its silence, the researchers took the path that required the least communication of information to stakeholders, which later on resulted in offended stakeholders and violated customary laws, ethics and sensibilities.

## 2. Omissions in Considering Laws and Policies Relating to Patenting of Human Genes

One of the contributing factors to the *Hagahai* controversy was the lack of transparency of the laws and policies in PNG. There were neither concrete nor lucid laws or policies to address the *Hagahai* case both prior to and following the incident.

Despite the controversies and popularity surrounding the *Hagahai* case that spurred a world campaign against gene patenting,[15] the PNG government was silent and slow in responding to the issue. In fact, it was the parties who were directly involved in the incident who quickly reacted to the opposition against the patenting of the genes of the *Hagahai* tribesmen.[16] One reason for the slow response on the PNG side was the technicality and complexity involved in the issue, which the PNG government did not possess the capacity to handle immediately.

At the time of the *Hagahai* case, PNG is assumed to have had no clear policy or legislation in place to handle R&D and the issue of patentability or non-patentability of life forms including human, plant and animal inventions. But in the first place, PNG legislation is not completely silent on human gene patenting. A careful inquiry into both hard and soft laws that exist to this day establish some grounds that object to the patentability of human genes, or at least provide some grounds for precautionary measures to be taken. These grounds provide enough ground for legal principles or norms, traditional jurisdictions of law and the professional rules to guide biomedical R&D and ownership of genes or life forms. These grounds include the PNG Constitution, the Intellectual Property Legislation and Guidelines and the Customary Laws and Practices (*Kastam*). Biomedical researchers may not be lawyers but they are duty bound by professional rules and ethics of biomedical research to exercise the precautionary principle in conducting their activities. Their ignorance led to the inadequate consideration of the risks and benefits could constitute an act of negligence under the underlying laws of PNG, at least under the tort law.[17] If at all an argument is still raised pointing out that no specific case law on human gene patentability exists in PNG, that argument could be foiled by citing that the non-existence of a case law on the patentability of human genes does not necessarily allow the patenting of human genes.



*a) The Constitution of PNG – Fundamental Human Rights and Freedoms*

The right to life is a fundamental right, which all civilized nations, including PNG, uphold in their constitutions. Section 35 of the PNG Constitution outlaws the deprivation of life. The deprivation of the right to life must not be limited to merely physically taking life through either legal[18] or illegal means but must also include any reduction of the full enjoyment of it. In such circumstances, the State has a duty to prevent any deprivation or reduction of the right or freedom of its citizens.[19] In the *Hagahai* case the PNG government failed in upholding this duty.

Patenting of human genes is an issue of human rights deprivation. It can infringe upon the fundamental rights and freedoms of human beings, mainly the right to life. The relevance between patenting genes and the deprivation of life is derived from the fact that a gene contains DNA, which is the code of life. Thus, patenting genes, the building blocks of life, implies that life itself is being patented. Patents are monopolistic or exclusive rights over a process, invention or thing, which means that if human genes were the subject matter of a patent, then exclusive rights would exist over the genes, constituting a deprivation of life. The taking of a patent on a gene involves a risk in which a second- or third-party can own the gene, DNA or life of the donor, and the patent could exclude the donor from using it freely. Moreover, the patenting of genes can restrict or reduce the donor's rights and freedoms.

Some observers equate the patenting of human genes as "modern day slavery" that treats human beings as property or mere objects without any value of life.[20] Patenting human genes or slavery is closely related to inhuman treatment[21] in the non-violent sense, where the taking of a patent on a gene degrades the freedom to enjoy life to its fullest. Modern biotechnology certainly poses critical questions of non-violent crimes, infringements and deprivation of rights and freedoms through the patenting of life forms especially when human genes are the subject matter of patents, and adequate consideration of the risks and benefits is essential. Hence, the PNG Constitution already lays the foundations for the respect for human life and freedoms, which must be upheld in every sector, including biomedical R&D and the debate on patenting of life forms.

*b) Intellectual Property Legislation and Guidelines*

After several years since the evolution of the *Hagahai* case, PNG finally enacted the Patents & Industrial Designs Act[22] in 2000, which provides some form of direction on the issue of patentability or non-patentability of life-forms, including human genes. The patent legislation was established in fulfillment of PNG's obligations under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS),[23] rather than it being a direct response to the *Hagahai* case.[24] This being the case, it is not a direct retroactive legislative response to the *Hagahai* case.

With its legislative roots established, the Patents & Industrial Designs Act could now be seen to provide some room for discussing the patentability or non-patentability of human genes. The common argument against patenting of genes or life-forms generally stems from a number of fundamental issues which include the interpretation of what "inventions" may entail, or on moral and environmental grounds and *public ordre*. What is most relevant in the context of human gene patenting is the provision related to "inventions." Thus, Section 2 of the Patents and Industrial Designs Act, 2000, defines an invention in the following manner:

*"...'invention' means an idea of an inventor, which permits in practice the solution of a specific problem in the field of technology and may be, or may relate to, a product or a process, but does not include:*

*(a) a discovery, scientific theory or mathematical method; or*

*(b) a scheme, rule or method for - (i) doing business; or*

*(ii) performing purely mental acts; or*

*(iii) playing games; or*

*(c) diagnostic, therapeutic and surgical methods, but not including any products for use in any such methods, for the treatment of humans or animals;..."*

Accompanying the legislation is the Explanatory Notes and Guide on Filing New Patent and Industrial Designs Application in Papua New Guinea (hereafter referred to as the Patent Application Guide) prepared by the PNG Intellectual Property Office (IPO). The Patent Application Guide explains that human genes are not for patenting. The document thus states:

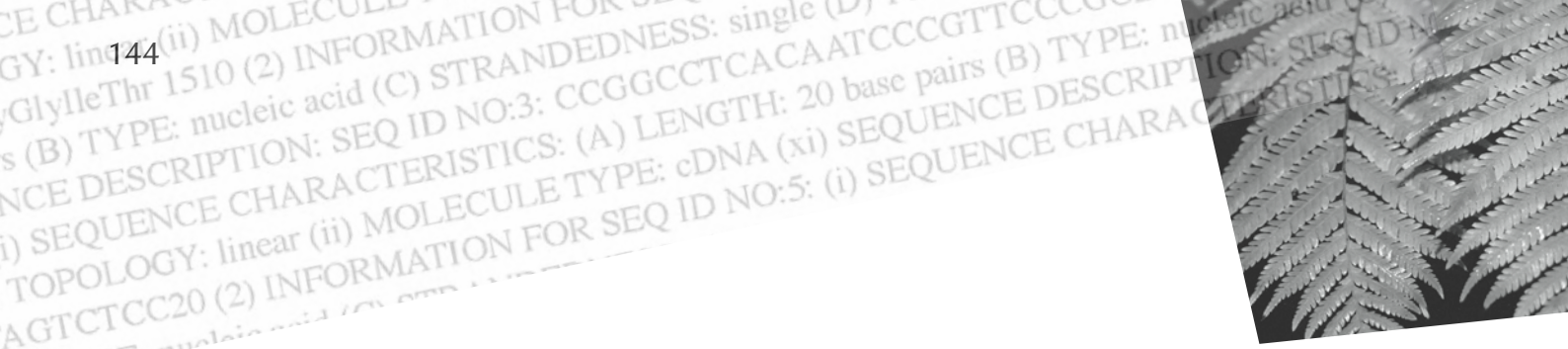
*"...It should be noted also that essentially biological processes cannot be patented. Microbiological processes, however, are patentable. This means that an invention that has very little "human input" but which generally allows natural biological processes cannot be protected. Essentially biological processes would include the art of cloning or simply nurturing plants or animals. Similarly human genes (occurring naturally) cannot be patented."*[25]

Both the Patents and Industrial Designs Act and the Patent Application Guide are clear on the issue of patentability or non-patentability of human genes. It is clear that human genes are not patentable subject matter. The documents distinguish between an "invention" and a "discovery." Genes are not "inventions" by humans i.e., humans did not create genes. They are the works of nature existing naturally and can only be discovered. As such they cannot qualify as patentable subject matter.

### *c) Customary Laws and Practices (Kastam)*

Customary laws and practices (or *Kastam*) is one source of law which the majority of the people in PNG upholds and thus, may provide some authoritative guidance to the issue of human gene patenting. *kastam* is one component of the underlying laws of PNG.[26] Thus *kastam* is comprised of norms and principles, values, wisdom and processes existing in both formal and informal law and institutions. While the *kastam* entwined in the formal law and institutions might be silent on human gene patenting, the *kastam* existing in the informal setting may possess fundamental principles which the patenting of human genes clearly violate and contradict or could provide some guidance.

In PNG, 85 per cent of the people still practice communal life, which is governed primarily by *kastam*. Such a communal life implies that most issues affecting the community are dealt with collectively, highlighting the principles or rules of communitarianism,[27] consultation and consensus. For instance, the ownership of land or a resource is collectively owned and managed for the benefit of the community. Thus, it is implied that individualistic behavior such as the bestowing of individual ownership of something taken from the community can be contrary to virtues of communitarianism and can be regarded offensive. If any issue relating to the use or disposal of land or any other matter or decision affecting the entire community arose, the community would consult and determine the outcome of what measures should be taken based on *kastam*. Consultation with the members of the community is



an inherent component of the process in determining any major issue affecting all. What then follows in the process is consensus, which must be reached by a majority of the community before any action is pursued. The process described above and governed by *kastam* follow a democratic process, which is transparent and truly represents the socio-historical nature of life in PNG.

If patents were to be taken on a subject matter associated with human genes, it is natural and would be reasonable to conform to the practices of kastam, especially following the principle of communitarianism, consultations, leading to consensus. In the *Hagahai* case, most members of the community throughout the country or stakeholders were not consulted except for a few. The Constitution of PNG in its preamble speaks of any national affairs or development to be conducted through "PNG Ways". If communal life and the communitarianism principle are observed by 85 per cent of the population, they are without doubt "PNG Ways" which should have been followed in the *Hagahai* case. Regrettably, the *Hagahai* case failed to consider the reality of this socio-cultural practice in PNG and as such, was inconsistent with *kastam* and the spirit of the Constitution.

## 3. Omission of the Ethical and Religious Milieu on Patenting of Human Genes

The Christian faith is entrenched in the Constitution of PNG, where the preamble declares that the country should be guided by Christian principles.[28] With that, it is clear that PNG declares itself to be a Christian country and more than 90 per cent of the population upholds this faith. One of the principles of this faith perceives animal, plant and human life to be God's creation and in this regard, no one should meddle with or own them. The Catholic Church and many other Christian denominations further defend the belief by stating that life is sacred and a gift from God. This belief evolves from the Book of Genesis and Psalms in the Old Testament and also sections of the New Testament. Christian philosophers such as Immanuel Kant have supported the teaching and belief that humans and their body parts are ends in themselves and not means to ends. With this perspective, body parts are sacred and are not items to be commodified. Although one may argue that there were no laws in PNG that forbade the patenting of life forms, there are higher laws of ethics including religious beliefs and teachings than written law, which must be followed even in the absence of written laws. These unwritten laws are universal teachings or fundamental principles that are common to humankind. The connotation behind this teaching is that life or the very basic building blocks of life, which are genes, are not within human powers to create and control because they are God's creation. For such reasons, they should not be entities to be owned. The Christian churches in PNG were never even consulted on their views on the issues associated with the patenting of life forms. In the context of ethical, moral and religious beliefs, there was a clear indication that the *Hagahai* case disregarded these important Christian principles.

## Conclusion

The *Hagahai* case has spawned controversy that has crossed legal, policy and ethical boundaries. Looking back at the case, it was an incident that clearly degraded the sense of humanity on moral, ethical, legal and cultural grounds. However, in its wake, PNG and the rest of the world, are left with a number of significant lessons.

One crucial lesson for biomedical R&D is to crucially emphasize the need to adopt a holistic approach that considers all relevant fields including the legal, ethical, social and cultural dimensions that bear on the research. Akin to this lesson is the communication strategy that would have facilitated the free flow of information between and among all stakeholders that would have enhanced understanding and elicited trust from the broader community. This would have been key in acquiring a PIC, which the community as a whole could have agreed to give. This should have been done because of and not despite of the ambiguity of provisions on human gene patenting by the Public Health Act in order to demonstrate good faith and minimize the impact of any controversy or conflict that may later arise.

A second lesson learned from the *Hagahai* case is the insistence on the primacy of existing principles of law in assessing the consistency of cases like *Hagahai*. The principle, i.e., the spirit of the PNG Constitution, and not the absence of a specific provision on human gene patenting should have decided the legal fate of the matter. The PNG Constitution sets out the observance of "PNG Ways" that include both *kastam* and communitarianism. The respect for the supreme law of the land and its contents must be upheld. The right to life entrenched in the PNG Constitution is also relevant to the patenting of genes and must be applied to any case involving patenting of genes. Furthermore, PNG ways including *kastam* and the rule of communitarianism are rules and principles that promote democracy and transparency which must exist in every occasion when any decision regarding issues of public or common concerns, such as human gene patenting. The Christian principles upheld in the Constitution that preach against patenting of life forms were not given due regard and must therefore be considered in the future.

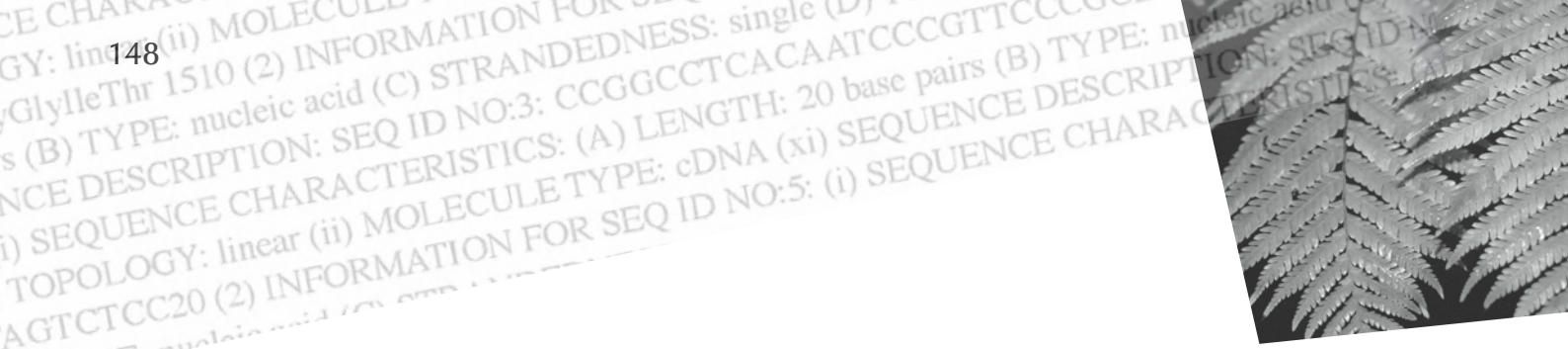
Third, there has been the omission of due diligence in the consideration of the risks and benefits inherent in the case. This refers to the precautionary principle, which is now a commonly accepted legal principle[29] that exists to be applied to avoid plausible threats in the absence of factual uncertainty.[30] In R&D involving the patenting of human genes, the precautionary principle must be applied extensively to ensure that all risks are calculated.

Finally, despite the weaknesses in policy and law on R&D and human gene patenting, PNG has made some progress on the issue by enacting the Patents and Industrial Designs Act and its accompanying Patent Application Guidelines, which speak against patenting of human genes. These wise actions strengthen the existing legal, moral, ethical and cultural grounds that speak against the patenting of human genes. What remains vital now for PNG is to tighten its policy on R&D and the patenting of human genes so that a *Hagahai* case will never again occur.

# Footnotes

1. The author is Director of Ishikawa International Cooperation Research Centre (IICRC), a Special Programme of the United Nations University-Institute of Advanced Studies (UNU-IAS). He is also a traditional chief of the *Bindeku* Tribe of Papua New Guinea. The opinions expressed in this paper are those of the author and do not necessarily represent the opinions of IICRC or UNU-IAS.
2. A classical illustration regarding land rights is the application of the doctrine of *terra nullius* to the continent of Australia by the British Government which disregarded antecedent sovereign rights of Aboriginal Australians while at the same time confiscating land rights of Aboriginal peoples and displacing them from their rightful land and home. However, the Supreme Court in the *Mabo* Case of 1992 disregarded the doctrine of *terra nullius* and restored some of their land rights under the native title regime. For a detailed discussion also see Stephenson and Ratnapala (eds.), 1993. *"Mabo: A Judicial Revolution - The Aboriginal Land Rights Decision and Its Impact on Australian Law,"* University of Queensland Press.
3. The use of the rule of open access to genetic resources and cases of biopiracy, such as the case of kava (Piper methysticum), neem (*Azadirachta indica*) and tumeric (*urcuma longa*) are a few examples. These are cases of misappropriation of information and knowledge that is already part of the public domain of indigenous and local communities. Public domain is a space free from intellectual property.
4. See Eric Kwa in this volume for a background discussion on the *Hagahai* Case.
5. See note 7 above.
6. See note 5 ibid.
7. See Alpers, 1995: "Past and present research activities of the Papua New Guinea Institute of Medical Research" in *Papua New Guinea Medical Journal* 1999 March – June; 42 (1-2):32 – 51. Available at http://www.pngimr.org.pg/Activities%20-%20Mar_Jun%2099.pdf. Last visited on 19 February 2006. Medical research in PNG has contributed to the information and knowledge of various diseases, which allows one to find ways of improving the quality of health for its citizens.
8. See ETC group, 2006: Patents, Indigenous Peoples, and Human Genetic Diversity. Available at http://www.etcgroup.org/article.asp?newsid=223. Last visited 24 February 2006.
9. See Kambu, 2000: "Environment and Sustainable Development: A Developing Nation Perspective (Papua New Guinea)". In: *Journal of Social Sciences and Humanities*, Volume 4, Chiba University.
10. See Plomer, 2005: The *Law and Ethics of Medical Research: International Bioethics and Human Rights*. Cavendish Publishing Limited.
11. Patents are monopolistic rights granted to the inventor, and exclude others from the use and the enjoyment of benefits reaped from the development of products based on the patents.
12. Dr. Carol Jenkins claims that the *Hagahai* will benefit from the patent through the trust fund that was set up for the *Hagahai*.
13. Take for instance the case of the Kerowagi health center in the Simbu Province located in the central Highlands of PNG. The health center was established by the Australian Colonial Administration in 1963, and on paper it is ranked a level four health center under PNG standards, which is supposed to be big in terms of its staff and service capacity. Contrary to what is on paper the health center is deteriorating and most of the services and outposts have been forced to shut down due to lack of funds, medical supplies and staff. The main health center has also been forced to close in September 2003 due to lack of essential drugs, which the government could not afford. This situation placed the 54,000 residents at risk. The drug supply received at the time of writing is on a quarterly basis where the possibility of sustainable operation is unpredictable and largely depends on availability of funds to purchase drugs. The situation puts to test the good intentions of biomedical research for drug discovery and the improvement of health care.

14. See Matainaho, 2000: "Genetic, biochemical and medicinal resources: how much can we own, protect and receive credit for?" In *Protection of intellectual, biological & cultural property in Papua New Guinea* (eds.) Kathy Whimp & Mark Busse. Asia Pacific Press, 2000, Australia National University.
15. See Resinik, 2004: *Owning the Genome A Moral Analysis of DNA Patenting*, State University of New York Press, New York.
16. The PNG-IMR and Dr. Carol Jenkins have organized forums and started making contact with the scientific community to provide an explanation of the scandal arising out of the patenting of the *Hagahai* genes in defense of their actions.
17. See Bolam v Friern Management Committee (1957) 1 WLR 582.
18. This is the legitimate taking of life by the State through execution or some other form of killing for an offence that carries the death penalty.
19. For more discussion, see Douglas-Scott, 1996: "Environmental rights in the European Union: Participatory democracy or democratic deficit?" In: *Human Rights Approach to Environmental Protection*, B. Alan and M. Andersen (eds.), Clarendon Press, Oxford, UK.
20. See von Tigerstrom, 2001: "Human Rights Issues in Patenting of Higher Life Forms – The Role of the Canadian Charter of Rights and Freedoms." Available at http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00391e.html. Last visited on 19 February 2006.
21. See Brunton and Colquhoun-Kerr, 1985: *The Annotated Constitution of Papua New Guinea*. University of Papua New Guinea Press. See especially Section 36 of the PNG Constitution.
22. The legislation is administered by the Intellectual Property Office of PNG, which is housed within the Investment Promotion Authority. The Intellectual Property Office also oversees two other pieces of intellectual property legislation, namely, the Trade Marks Act and the Copyright and Neighbouring Rights Act 2000. At the time of writing the Patents and Industrial Designs Act is undergoing review and amendments are expected in the future.
23. Member countries of the WTO have specific obligations under the TRIPS Agreement to comply within a given time and developing countries including PNG were obliged to implement the TRIPS Agreement by 2000.
24. Personal communications with David Kil, Intellectual Property Office of PNG, October 2005.
25. See "Explanatory Notes and Guide on Filing New Patent and Industrial Designs Application in Papua New Guinea," 2005.
26. The Underlying laws of PNG include the customary laws and practices of PNG and the common law of England that PNG adopted prior to its Independence. Any development in the common law in England or Australia following the independence in September 1975 is not recognized by PNG. To date, over 85 per cent of the people in PNG observe customary laws and practices.
27. For further discussions, see Glannon, 2005: *Biomedical Ethics*. Oxford University Press, Inc. New York.
28. See note 18 ibid. Some commentators have mentioned that the Constitution of PNG is one of the well-developed documents. However, it is perhaps too good that implementation of principles and its spirit become too difficult to achieve.
29. For further discussions on the precautionary principle/approach, see O'Riordan & Cameron, 1994: *Interpreting the Precautionary Principle*. Earthscan Publications Ltd, London, UK. Also, see note 5 ibid.
30. See European Commission, 2000: Communication from the commission on the precautionary principle. Brussels, European Commission.



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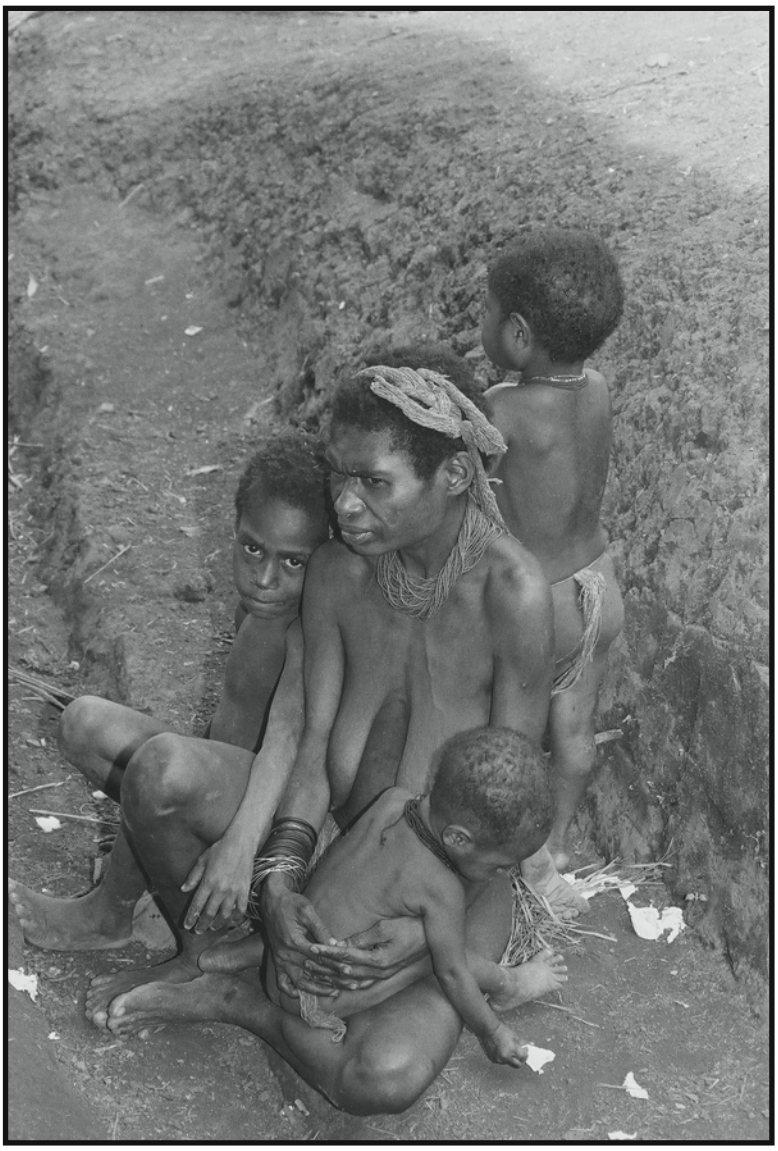


Hagahai family awaiting blood testing (PNG Institute of Medical Research, Goroka)

# In the Wake of the Hagahai Patent: Policy and Legal Development on Gene Ownership and Technology

By Eric L Kwa

## Introduction

In 1996, a small group of people called the Hagahais or Yilu who live in the interior of Papua New Guinea (PNG) made headline news around the world without their knowledge or persuasion. In the safety of the forest and far away from the bustling life of the cities and towns, the Hagahais go about their daily chores of gardening, hunting and peaceful co-existence with their environment. Prior to 1983, they have had very little contact with foreigners and the State had very little to offer to the Hagahais in terms of security, resources and services. Many of them have not driven cars, flown in planes or seen television and none of them have used the internet–this magical wand of the technological age. But the Hagahais have no need of such materialism. They depend on their environment and each other for their daily sustenance. In this settlement there are no poor, homeless or hungry people. Every member of the community has a moral responsibility of looking after the others.

The Hagahais made history in 1995 by being the first indigenous peoples to have their cell line patented in the US and their case has since 1996 contributed significantly toward the fight against the industrialized countries' exploitation of indigenous peoples through 'genetic colonialism'[1]. The patenting and reversal of the patent of the Hagahai cell line raises a lot of ethical and legal issues. Some of the fundamental issues which have a bearing on PNG include: (1) who owns the genes? (2) Who should have access to these genes? (3) Is the ownership of genes transferable? (4) What are the legal mechanisms for protecting genes? This paper explores these fundamental issues from a Papua New Guinean perspective.[2]

## Background to Papua New Guinea

The Hagahai case must be considered against the political, social and economic backdrop of PNG for one to fully appreciate the events that led to the patenting of the Hagahai gene. Many of the commentaries on the Hagahai case make generalizations about the impacts of the case without acknowledging the wider political, socio-economic conditions that influenced the actions that Dr. Jenkins took. It is imperative to provide a brief snapshot of the political and socio-economic landscape of PNG.

### The Environment

PNG is located on the eastern side of the island of New Guinea. The western part of the island of New Guinea is Indonesia and to the east, Solomon Islands. To the north of the country is the Federated States of Micronesia, and to the south, Australia. The total land mass of PNG is 462 840 km2 which consists of 0.5% beaches and ridges, 11% swamps, 15% lowlands; 43% foothills, mountains up to 1000m above sea level; 25% mountains 1000-3000m and 4% above 3000m.[3] Natural forest covers almost 77% of the total land area.

The country occupies half of the world's largest and highest tropical island which is 0.14% of the earth's land area and supports 5-7% of the world's terrestrial biodiversity.[4] PNG has 5,000 lakes, extensive river systems, 5,000 miles of mangrove swamps (1.5 percent of land area), lagoons, wetlands, coral reefs and atolls plus island archipelagoes. PNG has jurisdiction over 800,000 km2 of ocean, including 40,000 km2 of coral reefs.[5]

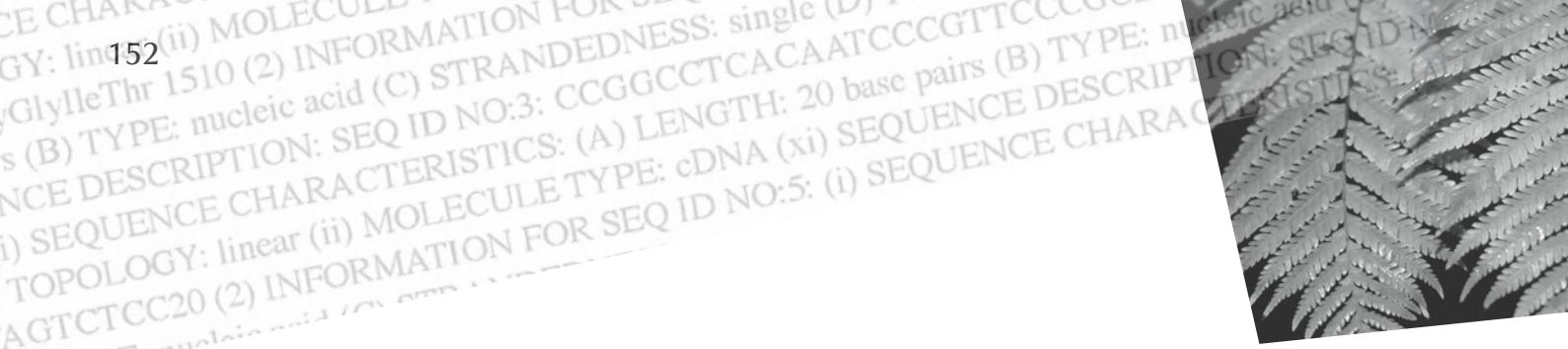
A World Bank funded project on PNG reported in 2002 that the country has:

- 20, 000 plant species;
- 600 fish species;
- 800 species of corals;
- 304 mammals species;
- 733 species of birds;
- 298 species of reptiles;
- 228 amphibian species; and
- 45 types of forest/wetlands.[6]

It was also reported recently that: "there is approximately 60 percent of plants which are endemic to PNG. There are about 500 species of food crops, 30 root and staple crops, 43 nut types, 100 fruits and 60 leafy green vegetables. There are a number of plants which are used by Papua New Guineans for different purposes."[7]

## Political Status

PNG became an independent State on 16 September 1975. It adopted a new constitution which is the supreme law of the country. The *Constitution* itself declares that every act (whether administrative or



judicial) is to be made subject to the *Constitution*.[8] The *Constitution* establishes a Westminster model of government with the traditional three separate braches of government – the legislature, executive and the judiciary.[9] These three arms of government are separate and independent of each other and were envisioned by the constitutional makers to keep a check on one another.[10]

PNG has a unicaramel Parliament which consists of 109 legislators who are elected to Parliament on a five yearly term. Prior to 2003, these 109 legislators were elected by the constituents through the First-Past-the Post electoral system. This electoral system was replaced by the Preferential Voting System in 2003. The country is a constitutional monarchy with Queen Elizabeth II as the Head of State. The representative of the Queen in PNG is called the Governor-General.

The country is divided into 20 provinces which are administered by 20 provincial governments. There are also 89 districts which cut across the 20 provinces. In 1995 the Parliament amended the *Constitution* and enacted the *Organic Law on Provincial Governments and Local-level Governments* which removed the old provincial government system and ushered in a new decentralized form of government with the creation of another level of government – the local-level governments.[11] There are currently 289 local-level governments spread throughout the country. These local-level governments comprise Ward Councillors who represent about 6000 Wards in the country. The members of the local-level and provincial governments hold office for a term of five years.

## Development Issues

The key development issues for PNG are:
(1) political instability;
(2) corruption within government and
(3) weak State institutions.

Political instability is brought about by the continuous changes in government. Since independence, no elected government has seen its full term in office. The frequent changes in government contribute to the non-implementation of national development programs and uneven development in the country.

Corruption has been described as a disease which has far more threats on development than the disease HIV/AIDS.[12] Corruption hinders development, increases poverty, threatens national sovereignty and is closely linked to crime.[13] According to the Transparency International's[14] 2003 Corruption Perception Index, PNG was listed as one of the 'most corrupt' countries in the world. PNG ranked 118th out of a total of 133 countries. Finland took the top honors coming at 1.[15] In 2004, PNG was ranked 102 out of a total of more than 143 countries.[16]

The factors that contribute to institutional incapacity include:
(1) lack of properly qualified and trained human-power;
(2) insufficient funds;
(3) political interference;
(4) lack of institutional infrastructure and
(5) lack of coordination.[17]

Institutional incapacity has become a major concern for the government and aid donors.[18] In an effort to address this problem, the government with the support of the international multilateral organizations such as the World Bank, the Asian Development Bank (ADB) and AusAid introduced the Public Sector Reform program in the late 1990s. The aims of the program are:

- Improving the critical process of decision-making and management;
- Redefining and focusing efforts and resources of government on its core functions;
- Strengthening the capacity of the State agencies in managing the operations of government; and
- Improving the delivery of basic goods and services.

The problems of political instability, corruption and institutional incapacity have not dampened the respite of the majority of Papua New Guineans to ensure democracy and the rule of law is maintained and strengthened in PNG. Most Papua New Guineans continue to strive to fulfill their roles in serving the people of PNG.[19]

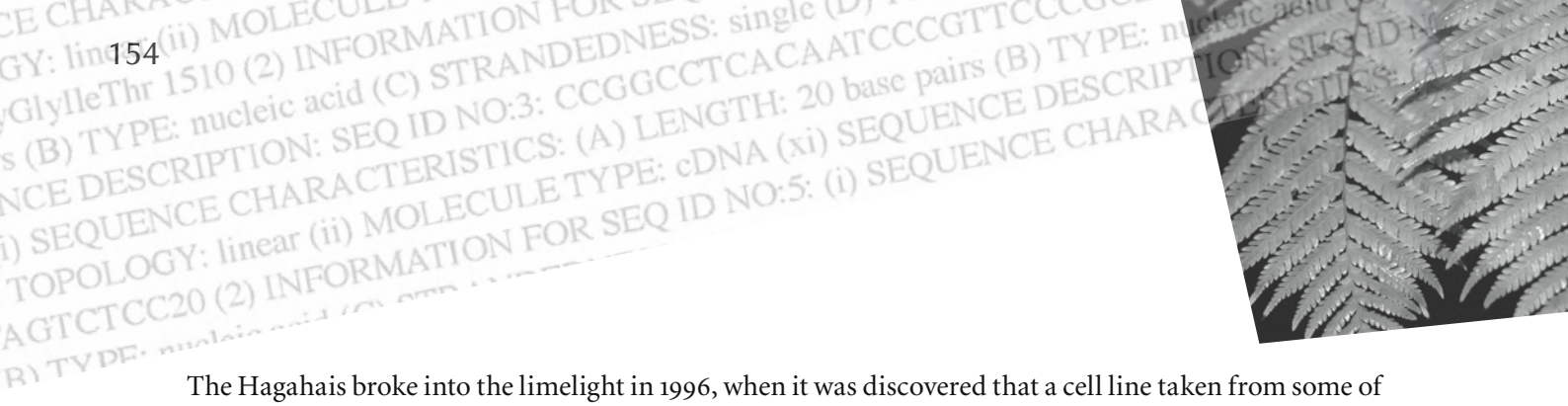
This political, social and economic setting triggered the actions of Dr. Jenkins. At the political level, the State institutions were weak partly because of corruption and also political instability. Patenting the Hagahai gene was considered by Dr. Jenkins as a long term investment for the Hagahais. If their genes were used to develop a commercial product, they would stand to gain in the future through royalties and thus improve their living standards in their village.

## The Hagahai Case

The development of PNG has been a cause of concern for many development planners, investors and development aid agencies.[20] Many development models seem to achieve very little in the way of basic health and education services, poverty reduction and crime prevention. In the rural areas where 85% of the people live, government services such as basic health, education and infrastructure had collapsed. In 2001, AusAid reported that there was a national development crisis in PNG. AusAid was very concerned about the plight of rural communities and suggested the adoption of certain measures to arrest the declining development trend.[21]

The Hagahais are a small fraction of the masses that live in the rural areas. They live along the Yuat River and belong to the Yilu Ward of the Simbai Local-level Government in the Middle Ramu District of the Madang Province. Until 1983 they lived a nomadic life and were unknown to many Papua New Guineans. The Simbai District is difficult to access by road and for the Hagahais they have limited access to government services such as basic health and education.

It is their remoteness that attracted the attention of Dr. Carol Jenkins and her employer the Institute of Medical Research (IMR). Dr. Jenkins began her work with the Hagahais in the late 1980s. In the absence of government services to the remote Hagahais, Dr. Jenkins helped to set up an aid post and a school for the people. She even arranged for the Hagahais to be transported to cultural shows around the country.[22] The efforts of Dr. Jenkins and the work of the IMR in the Yilu Ward of the Simbai Local-level Government went unnoticed by the provincial and national governments, and the public in PNG.



The Hagahais broke into the limelight in 1996, when it was discovered that a cell line taken from some of their members by Dr. Carol Jenkins, had been patented in the US without their knowledge or consent. The patent – US 5,397,696 was issued on 14 March 1995 and related to "a human T-cell line (PNG-1) and to the infecting virus" which is a self-perpetuating culture of virus-infected white blood cells. Dr Jenkins and four US government researchers were listed as 'inventors" and the National Institutes of Health (NIH) as assignee.[23] The Hagahais, the IMR and the government of PNG were left out of the scheme.

The patent had been quietly filed on August 24, 1990 after a decision to patent the cell line was made in April of that year. The decision to file the patent application was made without the consent and knowledge of the Hagahais and the government of PNG. Although the Hagahais made history by being the first people to have their genes patented in the US, the issuance of the patent went without any fanfare from the people of Yilu Ward and the government of PNG. The secrecy of patent US 5,397,696 was uncovered by the Canadian based non-government organization - Rural Advancement Foundation International (RAFI) which attacked the patent on October 4, 1995.[24] The action of RAFI drew strong support from various sections of the international community and forced the NIH to file for the revocation of the patent on October 24, 1996. Patent US 5,397,696 was revoked by the United States Patent and Trademarks Office in the same year. The revocation meant that all of the US government's "past and future rights in each and every claim of United States Patent 5,397,696, [was forfeited] thereby relinquishing all control over the said patent."[25]

There are several pertinent questions that may be raised. These include:
(1) why was Dr. Jenkins allowed to remove the genes from PNG?
(2) Why was the gene patented in the US?
(3) What penalties should be imposed on people like Dr. Jenkins? And more importantly,
(4) why did the IMR, an agent of the State permit Dr. Jenkins to transfer the gene and patent it in the US?

These questions have both ethical and legal dimensions.

## Policy and Legal Issues

The biodiscovery of genetic material, its ownership, use and financial benefits has pervaded many international forums for years culminating in the *Convention on Biological Diversity* and the *Cartagena Protocol on Biosafety* and the *Agreement on Trade Related-Aspects of Intellectual Property* (TRIPS). A review of the scheme of these instruments reveals the inherent contradictions and the tussles between the industrialized North and the developing South. At the heart of the disputes between these two disputing groups are issues of ownership, access to genetic resources, benefit sharing and intellectual property rights (IPR). International action on the protection, sustainable use and management of biological resources began to mature mostly in the 1990s. In many of the developing countries and particularly those in the South Pacific, no serious efforts were made at the national level to protect the ownership, use and management of biological resources. The two regional treaties, the *Convention on Conservation of Nature in the South Pacific Region* 1976 (Apia Convention) and the *Convention for the Protection of Natural Resources and Environment of the South Pacific Region and Related Protocols* 1986

(Noumea Convention) provided very little practical guidance on this matter.[26] At the national level, many of the laws on natural resources and the environment were mostly first generation environmental laws – focusing on conservation and pollution.

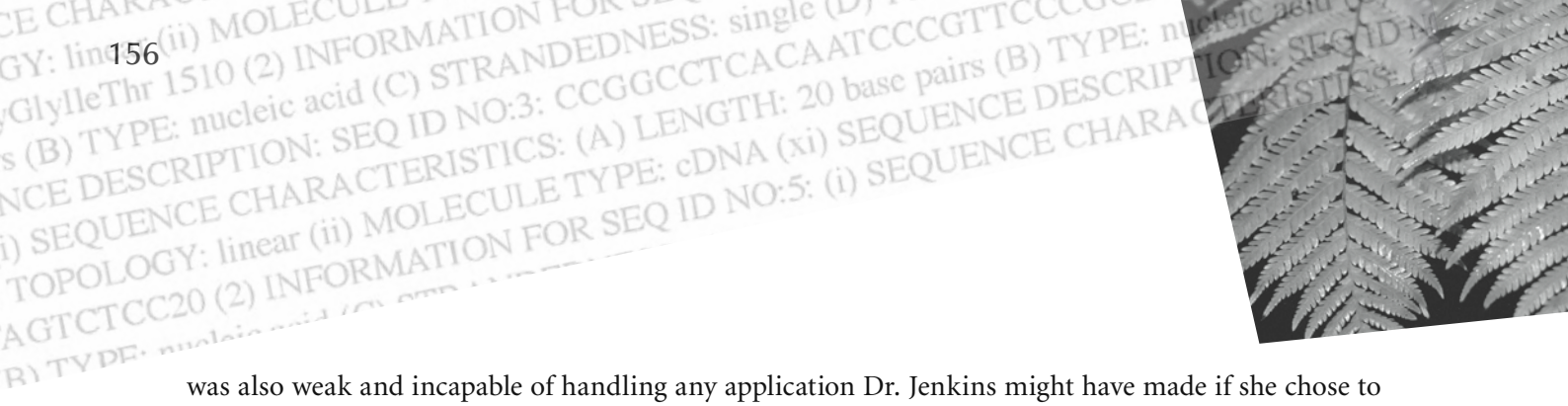
In PNG, the first generation environmental laws provided little protection to the local communities and their genetic resources. There are volumes of evidentiary material which show beyond a reasonable doubt that these laws failed the people. The ownership of biological resources rests with the traditional landowners because of the age old concept of traditional land ownership.[27] The policy and legal framework provided broad protection to traditional landowners and their resources. Unfortunately, there were no specific laws or policies which dealt with gene ownership and use.

There are scattered through the policy and legal framework, provisions relating to the respect for traditional resource owners' rights to their resources and their participation in the use of these resources. A review funded by the PNG government through the Papua New Guinea Institute of Biodiversity (PINBio) in 2004 revealed that the policy and legal framework provides inadequate control over the ownership, sustainable use and management of biological resources. Two important recommendations where made in the report. The first is the strengthening of PINBio as a specialized institution to regulate the use, management and development of national genetic resources. And the second is the development of a law to deal specifically with genetic resources.[28]

Ethical questions such as prior informed consent (PIC) are outside the scope of the political, social and economic discourse in PNG. The scheme of the various national laws and policies is designed to pre-empt the decision of the local communities. Thus they are not allowed to discuss amongst themselves or seek independent advice on the issues affecting them, but are forced to accept the terms and conditions that are presented to them by the government and developers or researchers. Many of the legal provisions on public participation are curtailed by time limits inserted in the law to make active and full participation of the people impractical.[29] This practice is rampant in the industrial, forestry and mining sectors.[30]

The sharing of benefits is also predetermined by the State. Thus there is no room for negotiation in relation to the use of natural resources. In the mining and petroleum sector, the law specifies the amount of benefits the government and developer are entitled to share. In real terms the traditional landowners are left out of the equation. There are no specific provisions for genetic resources use and management. Any benefits arising from the development of genes or genes taken from local communities belongs to the developer. Also absent in the legal regime is the concept of IPR. The PINBio report shows that this issue is fairly new to Papua New Guineans and in the area of genetic resources, very few Papua New Guineans are familiar with this concept.

It is against this backdrop that the actions of Dr. Jenkins must be considered. The collaborator of Dr Jenkins, the IMR is created by the Institute of Medical Research Act 1967. The legislation gives wide powers of research to the IMR. This general power has been utilized extensively by the IMR to conduct research into various diseases in PNG. The IMR Act under which Dr. Jenkins conducted her research is silent on gene ownership, transfer and IPR. Thus, in 1989 when the Hagahai gene was transferred to the US, Dr. Jenkins did not actually breach the IMR Act or any PNG law. The discovery could also not be patented in PNG because there was no patent law[31] in PNG at that time. The institutional framework



was also weak and incapable of handling any application Dr. Jenkins might have made if she chose to take that course of action.

But does this mean that Dr. Jenkins, a very experienced and internationally acclaimed scientist had no ethical or moral obligation to the people of PNG expressing themselves through their government and its institutions? As an experienced scientist Dr. Jenkins was ethically required to inform the government of PNG of her plans to transfer and patent the Hagahai cell line in the US.[32] Her failure to do so brings into question her genuineness in helping the Hagahais. Patenting the cell line under her own name also raises serious doubts about the argument that "because the Yilu were illiterate and unsophisticated she was acting as their trustee." Why did she not register the patent under the name of the Independent State of PNG which is the custodian of the people and their resources and has a fiduciary duty to each and every citizen of PNG?

The Hagahai saga revealed huge gaps and weaknesses in the PNG legal system. There was an urgent need to fill the gaps in the law and also establish or strengthen existing institutions to deal with gene ownership and sustainable use.[33]

The tale of the Hagahais is the tale of a nation. The exploitation of the Hagahais by the NIH and the US is by extension an exploitation of Papua New Guineans generally. But what caused Dr. Jenkins to take the actions she took to patent the cell line in the US? The answer to this question lies in the policy and legal framework of PNG. At the time (1989) Dr. Jenkins transferred the genetic material to the US, PNG had no appropriate law or policy setting the parameters for dealing with genetic material.

## Policy and Legislative Reform post-Hagahai Saga

The government has initiated a string of policy and legislative reforms since the 1990s which may be attributed in some way to the Hagahai case. The first major policy and legislative reform begin in 1995 with the enactment of the *Organic Law on Provincial Governments and Local-level Governments* (OLPGLLG). The legislation provides the vehicle for the decentralization of legislative, administrative and financial powers to the two lower levels of government – the provincial and local-level governments. Two provisions of the Organic Law are pertinent to our discussions. These are Sections 115 and 98. Section 98(1) defines natural resources as including minerals, petroleum, gas, marine products, water, timber (including forest products), fauna, flora. Section 115 then states that the development of any of these resources requires the full and active participation of the local communities who are the resource owners.[34] The provision promotes the prior informed consent (PIC) principle.

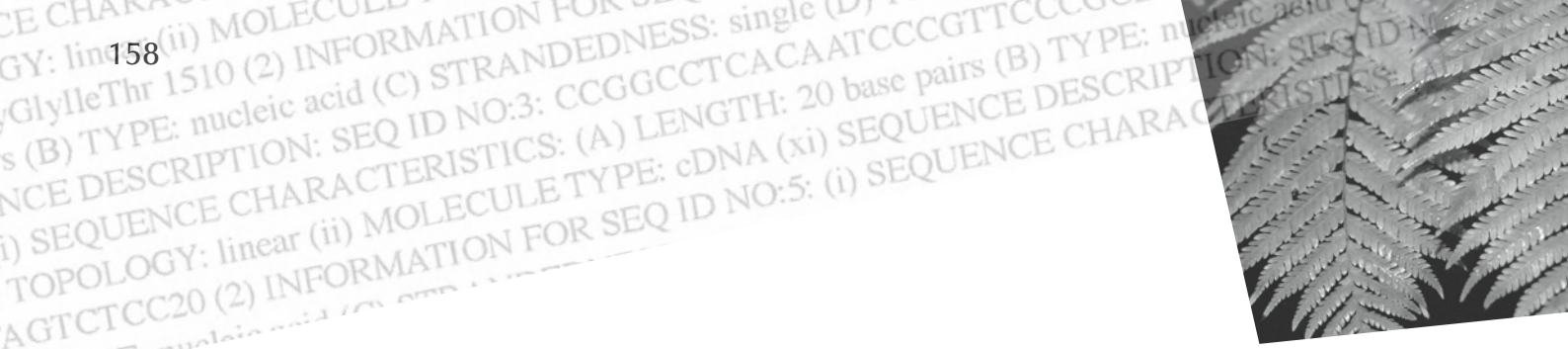
In the mining and petroleum sectors, the legal system is more advanced. The participation of resource owners in the planning and development process and the distribution of benefits from mining, gas and petroleum projects are amicably covered by the *Mining Act* 1992 and the *Oil and Gas Act* 1998. In the fisheries and forestry sectors, there still remain a lot of grey areas insofar as the rights and participation of local communities are concerned. Both the *Forestry Act* 1991 and the *Fisheries Management Act* 1998 pay lip service to the recognition of the rights of traditional resource owners over their resources. The Forestry Policy of 1990 does little to enhance the rights of local communities.

The polarization of the Hagahai case in 1996 had very little practical impact on the government of PNG. If there was any concern it was from a small fraction of public servants and individuals who were familiar with the issues of biocolonialism. However, three key pieces of legislation which were enacted soon after the Hagahai case provided a glimmer of hope for the transformation of the legal system to accommodate the ownership, sustainable use and management of genetic resources. These were the *National Agriculture and Research Institute* 1997; the *Patent and Industrial Designs* Act 2000; and *Copyright and Neighboring Rights Act* 2000. The first legislation relates to the establishment of the National Agriculture and Research Institute and its roles and functions. Although the scope of the law is on agricultural research, it is silent on the issue of – access, PIC and benefit sharing arising from genetic research for food crops. What the law does clarify is that all "intellectual properties and patents designed and derived from the work of the Institute are the sole property of the Institute, and the Institute shall have legal and sole right to protect these properties and patents and may take legal action against any person or organization violating this right" (Section 40). This provision is quite innovative as it seeks to tackle one part of the Hagahai problem. For the first time we see the advancement of the legal system to tackle the issue of ownership and IPR. The other part of the problem that has not been clarified by the legislation is access to genetic resources belonging to local communities and villages which are used to modify a food crop and how the Institute will share the benefits with the holders of TK and the use of their genetic resources.

In 2000, at the behest of the WTO and WIPO, the government enacted the *Patent and Industrial Designs* Act 2000 and the *Copyright and Neighboring Rights Act* 2000. The two laws are inter-related. The former relates to industrial property rights while the C*opyrights and Neighbouring Rights Act* is primarily to protect intellectual property rights taking the form of works, performances, sound recordings and broadcasts. A review done by the author in 2004 for PINBio found that the scope of these two pieces of legislation did not extend to the protection of naturally occurring biological resources.[35] A genetic engineering process may be protected under the *Patents and Industrial Designs Act*, but the actual gene cannot be patented under this legislation. The Act defines patent as "the title granted to protect an invention." According to the definition of "invention" under the Act, the following activities cannot be patented under the Act:

- A discovery;
- Scientific theory;
- Mathematical method;
- Scheme, rule or method for doing business;
- Scheme, rule or method for performing mental acts;
- Scheme, rules or method for playing games;
- Diagnostic method;
- Therapeutic method; and
- Surgical method.[36]

The law is thus silent on the patenting of genes. Does this mean that the law makes it unlawful for the patenting of genes? This issue was unfortunately not considered at all when designing the law. In fact, PNG had very little to say about the form and structure of the two laws because they were the creation of the WTO. One of the conditions for joining the WTO was that countries adopt these two laws.



Thus the patenting of genes in PNG is *not unlawful or illegal* but, not supported by the current legal regime. What then is the legal position on genes in PNG? With the exception of the *National Agriculture Research Institute Act*, there are no specific stipulations in any national law that clarifies this situation. There is however tacit recognition by the PNG legal system that all natural resources apart from mineral resources are owned by the traditional landowners of PNG. The *Forestry Act*, the *Fisheries Act*, the *Organic Law on Provincial Governments and Local-level Governments*, the *Land Act* 1996, the *Conservation Areas Act* 1978, the *National Parks Act* 1982 and the *Environment Act* 2000 contain special provisions which recognize the rights of traditional landowners and local communities and their participation in the pursuit of the objectives of these pieces of legislation.

This issue is currently being considered in PNG through various initiatives which are being supported by the government and its local and international partners. Some of these projects are discussed below.

In 2003, the government, through the Department of Environment and Conservation (DEC) undertook the task of developing a biosafety framework under the auspices of the UNEP/GEF Biosafety Project. The aim of the project is to develop a policy and legal instrument to implement the Cartagena Protocol on Biosafety. Since 2003, the government has been conducting wide community consultations to gauge the views of the stakeholders on the form and structure of the biosafety framework.[37] By March 2005, a draft Biosafety and Biotechnology Policy and Biosafety and Biotechnology Bill had been completed under the project.[38] It is important to note that the central focus of the biosafety framework is on modern biotechnology. Conventional propagation of genes is outside of the scope of the draft documents. There are however several key aspects of the Bill relevant to gene ownership and use which are worth mentioning.

### *Ownership and Access to Genetic Resources*

The Bill strengthens the position that Papua New Guineans are owners of genetic resources. The Bill stipulates that access will only be granted after the local communities have given their PIC. It is a requirement of the draft Bill that provincial governments must be informed of the proposed activity. A person (including public and foreign institutions and corporations) who intends to conduct biological research and development in PNG is required to obtain a licence from the proposed National Biosafety and Biotechnology Council. This strategy has been designed to ensure that a researcher, institution or corporation must engage the local communities in the research and development exercise and also enable the transparency of the process.

### *Benefit Sharing*

The Bill makes it mandatory for the applicant for the biological research and development to negotiate with local communities about benefit sharing arrangements before the actual project undertaken. The distribution of benefits is provided by the Bill. According to the Bill - the applicant or developer is entitled to 67 percent of the benefits; local communities 15 percent; 5 percent to local-level government; provincial government 3 percent and national government 10 percent. These allocations were inserted in the law to prevent any disparity in the distribution of benefits among the stakeholder.

Given the incapacity of local community to handle complex negotiations, the Bill makes it mandatory for the appointment of independent experts, funded fully by the government, to assist local communities. This provision has been inserted to negate the point raised by Dr. Jenkins that the Hagahais were illiterate and incapable of understanding the complex issues of patenting and so she acted for and on their behalf.[39] It is envisaged that this provision will enable the local communities to identify qualified persons to assist them in negotiating the terms and conditions of the agreement with the developer of genetic resources.[40]

### *IPR*

Issues relating to IPR became more prominent fairly recently in PNG. As mentioned above, it was only in 2000 that legislative reform in this area was initiated. The twin WTO law – the *Patent and Industrial Designs* Act 2000 and the *Copyright and Neighboring Rights Act* 2000 regulate IPR matters in PNG. The PINBio review of 2004 revealed that this legal framework does not adequately cater for traditional biological knowledge. In fact the use of traditional biological knowledge in scientific discoveries is unprotected.[41] In the light of this legislative gap, the Bill recognizes the value of traditional knowledge in scientific discoveries and makes it mandatory for the payment for the use of such knowledge and also for the equitable distribution of benefits to the holders of such knowledge with the development of a product.

### *Institutional*

Biological research and development in PNG falls under the jurisdiction of a new institution that was created by the government two years after the Hagahai saga. This is the Papua New Guinea Institute of Biodiversity (PINBio). PINBio was established in 1998 and tasked it with the responsibility of developing and establishing a conservation based industry in PNG through appropriate research and development mechanisms.[42] PINBio is a conglomeration of public and private institutions and non-governmental organizations. The Institute's operations are managed by a Board which is supported by a Secretariat comprising officers from the DEC. The Board is assisted by a Technical Steering Committee which provides professional and technical advice to the Board.

PINBio conducts its activities through nine programs: These are:
(1) Biodiversity Inventory;
(2) Biodiscovery;
(3) Agrobiodiversity;
(4) Biotechnology;
(5) Biodiversity Conservation through Carbon off-sets and Trade Initiatives;
(6) Biodiversity Database and Management System;
(7) Policy and Legislation;
(8) Training and Infrastructure Development; and
(9) Education and Awareness.

PINBio has since 1998, sparingly supported various initiatives under only some of these programs. Some concerns had been raised that PINBio should support projects that encouraged the collaboration

between two or more of these programs. The Board and the Technical Steering Committee have accepted this concern and have more recently, vigorously pushed for intra-program projects.

One of the key roles of PINBio is to scrutinize all applications for biological research and development in PNG. PINBio relies a lot on various experts to assist it to successfully perform this function. In 2002, I was asked by my employer the University of Papua New Guinea (UPNG) and PINBio to advice them on the legal implications of several agreements that UPNG wanted to enter into with several international institutions for genetic research in PNG. After reviewing the agreements I advised UPNG to execute the agreements with these institutions. At the core of the agreements is: co-ownership of outputs; equitable sharing of benefits; joint publications; capacity building and transfer of technology. PINBio was satisfied with the terms and endorsed the agreements. These agreements are shown in the Table below.

MOUs Between PNG Institutions and Foreign Organizations[43]

| *Research Disciplines* | *Participating Collaborator* | *National Collaborator* | *International & MTAs* | *MOUs by TSC/DEC* | *Approval Program* |
|---|---|---|---|---|---|
| **Drug Discovery/ Screening**<br>• HIV/Aids<br>• TB<br>• Malaria<br>• Cancer<br>• Other anti bacterial | **Biochemistry**<br>• Molecular Genetics<br><br>**Biology**<br>• Ethnobotany<br>• Material Collection/ Taxonomy<br>• Voucher prep (plants and marine) | FRI, Lae<br>• Plant Id<br>Chemical Technology/ UOT<br>• Material extraction<br>• Assay/antibacterial<br>IMR/Goroka | US NCI<br>• Cancer<br>• HIV/AIDS<br><br>University of Utah<br>• Cancer<br>• HIV/AIDS<br>• Malaria<br>• TB | UPNG & NCI (2001)<br>UPNG & Utah (2001, 2003) | Research Permits approved on request, i.e, Research Proposals |
| | Chemistry<br>• Bioassay guided fractionation | | University British Columbia<br>• Cancer | UPNG & UBC (2002) | |
| | Microbiology<br>• Cell Culture<br>• Bioassay | | Consortium of universities: University of California, Santa Cruz, University of Michigan and Oregon State University<br>• Cancer | UPNG & USC (2003)<br><br>UPNG & UMich (2003)<br><br>UPNG & OSU (2003) | |
| | Pharmacology<br>• Cell Culture<br>• Bioassay<br>• In vivo assay<br>• Drug mechanism | | | | |

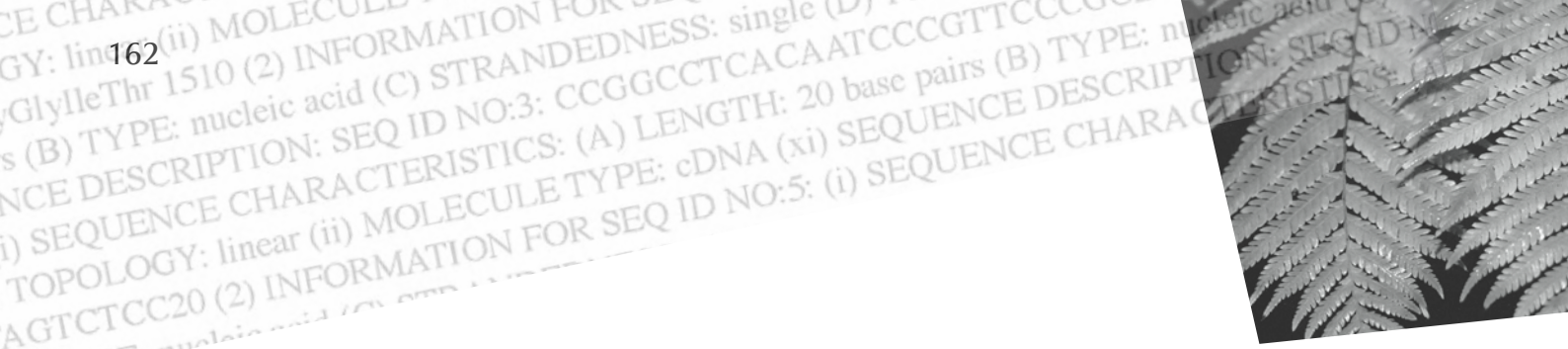
| | | | | | |
|---|---|---|---|---|---|
| | Physiology<br>• Cell Culture<br>• In vivo assay<br>• Physiological studies | | University of Illinois at Chicago<br>• TB<br>• Malaria | UPNG & UIC (2003) | |
| Venom & Toxins<br>• Snake Venom | Biology<br>Haematology<br>• Envenomation<br>• Anti-venom | IMR/Goroka<br>• Epidemiology | James Cook University<br>• Epidemiology<br>• Envenomation<br>• Anti-venom | UPNG & JCU (Final Draft) | Initial proposal with JCU approved in 2002 |
| | Pharmacology<br>• Envenomation<br>• Anti-venom | | University of Melbourne<br>• Epidemiology<br>• Envenomation<br>• Anti-venom | UPNG & UniMel (Draft) | |

The 2004 PINBio Report recommended that PINBio should be reformed and formally established under a legislation which would clarify its powers and functions, and strengthen its role in the regulation and management of the country's genetic resources.[44] The report suggested that this reformed institution should be called the 'Papua New Guinea Biodiversity Authority'. This recommendation was, from the perspective of the DEC, too radical and required further investigation and elaboration. PINBio continues to maintain the *status quo.*

The draft Biosafety and Biotechnology Bill seeks to establish a regulatory body called the National Biosafety and Biotechnology Council. The Council will come under the wing of the DEC. The principal function of the Council is to protect the biological diversity, health and safety of humans, and fauna and flora through the regulation of genetically modified organisms using modern biotechnology techniques. The Bill makes inroads by also regulating the research and development of genes for the production of genetically modified organisms. Under the Bill the Council will be the only authority to issue licences for the research of genetic resources and the development of genetically modified organisms.

The Council will clearly perform some of the functions which fall outside the mandate of PINBio. By clarifying the powers and functions of the Council, the Bill removes any doubt that PINBio may have in relation to its roles and functions. For example, all applications for genetic research and development of genetically modified organism will now be handled by the Council and not PINBio.

During the formative stages of the Bill, it was realized that there is an institutional gap between the Council and research and development institutions. Dr. Jenkins was able to export the Hagahai cell line to the US because there was a gap in the chain between the IMR and the regulatory agencies. This gap had to be closed to prevent similar situations occurring again. To address this problem, the Bill empowers DEC to establish in close consultation with research and development institutions and other relevant organizations Institutional Biological Safety Committees. The creation of Institutional



Biological Safety Committees is a 'stop gap' mechanism designed to prevent individuals and institutions from dealing, exporting, importing and testing genes and genetically modified organisms outside the country as in the Hagahai case. The underpinning of the mechanism is to promote collaboration and transparency between research and development institutions and the government.

The reform of the law and policy in PNG continues even today. At the time of writing the government has announced a number of initiatives which will have a direct bearing on gene ownership and use. These include the Eco-Forestry Policy 2003; the development of a legal framework for the creation of protected areas for biodiversity conservation and sustainable use under the Protected Areas Initiative 2004; the formulation of the National Sustainable Development Strategy (NSDS) and the National Biodiversity Strategy and Action Plan (NBSAP); and the development of a legal regime for Access Benefit Sharing and IPR.

## Conclusion

There is ample evidence to show that there has been a string of legislative and institutional reform since the Hagahai saga. These changes have however been sporadic and incoherent. It is suggested that these changes were not in any way influenced directly by the Hagahai saga, but are a result of the ongoing political, environmental and economic changes that are occurring both at the international and regional levels. If these policy, legal and institutional reforms were influenced directly by the Hagahai case, the government would have spontaneously effected the changes immediately after 1996.

Does this mean that the Hagahai saga had had no bearing on the legislative, policy and institutional reforms since 1996? The case did have an impact on the ongoing reforms in PNG, given that many of the gaps in the law and policy that were non existent prior to 1989 have now been rectified and continue to be addressed by the government.

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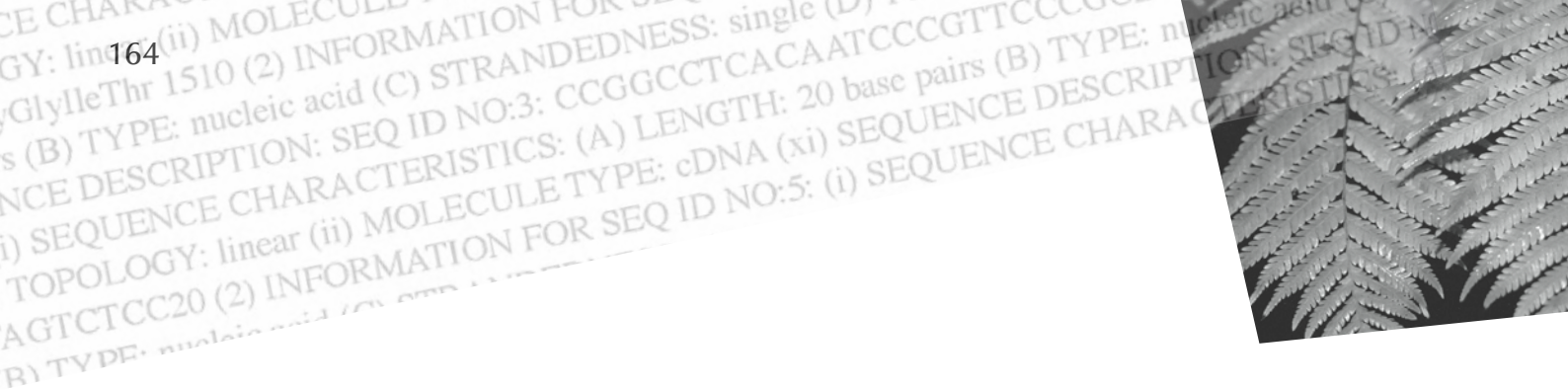

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# Autogen and bio-ethics in Tonga: An ethical and theological reflection[1]

Sr Keiti Ann Kanongata'a

## Introduction

As I was preparing this paper, I was reminded of a TV documentary that was done on the whales and their need to be protected and preserved as they are a dying species. In response to global condemnation, Japan argued that it had to kill the whales for "scientific purposes." Scientifically, the age of a whale is determined by its bones. The documentary also showed how after some bones were taken to the science laboratory the meat and the rest of the "properties" of the whale were sold very expensively to exclusive restaurants and markets. My immediate reaction to the fate of the whales was firstly to "feel sorry" for the "poor innocent whales"! Later, I reacted against the degrading manipulation technique which Japan used to fool the world with. The question we need to ask ourselves is, who is fooling who?

Today, it is not the bones of the whales that the scientists are after but the *blood* of the indigenous Tongans!

### *The Tonga Case*

I do not claim to have proven facts but the media, including the internet have exposed as news the fact that the Australian Biotech Company, the Autogen Limited "has secured exclusive rights to the entire gene pool of the people of Tonga". This implies that "someone" has given the "green light" to Autogen to use us, living human beings as "raw material" for scientific and medical research and later as a product for commercial commodity. News has it also that the Tongans have not been told of the deal though the collection of DNA samples was "to begin late last year or early this year". This is indeed a disturbing piece of news!

Whether the news is true or not the fact remains that the scientists and the genomic companies are in search of "human disease genes" and Tonga stands as a favorite target of research because it is geographically isolated and also because of its extended family groupings. The amount of money on offer by the companies present another problem as the irresistible temptation to become rich overnight may force people to freely give in to Autogen's research. It is however, very timely that we begin the process of community reflection on what biopiracy is about and how it is going to affect our lives in our little God given Kingdom.

### *Questions*

There are a number of aspects relating to what I would call the "3 Parties to bio-piracy". Party 1 is the donor, the Tongan people, whose blood is being sought as "raw material" for the Autogen Company. Party 2 is the Autogen Company and its researchers who need our blood for the advancement of medical science and for commercial purposes. Party 3 is the "middle man", who is the negotiator and go-between whom we still do not know for sure. Our approach to the issue is based on the following quotation:

> The development of science and technology,
> this splendid testimony of the human capacity for understanding
> and for perseverance, does not free humanity from the obligation
> to ask the ultimate religious questions.
> Rather, it spurs us on to face the most painful and decisive of struggles
> Those of the heart and of the moral conscience.

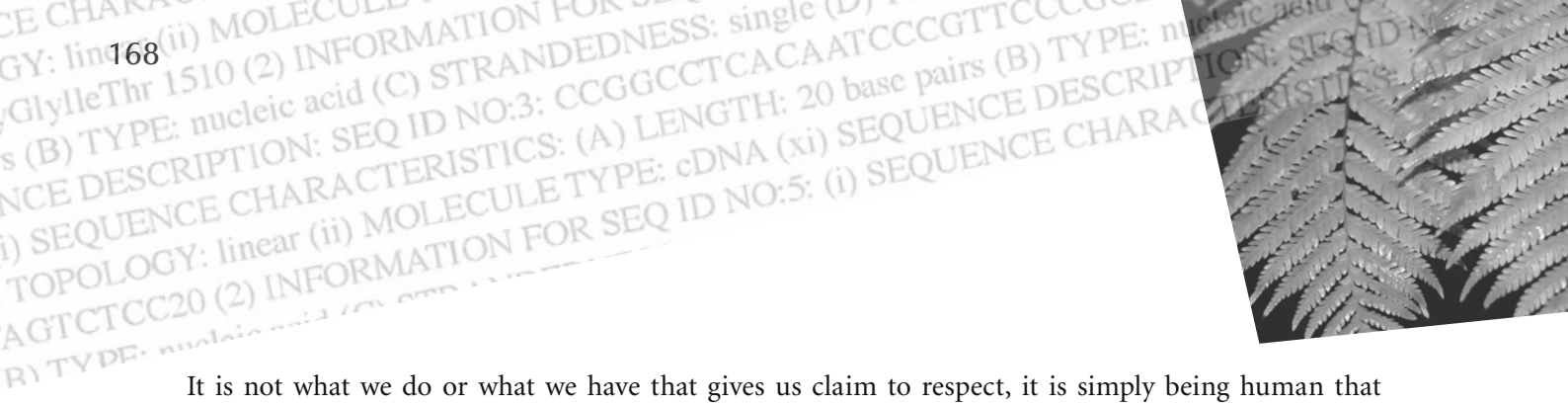
The questions that I am here to ask are questions from the "people of God" – people who are not just human beings but are also God fearing worshippers. The questions will be on Christian social principles. Principles described by William J. Byron, S.J. thus:

> … once internalized, lead to something.
> They prompt activity, impel motion, direct choices.
> A principled person always has a place to stand,
> Knows where he or she is coming from and likely to end up.
> Principles always lead the person who possesses them somewhere,
> For some purpose, to do something, or choose not to.

What then are the Christian principles that we must accept and apply in the debate on biopiracy? Outlined below are some of the Church's principles which guide our approach to the biopiracy debate.

### *Every Human Person has Dignity*

This is the "bedrock principle" of the teachings of the Church. Every person regardless of race, sex, age, national origin, religion, sexual orientation, employment or economic status, health, intelligence, culture, achievement or any other differentiating characteristic is worthy of respect.



It is not what we do or what we have that gives us claim to respect, it is simply being human that establishes our dignity. A person's human dignity is, in the Church view, not a means but an end.

The Church strives endlessly to secure every brother and sister his or her dignity, to be free from manipulation by any power, overt or subtle, anywhere on earth. Thus, we must be aware of the question on life patenting as it can be ethically and morally wrong to treat life as nothing more than a commodity – people and animals as no more than machines. Will genetic engineering enhance the dignity of the individual persons? How are the donors to be recruited and protected? Are they being informed correctly and properly and with respect? Are they given options for making choices?

Every human being is created in the image of God and remains, the beginning, the subject and the goal of all social institutions. Although the Church is not a political entity, she is called to serve the political community by proclaiming that the human person is the "source and centre and purpose of all socio-economic life".

### *Every Person has Human Rights*

Human rights derive from the God-given image and dignity of the human person. Referring to what the Vatican Second Council calls, the "abominable crime" of abortion, Pope John Paul II exhorts:

> Disregard for the sacred character of life in the womb
> weakens the very fabric of civilization; it prepares a mentality,
> and even a public attitude, that can lead to the acceptance of other
> practice that are against the fundamental rights of the individual.

Among the practices listed is the "forms of genetic engineering that go against life", which John Paul pointed out was a "danger… not yet fully known to the general public".

Our world today is continuously facing serious forms of social and economic injustice and political corruption. There is also a growing reaction of indignation on the part of very many people whose fundamental human rights have been trampled upon and held in contempt. John Paul II views our world as a "society which is sick" and is "creating profound distortions in the human person". Why is this happening? John Paul continues to say that it is so because, "we have broken away from the truth about the human person, from the truth about what man and woman really are as persons".

Again, the human being is not only sacred but also social. Because the human person is a social being he or she has a right and duty to participate in society. How we organize our society – in economics and politics, in law and policy directly affects human dignity and the capacity of individual spiritual growth in the community.

The "centre piece" of society is the family. Family stability must always be protected and never undermined. This also applies to our extended family institution in our Polynesian communities. We are told that one of the reasons the scientists are eyeing Tonga and the Pacific nations for their genetic engineering is because of our unique family ties – our extended family relationship.

This, however, has to be approached with sensitivity to the rights of each family. The community rights and their social structure, cultural norms, traditions and customs must be taken into consideration with highest respect before and always during the process of biotechnology.

Patent rights sells life just like the sale of Sunday hot bread in Tonga. It is the equivalent of today's "gold rush." But, it is also a confusing issue. Power and money are the gist of patent rights. Patent rights give to an individual (inventor) the power to own the information, to sell, to reproduce, to manipulate and to control, and more powerfully the right "to exclude" others from participating in the project. Does the provider of the raw material, be it blood, hair, seed, knowledge or whatever, have prior rights? How can gene engineering be free of dehumanizing manipulation?

Most of the discussion bout genetic engineering centres on health, finance and legal matters. Very few people raise the fundamental moral questions involved in creating genetically engineered organisms. Do human beings have the right to interfere in such an intrusive way, by introducing exogenous DNA into the genome of another species?

### *The Human Person has freedom of Choice*

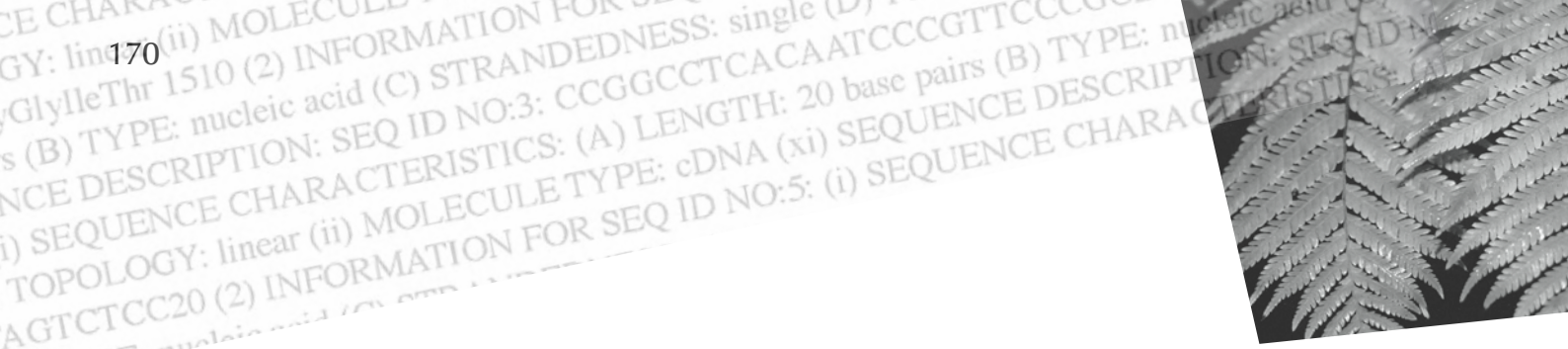
By forbidding man and woman to "eat of the tree of the knowledge of good and evil" (Gen 2:15-17), god made it clear that the human person does not originally possess such "knowledge" as something properly his or her own, but only participates in it by the light of natural reason and of divine revelation. Human dignity requires man and woman to act through conscious and free choice, as motivated and prompted by divine wisdom and not through "blind internal impulse or merely external pressure".

In our journey towards God, we must freely do good and avoid evil. But in order to accomplish this we must be able to distinguish good from evil. A most dangerous crisis that can afflict the human person is: the confusion between good and evil," as the book of Ishaia proclaims:

> Woe to those who call evil good and good evil,
> who put darkness for light and light for darkness,
> who put bitter for sweet and sweet for bitter

We are constantly tempted to turn our gaze away from the living and true God in order to direct it towards idols (cf. 1 Thes 1-9), exchanging "the truth about God for a lie" (Rom 1:25). But no darkness of error or of sin can totally take away from us the light of God the creator. In the depths of our heart there always remains a yearning or absolute truth and a thirst to attain full knowledge of it. This is proved by our tireless search for knowledge in all fields. It is proved even more by our search for the meaning of life.

And here we need to congratulate the contributions that science and technology have gifted our world and time with. I had the rare opportunity to visit the World Expo 2000 in Hanover, Germany four times. It was mainly for study purposes. The highlight of my Expo experience was the awesomeness of human technology. It was too far-fetched for me to absorb the technology of science and to imagine the human intelligence that have contributed so much to the material, cultural, economic, art and social advancement of our world. No wonder many people think and live as if God does not exist. Many too



are "playing God" by abusing their God-given talents and gifts of creation. Technology poses a real temptation to eat the "forbidden fruit."

### *Justice*

The question of human dignity is particularly lined with efforts on behalf of justice. Any violation of justice is an affront to human dignity. All forms of violence are a disgrace, and so long as they infect human civilization they contaminate those who inflict them more than those who suffer injustice.

We are astounded by the massive profits that big co-operations are reaping from using the knowledge, and the biological resources of "little communities" who in turn are "unrewarded". The Tongans who may be willing to give blood for money better be informed of the patent law that "the donor has no entitlement to any rights to his or her own cells after they had been removed from his or her body". If my intellectual property right is protected by law, how much more is there a need to protect my genetic property? My genetic property is me.

## Option for the Poor

Human rights become truly the rights of the poor when their basic necessities of life are defended and promoted. The Gospel of Mathew, 25:31-46 instructs us to put the needs of the poor and vulnerable first. The gap between the rich and the poor in our society is creating divisions and dehumanizing opposites. The opposite of rich and powerful is poor and powerless. Biopiracy is a modern form of colonization because human properties and resources are taken or removed from the people without their informed consent. The Church has an important responsibility to be the "voice of the poor" for their liberation and development.

When genetically engineered crops displace crops grown naturally by farmers in poor countries it will disrupt the life of millions of poor people. As more genetic tests become available, those on the margins of society, the poor, migrants, prisoners and welfare recipients will be subjected to tests. Will these tests be strictly monitored and the results kept absolutely confidential?

When the rights of the minorities are fostered, when the mentally or physically handicapped are assisted, when those on the margin of society are given a voice – in all these instances the dignity of human life, the fullness of life, and the sacredness of human life are furthered.

## Conslusion

### *Mission to Life*

We have tried, for the past two days to grapple with the controversial issue of gene engineering and the horror of biopiracy. Any adequate ethical framework for dealing with genetic engineering must be based on our contemporary understanding of the relationship between humans and the rest of the natural world. We are an integral part of the community of living beings and non- living reality. Each of us depends on the well-being of the whole and so we have respect for the community of living being,

for people, animal, plants and for the preservation of earth, water and soils. The earth is a single ethical system.

To continue the reflection to the wider community we need to make a definitive stand for human life and its sacredness. Indeed the Church has the right always and everywhere to proclaim moral principles, and to make judgments about any human matter in so far as this is required by fundamental rights or the sanctity of life.

If our technology is to promote the welfare of our brothers and sisters and our earthly world then we must always take heed to remember that "the steward is the manager, not the owner."

Finally, the mission of the church, at the service of human life finds its summit in leading the people of God to the fullness of life and salvation in Christ:

"I have come that they may have life
And have it to the full…"
(John 10:10)

## Footnotes

1. This paper was first presented at the Bio-Ethics Consultation, held at the Tonga National Council of Churches Ecumenical Center Nuku'alofa-Tonga, 12-14 March 2001. The author re-presented it at the 2005 Call of the earth/WCC and USP Pacific Regional Dialogue on the Use & Ownership of Genes held in Suva.

# Ngeia ʻo e Tangata – It's about human dignity!

Lopeti Senituli

In October 1995 the University of the South Pacific (USP) in Suva, Fiji was on the verge of signing a bio-prospecting contract with Smith-Kline Beecham (now Glaxo Smith Kline) for the collection of plant samples from the villages and surroundings of Namosi and Ucunivanua in the eastern part of Viti Levu, the main island. Marine samples were to be also collected from sections of the coastline to which these two villages had traditional rights. A subsidiary agreement between USP and the villages concerned was expected to come into effect soon after.

As the Director of the Suva-based Pacific Concerns Resource Centre (secretariat of the Nuclear Free and Independent Pacific Movement), I publicly challenged the authorities at USP to freeze the signing of the contract.

I explained via the media that in negotiations of this nature, information is everything and pharmaceutical conglomerates such as Smith Kline-Beecham hold and have access to information and specialist advice far beyond that possessed by any village or indeed any Pacific Island country. I said, "The number one consideration should be that the villagers and resource owners are fairly compensated for allowing and assisting in the identification and collection of samples. We need to bear in mind that a sample will be sold for a one-time payment, but if successfully converted into a drug or medicine, will generate profits year after year indefinitely. It's a share of these profits we should be focusing on."

I also informed the media that a Pacific regional consultation on "Indigenous Peoples Knowledge and Intellectual Property Rights" held in Suva in April of that year found that bio-prospecting activities were happening in the Pacific region and that they were happening in a total policy and legal vacuum. That meeting had called for a moratorium on all bio-prospecting activities and urged indigenous peoples of the Pacific not to participate in such activities until adequate protection mechanisms were in place. I also pointed out that a legal framework is particularly needed considering that many villages share the same plant species and the situation might arise of villages under-cutting each other in order to win

contracts, or bio-prospectors simply shopping around until they found the cheapest and easiest source. Then of course there are the regional implications given that numerous plant and animal species (and their use, cultural and medicinal significance) are common to many Pacific island countries.

My challenge to USP to freeze the signing of the contract with Smith Kline-Beecham was accompanied by a list of issues and actions that it should consider. This list included the following:

- provision of a lawyer to represent and advise the villagers and resource owners
- provision of an expert in bio-prospecting arrangements to represent and advise the villagers
- transparency of the criteria for calculating the amount to be paid per sample
- prior agreement by the villagers and resource owners as to the ownership of samples and of intellectual property rights over any resultant drug or medicine
- prior agreement by the villagers and resource owners as to which side would have first right to patent any valuable substance discovered
- prior agreement by the villagers and resource owners as to the ownership of data arising from the collection, screening, research and development of each sample
- regular reporting by the pharmaceutical company to the villagers and resource owners regarding test results for each sample at the screening, research and development stages
- prior agreement by the villagers and resource owners as the criteria for calculating royalty payments to them in the event that a drug or medicine is developed from a sample
- voting shares in the company to be issued to the villagers and resource owners
- full disclosure by the company regarding all reasonable enquiries put to it.

To cut a long story short, Smith Kline-Beecham freaked out! Their delegation that had arrived in Suva for the signing of the contract left the country in a huff and the company soon dissociated itself from any bio-prospecting activity in Fiji and in the Pacific. (I later heard from one of the scientists at USP that SKB had dismantled its bio-prospecting department preferring to concentrate on Research & Development whilst out-sourcing the collection of plant samples.) USP to its credit quickly put together a bio-prospecting ethics code and created a multi-discipline committee to advise the University's Council and Senate on the issue. The Fiji Government also got into the act creating a new task force within the Fijian Affairs Board to study and propose how Fijian traditional knowledge and intellectual property rights could be protected.

In November 2000 an Australian company, Autogen Ltd., announced that it had signed an agreement with Tonga's Ministry of Health to establish a major research initiative aimed at identifying genes that cause common diseases such as diabetes among the "unique population resources of the Kingdom of Tonga." The research would involve the collection of tissue samples and health data from consenting individual Tongans. In return Autogen agreed to provide annual research funding to Tonga's Ministry of Health in addition to paying royalties on revenues generated from any discoveries that were commercialized. Any new therapeutics developed from the research would be provided free of charge to the people of Tonga.

The Tongan public was incensed that it knew nothing about the agreement or its implications prior to the Autogen announcement. There hadn't been any hint from the authorities that negotiations had been

ongoing. If Autogen's public announcement of the agreement via the Australian media was intended to coerce the Tongan Government into fast-tracking the approval of their proposal or railroading local opposition, they had another think coming.

As the Director of the Tonga Human Rights and Democracy Movement, I initiated the public opposition to the proposal. I urged the Tongan Government not to be blinded by the seemingly lucrative benefits that Autogen was offering. I said, "Existing international intellectual property right laws favor those with the technology, the expertise, and the capital. All we have is the raw material – our blood. We should not sell our children's blood so cheaply."

We opposed the Autogen research proposal for various reasons. Primary amongst them was the fact they were not going to look beyond individual prior informed consent. The Tongan extended family, the bedrock of Tongan society, would have no say even though the genetic material donated by individual members would reflect the entire family's genetic make-up. And although Autogen stated that their research would not involve the whole population of Tonga (only individual patients), the database they would establish would in effect be pretty close to complete given the limited size of the population, the ethnic homogeneity and the high incidence of diseases such as diabetes. (Incedence of diabetes amongst Tongans in 2001 was reported at 14%).

It was also our view that the benefits offered by Autogen were a literal drop in the Pacific Ocean. The promised royalties from any therapeutics and the provision of those therapeutics free of charge to the Tongan people were, we felt, prefaced by a huge "IF". In contrast, Autogen would reap rewards from the moment they were able to confirm that they had an "official" agreement with the Tongan Government. Such an agreement would immediately attract research and development capital from the giant pharmaceutical conglomerates such as Glaxo Smith Kline and Merck (of Darmstadt) to whom Autogen was actually sub-contracted.

Autogen's "Ethics Policy" made clear that participants may elect how their samples and data can be used and that samples will be securely stored and will be discarded once the purpose for which the sample was collected had been achieved. But scientists often share their collections with their colleagues as a matter of course or for a price. In any case, no enforcement mechanism was spelled out in the document.

Like the situation in Fiji in 1995 Tonga did not have any national legislations or mechanisms to regulate biological and genetic research or the transfer of samples and data. Its intellectual property legislations were still in infancy.

In January 2001 the Hon. Minister of Health denied he had signed an agreement with Autogen but admitted that discussions had been ongoing. This denial was repeated by Chief Superintendent of Tonga's main referral hospital at a Pacific regional bio-ethics meeting for Church and community leaders in March. He also stated that any genetic research conducted on the Tongan people shall have the prior approval of the Tongan Government and that his Ministry was in the process of setting up a National Health Ethics and Research Committee. (This was formalized in February 2002.)

Autogen on the other hand had not given up on its proposal. By the end of 2001 it had not altered its website to delete references to Tonga. In January 2002, I believe Autogen made one last attempt to revive its proposal by "planting" an article in the regional media via Radio Australia. Part of the article read "… Australian authorities are helping to tackle a growing health crisis in Tonga. The Government of the island country admits it is in the middle of a national health disaster caused by years of overeating and a taste for junk food…. Ironically the country's best chance of tackling diabetes is the one they are almost certain to refuse…. Autogen has been attempting for more than a year to persuade the Tongan Government to allow it to construct a DNA database of the country's 108,000 residents. One company source says that the data they want to collect would be vital in tackling diabetes and related illnesses. Officially the proposal is being considered by a special government health, ethics and research committee but few people believe it would go ahead."

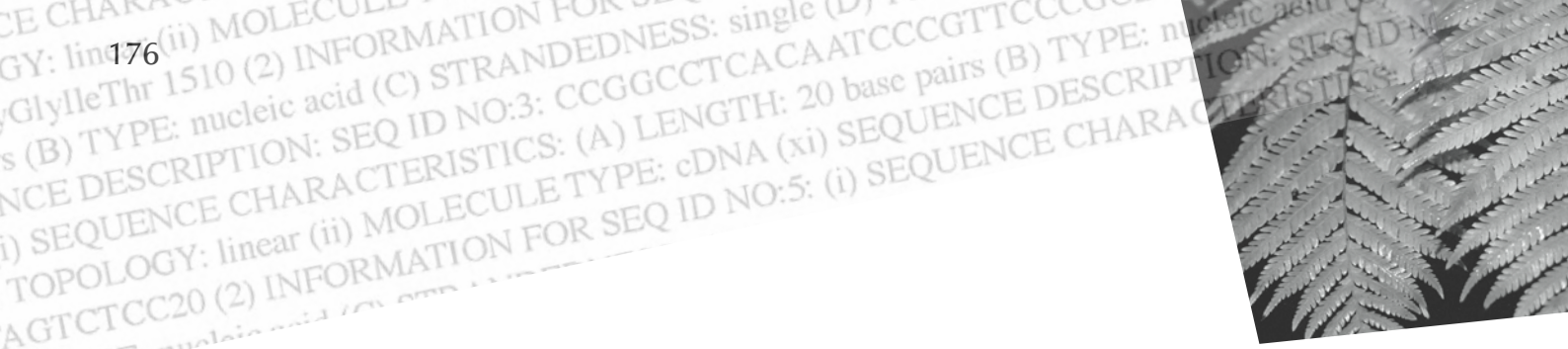
We used this as a pretext to accuse the Ministry of Health of lying to us and to do a little "planting" of our own by dropping hints to the media that perhaps Autogen could be attempting to disguise its genetic research proposal behind an already approved Australian Government funded heath-aid project. It had the desired effect.

In March 2002 I was informed by Autogen's Chief Scientific Officer, Dr.Greg Collier that Autogen "…had no intention of doing any research in Tonga in the future at all." He continued, "Most of our research at the moment with population and family DNA collections are concentrated in Tasmania as there are some very interesting family structures (I'd say!) and plenty of interested researchers to support our work. It is a pity about the work I had planned in Tonga- but as we discussed we did not handle the potential collaboration very well with the Ministry of Health and the wrong messages emerged. This has gone past any chance of rescue but one day we may work with families on islands in other parts of the world." Autogen has since disappeared from the face of the earth but there is no doubt in my mind that its principals are in a huddle refining their strategy, polishing their tactics and sweetening their offer before they will re-converge on, as Dr. Collier said, "…families on islands in other parts of the world."

One question that has been frequently posed to us is: If Autogen had sweetened its offer and the issue of the extended family's prior informed consent had been resolved, would we drop our opposition to Autogen's proposal?

The Tongan people in general still find it inconceivable that some person or Company or Government can own property rights over a human person's body or parts thereof. We speak of the human person as having "ngeia", which means "awe inspiring, inspiring fear or wonder by its size or magnificence." It also means "dignity." When we speak of "ngeia 'o e tangata" we are referring to "the dignity of the human person" derived from the Creator.

Immanuel Kant explains the meaning of "dignity" by distinguishing it from economic value: "What has a price can be replaced by something else that is equivalent. What exists above all price, what does not allow any equivalent, has 'dignity'." The Tongan people believe that the human person has "ngeia" because he/she is the culmination of God's Creation. Therefore the human person should not be treated as a commodity, as something that can be exchanged for another but always as a gift from the Creator.



In a coconut-shell, our answer to the question, "Would we drop our opposition to Autogen?" is an emphatic "NO!"

This is reflected in the Final Statement from the Bioethics Consultation that was held in Tonga in March 2001, for Church and community leaders from throughout the Pacific Islands. The meeting was organized by the Tonga National Council of Churches and funded by the World Council of Churches. Amongst other things the final statement declared:

- We believe in God as the Supreme Creator of all living things.
- We believe all life-forms should be treated in a way that respects their intrinsic value as living generational manifestations of Creation.
- We believe scientific and commercial advances should not be allowed to proceed past the deliberations necessary for their social, moral, and ethical control.
- We believe the cloning of human beings is wrong
- We believe that all forms of genetic engineering of human genes should be rejected.

Autogen's research proposal is not the first and will definitely not be the last foray by the pharmaceutical conglomerates into the Pacific Islands region.

In March 1994 the US Department of Health and Human Services and the National Institutes of Health were granted patents by the US Patent and Trademark Office on the human T-cell line of a Papua New Guinean man. According to the application, blood samples were taken from 24 people who belong to the Hagahai people of the Madang Province in May 1989. The cell line, the first of its kind, was potentially useful in treating or diagnosing individuals infected with a human T-lymphotropic virus type 1 (HTLV-1). This virus is associated with adult leukemia and with a chronic degenerative neurologic disease. The novel cell line was of potential value in understanding the enhancement or suppression of immune system response to this virus. The patent holders faced a major challenge from the Government of Papua New Guinea and the NIH abandoned the patents. However, the Hagahai cell line is now available to the public at the American Type Culture Collection as ATCC Number: CRL 10258 Organism: Homo Sapiens (human) for $216 per sample.

A second patent application was filed by the US Department of Commerce on the human T-cell line of a 40-year-old Solomon Island woman from the Marovo Lagoon in the Western Province and a 58-year-old man from Guadalcanal Province. The blood samples were taken in March and August 1990. Similar to the patent application on the Hagahai cell line, the Solomon islanders' T-cell lines were potentially useful in producing vaccines and/or diagnosing human T-lymphotropic virus type 1. As a result off protests by the Solomon Islands Government the application was abandoned.

The Pacific Indigenous Peoples' Knowledge and Intellectual Property Rights Consultation that was held in Fiji in April 1995 agreed to establish a Treaty for a Lifeforms Patent-Free Pacific. The treaty was completed in 1997 and is called the Hagahai Treaty. In the Protocol concerning Human Genetic Research in the Pacific region, the parties to the Treaty declared their intention to do their best to ensure that no patenting is allowed on any specimen – or anything derived from the specimen – taken from any person.

Although the Hagahai Treaty has not evolved much further it accurately encapsulates the dismay and anger of the indigenous peoples of the Pacific regarding what is in effect the ultimate encroachment on the "ngeia 'o e tangata", dignity of the human person. They came for sandalwood. Now the b…s are after our genes!

Blood sampling of the Hagahai (PNG Institute of Medical Research, Goroka)

# The Mamala Patents

Clark Peteru

Plants hold potential cures for diseases. But the same claim can be made for animals and microbes in short any living thing. Modern technology enables us to identify and isolate useful genes or biochemicals.

Bioprospecting is the activity whereby genetic resources from living things are collected and analyzed for the ingredients that show certain useful characteristics, for example, effectiveness against certain illnesses.

Where a useful biochemical is found, it is usually patented. Patents are documents giving legal protection over inventions. Inventiveness, novelty and usefulness are required to be shown before a patent is granted. A patent gives the holder exclusive use of the invention for a limited amount of time, typically 20 years. Anyone that infringes the patent can be taken to court.

Mamala is a plant found throughout the Pacific[1] but it was in Samoa that it was "discovered" and brought to the scientific community's attention around 1990 when it was found that it had activity against AIDS. The chemical responsible for this was prostratin, and although it had already been isolated in Australia and New Zealand it had never been tested for viral activity. Prostratin was patented[2] without the knowledge or consent of anyone in Samoa.

It appears that access to the plant was possible through a covenant[3] between the "discoverer" and a number of chiefs purporting to sign on behalf of the village of Falealupo. Although signed in 1989, bioprospecting had been carried out in the village for sometime previously. Strangely, no signed record of the covenant is available anywhere, particularly of those chiefs purporting to bind the village.

In 2001 another agreement was signed, this time between the Samoan Government and the AIDS Research Alliance of America, an organisation that had licenced prostratin in order to put it through three phases of human trials. From 20% of any commercial revenues it made, the Alliance undertook to make the following distributions:

- 12.5% to Government
- 6.7% to the village of two women healers
- 0.4% for each of the families of the 2 healers

A goodwill payment of $5000 was given to Government upon signing.

Yet again in 2004 another Agreement this time between the Samoan Government and the University of California at Berkeley for the licensing of gene sequences. The Agreement states that:[4]

> *In consideration for the assistance of the Samoan people in bringing prostratin to the attention of researchers developing treatments for viral diseases, and in consideration for their preservation of genetic resources of Homalanthus nutans and related diseases, UC Berkeley agrees to the following terms as reciprocation for the public health benefits that the Samoan people made possible. From the proceeds of all of licenses, benchmark payments, royalties, technologies and any other income that results from UC Berkeley's licensing of intellectual property arising directly from this research under the direction of Professor Jay D. Keasling at UC Berkeley or at Samoa (after first reimbursing to UC Berkeley all reasonable and necessary patent costs, legal fees, and other necessary and reasonable costs pursuant to obtaining, maintaining, and protecting the intellectual property, and provided that all UC Berkeley inventors of a given patent application agree in writing to the following revenue distribution) UC Berkeley will provide 50% of such net revenue to Seacology, a non-profit Foundation incorporated under the laws of the United States, and with offices in Berkeley, California, which shall distribute their share of the royalties as follows:*
>
> - 50% of net revenue to Government of Samoa
> - 33% to Falealupo village
> - 2% to Saipipi village
> - 2% to Tafua village
> - 8% to other villages
> - 2% to descendants of Epe Mauigoa
> - 2% to descendants of Pela Lilo
> - 1% to Seacology

The Agreement claimed that Samoa would make any resulting drugs available at minimal cost to the world at large.

All three agreements while ostensibly of benefit to Samoa at the same time evoke an unmistakable air of parochialism. The sequence of agreements referred to above appear to have been orchestrated by the "discoverer" of the mamala plant with somewhat less than full consultation with the Samoan people. In particular we might ask:

- Did Falealupo village understand what it was they were doing when they signed the agreement allowing the discoverer access to their rainforest?
- Was permission ever sought by the patent-holders from anyone in Samoa to patent prostratin?
- In the ARA and Berkeley agreements, who determined who the beneficiaries would be and their entitlements?
- Who actually determined that any benefits from the chemical would be gifted to the international community?

ANNEX 1

First 2 pages only of 10 page document.

**United States Patent** **5,599,839**
**Boyd, et al.** **February 4, 1997**

## Antiviral composition

*Abstract*

The present invention relates to an antiviral composition and to methods of treating patients with viral infections. The antiviral composition of the present invention comprises prostratin, a phorbol ester derivative, and a pharmaceutically acceptable carrier. The present composition while having antiviral activity does not have substantial tumor promoting activity and does not have other substantial adverse toxicological properties that would preclude its use in antiviral therapy.

Inventors: **Boyd; Michael R**. (Ijamsville, MD); **Cox; Paul A**. (Provo, UT); **Cragg; Gordon M**. (Bethesda, MD); **Blumberg; Peter M**. (Frederick, MD); **Sharkey; Nancy A**. (Rockville, MD); **Ishitoya; Junichi** (Bethesda, MD); **McMahon; James B**. (Frederick, MD); **Beutler; John A**. (Braddock Heights, MD); **Weislow; Owen S**. (Reston, VA); **Cardellina, II; John H**. (Walkersville, MD); **Gustafson; Krik R**. (Wheaton,MD)

Assignee: **The United States of America as represented by the Department of Health** (Washington, DC); **Brigham Young University** (Provo, UT)

Appl. No.: **424558**
Filed: **April 17, 1995**
**Current U.S. Class:** **514/546**
**Intern'l Class:** A61K 031/22
**Field of Search:** 514/546

*References Cited*

**U.S. Patent Documents**

| | | | |
|---|---|---|---|
| 4902716 | Feb., 1990 | Higa et al | 514/546. |

*Other References*

Chu et al., J. Med Chem. 1989, 32 612-617.
Cashmore et al., Tetrahedron Letters No. 20, pp. 1737-1738 (1976).
Boyd, in AIDS Etiology, Diagnosis, Treatment, and Prevention, 2nd Edition, J. B. Lippincott Co, N.Y., pp. 305-319, 1987.

International Search Report.
"The structure of prostratin: A toxic tetracyclic Di Terpene ester from pimelea prostrata", Tetrahedron letters, 20:1737-1738 (1976) entire reference.

*Primary Examiner:* Goldberg; Jerome D.
*Attorney, Agent or Firm:* Leydig, Voit & Mayer, Ltd.

### *Parent Case Text*

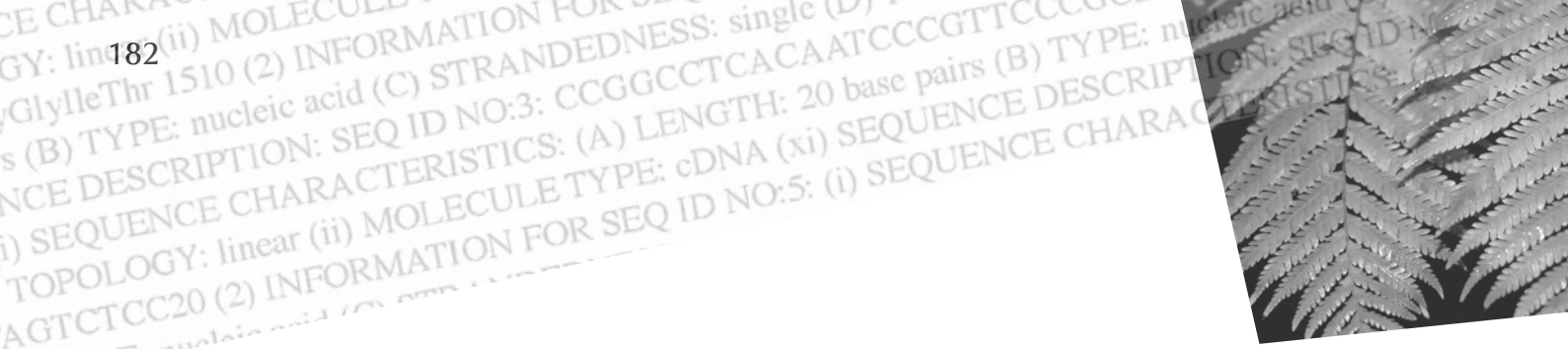
This is a continuation of copending application Ser. No. 07/530,562 filed on May 30, 1990.

### *Claims*

We claim:

1. A method of treating a viral infection sensitive to treatment with prostratin in a patient comprising administering to said patient prostratin in an amount sufficient to effect said treatment.
2. The method of claim 1, wherein said prostratin is administered to said patient with a pharmaceutically acceptable carrier.
3. The method of claim 1, wherein said virus is a retrovirus.
4. The method of claim 3, wherein said prostratin is administered to said patient with a pharmaceutically acceptable carrier.
5. The method of claim 3, wherein said retrovirus is a human immunodeficiency virus.
6. The method of claim 5, wherein said prostratin is administered to said patient with a pharmaceutically acceptable carrier.

The Samoan mamala tree, Homalanthus nutans, is the source from which the anti-AIDS compound prosratin was isolated, 2005 (UC Berkeley Media Relations)



ANNEX 2

# THE FALEALUPO COVENANT

(Note: this is an English translation of the Samoan text of the Falealupo covenant. Only the Samoan text is considered binding).

On this 9th day of February, 1989, we, the chiefs and orators of Falealupo, Savaii as the recognised authorities and leaders of Falealupo village, hereby affirm that we are legally and culturally empowered to represent Falealupo village in entering into a covenant with Mr. Rex Maughan, Mr. Ken Murdock, Dr. Paul Alan Cox, and other interested donors for the purpose of preserving the rainforests of the Falealupo for 50 years.

## Responsibility of the Donors

In consideration of the importance of the unique beauty and nature of the Falealupo rainforest, we, Mr. Maughan, Mr. Murdock, Dr. Cox, and the other donors covenant to assume the current debt for the construction of Falealupo Primary School as carried on the books of the Development Bank of Western Samoa and the accounts of Samoa Timber Products. The current debt is approximately $77,000 WS in the Development Bank and $31,000 at Samoa Forest Products.

We, the donors hereby affirm the perpetual sovereignty of Falealupo village over the Falealupo rainforest and renounce, any claim or title by ourselves or by our heirs to the rainforests of Falealupo village.

## Responsibility of Falealupo Village

In consideration of the funds and goodwill freely given by the donors, we, the chiefs and orators of Falealupo covenant and promise to preserve the rainforests of Falealupo for 50 years.

We, the chiefs and orators, further promise the preserve and protect the indigenous flora and fauna of the rainforests and specifically promise to prohibit the destruction and hunting of the Samoan flying fox Pteropus samoensis and the White-necked flying fox Pteropus tonganus. However the people of Falealupo will be allowed to hunt the Pacific pigeon or lupe during the appropriate seasons.

We, the chiefs and orators of Falealupo, covenant to allow in perpetuity Dr. Paul Alan Cox and his associates access to our rainforests for the purposes of scientific research including the limited and non-destructive harvesting of scientific and research specimens. If his search for new (or old) drugs is successful, 33% of the appropriate royalties will be returned to the village.

## Understandings

The chiefs and donors agree that limited cultural uses of the forests including collection of medicinal plants, selective harvesting of trees for kava bowl, canoe, and house construction may continue as long

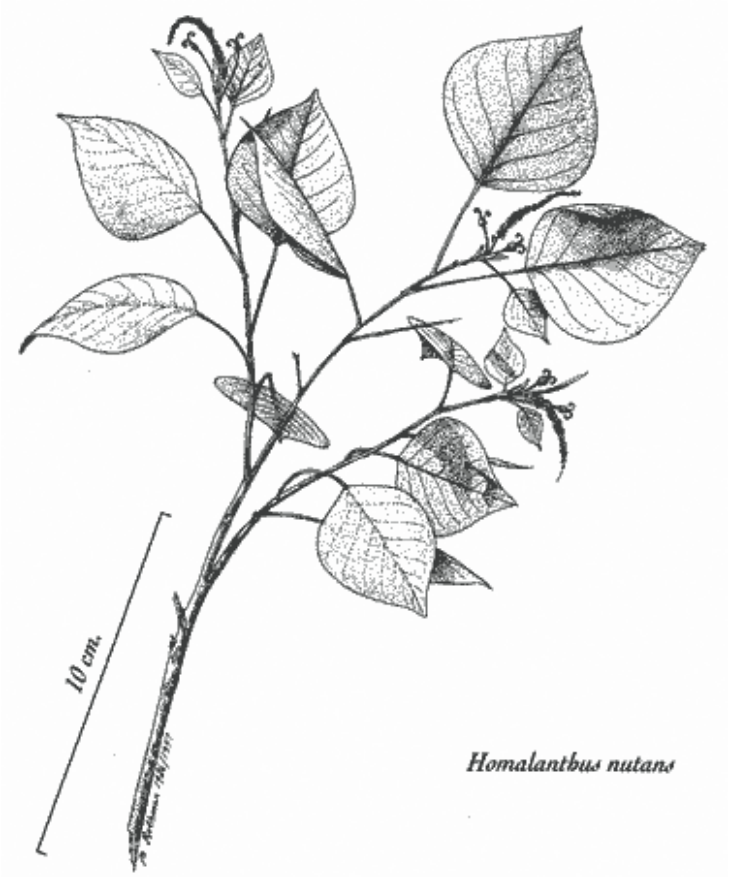
as (a) traditional techniques and tools are used, and (b) the uses are limited and do not significantly alter the pristine character of the rain forests. The donors and chiefs further agree to allow traditional garden plots to be used along the edges of the disturbed forest as long as these gardens are for subsistence use and do not involve the clearing of primary forests.

The chiefs and donors agree that indigenous flora and fauna will be otherwise protected against harvesting and hunting although fishing and the hunting of feral pigs, pigeons, and other noxious non-indigenous animals will be allowed if such activities are designed to protect the forests.

The chiefs and donors agree that all terms of this covenant shall be binding from the date of signature upon them and their heirs for 50 years.

The chiefs and donors agree that the donors may use various entities as conduits for their donations and hereby acknowledge with thanks the kindness of Brigham Young University for its good offices in these regards.

(signed by the donors and 12 matai)




Mamala plant

# Comments on The Pacific Regional Model Law on Traditional Biological Knowledge, Innovations and Practices

Clark Peteru

## Introduction

Pacific Island countries (PICs) along with other developing countries continue to face the unauthorized use of their traditional knowledge, innovations and practices (TBKIP). While conventional intellectual property laws (copyright, patent, trademark) exist in all PICs, and protect certain forms of intellectual property, in the main they fail to protect TBKIP from exploitation. To remedy this, various countries or regional blocs are developing what are popularly known as *sui generis* laws. These laws may complement conventional intellectual property laws or may override them. The Model Law on Traditional Biological Knowledge, Innovations and Practices (ML) does something of both.

The Model Law was drafted in 2000 to provide to Pacific Island countries a tangible constructive mechanism for their consideration. The Model Law has been discussed at a number of Regional meetings such as

the Pacific Islands Regional Biosafety Workshop, 2001, Apia, Samoa Samoa and the Access & Benefit Sharing, Traditional Knowledge & Customary Law Workshop, Cairns, Australia, 21-24 November 2005. . The lead agency for the Model Law is the Secretariat of thetheSouth Pacific Regional Environmental Programme (SPREP). According to SPREP, the Model Law provides the sort of protection needed against appropriation of genetic resources and associated knowledge. What still needs to be done is to get regional endorsement in order to attract funding to help with national implementation of the Model Law.

This paper provides comment on the nature and scope of the Model Law as well as the rationale underlying some of the ML's features.

There are a number of complex issues that arise which the ML deals with summarily, such as the following:

- whether TBKIP can be owned;
- what happens where there are no known owners of TBKIP;
- what rights are granted to holders of TBKIP;
- what happens when there are two or more owners;
- how to deal with TBKIP in the so-called public domain;
- the rights of the State as compared to the rights of non-State owners of TBKIP;
- what happens when the ML conflicts with conventional intellectual property laws; and
- should the ML have extraterritorial effect.

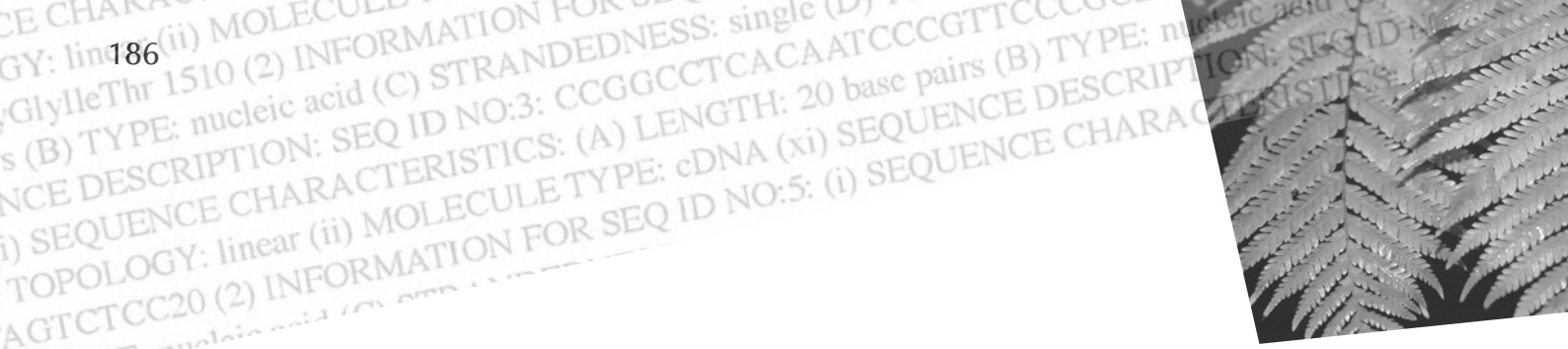
Such issues are currently being debated, and rather than enter into such debates, the ML has taken positions for which there was some support by PICs and which appeared to involve more work from a drafting perspective. This way, a PIC wishing to take a simpler position, from a drafting viewpoint, should more easily be able to modify the ML than if the situation were the other way around. In any event the ML as a non-binding instrument does not oblige any country to adopt it in whole or in part.

The last issue mentioned bullet-pointed above regarding conflict between the ML and existing IPRs can be dealt with by proposing detailed amendments to each of the various IPR laws in force in most countries: patent law, copyright, trademark, etc. Instead, the more economical solution was chosen of allowing the two regimes to co-exist side by side except where an inconsistency between the two arises, at which time the ML is to prevail to the extent of the inconsistency. This allows for the realisation of the benefits from the conventional system and the suppression of its less helpful aspects in favour of the ML.

The structure of the ML is to (i) define TBKIP (ii) assign rights (economic and moral) to it, and (iii) provide sanctions to deter infringement of these rights.

Additionally, the ML:

- provides a means to prevent the erosion and loss of TBKIP through the means of a database;
- allows owners to commercialise TBKIP if such is their desire;



- allows for regional cooperation;
- aligns itself with the Convention on Biological Diversity, using its language wherever possible and attempting the ambitious task of regulating the threefold grouping of knowledge, innovations and practices;
- aligns iteself to the "Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture".

As a concession to several PICs, some more extreme provisions in earlier drafts have been diluted, so that:

- the State is no longer bound by the ML, given that the ML charts new territory and the boundaries of State liability have yet to be delineated;
- There are no longer penalties of imprisonment for any of the offence provisions; they are all by way of monetary fines.
- The ML only has retrospective effect regarding moral rights, not economic rights. Economic activities in TBKIP which occurred prior to the ML entering into effect will therefore not be affected by the ML.
- Individuals per se may not "own" knowledge, innovations or practices, but can only do so on behalf of a social group.

The ML establishes the premise that all knowledge, innovations and practices are owned, hence foreclosing any argument that any of these elements may be ownerless. This makes it easier to design a system which can be enforced. Finally, the ML takes the character of a domestic law rather than a regional treaty which would entail much more work to conclude. The only indication of the ML's potential for extraterritorial effect is section 16 (reciprocal agreements).

## Features of The Model Law

The following section provides further explanation of the terms used in the Model Law and the intentions of specific Sections.

## Preamble

1. Article 8(j) of the Convention on Biological Diversity (CBD) uses the phrase "knowledge, innovations and practices" which is followed in this ML.

2. The ML encompasses not only knowledge, but products (ie, innovations) and practices, thus differing from Peru's recent law (2002) which focuses only on knowledge.

3. The term "biological" is used in preference to "ecological" which has a narrower meaning and has less usage in the provisions of the CBD.

## Section 4 Definitions

1. "Traditional biological innovation, means a product...". The focus of the ML is not only plants (eg, kava) but includes animals and microorganisms. The ML, which is partly inspired by the Third World Network's Community Intellectual Rights Act 1994 is therefore broader inasmuch as the focus of the latter is solely plant varieties.

2. The need for a generational time span has been dispensed with allowing recent yet still "traditional" knowledge, innovations or practices to be protected by the ML.

## Section 6 Ownership

3. A trust instrument will set out the terms of the trust: its purpose, holding and distribution of trust funds, rights of beneficiaries, duties of trustees etc. Trustee duties will include safeguarding the knowledge, innovations or practices by legal action where necessary. Most jurisdictions also have Trustees Acts which set out in detail the duties of trustees.

## Section 7 Database

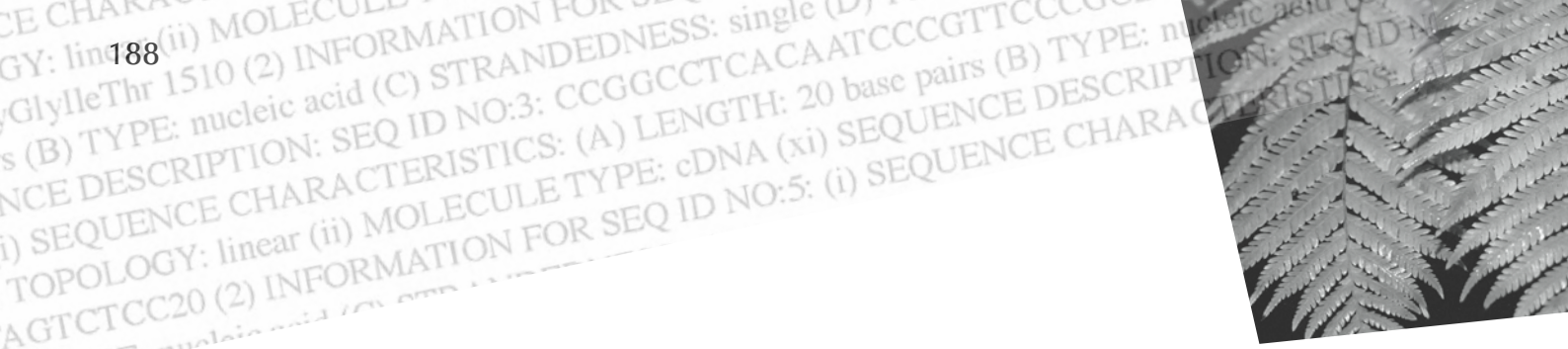
A database is used in preference to a register for these reasons:

- A register is formal. Owners who have reservations about disclosing their knowledge may be totally discouraged if there are too many requirements to be complied with. It may be that certain knowledge has become fragmented and different people will come forward with different pieces of the puzzle: a formal system may not cope well with such a piece-meal situation.
- A register is open. Owners may not wish to reveal their information but merely to record it for their descendants.
- A register imparts legitimacy. An adversarial ownership process at the outset will again discourage owners from coming forward with their information.

On the other hand, a database primarily records information and there is a great need to record as much traditional knowledge as quickly as possible before it become unobtainable. This means few formal requirements and an assurance of confidentiality. A detailed examination as to the veracity of ownership can be raised later but only when a challenge is brought or an enquiry by a prospective user made.

The urgent need to record the information it is felt overrides the possibility of a flood of spurious claims being made because of the initial lack of formal requirements. The task of sorting out the chaff from the wheat will be made later.

2. The offence provision is needed to deter individuals from bringing spurious or false claims.



## Section 8 Economic Rights

1. There are two economic rights. No definition of commercial purpose is attempted to keep that term as open as possible.

2. The exception in subsection (2) is made because plant genetic resources for food and agriculture are dealt with under a specific regime. Other exceptions may be added to this subsection in due course.

3. How effective is enforcement against an offender that resides or has fled overseas? Although subsection (4) is in the nature of a criminal sanction, extradition of the offender will not be possible unless:

- there exists an extradition treaty between the two countries involved;
- within the treaty the offence needs to be referred to either explicitly or by reference to length of imprisonment (eg, not less than 12 months) - usually only the more serious offences are covered;
- the offence needs to be recognised as such in both countries.

In some jurisdictions however, judgment can be given in the accused's absence (eg, Vanuatu: Criminal Procedure Code, sections 34-36 and 44; and Samoa: Criminal Procedure Act 1972, section 42) if the punishment is a fine only, or a period of imprisonment of not more than 3 months.

Although the threat of imprisonment has great deterrent value, this ML adopts the fine as the only sanction. A fine alone is more easily imposed by judges than a term of imprisonment. A fine against an overseas offender still represents a moral victory and has the added advantage that an offender that has repented can still return to the country, pay the fine and start afresh.

## Section 10 Identity Of Owner And Prior Informed Consent

1. This procedure needs to complied with even where prior informed consent has already been obtained.

2. Subsection (5) requires a 21 day wait in case a enquiry is brought in response to the publicised information.

## Section 11 Access And Benefit Sharing Agreement

Subsection (3) recognises that separate work may be in progress regarding knowledge or innovations or practices. A model law on access to genetic resources, (whether associated with traditional knowledge or not) has been drafted which details the procedures and requirements that need to be met by owners and users.

## Section 12 Ownership Enquiry

No time bar exists regarding the lodging of a challenge.

## Section 15 Legal Proceedings

Civil proceedings are always available in addition to criminal prosecutions. Some national laws make this explicit, eg, section 172 of Samoa's Criminal Procedure Act 1972 provides "No civil remedy for any act or omission shall be suspended by reason that such act or omission amounts to an offence".

The aim of civil proceedings might be to prevent continued non-compliance, to seek damages for wrongful use (conversion) of the knowledge, innovation or practice or alternatively to request that the monetary gain by the offender be surrendered to the owner (account of profits).

The owner would be expected to bring a civil action in contrast to the [Competent National Authority] which would be expected to initiate prosecutions.

## Conclusion

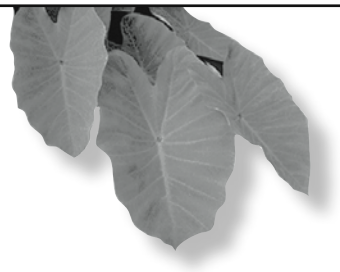
Some of the key issues that Pacific Island Countries have identified in relation to national adoption of the Model Law are:

1 Its relationship to access and benefit sharing issues.
2 Its relationship with existing (conventional) IPR laws.
3 How enforceable it would prove in practice.
4 How its implementation would be funded.
5 Which office shwould administer the ML.

Which office should administer the ML?

- a Department of Culture has expertise in traditional knowledge and may provide expert and impartial advice in ownership disputes;
- a Department of Environment has expertise on biological materials, Access and Benefit Sharing laws and the Convention on Biological Diversity;
    - a Department of Justice looks after intellectual property matters, has experience with registration procedures, and may facilitate dispute resolution through the Court system.

A further consideration is the inter-relationship between the Pacific Island Forum's initiative to establish a Pacific Regional Intellectual Property Office , and the progression of this Model Law.



# *VWEU I NAGOLUMUN RAHUANA* SAFEGUARDING GENETIC INHERITANCE - TURAGA EXPERIENCE

Chief Viraleo Boborenvanua and Motarilavoa Hilda Lini

## Turaga

TURAGA literally means everything that was created, including people, to co-exist and sustain all life forms in RAGA society. The island of VANUAROROA consists of three indigenous nations and cultural boundaries: TURAGA NATION situated in the north, LOLOVINI NATION in the central and WAWAN NATION in the southern part. TURAGA NATION is bound together by Raga language, culture, tradition and custom, and is inhabited by two distinct tribes, TABI and BULE, who by customary law, inter-marries. VANUAROROA is also known as Pentecost Island in the Republic of Vanuatu.

## Turaga Philosophy

Turaga indigenous philosophy is peaceful co-existence. The creation law and seven natural laws of the land regulate the indigenous concept of peaceful co-existence and interdependency. Peace is paramount and is collectively owned. It becomes the central focus to all conduct of activities. It encompasses the cultural, customary and traditional environment, under which the people have lived in harmony and survived over centuries as tribal communities. The laws regulate, supervise, protect, guide and monitor our spiritual, physical, cultural, customary and traditional ownership rights, inheritance and relationships.

## Turaga Ownership of Cultural and Genealogical Property and Knowledge

All cultural and genealogical property and knowledge from the past to present and all future intellectual inventions are owned by Bule and Tabi tribes of Turaga Nation. No one should use or transform any part without prior informed consent under Turaga customary law.

## Turaga's Response to Biotechnology and Globalisation

Having been asked to present Turaga Nation's Response to Biotechnology and Globalisation, our presentation is entitled: *Vweu i Nagolumun Rahuana*" *or* "Safeguarding Genetic Inheritance - Turaga Experience".

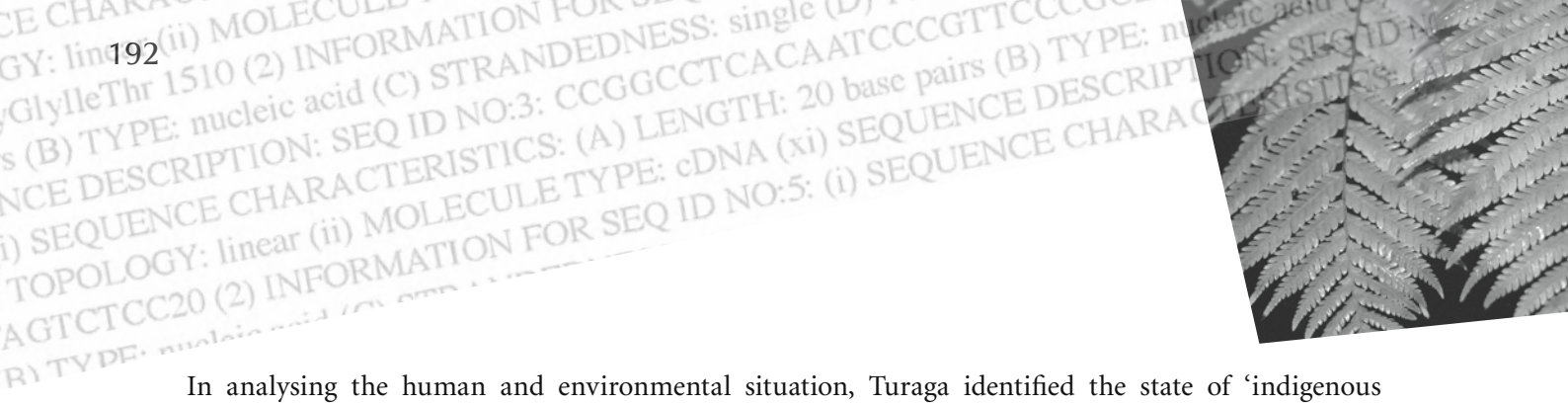
*Vweu i Nagolumun Rahuana* is the process of peaceful co-existence experienced in three stages according to the creation law. The first stage is the state of natural peace. This concept encompasses the process of spiritual interconnectedness to the universe, our indigenous origins, beliefs, land, language, genealogy, kinship and distinct cultures and the process of communication and relationship in its appropriate form with everyone and everything that share the same multi-dimensional natural world for inter-dependency.

Turaga, Tuvanuatu and Tutahituhida (Pacific) experienced the second stage of the process through the global colonisation process, during which, there had been so much interference to our natural peaceful environment, natural spirituality, natural belief system, natural state of mind, natural foods and medicines, natural immunities and natural genealogies, resulting in the creation of a new environment with new human species, us, whose behaviour is alien to the indigenous ways and protocols, communicating in foreign languages and lacking the interconnectedness and sense of belonging to the indigenous world.

Unfortunately many indigenous communities in Vanuatu, the Pacific and globally lost the holistic spiritual interconnectedness through the process of Christianisation, western system of education, western civilisation and cash economy.

The third stage is the process in which everyone is trying to find ways of restoring peaceful co-existence when there have been so many disturbances to peaceful coexistence or there is chaos and suffering. In trying to find solutions to stage two of the process, Turaga had to do a lot of our own research to rediscover the basic philosophy and spirituality that form the basis of life sustenance within our own mind set.

After 374 years of foreign influence and colonialism, Vanuatu regained her national independence, dignity, integrity and sovereignty in 1980 and declared its national development goal as "economic self reliance" with a stated message: "*This is only the beginning of our freedom as a nation. The next step is economic self-reliance and the road is even more difficult, but together we should try and achieve it within ten years*".



In analysing the human and environmental situation, Turaga identified the state of 'indigenous philosophical and spiritual poverty' as a major issue for Vanuatu indigenous peoples, tribal communities and indigenous governance. The need for decolonising ourselves became a reality.

Turaga indigenous nation, which played a major role in the independence struggle, immediately went into researching how we would use the indigenous community system of governance, social system, economic system, political systems and education system to contribute towards completing the process of decolonisation as well as strengthening the economic base for national sovereignty.

Turaga research on the economic production, barter and marketing began in 1963. By 1986 Turaga piloted the implementation of the system under Tanbunia Non Ratahigi (custom banking system). As it proved its appropriateness in the rural community, in 1996 Tanbunia opened a branch in the capital city Port Vila and piloted its external market and trade systems. By November 2000, Turaga officially launched Tanbunia as its coordinating arm of the economic and banking system. In June 2004 it became a completed system with the establishment of Tanmarahi, the chiefs' reserve system of indigenous currencies.

Research into Turaga indigenous education system began in 1977 and by 1993 study of script writing was completed and launched. The Melanesian Institute of Philosophy and Technology was officially opened by the Minister of Culture in 1997 as a coordinating centre for all indigenous knowledge transfer.

Research into the governance system, leadership structure, administration and authority began in 1970 and by 1994 Turaga formally re-enforced its decision making body in a sacred ceremony known as *Galo La Bwatiele*. The decision making process was allocated to 60 high ranking tribal community chiefs who were/are accountable to 10 paramount chiefs. The administrative leadership and responsibilities were allocated to two high ranking chiefs known as *Guingatanleontagaro* who were/are accountable to the decision makers. With Turaga's long term commitment and practice of the indigenous governance system, by 2004 Turaga and Lolovini indigenous nations launched the chiefs' administrative payroll for all community members.

## Major Turaga Programmes

Turaga first major programme was and continues to be large scale food production to provide natural immunity as well as sustaining food security. In was launched in 1960s after the return of plantation workers and their experiences in foreign foods replacing indigenous foods and vital elements to body building and natural immunity. Food supply is administered through the tribal economic system of land use and benefits by clan members.

The second major programme was the philosophical and spiritual force behind the liberation movement launched in 1970 and continued until Vanuatu regained its political independence in 1980. The major aim was to regain indigenous identity through land ownership and make laws to protect the interest of Vanuatu.

The third major programme is the economic self reliance programme, declared in 1980. Under this programme the Tanbunia indigenous bank was launched in 1983. By 1993 Turaga had recovered its indigenous script writing and all records were written in script writing.

Realising that after fourteen years the national government through its inherited colonial governance, laws, education and economic systems had neither mobilised the indigenous community institutions for economic self reliance nor included economic self reliance in education and training curriculum, in 1994 Turaga launched its 5 year Economic and Sustainable Development Programme in a sacred indigenous ceremony known as '*Galo La Bwatiele*'.

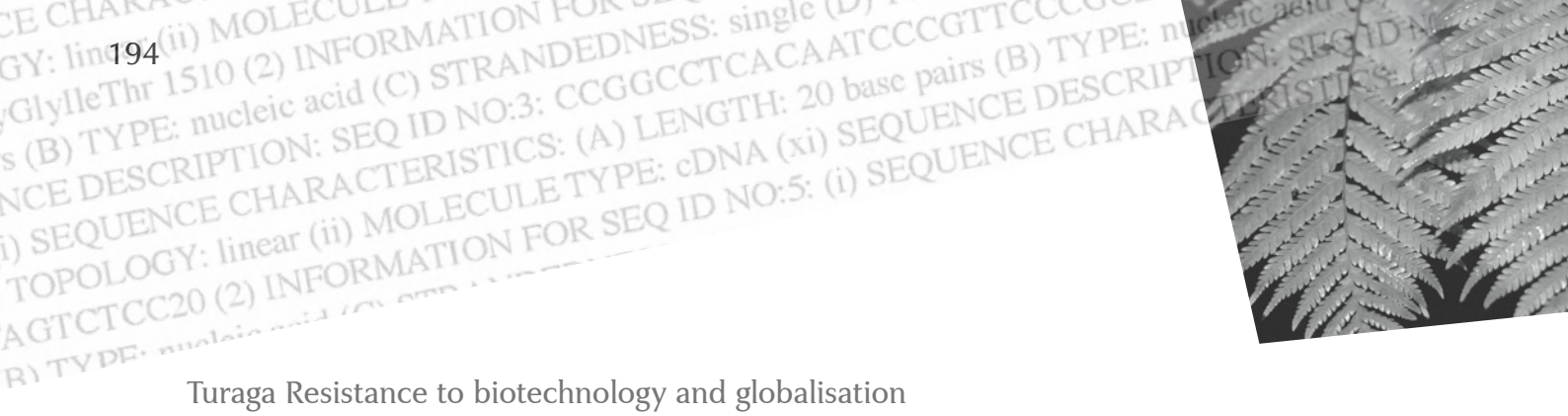
This is an intensive programme that would determine the future direction of Turaga Nation. Firstly it was realised that to take ownership of our genealogical identity, use of our land for economic self reliance and sovereignty, we must:

- Operate within our own Philosophy of Life
- Have clear Vision
- Community Sense of Ownership and Belonging
- Community governance, authority, administration and leadership
- Community owned school to teach our own Philosophy, vision and development concepts in our own language
- Clear Economic Development Strategies
- Community Labour Force
- Build relationships with indigenous nations in Vanuatu and globally to establish genuine global indigenous ownership of genealogies.

## Turaga Achievements

Turaga achievements have been in awareness raising, strengthening the indigenous leadership structure and authority of society and the mobilization for change through the Turaga Development Model. The model has been presented at provincial level, national level and internationally. There are now coordinated activities in 250 communities with over 2000 community members on the monthly payroll, three bank branches established, over 1000 depositories into the chiefly reserve of indigenous currencies, over 2000 community members on the payroll, organized trading of community products locally, nationally and internationally, production of own lighting fuel, strengthening the coordination of Tansip herbal medicine village, the banning of processed food, foreign methods of cooking, vaccination and modern medicine.

At national level Turaga indigenous models have generated discussions on the review of the national constitution, the electoral system, the parliamentary system, the governance and decentralisation structure, the Land Tribunal Act, the introduction of mother tongue in the education system, the use of indigenous currencies in mainstream economy etc. Progress on Turaga coordinated activities is attached for your information.



## Turaga Resistance to biotechnology and globalisation

In 1993, Turaga banned all immunisation of children. This was followed by the banning of retail shops, processed food, matches, foreign cooking methods, foreign fuel for lighting, all modern medicines including adult vaccinations. It promotes speaking in mother tongue, script writing, indigenous arts, dances, traditional musical instruments and traditional costumes when attending high-level meetings.

Lavatmagemu Declaration which is the outcome of the Turaga and Tuvanuatu preparatory Dialogue towards the 2005 4th Session of the United Nations Permanent Forum on Indigenous Issues, also calls for community resistance to the recent EU funded agro-biotechnological study of 10 indigenous root crops and the biodiversity study on the largest island Santo, by a large team of international scientists. Turaga nation is a signatory to the petition opposing the modified genome project. This is to ensure that there is respect of the integrity to natural generational species according to the creation law, natural laws and protocols, therefore not disturbing the spirit of peace within an individual, family, tribe, community and the entire biological world.

Turaga Philosophy under Creation Law is implemented under the following guidelines:

## Turaga Development Vision

Turaga development vision is based on the indigenous philosophy of life that respects peaceful co-existence as paramount in life. There is natural obligation to take collective ownership, responsibility and accountability to peace. This is the way of life, which is still practiced in genuine indigenous communities of Vanuatu and has proved to be more organized, disciplined and civilized.

## Turaga Development Goal

Turaga development goal is to maintain food security, economic self-sufficiency and sustainable peace at family, community and national levels. It became obvious that Turaga philosophy and vision must be taught in indigenous institutions and mother tongue for effective transfer of knowledge.

## Turaga Governance

Turaga governance system consist of Sarabalaleo, the highest decision making body, Tarigogobwatiele the overall administrative arm and nakamal system of community owned governance.

## Turaga Administration

Turaga Nation administrative headquarter coordinates all administrative requirements including the Sarabalaleo (indigenous system of parliament and the Tarigogo Bwatiele (indigenous system of community government, authority and leadership).

## Turaga Finance

Turaga economic arm is administered under Ginau Gan Tamaragai i Ratahigi (chiefs basket of food, land resources and food products) which form the basis for Tanbunia indigenous bank and the Tanmarahi chiefly reserve of indigenous currencies.

## Turaga Knowledge Coordination

TURAGA indigenous nation recognises indigenous education as its priority programme in order to assist everyone to feel secure on our land, in our families, clans, tribes, villages, towns, nations and on this planet. The Melanesian Institute of Philosophy and Technology is responsible for coordinating all research, nurturing and knowledge transfer on Turaga Philosophy at all the six levels of the indigenous education system, ensuring that everyone respect peace in the words that are spoken, the actions taken and the attitudes portrayed. It teaches 50 study areas including creation stories, creation law, natural laws, indigenous concept of spirituality, value systems, governance, clan and tribal identity and administration.

## Turaga Future Development Outlook

Turaga future development outlook is to continue empowering the people to take control of their own lives so that they can determine their own social, economic and political status. Continue with meaningful schemes that complement cultural values and raise standard of livelihood without having to alienate people from their cultural environment are encouraged. Maintain first education within family homes and in community nakamals in order to build up skilled human resources for sustainable livelihood, produce sufficient food for communal needs and contribute to government annual revenue, therefore assisting people to be self reliant in sustaining Vanuatu's national sovereignty.

We are confident to continue taking ownership and control of our indigenous cultural genealogies and knowledge. We believe that each and every one of us are capable of developing our own development strategies and at the same time resist biotechnology and globalisation.

*Note from the Editors: Since this paper was written, the Turaga nation opened their fourth branch of the Tanbunia Kastom Bank with a custom capital value of 2.1 million vatu. In his opening address, the Founder and President of the Tanbunia abnking system, Chief Viraleo Bobrenvanu, encouraged the setting up of more branches in line with the indigenous method of the economy to maintain peace and harmony in the communities and contribute towards the country's second goal whichis economic self-reliance.*

# SECTION TWO

## PACIFIC INSTRUMENTS RELATING TO GENES AND GENE PATENTS

# The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples (1993)

First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples, Whakatane 12-18 June 1983 Aotearoa New Zealand. In recognition that 1993 is the United Nations International Year for the World's Indigenous Peoples: The Nine Tribes of Mataatua in the Bay of Plenty region of Aotearoa New Zealand convened the First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples, (12-18 June 1993, Whakatane).

Over 150 delegates from fourteen countries attended, including indigenous representatives from Ainu (Japan), Australia, Cook Islands, Fiji, India, Panama, Peru, Philippines, Surinam, USA and Aotearoa.

The Conference met over six days to consider a range of significant issues, including; the value of indigenous knowledge, biodiversity and biotechnology, customary environmental management, arts, music, language and other physical and spiritual cultural forms. On the final day, the following Declaration was passed by the Plenary.

## Preamble

Recognising that 1993 is the United Nations International Year for the World's Indigenous Peoples:

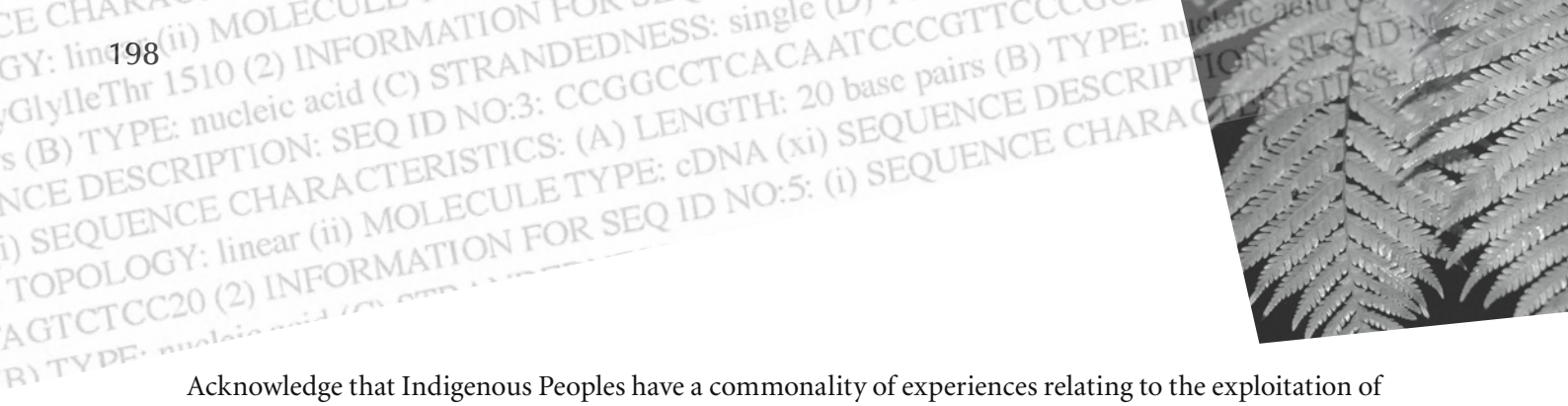
Reaffirming the undertaking of United Nations Member States to:
"Adopt or strengthen appropriate policies and/or legal instruments that will protect indigenous intellectual and cultural property and the right to preserve customary and administrative systems and practices." - United Nations Conference on Environmental Development: UNCED Agenda 21 (26.4b)

Noting the Working Principles that emerged from the United Nations Technical Conference on Indigenous Peoples and the Environment in Santiago, Chile from 18-22 May 1992 (E/CN.4/Sub.2/1992/31)

Endorsing the recommendations on Culture and Science from the World Conference on Indigenous Peoples on Territory, Environment and Development, Kari-Oca, Brazil, 25-30 May 1992.

## We:

Declare that Indigenous Peoples of the world have the right to self determination, and in exercising that right must be recognised as the exclusive owners of their culture and intellectual property;



Acknowledge that Indigenous Peoples have a commonality of experiences relating to the exploitation of their cultural and intellectual property;

Affirm that the knowledge of the Indigenous Peoples of the world is of benefit to all humanity;

Recognise that Indigenous Peoples are capable of managing their traditional knowledge themselves, but are willing to offer it to all humanity provided their fundamental rights to define and control this knowledge are protected by the international community;

Insist that the first beneficiaries of indigenous knowledge (culture and intellectual property rights) must be the direct indigenous descendants of such knowledge;

Declare that all forms of discrimination and exploitation of Indigenous Peoples, indigenous knowledge and indigenous cultural and intellectual property rights must cease.

## 1. Recommendations to Indigenous Peoples

In the development of policies and practices, Indigenous Peoples should:

1.1 Define for themselves their own intellectual and cultural property.

1.2 Note that existing protection mechanisms are insufficient for the protection of Indigenous Peoples' Intellectual and Cultural Property Rights.

1.3 Develop a code of ethics which external users must observe when recording (visual, audio, written) their traditional and customary knowledge.

1.4 Prioritise the establishment of indigenous education, research and training centres to promote their knowledge of customary environmental and cultural practices.

1.5 Reacquire traditional indigenous lands for the purpose of promoting customary agricultural production.

1.6 Develop and maintain their traditional practices and sanctions for the protection, preservation and revitalisation of their traditional intellectual and cultural properties.

1.7 Assess existing legislation with respect to the protection of antiquities.

1.8 Establish an appropriate body with appropriate mechanisms to:

1. preserve and monitor the commercialism or otherwise of indigenous cultural properties in the public domain
2. generally advise and encourage indigenous peoples to take steps to protect their cultural heritage
3. allow a mandatory consultative process with respect to any new legislation affecting Indigenous Peoples Cultural and Intellectual Property Rights.

1.9 Establish international indigenous information centres and networks.

1.10 Convene a Second International Conference (Hui) on the Cultural and Intellectual Property Rights of Indigenous Peoples to be hosted by the Co-ordinating Body for the Indigenous Peoples Organisations of the Amazon Basin (COICA).

## 2. Recommendations to States, National and International Agencies

In the development of policies and practices, States, National and International Agencies must:

2.1 Recognise that indigenous peoples are the guardians of their customary knowledge and have the right to protect and control dissemination of that knowledge.

2.2 Recognise that indigenous peoples also have the right to create new knowledge based on cultural traditions.

2.3 Note that existing protection mechanisms are insufficient for the protection of Indigenous Peoples Cultural and Intellectual Property Rights.

2.4 Accept that the cultural and intellectual property rights of Indigenous Peoples are vested with those who created them.

2.5 Develop in full co-operation with Indigenous Peoples an additional cultural and intellectual property rights regime incorporating the following: collective (as well as individual) ownership and origin retroactive coverage of historical as well as contemporary works protection against debasement of culturally significant items co-operative rather than competitive framework first beneficiaries to be the direct descendants of the traditional guardians of that knowledge multi-generational coverage span.

Biodiversity and customary environmental management

2.6 Indigenous flora and fauna is inextricably bound to the territories of indigenous communities and any property right claims must recognise their traditional guardianship.

2.7 Commercialisation of any traditional plants and medicines of Indigenous Peoples, must be managed by the Indigenous Peoples who have inherited such knowledge.

2.8 A moratorium on any further commercialisation of indigenous medicinal plants and human genetic materials must be declared until indigenous communities have developed appropriate protection mechanisms.

2.9 Companies, institutions both governmental and private must not undertake experiments or commercialisation of any biogenetic resources without the consent of the appropriate indigenous peoples.

2.10 Prioritise settlement of any outstanding land and natural resources claims of indigenous peoples for the purpose of promoting customary, agricultural and marine production.

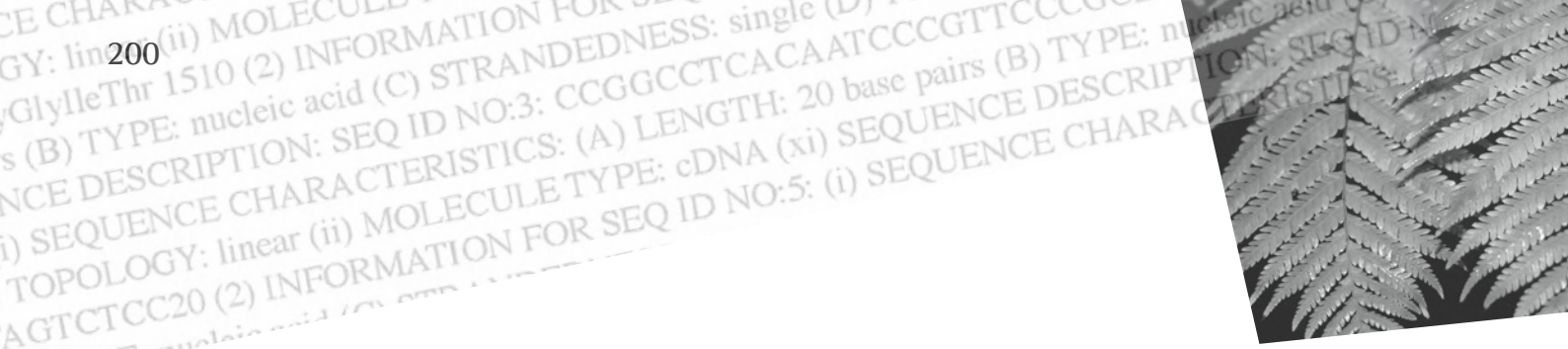
2.11 Ensure current scientific environmental research is strengthened by increasing the involvement of indigenous communities and of customary environmental knowledge.

Cultural Objects

2.12 All human remains and burial objects of Indigenous Peoples held by museums and other institutions must be returned to their traditional areas in a culturally appropriate manner.

2.13 Museums and other institutions must provide, to the country and Indigenous Peoples concerned, an inventory of any indigenous cultural objects still held in their possession.

2.14 Indigenous cultural objects held in museums and other institutions must be offered back to their traditional owners.



## 3. Recommendations to the United Nations

In respect for the rights of Indigenous Peoples, the United Nations should:

3.1 Ensure the process of participation of Indigenous Peoples in United Nations fora is strengthened so their views are fairly represented.

3.2 Incorporate the Mataatua Declaration in its entirety in the United Nations Study on Cultural and Intellectual Property of Indigenous Peoples.

3.3 Monitor and take action against any States whose persistent policies and activities damage the cultural and intellectual property rights of Indigenous Peoples.

3.4 Ensure that indigenous peoples actively contribute to the way in which indigenous cultures are incorporated into the 1995 United Nations International Year of Culture.

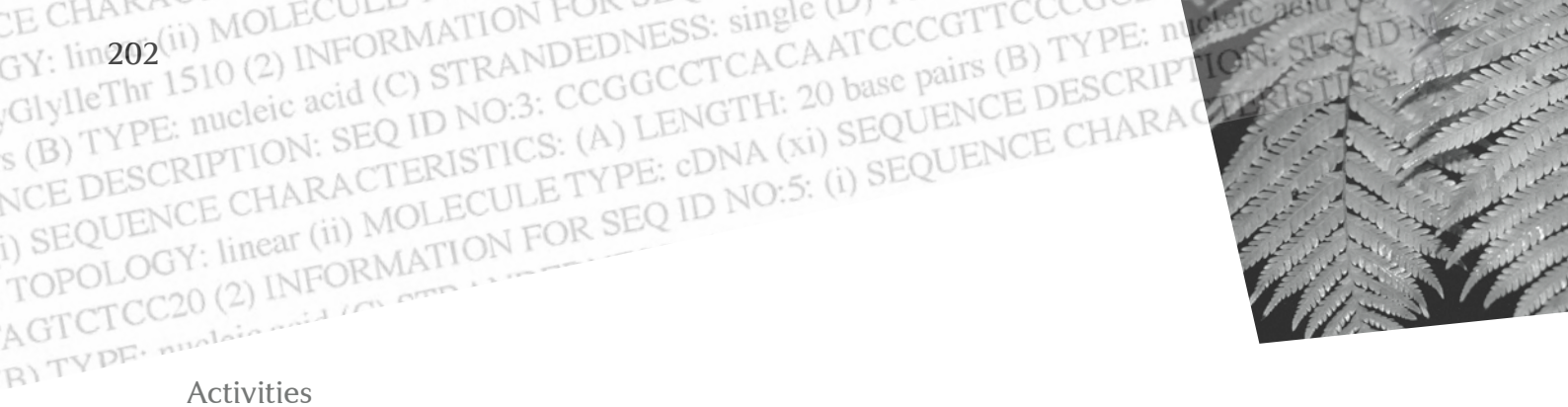
3.5 Call for an immediate halt to the on-going 'Human Genome Diversity Project' (HUGO) until its moral, ethical, socio-economic, physical and political implications have been thoroughly discussed, understood and approved by Indigenous Peoples.

## 4. Conclusion

4.1 The United Nations, International and National Agencies and States must provide additional funding to indigenous communities in order to implement these recomendations.

# Treaty For A Lifeforms Patent-Free Pacific And Related Protocols (1995)

CONTENTS



## Activities

In their continuing quest to locate new resources as well as new sources of knowledge for commercial exploitation, companies (and some governments) have established footholds in the sparsely populated, isolated and vulnerable communities of the Pacific.

The region is being exploited in ways which profoundly affect its indigenous peoples who, because they are largely unaware of the nature and extent of the exploitation, have become unwitting parties to its perpetration.

The range of activities is diverse and is being carried out by researchers and scientists from both the private and public sectors. One activity involves attempts by pharmaceutical companies to develop new medicines based on indigenous customary healing practices and indigenous flora and fauna. The medicines are derived from plants and animals or microbes found in the soil and in the ocean.

Indigenous peoples know which plants to use in order to treat certain ailments. Pharmaceutical companies need such information so they can isolate useful substances from those plants in order to produce drugs. The people they employ to identify and procure plant samples are known as biological prospectors. Biological prospectors have been, or are still, active in Western Samoa, New Caledonia, Vanuatu and Fiji to name a few island nations. If something useful is obtained (a gene, a process, or a chemical) the company will patent it. A patent gives the company exclusive ownership over the material for a stipulated number of years.

Another particularly disturbing activity involves collection of human tissue samples - blood, hair, saliva - from indigenous peoples. Samples have already been taken from indigenous groups in Papua New Guinea and the Solomon Islands. The samples are collected and stored in national and international "gene banks" and immortalised or reproduced artificially in the hope that genes may be found with properties resistant to certain diseases. If such genes are found they will almost certainly be patented and become the property of the patent-holder. Even the person from whom the gene was obtained will be unable to claim ownership over it.

## Exploitation

These two activities are recent examples of economic exploitation of indigenous peoples. Pacific islands are notable for their lack of natural resources. However, because of their tropical location they are blessed with a multitude of species, especially plants and marine life - much more than in colder climates where the major pharmaceutical companies are based. Serious consideration must be given to this abundance of biological diversity as a major revenue earner for island economies. Pacific island peoples will have no chance of fully sharing in the benefits of their knowledge or biological diversity unless they realise what is happening.

In the case of human genetic research the exploitation is more reprehensible because it deals with the private ownership of inherited human characteristics. If current trends are not reversed it will become

common for human cells, and the living material that determines human life itself, to become private property and even traded like any other commodity.

## Treaty Law

A meeting on "Indigenous Peoples and Intellectual Property Rights" held in Fiji in April 1995, mandated the establishment of this Treaty and its Protocols.

Treaties are usually agreements made between governments and often create or modify international law in regard to some matter. This Treaty is not an agreement between governments. It is an agreement between the Parties as defined in the Treaty. The Treaty does not create or modify international law, it merely creates rights and obligations between the Parties to it.

Parties to the Treaty and Protocols bind themselves to the obligations contained in these documents. Compliance is entirely voluntary. They obey out of a moral conviction that what they are doing is right and out of a sense of solidarity created whenever groups or communities unite on an issue.

A list of the Parties will be available from the Depositary.

To simplify formalities no ratification is required, nor is there any opportunity given for the making of reservations. There is no provision for meetings of the Parties. Limited secretarial functions will be handled by the Depositary in addition to its normal functions.

## Future Action

This Treaty is symbolic. It expresses the dismay and anger of the Parties regarding biological prospecting and human genetic research. It is hoped that in due time governments will recognise the nature and urgency of the problems expressed and have the courage to tackle these head on. Whether or not this happens the Parties will continue to fulfil their commitments, sharing and exchanging information and assisting in establishing a regulatory regime for the Pacific.

TREATY FOR A LIFEFORMS PATENT-FREE PACIFIC

- The Parties, Believing in the sanctity and integrity of life even in its smallest form;
- Aware that prospecting for biological materials is occurring throughout the Pacific;
- Aware that collection and research into human genetic materials of Pacific indigenous peoples is occurring;

Aware also that patents are being granted on living organisms including microbial, plant, animal and human genetic material;

Gravely concerned that these activities are occurring in a policy vacuum and without the full knowledge or consent of those affected;

Affronted by the use of intellectual property rights systems and western science and technology to control and exploit the lands, territories, resources and integrity of indigenous peoples;

Concerned that the heritage of future descendants will be diminished through the commercialisation of the biological resources of the Pacific;

Convinced that immediate and united action must be taken;

Have agreed as follows:

## Article 1 Objective

The over-all objective of this Treaty and its Protocols is to establish the Pacific as a lifeforms patent-free zone by way of regional agreements and national laws.

## Article 2 Definitions

For the purposes of this Treaty and its Protocols:

(a) "Associate" means a Group from outside the Pacific which has signed this Treaty and one or all of its Protocols with the genuine intention of carrying out the obligations contained in those documents. It is subject to an Associate's fee and shall not have the right to directly propose amendments, to object or to vote but shall possess all other rights and obligations of a Party. Subject to these qualifications, all references to a Party, except in paragraph (f) following, shall include an Associate.

(a) "Gene" means a unit of heredity in the chromosome controlling a particular inherited characteristic of an individual.

(b) "Group" means an organised body of people having charge over its own affairs and a structure of leadership, which is constituted according to law or custom and which has a commitment to the advancement of indigenous peoples. It includes, but is not limited to, governments, non-governmental organisations and village communities.

(c) "Lifeform" means any living thing or any part thereof or any product or process derived from such a thing.

(d) "Pacific" means the following countries of the Pacific Ocean and includes their marine jurisdictions: American Samoa, Australia, Cook Islands, Federated States of Micronesia, Fiji, French Polynesia, Guam, Hawaii, Kiribati, Marshall Islands, Nauru, New Caledonia, New Zealand, Niue, Northern Mariana Islands, Palau, Papua New Guinea, Pitcairn Islands, Solomon Islands, Tokelau, Tonga, Tuvalu, Vanuatu, Wallis and Futuna, West Irian, and Western Samoa.

(e) "Party" means a Group from within the Pacific which has signed this Treaty and one or all of its Protocols with the genuine intention of carrying out the obligations contained in those documents.

(f) "Patent" means the grant of an exclusive right to exploit an invention.

## Article 3 Principles

The following principles underlie the Treaty and its Protocols:

(g) All human beings are born equal in dignity and rights.

(h) The quality of life is based on the development of human relationships, spiritual fulfilment, and reverence for life and the natural world.

(i) Commitment to the quality of life of future generations is fundamental to the world view of the indigenous peoples of the Pacific.

(j) Scientific and commercial advances should not be allowed to proceed past the deliberations necessary to provide for their social, moral and ethical control.

(k) Indigenous peoples should be respected and valued for their identity as distinct peoples.

(l) No person should be subject to medical or scientific experimentation without that person's prior informed consent freely given;

(m) All lifeforms should be treated in a way that respects their intrinsic value as living generational manifestations of creation.

(n) The conversion of lifeforms, their molecules or parts, into corporate property through patent monopolies is counter-productive to the interests of the peoples of the Pacific;

(o) National laws and provisions in international agreements which encourage and facilitate the patenting of lifeforms - such as the Trade Related Aspects of Intellectual Property Rights of the General Agreement on Trade and Tariffs - should be repealed.

(p) Indigenous peoples are the guardians of their heritage and have the right to protect and control dissemination of that heritage.

(q) All forms of the heritage of the indigenous peoples of the Pacific, that have been or will be taken without their full and informed consent, should be returned or joint mechanisms established to ensure the equitable sharing of any benefits.

## Article 4 Commitments

In relation to this Treaty and its Protocols, each Party undertakes:

(r) to carry out in good faith and in as practical a manner as possible the commitments contained in the documents to which it is a Party;

(s) to inform its community of the issues and dangers raised by life-patenting, biological prospecting and human genetic research;

(t) to lobby its government and multilateral bodies to oppose patenting of lifeforms endorsed in national legislation and regional and international agreements; or, where the Party is a government, to press for the repeal of such laws or introduce laws opposing patenting of lifeforms;

(u) to exchange information on biological prospecting and human genetic research;

(v) to work together with other Parties on projects to further the objective of this Treaty;

(w) at least every 6 months, to convey to the Depositary information on the measures adopted by it in the implementation of this Treaty and of the Protocols to which it is a Party;

(x) to maintain consultation with other Parties with the object of giving effect to the provisions of this Treaty and its Protocols;

(y) to support the right to self-determination of the indigenous peoples of the Pacific.

## Article 5 Reservations

No reservations or exceptions may be made to this Treaty or its Protocols.

## Article 6 Date to Take Effect

(z) This Treaty shall take effect on the date the third copy to be signed has been deposited with the Depositary.

(aa) Any Protocol to this Treaty shall take effect on the date the second copy of such Protocol to be signed has been deposited with the Depositary.

## Article 7 Relationship Between the Treaty and its Protocols

(bb) The Treaty provides a framework agreement for the objective of establishing the Pacific as a lifeforms patent-free zone. Protocols provide more specific obligations for carrying out that objective.

(cc) No Group may become a Party to this Treaty unless it becomes at the same time a Party to one or more Protocols. No Group may become a Party to a Protocol unless it is, or becomes at the same time, a Party to this Treaty.

## Article 8 Amendment of the Treaty and its Protocols

(dd) Any Party may propose to the Depositary amendments to this Treaty.

(ee) Any Party to a Protocol may propose to the Depositary amendments to that Protocol.

(ff) Annexes and Protocols may be added by way of amendment.

(gg) A proposed amendment to the Treaty or a Protocol shall be communicated to the Depositary, which shall promptly transmit such proposal for consideration to all other Parties.

(hh) If, within a period of 4 months from the date of the circulation of the communication, objections are received from one third of the Parties, the amendment shall be considered rejected. The Depositary shall immediately notify all Parties accordingly.

(ii) If, 4 months from the date of the circulation of the communication, less than one third of the Parties have objected to the proposed amendment, it shall be considered adopted. The Depositary shall notify all Parties accordingly.

## Article 9 Status of Annexes

In the event that Annexes are added to this Treaty or to its Protocols they shall form an integral part of the Treaty and its Protocols, and unless expressly provided otherwise, a reference to this Treaty or its Protocols includes a reference to any Annexes relating thereto.

## Article 10 Settlement of Disputes

In the case of a dispute between the Parties as to the interpretation or implementation of this Treaty or its Protocols, they shall seek a settlement of the dispute through negotiation or any other peaceful means of their own choice. Failing this, the dispute shall be referred to the Depositary for a final ruling.

## Article 11 Withdrawal

(a) A Party may withdraw from this Treaty or a Protocol by written notification to the Depositary at any time after 1 year from the date the Treaty or the Protocol, as the case may be, came into effect. The withdrawal shall take effect 3 months after the date of its receipt by the Depositary.
(b) Any Party which withdraws from this Treaty shall be considered as having withdrawn from any Protocol to which it is a Party.

## Article 12 Termination

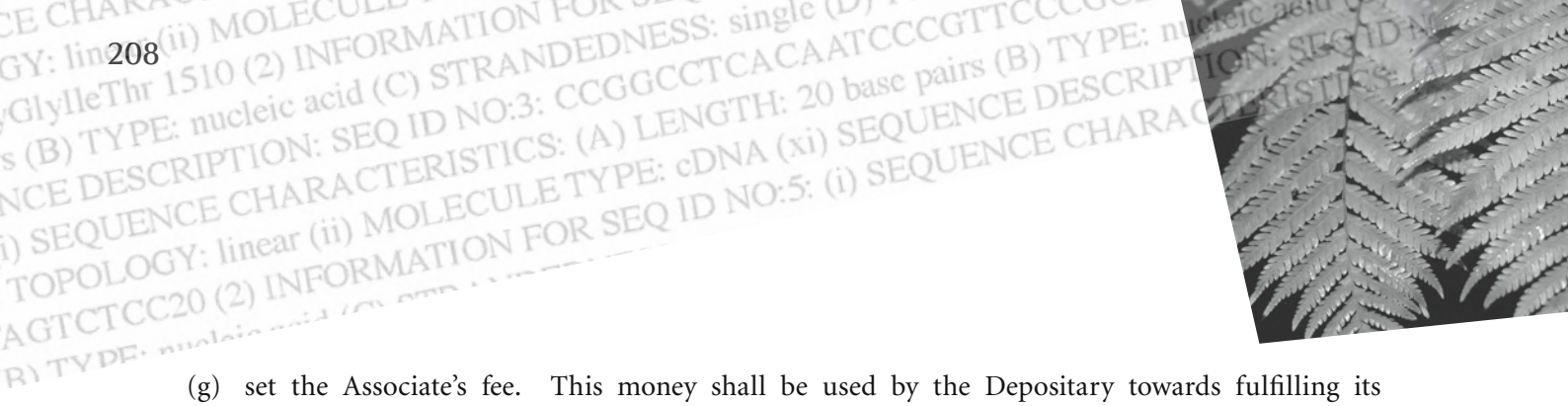
(a) This Treaty shall continue in force indefinitely unless terminated by a two-thirds vote of the Parties to it.
(b) Any Protocol under this Treaty shall continue in force indefinitely unless terminated by a two-thirds majority vote of the Parties to it.
(c) Termination of the Treaty automatically terminates all Protocols.

## Article 13 Appointment of Depositary

The Depositary for the Treaty and Protocols shall be publicised prior to the 1st of December 1995.

## Article 14 Responsibilities Of Depositary

The Depositary shall:
(a) distribute to Parties a list of Parties to the Treaty and its Protocols and shall inform them of any amendments to the Treaty or its Protocols;
(b) perform in as practical a manner as possible the tasks assigned to it by this Treaty and its Protocols;
(c) transmit to the Parties notifications, reports and other information received in accordance with this Treaty or its Protocols;
(d) consider enquires by, and information from, the Parties and consult with them on questions relating to this Treaty or its Protocols;
(e) establish, maintain and issue to the Parties from time to time, a register of individuals, companies or other bodies known to be involved in biological prospecting or human genetic research in the Pacific;
(f) report to all Parties on issues of a general nature that have arisen with respect to this Treaty or its Protocols;



(g) set the Associate's fee. This money shall be used by the Depositary towards fulfilling its responsibilities under this Article.

## Article 15 Text

The original text of this Treaty and Protocols is English.

To the Depositary:

I/we, .....
[signature(s) and position(s)]
.....

representing .....[
name of Group]

commit my/our Group to this Treaty.

Date:

Phone:

Fax:

E-mail:

Postal Address:

PROTOCOL CONCERNING BIOLOGICAL PROSPECTING IN THE PACIFIC

*The Parties to the Protocol,*

*Being Parties* to the Treaty for a Lifeforms Patent-free Pacific;

*Recognising* that the Pacific holds a significant proportion of the world's indigenous cultures, languages and biological diversity;

*Recognising* the growing value to industry of Pacific peoples' traditional knowledge;

*Condemning* attempts to undervalue the traditional science and knowledge of indigenous peoples;

*Condemning* those who use the biological diversity of indigenous peoples for commercial and other purposes without their full knowledge and consent;

*Declaring* the willingness of indigenous peoples to share their knowledge with humanity provided they determine when, where and how it is used;

*Have agreed as follows:*

## Article 1 Objective

Parties to this Protocol shall co-operate nationally and regionally to monitor, publicise and control biological prospecting in the Pacific.

## Article 2 Definitions

For the purposes of this Treaty and its Protocols:

(jj) "Biological prospecting" means the research, collection and utilisation of biological and genetic resources, and knowledge about them, for scientific or commercial purposes or both.

(kk) "Ex situ conservation" means off-site conservation or the conservation of components of biological diversity outside their natural habitats, such as in gene banks or botanical gardens.

(ll) "In situ conservation" means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, the surroundings where they have developed their distinctive properties.

## Article 3 Principles

(a) Indigenous peoples own their traditional medicines and health practices and have a right to the protection of vital medicinal plants, animals and minerals and knowledge pertaining to them.

(b) No biological resources, or knowledge about them, should be taken from Pacific peoples without the prior informed consent of the owners, possessors or guardians of such resources or knowledge.
(c) Respect for indigenous knowledge, cultures and traditional practices should be encouraged and supported and indigenous peoples assisted in contributing to sustainable and equitable development and proper management of the environment.
(d) In-situ conservation by indigenous peoples should be encouraged and supported as the best method to conserve and protect biological diversity and indigenous peoples' knowledge about biological diversity.
(e) Patenting should not be allowed on any living thing or product derived from it. This is without prejudice to the rights of indigenous peoples, traditional farmers and traditional fishermen to maintain exclusive control over, access to, and use of knowledge, innovations, cultural traditions, and management practices concerning biological diversity and their right to just compensation for sharing any of these.
(f) Indigenous peoples should have returned to them cultural, intellectual, religious and spiritual property taken without their free and informed consent or in violation of their laws, traditions and customs and are entitled to compensation and royalties from commercial developments resulting from these.

## Article 4 Moratorium

(a) The Parties declare a moratorium on biological prospecting in the Pacific and urge indigenous peoples not to co-operate in biological prospecting activities until appropriate protection mechanisms are in place.
(b) The collection by biological prospectors of any form of the biological resources - animal, plant or microbial - of the Pacific is prohibited until such mechanisms are in place.

## Article 5 Leadership

Chiefs, elders and community leaders should play leadership roles in protecting indigenous peoples' knowledge and resources and in enforcing the moratorium.

## Article 6 Legislation

Each Party shall lobby its government as well as regional and multilateral bodies to enact appropriate legislation or enter into a regional agreement to control biological prospecting. Where the Party is a government, it shall work towards introducing appropriate national legislation as well as work towards a regional agreement for the foregoing purpose.

## Article 7 Rationalisation of Efforts

Parties shall maintain contact with one another and exchange information in order to allow the Depositary to compile a database regarding biological prospecting in the Pacific and in order that their efforts in dealing with this activity can be streamlined and harmonised.

## Article 8 Relationship Between this Protocol and the Treaty

The provisions of the Treaty relating to any protocol shall apply with respect to the present Protocol.

To the Depositary:

I/we, .....

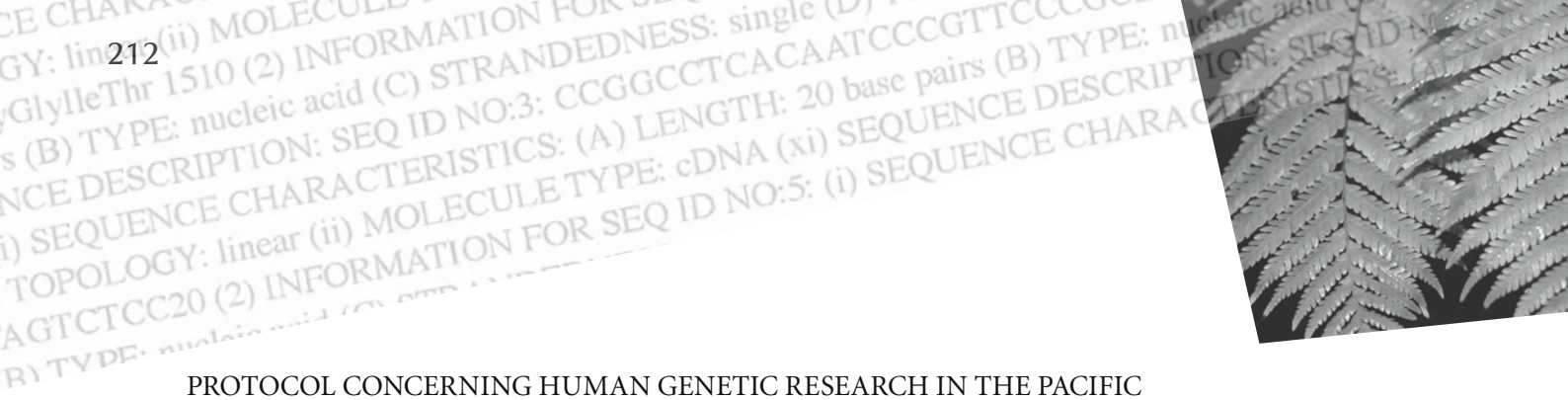
[signature(s) and position(s)]

.....

representing .....

[name of Group]

commit my/our Group to this Treaty.



PROTOCOL CONCERNING HUMAN GENETIC RESEARCH IN THE PACIFIC

*The Parties to the Protocol,*

*Being Parties* to the Treaty for a Lifeforms Patent-free Pacific;

*Recognising* that indigenous peoples exist as unique and distinct peoples irrespective of any differences in political status;

*Acknowledging* the inter-generational responsibility of indigenous peoples to protect the integrity of their heritage and genealogy;

*Asserting* the inherent right of indigenous peoples to define who they are and their disapproval of any other definition;

*Have agreed as follows:*

## Article 1 Objective

Parties to this Protocol shall co-operate nationally and regionally to monitor, publicise and control human genetic research in the Pacific.

## Article 2 Integrity

The Parties oppose any action which has the aim or effect of depriving indigenous peoples of their integrity as distinct peoples.

## Article 3 Human Genome Diversity Project

Indigenous peoples of the Pacific do not support the objectives of the Human Genome Diversity Project or any other project which seeks to collect, store, immortalise, research or commercialise the genetic materials of the indigenous peoples of the Pacific.

## Article 4 Patenting

Parties shall use their best endeavours to ensure that no patenting is allowed on any specimen - or anything derived from that specimen - taken from any person.

## Article 5 Legislation

Each Party shall lobby its government as well as regional and multilateral bodies to enact appropriate legislation or enter into a regional agreement to control human genetic research and ensure that no human genetic material or its derivatives can be patented. Where the Party is a government, it shall work towards introducing appropriate national legislation as well as work towards a regional agreement for the foregoing purpose.

## Article 6 Rationalisation of Efforts

Parties shall maintain contact with one another and exchange information in order to allow the Depositary to compile a database regarding human genetic research in the Pacific and in order that their efforts in dealing with this activity can be streamlined and harmonised.

## Article 7 Relationship Between this Protocol and the Treaty

The provisions of the Treaty relating to any protocol shall apply with respect to the present Protocol.

To the Depositary:

I/we, .....

[signature(s) and position(s)]

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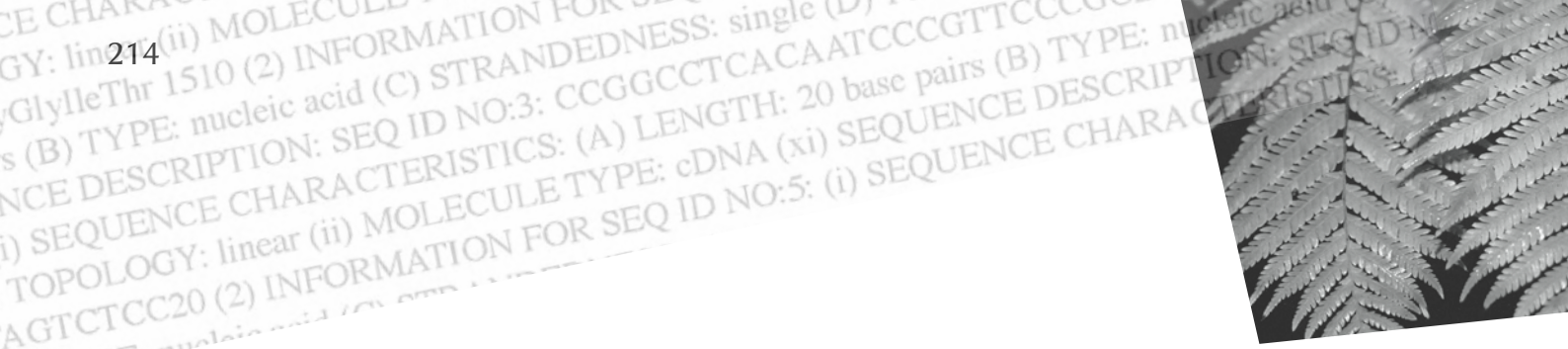
representing .....

[name of Group]

commit my/our Group to this Treaty.



# United States Patent 5,397,696
# Yanagihara, et al. March 14, 1995
# Papua New Guinea human T-lymphotropic virus

## Abstract

The present invention relates to a human T-cell line (PNG-1) persistently infected with a Papua New Guinea (PNG) HTLV-I variant and to the infecting virus (PNG-1 variant). Cells of the present invention express viral antigens, type C particles and have a low level of reverse transcriptase activity. The establishment of this cell line, the first of its kind from an individual from Papua New Guinea, makes possible the screening of Melanesian populations using a local virus strain. The present invention also relates to vaccines for use in humans against infection with and diseases caused by HTLV-I and related viruses. The invention further relates to a variety of bioassays and kits for the detection and diagnosis of infection with and diseases caused by HTLV-I and related viruses.

| | |
|---|---|
| Inventors: | Yanagihara; Richard (Frederick, MD); Nerurkar; Vivek R. (Frederick, MD); Jenkins; Carol (Goroka, PG); Miller; Mark (Fort Lee, NJ); Garruto; Ralph M. (Boyds, MD) |
| Assignee: | The United States of America as represented by the Department of Health (Washington, DC) |
| Appl. No.: | 743518 |
| Filed: | August 12, 1991 |
| Current U.S. Class: | 435/5 ; 435/235.1; 435/239; 435/7.1; 435/7.2; 435/7.21; 435/7.24; 435/7.92 |
| Field of Search: | 435/5,7.1,7.2,7.21,7.24,7.92,235.1,239,237 |

## Other References

Asher et al: "Ab to HTLV-I in Populations of the Southwestern Pacific" J. of Med Vir 26:339-51 (1988). . Popovic et al "Transformation of Human Umbilical Cord Blood T-cells by HTLV" PNAS 80:5402-6 (1983). .

Gallo et al "Comparison of Immunofluorescence, EI, & WB Methods for Detection of Ab to HTLV-1" J. of Clin Microb V26 #8 pp. 1487-1491 (1988)..

*Primary Examiner:* Nucker; Christine M.
*Assistant Examiner:* Stucker; Jeffrey
*Attorney, Agent or Firm:* Morgan & Finnegan

## Parent Case Text

This is a continuation-in-part application of Yanagihara et al. Ser. No. 07/572,090, filed Aug. 24, 1990, now abandoned, the entire contents of which are hereby incorporated by reference.

## Claims

What is claimed is:

1. A cell line, designated papua New Guinea-1(pNG-1) ATCC CRL 10528.

2. A viral preparation comprising the HTLV-I-variant in the cell line ATCC CRL 10528 of claim 1.

3. A bioassay for the diagnosis of infection with PNG-1 variant comprising the steps of:

i) fixing said cell according to claim 1 to a solid support;

ii) contacting said cell with a biological sample from a human suspected of being infected; and

iii) detecting the presence or absence of a complex formed between protein of said cell and antibodies specific therefor present in said sample.

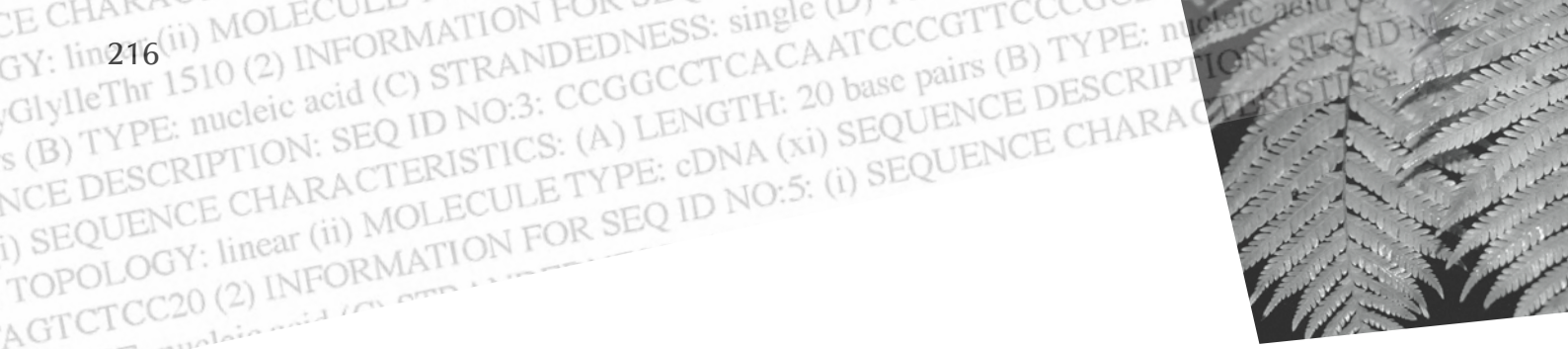
4. The bioassay according to claim 3 further comprising permeabilizing said fixed cell prior to contacting said cell with a biological sample.

5. A bioassay for the diagnosis of infection with PNG-1 variant comprising the steps of:

i) preparing a lysate from said cell according to claim 1;

ii) contacting said lysate with a biological sample from a human suspected of being infected, under conditions such that a complex is formed between protein of said lysate and antibodies specific therefor present in said sample; and

iii) detecting the presence or absence of said complex.



## DESCRIPTION

### BACKGROUND OF THE INVENTION

### 1. Field of the Invention

The present invention relates to Papua New Guinea variants of HTLV-I. In particular, the present invention relates to a human T-cell line persistently infected with a Papua New Guinea HTLV-I variant. The present invention further relates to bioassays and kits for the diagnosis of HTLV-I infections.

### BACKGROUND INFORMATION

The human T-cell leukemia lymphoma viruses (HTLV) represent a group of type C, exogenous and replication-competent retroviruses linked antigenically and by sequence homology (Retrovirus Biology and Human Disease. Eds. Gallo and Wong-Staal, Marcel Dekker Inc., NY 1989). HTLV-I, a member of this group, is the causative agent of adult T-cell leukemia/lymphoma (Poeisz et al., PNAS USA 1980; 77:7415-7419 and Hinuma et al., PNAS USA 1981; 78:6476-6480) and tropical spastic paraparesis/HTLV-I-associated myelopathy (Gessain et al., Lancet 1985; 2:407-410; Rodgers-Johnson et al., Lancet 1985; 2:1247-1248; and Osame et al., Lancet 1986; 1:1031-1032) Due to the genetic variability between HTLV-I isolates from Melanesia and other geographical locales, the widespread screening for infection in human populations in Melanesia can be best served by using a virus strain which is indigenous to that area.

High prevalences of antibodies against HTLV-I have been reported for several coastal and inland Melanesian populations, by using screening tests such as enzyme immunoassay and gelatin particle agglutination (Kazura et al., J. Infect. Dis. 1987; 155:1100-1107; Asher et al., J. Med. Virol. 1988; 26:339-351; Brindle et al., Epidemiol. Infect. 1988; 100:153-156; Brabin et al., Int. J. Cancer 1989; 44:59-62; Re et al., AIDS Res. Hum. Retroviruses 1989; 5:551-554; Armstrong et al., Am. J. Phys. Anthropol. 1990; 81:465-470; Garruto et al., Am. J. Hum. Biol. 1990; 2:439-447; and Imai et al., Jpn. J. Cancer Res. 1990; 81:1218-1221). These reported high prevalences of antibodies against HTLV-I, however, have been viewed with skepticism by some investigators because of the failure of such Melanesian sera to neutralize a prototype strain of HTLV-I (Weber et al., J. Infect. Dis. 1989; 159:1025-1028). The present inventors, however, have demonstrated an HTLV-I seroprevalence of 14% among the Hagahai (Yanagihara et al., J. Infect. Dis. 1990; 162:649-654), a remote, recently contacted hunter-horticulturalist group living in the highland fringe of Papua New Guinea (Jenkins, Soc. Sci. Med. 1988; 26:997-1006), and seroprevalences of 2% to 10% among inhabitants from widely separated regions in the Solomon Islands (Yanagihara et al., Am. J. Trop. Med. Hyg. 1991; 44:122-130). The serological data are consistent with the existence of variant viruses, phylogenetically related to but distinct from cosmopolitan prototype HTLV-I (Asher et al., J. Med. Virol. 1988; 26:339-351; Garruto et al., Am. J. Hum. Biol. 1990; 2:439-447; Yanagihara et al., J. Infect. Dis. 1990; 162:649-654; and Yanagihara et al., Am. J. Trop. Hyg. 1991; 44:122-130). The present inventors have also established the existence of HTLV-I in Melanesia with the isolation of HTLV-I-like viruses from a healthy Hagahi man (Yanagihara et al., N. Engl. J. Med. 1990; 323:993-994; and Yanagihara et al., PNAS USA 1991; 88:1146-1150) and from unrelated Solomon Islanders (Yanagihara et al., Jpn. J. Cancer Res. 1991; 44:240-244).

The establishment of a cell line persistently infected with an HTLV-I variant, derived from a healthy New Guinean, would facilitate testing in Melanesia, where high prevalences of HTLV-I infection have been found. Such a cell line would also have important application in testing populations elsewhere in the world and in the development of a vaccine for the prevention of infection with and of diseases caused by HTLV-I and related viruses. In addition, methods and diagnostic kits which detect Melanesian HTLV-I variants may obviate serodiagnostic problems encountered in Melanesia and in other geographical regions where serological tests employing cosmoplitan prototypes of HTLV-I yield high frequencies of indeterminate results.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a human T-cell infected with an HTLV-I variant and the bioassays and diagnostic kits this variant affords.

It is another object of the present invention to provide a cell line persistently infected with a Papua New Guinean HTLV-I-related virus.

Various other objects and advantages of the present invention will become apparent from the figures and the following description of the invention.

In one embodiment, the present invention relates to a cell line, designated Papua New Guinea-1 (PNG-1) comprising an HTLV-I variant, for example, (ATCC CRL10528).

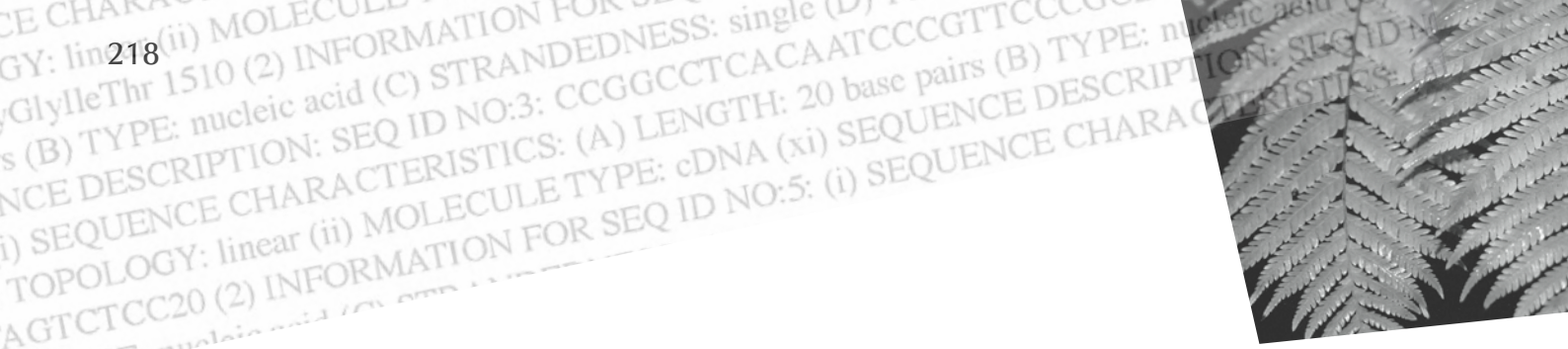
In another embodiment, the present invention relates to a purified antibody specific for a PNG-1 viral protein.

In a further embodiment, the present invention relates to a vaccine for humans against infection with and diseases caused by HTLV-I and related viruses comprising a non-infectious antigenic portion of the PNG-1 variant, in an amount sufficient to induce immunity against said infection and disease, and a pharmaceutically acceptable carrier.

In another embodiment, the present invention relates to bioassays for the diagnosis of infection with the PNG-1 variant. In one such bioassay PNG-1 cells are fixed on a solid support. The cells are then contacted with a biological sample from a human suspected of being infected and the presence or absence of a complex formed between proteins of cell and antibodies specific therefor present in said sample is detected.

In another bioassay a solid support is coated with viral protein and contacted with a biological sample from a human suspected of being infected, under conditions such that a complex is formed between the protein and antibodies specific therefor present in the sample. The presence or absence of the complex is then detected.

A further bioassay to which the present invention relates involves preparing a lysate from PNG-1 cells and contacting the lysate with a biological sample from a human suspected of being infected, under



conditions such that a complex is formed between protein of the lysate and antibodies specific therefor present in the sample. The presence or absence of the formed complex is then detected.

The present invention also relates to bioassays for the diagnosis of infection with the PNG-1 variant by the detection of PNG-1 specific genomic sequences. The presence or absence of PNG-1 sequences can be detected by amplifying RNA in a biological sample using reverse transcriptase-directed polymerase chain reaction.

The present invention also relates to bioassays utilizing antibodies specific for PNG-1 viral proteins. In one bioassay, a solid support is coated with such antibodies and then contacted with a biological sample from a human suspected of having the infection under conditions such that the antibody forms a complex with PNG-1 viral proteins within the sample. The presence or absence of the complex is then detected.

In another embodiment, the present invention relates to a diagnostic kit comprising variant-specific peptides for the Papua New Guinea HTLV-I variant and ancillary reagents suitable for use in detecting the presence or absence of antibody-peptide complexes.

In a further embodiment, the present invention relates to a diagnostic kit comprising variant-specific oligonucleotide primers for the Papua New Guinea HTLV-I variant and ancillary reagents suitable for use in DNA amplification and detection.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A to 1B show virus-specific fluorescence in PNG-1 cells by double-label immunofluorescence test, using sera from (FIG. 1A) a Colombian patient with serologically confirmed HTLV-I myeloneuropathy and (FIG. 1B) a rabbit experimentally infected with HTLV-I, and antibodies to the respective IgG conjugated with fluorescein isothiocyanate (green) and rhodamine (red). Similar staining was observed using sera from HTLV-I-seropositive Hagahai, a Solomon Islander with HTLV-I myeloneuropathy and a rabbit antiserum prepared against the C-terminus of the major envelope glycoprotein gp46 of HTLV-I. No staining was observed with sera from HTLV-I-seronegative humans and rabbits, or monoclonal antibodies against HTLV-I gag-encoded proteins p19 and p24. (Original magnification, .times.500)

FIG. 2 show a thin-section electron micrograph of PNG-1 cells demonstrating a solitary mature virus particle resembling HTLV-I (arrow). (Original magnification,.times.90,000)

FIGS. 3A-1 to 3A-4, 3B-1 to 3B-4, 3C-1 to 3C-4, 3D-1 to 3D-4 and 3E-1 to 3E-4 show the sequence analysis of amplified, cloned DNA. DNA from virus infected cell lines was amplified and (FIGS. 3A-1 to 3A-4) pX, (SEQ ID NO:12 and SEQ ID NO:18), FIGS. 3B-1 to 3B-4 (SEQ ID NO:19 AND SEQ ID NO:20) pol, (FIGS. 3C-1 to 3C-1) gp21 (SEQ ID NO:21 and SEQ ID NO:22) and (FIGS. 3D-1 to 3D-4 and FIGS. 3E-1 to 3E-4) gp46 (SEQ ID NO:23 and SEQ ID NO:24) regions were sequenced. Fractions above a nucleotide change indicate the frequency of that mutation seen in different clones from an individual patient. For comparison the sequences of the corresponding regions of the HTLV-I-infected cell line, HS-35, derived from a Caribbean patient, and the STLV-I-infected cell line, PtM3, from a pig-tailed macaque

(Macaca nemestrina) originally imported from Indonesia, are included where data was available. Sites of insertion are as indicated and deletions are represented by an asterisk. Dashed lines are regions where the sequence of the isolate can not be determined because the primers themselves are incorporated into the amplified product. Amino acid changes are shown for regions between the primers.

FIG. 4A to 4E show the nucleotide sequence alignment of the 522-base pair, gp21-encoding region of the env gene amplified from DNA from six Melanesians (HTLV-I Melanesia 1 to 6) and two Polynesians (HTLV-I Bellona 1 and 2), and comparison with the DNA sequence of a Japanese prototype HTLV-I.sub. ATK-1 (SEQ ID NO:25) (Seiki et al., PNAS USA 1983; 80:3618-3622). The arrow indicates the cleavage site between the carboxy terminus of gp46 and the amino terminus of gp21. There were no deletions or insertions, and none of the point mutations resulted in the introduction of stop codons.

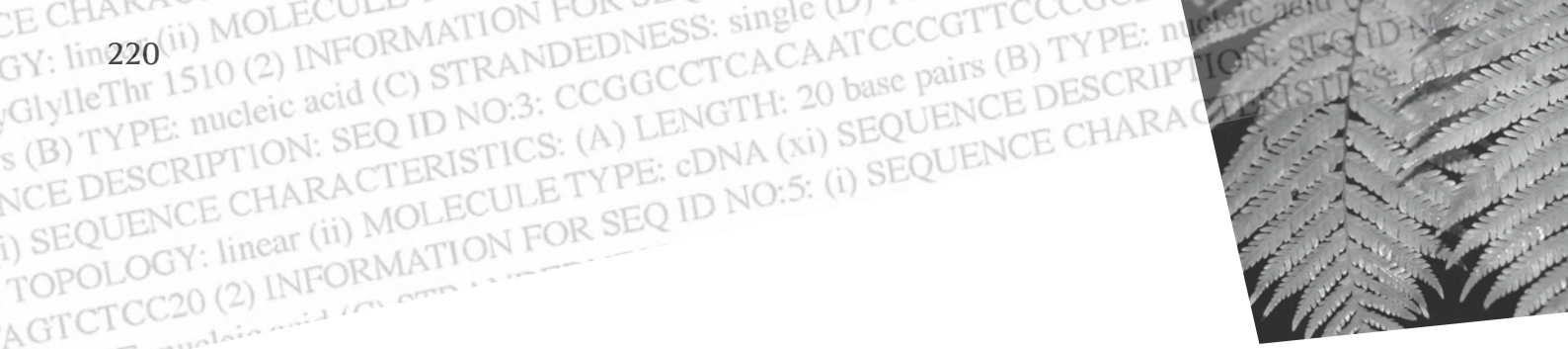
FIGS. 5A to 5C show the comparison of deduced amino acid sequences of the env gene region from a Japanese prototype HTLV-I.sub.MT-2 (Gray et al., Virology 1991; 177:391-395), two Polynesian strains of HTLV-I (Bellona 1 and 2) and six Melanesian HTLV-I variants (Melanesia 1 to 6). The respective sequences of HTLV-II.sub.C344/MO (Shimotohno et al., PNAS USA 1985; 82:3101-3105) and STLV-I.sub.macaque (Watanabe et al., Virology 1985; 144:59-65) are also shown. Blanks indicate homologous sequence with prototype HTLV-I.sub.MT2. Note shared amino acids between the Melanesian HTLV-I variants and HTLV-II (and STLV-I) at positions 305, 328, 330 and 372. The single letter amino acid code was used.

FIGS. 6A to 6B show a hydropathy analysis of the deduced amino acid sequence of the env protein (SEQ ID NO:26). The plot shows a large hydrophobic region and alternating hydrophobic and hydrophilic domains typical of membrane proteins. The positions of the amino acid residues and the values of the hydrophobic indices are shown on the x and y axes, respectively. The cleavage site between the C-terminus of the major envelope glycoprotein gp46 and the N-terminus of the transmembrane protein gp21 is indicated by an arrow.

FIGS. 7A to 7B show dendrograms evolutionary trees for the HTLV/STLV family of retroviruses. (FIG. 7A). Relationship based on the regions sequenced from pol, env (gp21, gp46) and tax. (FIG. 7B). Relationship based on sequences from env (gp21, pg46) and tax.

## DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a cell line, preferably a human T-cell line, persistently infected with a Papua New Guinea (PNG) HTLV-I variant. Cells of the present invention express viral antigens, type C particles and have a low level of reverse transcriptase activity. The inventors have established a human T-cell line, designated PNG-1, derived from peripheral blood mononuclear cells of a healthy New Guinean with the above described characteristics. PNG-1, a CD8 T-cell line, is infected with a HTLV-I variant indigenous to Papua New Guinea, referred to herein as the PNG-1 variant. The establishment of this cell line, the first of its kind from an individual from Papua New Guinea, makes possible the screening of Melanesian populations using a local virus strain.



The present invention further relates to the virus infecting PNG-1 cells. A substantially pure preparation of the infecting PNG-1 variant can easily be isolated from the cell line or a lysate thereof by one skilled in the art without undue experimentation. Unlike strains of HTLV-I from Japan, the West Indies, the Americas and Africa which share.gtoreq.97% sequence homology, the PNG-1 variant is only about 92% identical to a Japanese prototype HTLV-I (ATK-1) (Seiki et al., PNAS USA 1983; 80:3618-3622) and to HTLV-I strains isolated from Japanese patients with HTLV-I-associated myelopathy (Kinoshita et al., Int. J. Cancer 1991; 47:491-495) and from Jamaican patients with tropical spastic paraparesis (Daenke et al., J. Virol. 1990; 64:1278-1282). The env sequences of the PNG-1 variant, in turn, differs by approximately 4% from that of the variants from Melanesian Solomon Islanders, indicating the existence of new HTLV-I quasispecies. Although the PNG-1 variant lacks close sequence homology with a prototype strain (C344/Mo) of HTLV-II (Shimotohno et al., PNAS USA 1985; 82:3101-3105) and an Asian subtype of STLV-I (Watanabe et al., Virology 1985; 144:59-65), it is somewhat more closely related to HTLV-II than are cosmopolitan prototypes of HTLV-I.

In addition, the present invention relates to antibodies specific for the PNG-1 variant or viral proteins expressed by PNG-1. One skilled in the art using standard methodology can raise monoclonal and/or polyclonal antibodies to the variant or viral proteins expressed by the cells of the present invention without undue experimentation.

The present invention also relates to a vaccine for use in humans to prevent infection with and diseases caused by HTLV-I and related viruses. Diseases to which the present invention relates include, adult T-cell leukemia/lymphoma and tropical spastic paraparesis/HTLV-I-associated myelopathy. A non-infectious antigenic portion of the PNG-1 variant can be delivered to a human in a pharmacologically acceptable vehicle. Antigen preparations for use in the vaccine can take the form of inactivated/attenuated whole virus concentrates, for example, PNG-1 cell lysate, or viral proteins (or fragments thereof). The viral proteins and protein fragments can be produced, for example, by recombinant DNA techniques.

Vaccines of the present invention can also include effective amounts of immunological adjuvants known to enhance an immune response. The non-infectious antigenic portion of PNG-1 variant is in the vaccine in an amount sufficient to induce an immune response against the antigenic portion and thus to protect against infection with and diseases caused by HTLV-I and related viruses. The vaccines can be administered via the intradermal, subcutaneous or intra-muscular route. The vaccination may consist of a single administration or a series of administrations. This will vary depending on several factors, such as the patient's age and condition and the route of administration. These factors are easily assessed by the attending physician and an appropriate vaccination schedule determined therefrom.

PNG-1 and variant-specific peptides thereof can be used in a variety of serological test systems, including but not limited to immunoassay, gel particle agglutination, immunofluorescence, Western immunoblot, radioimmunoprecipitation and antigen-capture assays. (Variant-specific peptides as used herein refer to peptides unique to the Melanesian HTLV-I variants.) Accordingly, the present invention relates to bioassays for use in human medicine. For diagnosis of adult T-cell leukemia/lymphoma, tropical spastic paraparesis/HTLV-I-associated myelopathy or an infection of the causative agent thereof, the presence of antibodies to PNG-1 proteins or the presence of the viral proteins in a biological sample such as, for

example, serum or culture fluid, can be determined. Many types of tests, as one skilled in the art will recognize, can be used for detection and bioassays can be performed using standard protocols.

Specifically, in one bioassay of the present invention, antibodies against Papua New Guinea HTLV-I variants are detected with the use of variant-specific peptides. The variant-specific peptides can be isolated from natural sources, recombinantly produced or synthesized using standard automated methods. Suitable peptides include those encoded by variant-specific regions of the env gene sequences, such as, gp46 aa 17-28 and gp21 aa 324-335. Preferred peptides include, ProIleLeuSerPheTyrSerProSerCysCysThr (amino acids 17-28) (SEQ ID NO:1) for the major envelope glycoprotein gp46 and LeuAlaIleGlyThrGlyIleAlaGlyGlyIleThr (amino acids 324-335) (SEQ ID NO:2) for the transmembrane glycoprotein gp21. The peptides are purified such as, by preparative high-performance liquid chromatography. Peptide sequence and purity can be confirmed by amino acid composition and sequence studies.

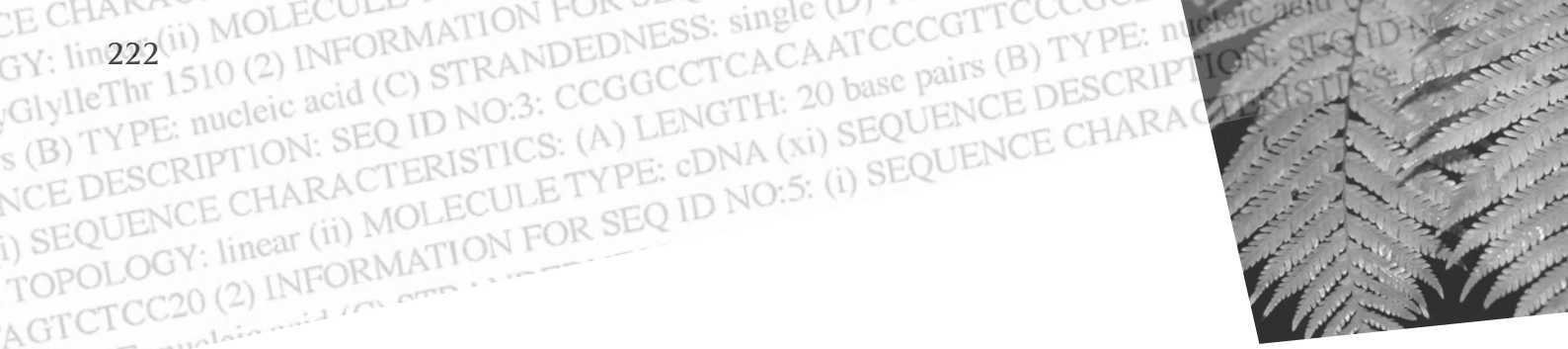
The variant-specific peptides are used to detect IgG, IgM or IgA antibodies in a biological sample (such as serum or cerebrospinal fluid) using immunoassays. Wells of plates, such as polyvinyl chloride plates, are coated with the peptides. The wells are then coated with an agent to block excess reactive sites, such as 3% bovine serum albumin. The biological sample is then diluted (for example, 1:20) and added to the wells. The antibody-antigen complexes are detected by labelled antibody against human IgG, IgM or IgA. For example, the antibody can be labelled with alkaline phosphatase which causes a change in color detectable by an ELISA reader.

In another assay of the present invention, PNG-1 cells are fixed on a surface and then their membranes are permeabilized, such as with acetone. The fixed cells are contacted with serum from a patient and the presence or absence of the viral protein-antibody complex is then detected using methods well known in the art.

In another assay of the present invention, a surface (i.e., a solid support), for example, a nitrocellulose membrane used in Western blots on which PNG-1 cell lysates or purified virus or variant specific recombinant proteins have been electrotransferred is contacted with a sample, such as serum, from a patient suspected of having disease or infection. The presence of a resulting complex formed between the viral protein(s) and antibodies specific therefor in the serum can be detected by any of the known methods common in the art, such as biotinylated or enzyme-labeled secondary antibodies.

Alternatively, the PNG-1 protein or variant-specific peptide thereof can be bound to an inert particle of, for example, bentonite or polystyrene latex. The particles are mixed with serum from a patient in, for example, a well of a plastic agglutination tray. The presence or absence of antibodies in the patient's serum is determined by observing the settling pattern of the particles in the well.

In a further bioassay of the present invention, the presence or absence of viral nucleic acid in a serum sample is detected. Viral genomic sequences can be amplified (for example, polymerase chain reaction) and detected by, for example, ethidium bromide staining or Southern blot analysis. Confirmation of the specificity of the amplified product may be accomplished by sequencing, or restriction enzyme mapping and hybridization using specific oligoprobes.



Suitable variant-specific primers for env gene amplification include 5'-CCGGCCTCACAATCCCGTTCCCGC-3' (SEQ ID NO:3) and 5'-TGGCGGTCTGGCTAGTCTCC-3' (sense primers) (SEQ ID NO:4) and 5'-AAACGTGGGAATTAGTGATGTTTA-3' (SEQ ID NO:5) and 5'-CTTGTAGCGCCTTGCATAATCC-3' (SEQ ID NO:6) (antisense primers). The amplified sequences can be detected with an oligoprobe, such as 5'-CAGACGAGGCCTTGATCTCC-3'(SEQ ID NO:7).

In another bioassay of the present invention, the presence or absence of PNG-1 variant-specific protein in a serum sample is detected with antibodies. Antibodies of the present invention specific for a virus protein thereof can be coated onto a solid surface such as a plastic and contacted with the serum sample. After washing, the presence or absence of the virus protein from the serum bound to the fixed antibodies is detected such as by addition of a labeled (e.g. enzyme-labeled) antibody specific for the virus.

The present invention further relates to kits for the diagnosis of HTLV-I infections, particularly PNG-I infections. Such kits provide an easy and safe means of diagnosing infections. One kit of the present invention includes variant-specific peptides from the Papua New Guinea variant virus, such as LeuAlaIleGlyThrGlyIleAla GlyGlyIleThr (SEQ ID NO:2). The kit also includes ancillary reagents suitable for use in detecting the presence of antibody-peptide complexes.

Another diagnostic kit of the present invention contains oligonucleotide primers specific for the Papua New Guinea variant virus and ancillary reagents suitable for DNA amplification and DNA detection. Suitable primers include, 5'-CCGGCCTCACAATCCCGTTCCCGC3' (SEQ ID NO:8) and 5'-TGGCGGTCTGGCTAGTCTCC-3' (SEQ ID NO:10) (sense primers) and 5'-AAACGTGGGAATTAGTGATGTTTA-3' and 5'-CTTGTAGCGCCTTGCATAATCC-3' (SEQ ID NO:11) (antisense primers). For example, one such kit contains PCR reaction mix (Tris HCl at pH 8.3, KCl, MgCl.sub.2, dNTPs and AmpliTaq DNA polymerase), and primers for routine PCR and for nested PCR. The PCR reaction is carried out at 94.degree. C. for 5 min., followed by 35 cycles of 94.degree. C. for 1 min.., 55.degree. C. for 1 min. and 72.degree. C. for 3 min. PCR is then continued at 72.degree. C. for 7 minutes and cooled to 4.degree. C. until separation. The amplified product can be detected using the standard methods. For example, agarose gel electrophoresis and ethidium bromide staining can be employed. Alternatively, the amplified product can be detected using Southern blot analysis with a full-length HTLV-I probe or internal oligonucleotide probes, such as, 5'-CAGACGAGGCCTTGATCTCC-3' (SEQ ID NO:7), labeled with .sup.32 p and high stringency wash conditions.

The following examples are given to further illustrate the present invention without being deemed limitative thereof.

EXAMPLES

## Statement of Deposit

The human T-cell line PNG-1 was deposited on Aug. 14, 1990 at the American Type Culture Collection (Rockville, Md.), in accord with the requirements of the Budapest Treaty. The cell line PNG-1 has been assigned the ATCC accession number CRL 10528.

## Study Population

The Hagahai, a 260-member, hunter-horticulturist group which made first sustained contact with government and missionary workers in 1984 (Jenkins, Soc. Sci. Med. 1988; 26:997-1006; and Jenkins et al., Hum. Ecol. 1989; 17:27-57) occupy an area totalling 750 km.sup.2 along the northern banks of the Yuat River Gorge in Madang Province of Papua New Guinea. Linguistically, the Hagahai have been classified into the Piawi family, tentatively assigned to the Sepik-Ramu phylum, a non-Austronesian language group.

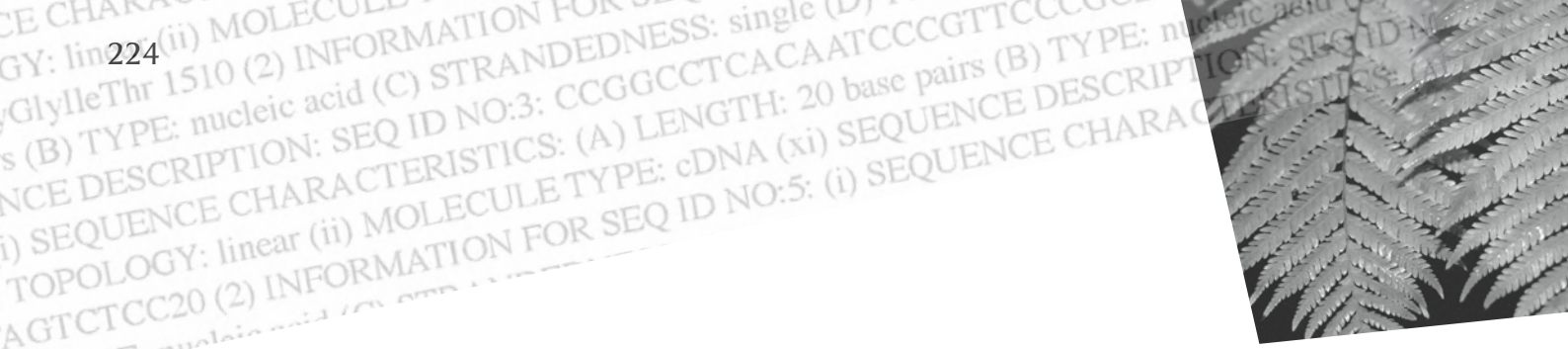
Like the highland and Sepik groups, the Hagahai lack the HLA-A2 antigen associated with recent Austronesian admixture, suggesting that they predate the last Austronesian migration into Papua New Guinea, currently dated to 5400 B. P. (Jenkins, Soc. Sci. Med. 1988;26:997-1006; Jenkins et al., Hum. Ecol. 1989;17:27-57; and Bhatia et al., Hum. Biol. 1989;61:45-64).

As verified by strict Western immunoblot criteria (Centers for Disease Control, MMWR 1988; 37:736-747), an HTLV-I seroprevalence of 14% was found among 120 Hagahai bled between February 1985 and January 1988 (Yanagihara et al., J. Infect. Dis. 1990; 162:649-654). A high frequency of indeterminate Western immunoblots was also found among ELISA-positive Hagahai.

Also studied were six unrelated Solomon Islanders (including two residents of Bellona Island) from three of whom HTLV-I-infected T-cell lines were derived (Yanagihara et al., Jpn. J. Cancer Res. 1991; 82:240-244; and U.S. application Ser. No. 07/662,368, filed Feb. 28, 1991) (Table II). Bellona (population 650), known also as Mu Ngiki (or "small island"), is, along with Rennell, Tikopia, Anuta (Cherry Island), Sikaiana (Stewart Island) and Ontong Java (Lord Howe Atoll), a Polynesian Outlier within the Solomon Islands. It lies 180 km south of Guadalcanal and is populated by Polynesians. Genetic distance analysis, based on allele frequencies of ABO blood groups, red cell enzymes and serum proteins, indicate that the inhabitants of Bellona are distinct from Melanesians despite their close geographical proximity (Blake et al., Am. J. Phys. Anthropol. 1983; 62:343-361).

### PNG-1 Virus Isolation

In May, 1989, 25 ml of heparinized blood was drawn from each of 24 Hagahai men and women, of whom 7 had confirmatory and 17 had indeterminate HTLV-I Western immunoblots. Blood samples were collected in the field, and were rushed to the Papua New Guinea Institute of Medical Research in Goroka, where they were processed in a laboratory in which HTLV-I and other human retroviruses had not previously been handled. Lymphocytes were separated using Sepracell (Supratech Corporation, Inc., Oklahoma City, Okl.), then washed twice with phosphate buffered saline (pH 7.4) before being incubated in RPMI 1640 (M.A. Bioproducts, Inc., Walkersville, Md.) supplemented with 20% (vol/vol) heat-inactivated fetal bovine serum, 4 mM L-glutamine, 50 .mu.g of gentamicin per ml and 2 .mu.g of phytohemagglutinin (PHA) per ml (Wellcome Diagnostics, Dartford, England). Following mitogen stimulation for two days, cells were maintained in medium containing 10% (vol/vol) interleukin 2 (IL-2) (Advanced Biotechnologies, Inc., Columbia, Md.). Except for a 60-hr period while being transported from Goroka to the National Institutes of Health in Bethesda, the cultures were incubated at 37.degree. C. in a humidified 5% CO.sub.2 atmosphere. Growth medium was changed twice weekly. Cultures were



examined periodically for HTLV-I antigens by indirect immunofluorescence, for reverse transcriptase activity, and for viral particles by electron microscopy.

## Re-isolation Attempts

Re-isolation attempts were conducted in an HTLV-I-free laboratory on lymphocytes from 15 Hagahai. Lymphocytes, preserved in 10% DMSO and stored in liquid nitrogen, were rapidly thawed in a 37.degree. C. water bath and were stimulated with PHA, as described above. Cells were then co-cultivated with approximately 2.times.10.sup.6 PHA-stimulated umbilical cord blood mononuclear cells obtained from healthy Caucasian neonates (Advanced Biotechnologies, Inc.), who lacked evidence of HTLV-I infection as determined by the polymerase chain reaction. Cultures were maintained with growth medium supplemented with IL-2. Fresh PHA-stimulated cord mononuclear cells were added, as needed, to maintain the cell density at 10.sup.6 per ml. Cells were examined weekly for viral antigen by immunofluorescence.

## Indirect Immunofluorescence Test

Cultured lymphocytes, spotted onto 10-well slides (Cell-line Associates, Newfield, N.J.) and fixed with cold acetone for 10 min, were examined for the expression of HTLV-I antigens by the indirect immunofluorescent antibody technique, using monoclonal antibodies against HTLV-I p19 (Pan-Data Systems, Inc., and Cambridge Biotech Corp., Rockville, Md.) and p24 (Cambridge Biotech Corp.); rabbit antiserum prepared against native p24 protein and against synthetic peptides of the C-terminus of gp46 (generously provided by Steve S. Alexander and Erik Lillehoj); sera from rabbits experimentally infected with strains of HTLV-I isolated from Colombia; and sera from Colombian and Chilean patients with virologically confirmed tropical spastic paraparesis/HTLV-I-associated myelopathy (Cartier-Rovirosa et al., Lancet 1989; i: 556-557; and McKhann et al., J. Infect. Dis. 1989; 160:371-379). Virus-specific antibodies were then detected using either rhodamine-labeled goat antibodies against mouse or rabbit IgG F(ab')2 (Accurate Chemical & Scientific Corp., Westbury, N.Y.), or fluorescein isothiocyanate-labeled goat antibodies against human IgG (Cappel Laboratories, Inc., Cochranville, Pa.). Incubations were performed in a humidified chamber at 37.degree. C. for 30 min, and slides were washed with 0.01M phosphate buffered saline (pH 7.2). Appropriate dilutions of mouse, rabbit and human negative control sera and HTLV-I infected (MT-2 cells) (Miyoshi et al., Nature 1981; 294:770-771) and uninfected cells (MOLT-3) (American Type Culture Collection, Rockville, Md.) were included in each test. Fluorescence was observed using a Leitz epifluorescence microscope.

## Analysis of Viral Proteins

Cell lysates were prepared by gently mixing 50.times.10.sup.6 cells in 2 ml 0.1M Tris-HCl (pH 7.4) containing 0.5% sodium deoxycholate (Sigma Chemical Co., St. Louis, Mo.), 0.5% Triton X100 and 0.05% sodium dodecyl sulfate at 4.degree. C. for 30 min. Lysates were clarified by centrifugation at 35,000 rpm (100,000 g) in a Beckman 50.2 Ti rotor for 1 hr. The supernatant was then mixed with sample buffer, and viral proteins were separated by electrophoresis on sodium dodecyl sulfate/polyacrylamide

gels (Laemmili, Nature 1970;227:680-685) Proteins were transferred electrophoretically to nitrocellulose membranes (Schleicher & Schuell, Dassel, FRG) in 25 mM Tris, 192 mM glycine and 20% methanol at 100 v for 1 hr. at 4.degree. C. Membranes were blocked for 2 hrs. at room temperature with 50 mM Tris-HCl (pH 7.4) and 0.85% NaCl containing 5% fat-free dry milk, then reacted overnight with autologous sera, with sera from Colombian and Chilean patients with virologically confirmed HTLV-I myeloneuropathy (Cartier-Rovirosa et al., Lancet 1989;i:556-557; and McKhann et al., J. Infect. Dis. 1989;160:371-379) and from rabbits experimentally infected with a Colombian isolate (strain 394) of HTLV-I, and with monoclonal and polyclonal sera directed against HTLV-I p19, p24 and gp46. As controls, sera from HTLV-I-seronegative individuals, rabbits and mice were tested simultaneously. Membranes were incubated successively with either biotinylated goat antibodies against human IgG (H&L) and avidin-horse radish peroxidase or alkaline phosphatase-labeled goat antibodies against rabbit or mouse IgG F(ab')2. Color was developed using 4-chloro-1-naphitol (Kirkregard & Perry Laboratories, Inc., Gaithersburg, Md.) or nitroblue tetrazolium (330 .mu.g per ml) and 5-bromo-4-chloro-3-indolylphosphate (166 .mu. g per ml) (Sigma), respectively.

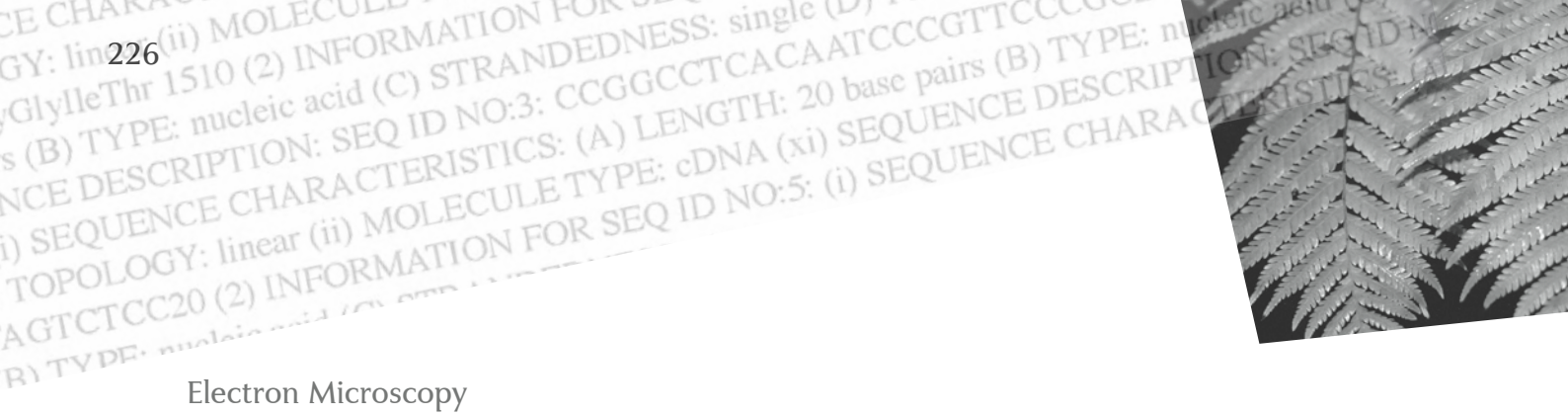
Polymerase Chain Reaction. Genomic DNA was isolated from approximately 25.times.10.sup.6 cells (PNG-1, MT-2 and MOLT-3) using a non-organic method (Oncor, Gaithersburg, Md.). One microgram of DNA was then amplified using oligonucleotide primers, synthesized on a PCR-Mate DNA synthesizer (Applied Biosystems), which were specific for env, gag and tax sequences of ATK-1, a prototype Japanese strain of HTLV-I (Seiki et al., PNAS USA 1983; 80:3618-3622). The reaction mixture consisted of 50 mM KCl, 10 mM Tris-HCl (pH 8.3), 1.5 mMMgCl.sub.2, 0.01% gelatin, 0.05% Nonidet P-40, 0.2 mM each dATP, dCTP, dTTP and dGTP, 1 .mu.M each oligonucleotide primer, and 2.5U of TaqDNA polymerase (Perkins-Elmer Cetus, Norwalk, Ct.). Following denaturation at 93.degree. C. for 4 min, the reaction mixtures were cycled 35 times at 93.degree. C. for 1 min, 55.degree. C. for 2 min and 72.degree. C. for 3 min. After one round of amplification with env primers, products were further amplified using "nested" primers. Amplified DNA was size-fractionated by agarose gel electrophoresis and transferred to nylon membranes for hybridization using oligoprobes or a full-length HTLV-I probe labeled with .sup.32 P.

## Restriction Endonuclease Analysis

Genomic DNA, extracted from PNG-1, MT-2 and MOLT-3 cells, was digested with several restriction endonucleases (EcoRI, PstI, SacI, HindIII). The digested DNA was separated on a 0.8% agarose gel, transferred onto Nylon membrane (Schleicher & Schuell) and hybridized with a full-length HTLV-I genomic probe labeled with .sup.32 P.

## Cytofluorographic Analysis

The surface phenotype of PNG-1 cells was determined by cytofluorographic analysis (Becton-Dickinson), using monoclonal antibodies directed against T-restricted (CD2, CD3, CD4, CD7 and CD8) and B-restricted (CD19 and CD20) antigens.



## Electron Microscopy

Cells were centrifuged at 1000 rpm for 10 min, and pellets were fixed in 2% glutaraldehyde for 2 hrs. at 4.degree. C., postfixed in 1% osmium tetroxide for 2 hrs., dehydrated through a graded series of ethanol and propylene oxide and embedded in Embed (Electron Microscopy Sciences, Fort Washington, Pa.). Ultrathin sections, stained with lead citrate and uranyl acetate, were examined using a Hitachi H7000 transmission electron microscope at 75 kV.

One culture, designated PNG-1, derived from a 20-year old Hagahai man, who had IgG antibodies against HTLV-I gag and env-encoded proteins by Western immunoblot, exhibited virus-specific fluorescence in approximately 1% of cells at two weeks, but cell growth remained sluggish for five months, with no increase in the percentage of viral antigen-bearing cells. Consequently, the lymphocytes were co-cultivated with newly acquired MOLT-3 cells (American Type Culture Collection, Rockville, Md.). This resulted in the establishment of a T-cell line which grew rapidly, but remained dependent on exogenous interleukin 2. The percentage of cells expressing viral antigen, as determined by indirect immunofluorescence, increased to more than 85% at 39 days following co-cultivation with MOLT-3 cells (FIGS. 1A to 1B).

Like some HTLV-I-infected T-cell lines, mature viral particles resembling HTLV-I were found only rarely in extracellular spaces of PNG-1 cells, by thin-section electron microscopy (FIG. 2). However, lysates of PNG-1 cells, analyzed by Western immunoblot, exhibited virus-specific bands at 15, 19, 24, 46 and 53 kilodaltons, using sera from Colombian and Chilean patients with virologically confirmed HTLV-I myeloneuropathy and from rabbits experimentally infected with HTLV-I. Moreover, HTLV-I sequences were detected in DNA extracts from PNG-1 cells by polymerase chain reaction (PCR), using oligonucleotide primers specific for gag, env and tax sequences of ATK-1, a prototype strain of HTLV.

## Analysis of PNG-1 pol, pX and env Genes

PNG-1 was more extensively compared with other HTLV-I and HTLV-II isolates to determine the variability of PNG-1 from cosmopolitans prototype strains of HTLV-I (see Table I below).

PCR amplification and subsequent liquid hybridization using primer pairs and detectors to different regions of the HTLV genome were performed on DNA from four HTLV-I and one HTLV-II-infected cell lines, as previously described (Abbott et al., J. Infect. Dis. 1988; 158:1158-1159). Primers specific for four different regions of the HTLV-I genome and two corresponding regions of the HTLV-II genome were employed to amplify target DNA which was subsequently cloned into the M13mp18 vector and sequenced. The linker sequence ACAGGTACCTGCAGATCTAGA (5'-3') (SEQ ID NO:12), which contains a restriction site for Kpn-I was synthesized on the 5' end of the positive strand primers while the linker sequence TACGAGCTCGCGAATTCATGA (5'-3') (SEQ ID NO:13), which possesses a Sst-I restriction site, was added to the 5' end of the negative strand primers. Amplified DNAs and the M13mp18 vector DNA were digested with both Kpn-I and Sst-I and then ligated together with T4 ligase. After hybridization with end-labelled probes for each respective primer pair, the DNA from each plaque was sequenced by the dideoxy nucleotide termination method.

DNA from the HTLV-I-infected cell lines PNG-1 and HSC-CTCL-11B was amplified and sequenced in specific regions of the pol, pX, and env (gp21 and gp46) genes. In addition, DNA from the cell line MoT and from two HTLV-II-infected patients (RW and FF) was amplified in equivalent regions of the pol and pX genes.

Input DNA from each isolate was normalized to 10,000 copies. The isolate, HSC-CTCL-11B, was used to verify the efficiency of each set of primers and probe. This isolate could be consistently detected at an input of 10 copies of HTLV-I DNA for all except one HTLV-I primer pair described, thereby demonstrating their sensitivity.

TABLE I

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PCR results using various HTLV-I/II primers on different HTLV-I or HTLV-II isolates. HTLV-I isolates HTLV-II HSC-CTCL HUT isolate Primers Prove Region PNG-1 11B 102B2 MT-2 MoT
_____ HTIL(490-515)+/ HTIL(655-630)- HTIL(564-596) + d LTR - + + + - HTIG(863-886)+/HTIG(1397-1375) - HTIG(981-1023) + d GAG +* +* +* +* - HTIG(1215-1235)+/HTIG(1393-1370)- HTIG(1238-1277) + d " - + + + - HTIG(1388-1411)+/HTIG(1660-1641)- HTIG(1451-1412) + d " +* + + + - HTIG(1423-1444)+/HTIG(1560-1537)- HTIG(1475-1507) + d " + + + + - HTIP(2801-2820)+/HTIG(3037-3018)- HTIP(2821-2860) + d POL +* + +* +* - HTIP(3365-3384)+/HTIP(3483-3465)- HTIP(3460-3426) + d " - + + + - HTIP(4757-4778)+/ HTIP(4942-4919)- HTIP(4870-4902) + d " + + + + + and and HTIIP(4735)-4736)+/HTIIP(4920-4897)- HTIP(4848-4880) + d HTIP(4825-4850) + d " + + + + - HTIIP(4880-4898) + d " - - - - + HTIE(5228-5247)+/HTIE(5596-5572)- HTIE(5305-5271) + d ENV + + +* - - HTIE(5270-5292)+/HTIE(5540-5521)- HTIE(5301-5340) + d " +* + +* +* - HTIE(6293-6324)+/HTIE(6527-6498)- HTIE(6330-6368) + d " + + +* +* - HTIpX(7358-7377)+/HTIpX(7516-7596)- HTIpX(7447-7468) + d pX + + + + + and and HTIIpX(7248-7267)+/HTIIpX(7406-7386)- HTIIpX(7337-7476) + d

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Oligonucleotides were named by a two letter initial for HTLV (HT) followed by the number of the designated virus (I or II), then by an initial for the gene or region of the indicated virus with the numbered position in the genome (EMBL system for HTLV-I and Shimotohno et al. for HTLV-II), and finally with a "+" or "-" to indicate the strand and a "d" to indicate a detector. PNG-1, HSC-CTCL-11B, HUT 102B2, and MT-2 are cell lines containing HTLV-I isolates from a Papua New Guinean, a Liberian of American slave descent, an African American and a Japanese, respectively. Input DNA from each isolate was normalized to 10,000 copies. A "+" symbol represents a band on liquid hybridization after 30 or 60. cycles of PCR. A "-" symbol represents no presence of hybridization after 30 or 60. cycles of PCR.

As seen from Table I, while PNG-1 belongs to the HTLV-I subgroup, it varies considerably from cosmopolitan prototypes of HTLV-I [MT-2 (Miyoshi et al., Nature 1981; 294:770-771), HUT 102B2 (Poiesz et al., PNAS USA 1980; 77:7415-7419), and HSC-CTCL-11B (Ehrlich et al., Am. J. Hematol. 1989; 30:128-139).

A protein-coding region in the tax gene (ORF pX-II) of HTLV-I was sequenced for PNG-1 and HSC-CTCL-11B and the corresponding HTLV-II region for MoT (Kalyanaraman et al., Science 1982; 218:571-573; and Shimotohno et al., PNAS USA 1985; 82:3101-3105) and two other HTLV-II isolates (RW and FF) (FIGS. 3A-1 to 3A-4). Published sequences for a prototype Japanese HTLV-I isolate (ATK-1) (Seiki et al., PNAS USA 1983; 80:3618-3622) (EMBL numbers are identical to the sequence of Seiki et al. for these regions), a Caribbean HTLV-I (HS-35) (Malik et al., J. Gen. Virol. 1988; 69:1695-1710), and STLV-I (Watanabe et al., Virology 1985; 144:59-64) were also included for comparison. Very little sequence variation was found among the isolates in this pX region. The HTLV-II isolates vary only 15% from the Japanese isolate as compared to 40% for the entire proviral DNA sequence. Others have also found strong conservation in the pX gene (Shimotohno et al., PNAS USA 1985; 82:3101-3105; and Shaw et al., PNAS USA 1984; 81:4544-4548) which is evidently maintained by the importance of its transactivating function. Two variants within the HSC-CTCL-11B isolate were identified here which is in agreement with previous data indicating two dominant proviral integrates in this cell line (Ehrlich et al., Am. J. Hematol. 1989; 30:128-139). From these data PNG-1 is most closely related to the HTLV-I family of retroviruses.

Strong conservation of the pol gene was also expected based on the importance of reverse transcription in the viral life cycle. Whereas there is a 36% difference between the prototype sequences of HTLV-I (ATK-1) and HTLV-II (MOT), there is strong conservation of sequence among the Japanese (ATK-1), Caribbean (HS-35), and Liberian (HSC-CTCL-11B) HTLV-I isolates and also among the HTLV-II isolates (FIGS. 3B-1 to 3B-4). By contrast, PNG-1 possessed 5 amino acid changes in the amplified region and at the nucleotide level, it varied by 8.6% from the prototype Japanese HTLV-I sequence and by 9.3% from the Caribbean, thereby establishing PNG-1 as a unique and distinct HTL-VI variant. The variation seen here far exceeds the inherent mutation rate involved in cloning of amplified DNA (Meyerhans et al., Cell 1989; 58:901-910).

Sequencing of a region of the transmembrane portion of the env gene (gp21), which includes the coding region of the putative immunosuppressive peptide (Ruegg et al., J. Virol. 1989; 63:3250-3256), indicated that PNG-1 was approximately 9.7% different from the prototype Japanese HTLV-I (ATK-1). However, 4 transitions from deoxyadenosine to deoxythymidine were noted that were conserved in all the sequences depicted, including HTLV-II and STLV-I (FIGS. 3C-1 to 3C-4). In addition, in sequencing this region of the HTLV-I env gene from 20 North American isolates, these 4 transitions were found to be conserved. Others have also described conservation of these changes in 8 of 8 Japanese adult T-cell leukemia/lymphoma patients (Kinoshita et al., Int. J. Cancer 1991; 47:491-495), in 11 of 12 HTLV-I-associated myelopathy patients (Kinoshita et al., Int. J. Cancer 1991; 47:491-495) as well as in 12 of 12 Jamaican tropical spastic paraparesis patients (Daenke et al., J. Virol. 1990; 64:1278-1282). Since these transitions are not conserved based on geography, species, or disease and 3 of the 4 cause amino acid substitutions, sequencing error of the original ATK-1 clone may account for the discrepancy.

A deletion in 6 independent env (gp21) clones of PNG-1 resulted in an altered reading frame of the transmembrane protein. One PNG-1 env (gp21) clone of 6 contained a deoxyguanidine that is not present in the others. Since the env gene FIGS. 3C-1 to 3C-4, FIGS. 3D-1 to 3D-4 and FIGS. 3E-1 to 3E-4) is more variable overall than the tax or pol genes, quasispecies (Shaw et al., PNAS USA 1984; 81:4544-4548) may

exist as defined by gp21 and gp46. In fact, two distinct gp46 clones for PNG-1 were found, indicating the presence of quasispecies. The phenomenon of multiple variants within a single individual has been described for both HIV (Saag et al., Nature 1988; 354:440-444; and Goodenow et al., J. AIDS 1989; 2:344-352) and HTLV-I (Daenke et al., J. Virol. 1990; 64:1278-1282).

FIGS. 3D-1 to 3D-4 and 3E-1 to 3E-4 show the sequence comparison of the HTLV variants from the 5' region of the env gene which encodes the extracellular membrane protein gp46. It was expected that portions of this gene region would be highly variable since the protein it encodes is under continuous selective pressure of the patient's immune system (Paquette et al., PNAS USA 1989; 86:3896-3900) and provides a target for neutralizing antibodies and antibody-dependent cellular cytotoxicity, while other portions would be strongly conserved since extracellular env proteins determine cell tropism (Paquette et al. 1989; PNAS USA, 86:3896-3900). Indeed, in FIGS. 3D-1 to 3D-4 and 3E-1 to 3E-4 one can see stretches of variability from a consensus sequence, interrupted by conserved regions, for an overall variation of 6.9% for PNG-1 from cosmopolitan prototype.

PNG-1 contained a deletion near the 5' end of gp46 (as indicated in FIG. 3D1) which changed the reading frame, but an insertion occurred shortly thereafter that restored the protein to the consensus frame. This specific region of the gp46 (EMBL No. 5250-5265) exhibited considerable variation in the STLV-I isolate and HTLV-II isolates, as well as the Caribbean and Liberian HTLV-I isolates. This nucleotide sequence and its corresponding peptide may be valuable in typing virus variants and for diagnosis of infection by creating specific oligonucleotide primers for PCR or specific peptides for ELISA and Western blot immunoassay.

## Sequence Analysis of PNG-1

Further sequence analysis was done to compare PNG-1 env gene with other Melanesian and Polynesian HTLV-I isolates. DNA was isolated from uncultured (fresh) peripheral blood mononuclear cells (PBMC), PBMC in culture for 4 weeks and HTLV-I infected T-cell lines derived from the Hagahai (PNG-1) (Yanagihara et al., N. Engl. J. Med. 1990; 323:993-994; and Yanagihara et al., PNAS USA 1990; 88:1146-1150) and Solomon Islanders (SI-1, SI-3, SI-5) (Yanagihara et al., Jpn. J. Cancer Res. 1991; 82:240-244; and Yanagihara et al., J. Infect. Dis. 1991, in press) using a non-organic method (Oncor, Gaithersburg, Md.), and was subjected to PCR. (See Table II below.) Oligonucleotide primer pairs derived from highly conserved regions of the HTLV-I env gene (sense strand, 5'-TTTGAGCGGCCGCTCAAGCTATAGTCTCCTCCCCTG-3' (SEQ IN NO:14); anti-sense strand, 5'-ACTTAGAATTCGGAGGTGTCGTAGCTGACGGAGG-3' (SEQ ID NO:5) and containing NotI and EcoRI restriction sites (underlined), respectively, were employed. The 522-base pair amplified region, which corresponded to bases 6046 to 6567 (equivalent to EMBL no. 6068 to 6589 of prototype HTLV-I.sub.ATK-1), encompassed the cleavage site of the envelope precursor protein and included nearly the entire coding region for the transmembrane glycoprotein gp21.

Amplified DNA was cloned into the NotI and EcoRI restriction sites of the Bluescript vector, then transformed into HB101 competent cells. Recombinant clones were screened by hybridization, under high stringency conditions, with a .sup.32 P-end-labeled internal oligonucleotide probe (5'-CAGACGAGGCCTTGATCTCC-3' (SEQ ID NO:16), corresponding to bases 6313 to 6332). Nucleotide

sequences of one to three clones from each DNA sample were determined by the dideoxynucleotide termination method, and sequence analysis was facilitated by using the Microgenie program (Beckman).

TABLE II

Demographic features of six Melanesians and two Polynesians in whom a 522-bp region of the HTLV-I env gene was amplified and sequenced. Patient Age/Sex Origin Island/Region Virus Provirus amplified from 1 21M Papua New Guinea Madang HTLV-I Melanesia 1 T-Cell line (PNG-1), Fresh PBMC 2 60F Madang HTLV-I Melanesia 2 Cultured PBMC 3 40F Solomon Islands New Georgia HTLV-I Melanesia 3 T-Cell line (SI-1) 4 60F Guadalcanal HTLV-I Melanesia 4 Fresh PBMC 5 58M Guadalcanal HTLV-I Melanesia 5 T-Cell line (SI-5) 6 38M Guadalcanal HTLV-I Melanesia 6 Cultured PBMC 7 60F Bellona HTLV-I Bellona I T-Cell line (SI-3), Fresh PBMC 8 50F Bellona HTLV-I Bellona 2 Cultured PBMC

Alignment and comparison of the nucleotide sequence of each provirus with the published genomic sequence of a prototype Japanese HTLV-I.sub.ATK-1 (Seiki et al., PNAS USA 1983; 80:3618-3622) revealed the existence not only of highly divergent variants of HTLV-I in Melanesia but of new quasispecies (or genetically distinct viral populations) within this HTLV-I variant (FIGS. 4A to 4E). A marked divergence of approximately 8% (39 to 43 base substitutions in the 522-bp region sequenced) was found in the six Melanesian HTLV-I variants (Table III). For any individual, the degree of sequence variation was identical (or nearly so) whether the DNA was extracted from uncultured (fresh) PBMC or PBMC cultured for four weeks or from T-cell lines derived from Melanesians (PNG-1, SI-1, SI-5), indicating that these variant sequences did not result from selection during prolonged maintenance of a few virus-infected cells in culture over many months.

The near identity (only a single base difference) between the two Papua New Guinean HTLV-I strains (Melanesia 1 and 2) was not unexpected, since they originated from a mother and her son, and is consistent with transmission from mother-to-child during infancy. Similarly, the env gene nucleotide sequences of the HTLV-I variants from the four Melanesian Solomon Islanders (Melanesia 3 to 6) exhibited a high degree of homology with each other, but they differed from the two HTLV-I strains from Papua New Guineans (Melanesia 1 and 2) by nearly 4% (Table III). Interestingly, the env sequence of the Melanesian Solomon Islander with HTLV-I myeloneuropathy (Melanesia 6) was as divergent (7.5%) from cosmopolitan prototype HTLV-I as the other Melanesian HTLV-I variants, suggesting that these variant viruses are capable of causing disease. By contrast, the env sequences in two Polynesians from Bellona were closely related to cosmopolitan prototype HTLV-I, differing by only 2.3% and 3.1% (Table III and FIGS. 4A to 4E), which is similar to that found in HTLV-I strains from Zaire, which hitherto exhibited the highest variability of 3.4%.

All Melanesian HTLV-I isolates lacked close sequence homology with a prototype strain (C344/Mo) of human T-lymphotropic virus type II (HTLV-II) (Shimotohno et al., PNAS USA 1985; 82:3101-3105) and an Asian subtype of simian T-lymphotropic virus type I (STLV-I), isolated from a pig-tailed macaque

(Macaca nemestrina) originally imported from Indonesia (Watanabe et al., Virology 1985; 144:59-65) (Table III). However, the Melanesian HTLV-I variants exhibited slightly closer homology to HTLV-II than did cosmopolitan prototype strains of HTLV-I (including the viruses from Bellona).

TABLE III

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Nucleotide Sequence Homology

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HTLV-I HTLV-I HTLV-I HTLV-I HTLV-I HTLV-I Virus Strain5 ATK-1 Bellona 2 Bellona 1 Melanesia 6 Melanesia 5 Melanesia 4

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HTLV-IATK-1 0 HTLV-IBellona 2 3.1 0 HTLV-IBellona 1 2.3 0.8 0 HTLV-IMelanesia 6 7.9 8.2 7.5 0 HTLV-IMelanesia 5 7.5 7.9 7.1 1.1 0 HTLV-IMelanesia 4 7.5 7.9 7.1 1.1 0 0 HTLV-IMelanesia 3 7.7 8 7.3 1 0.6 0.6 HTLV-IMelanesia 2 8.2 9 8.2 3.8 3.4 3.4 HTLV-IMelanesia 1 8.2 9 8.2 3.8 3.4 3.4 STLV-Imacaque 10.5 10.9 10.2 10.5 10.2 10.2 HTLV-IIC344/Mo 30.6 31 30.3 28.5 27.5 27.5

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HTLV-I HTLV-I HTLV-I STLV-I HTLV-II Virus Strain5 Melanesia 3 Melanesia 2 Melanesia 1 macaque C344/Mo

---

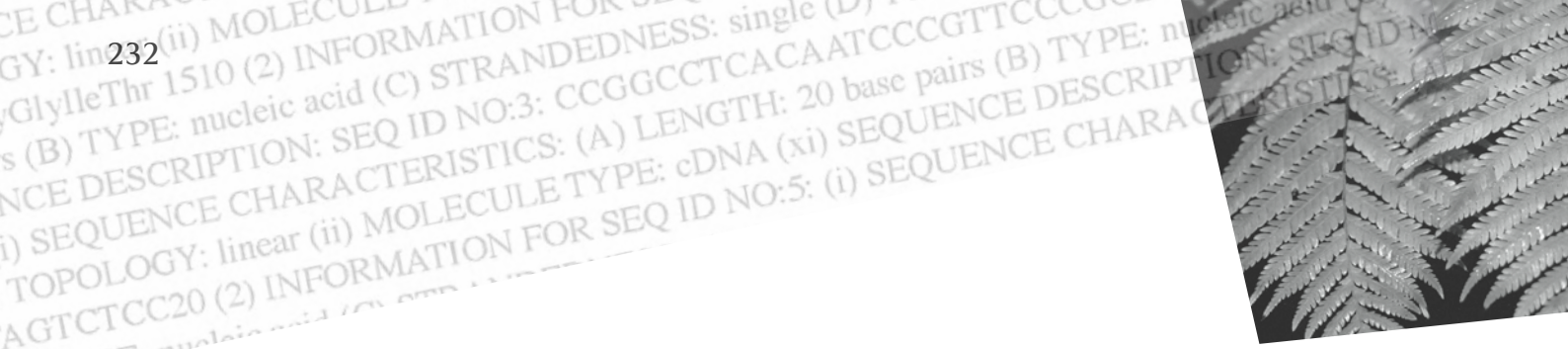
HTLV-IATK-1 HTLV-IBellona 2 HTLV-IBellona 1 HTLV-IMelanesia 6 HTLV-IMelanesia 5 HTLV-IMelanesia 4 HTLV-IMelanesia 3 0 HTLV-IMelanesia 2 3.6 0 HTLV-IMelanesia 1 3.6 0 0 STLV-Imacaque 10 11.7 11.7 0 HTLV-IIC344/Mo 27.7 28.5 28.5 29.3 0

---

Homology is expressed as percent divergence from the cosmopolitan prototype HTLVI.sub.ATK-1 .

The nucleotide changes identified in the HTLV-I variants from Melanesia corresponded primarily to single base substitutions within a given codon, the vast majority (85%) occurring at the third position, resulting in no amino acid change (see FIGS. 5A to 5C). Thus, at the level of the deduced amino acid sequence, the Melanesian HTLV-I variants differed by 2.3% to 4.0% (4 to 7 amino acids in 174 residues) from the prototype Japanese HTLV-I.sub.MT-2. Half of the nucleotide substitutions resulting in codon-altering amino acid changes were conservative and were restricted to the C-terminus and the N-terminus of the gp46 and gp21 envelope glycoproteins, respectively (FIGS. 5A to 5C). No nonconservative amino acid changes occurred in the region containing the immunosuppressive peptide.

As evidenced by hydropathy analyses (see FIGS. 6A and 6B), the envelope structure of these HTLV-I variants, like that of prototype HTLV-I, is under tight genetic constraint and few amino acid changes seem compatible with HTLV-I replication and infectivity. To what extent the use of peptides, encoded by the unique gene sequences of the Melanesian HTLV-I variants, will obviate the serodiagnostic problems encountered in Melanesia is uncertain (Yanagihara et al., Lancet 1991; 337:617-618).



## Evolutionary Relationship

To deduce the evolutionary relationships among members of the HTLV family, dendrograms were constructed using the unweighted pair-group method of assortment (UPGMA) (Nei, Frontiers of Biology Eds. Neuberger and Tatum, 199-202 1975) for comparing the divergence pattern for an HTLV-II isolate (MOT) (Kalyanavaman et al., Science 1982; 218:571-573) from a North American patient with a variant of hairy T-cell leukemia, an STLV-I isolate from Asia (PtM3) (Watanabe et al., Virology 1985; 144:59-64), and HTLV-I isolates from an asymptomatic Papua New Guinean (PNG-1), an African with adult T-cell leukemia/lymphoma (EL) (Paine et al., Virology 1991; 182:111-123) a Caribbean with adult T-cell leukemia/lymphoma (HS-35) (Malik et al., J. Gen. Virol. 1988; 69:1695-1710), a Liberian of American slave descent with ATLL (HSC-CTCL-11B) (Ehrlich et al., Am. J. Hematol. 1989; 30:128-139), a North American with adult T-cell leukemia/lymphoma (CH) (Paine et al., Virology 1991; 182:111-123), a Japanese with adult T-cell leukemia/lymphoma (ATK) (Seiki et al., PNAS USA 1983; 80:3618-3622), and a Japanese with HTLV-I-associated myelopathy (H5) (Tsujimoto et al., Mol. Biol. Med. 1988; 5:29-42) (See FIG. 7).

Since the evolutionary branching pattern of these related retroviruses differs from the pattern of the host species, there has been interspecies transmission between humans and nonhuman primates (Ina et al., J. Mol. Evol. 1990; 31:493-499). It has also been demonstrated that the HTLV family evolved with a relatively constant rate and that HTLV-II diverged from the common ancestor of STLV-I and HTLV-I (Ina et al., J. Mol. Evol. 1990; 31:493-499). From a relative rate standpoint (Sarich et al., Science 1990; 179:1144-1147) the present data are consistent with this interpretation. In FIG. 7A, the four sequenced regions (pol, pX, gp21 and gp46) were compared and the divergence pattern showed that PNG-1 diverged from a common ancestor of HTLV-I prior to strains from Africa (EL) (Paine et al., Virology 1991; 182:111-123), the Caribbean (HS-35) (Malik et al., J. Gen. Virol. 1988; 69:1695-1710), Liberia (HSC-CTCL-11B) (Ehrlich et al., Am. J. Hematol. 1989; 30:128-139), Japan (ATK) (Seiki et al., PNAS USA 1983; 80:3618-3622), and North America (CH) (Paine et al., Virology 1991; 182:111-123) and that PNG-1 is more closely related to HTLV-II than these other isolates. HTLV-I may have originated at the same time or prior to the time when the ancestors of these ancient Hagahai people of Papua, New Guinea became isolated.

A dendrogram, constructed exclusive of the pol region (FIG. 7B permits inclusion of STLV-I (Watanabe et al., Virology 1985; 144:59-64) and an isolate from a Japanese HTLV-I-associated myelopathy patient (H5) (Tsujimoto et al., Mol. Biol. Med. 1988; 5:29-42). The degree of divergence for PNG-1 decreased slightly relative to other HTLV-I isolates, but now an Asian subtype of STLV-I can be seen branching from HTLV-II prior to PNG-1. The Asian subtype of STLV-I varied from prototype HTLV-I by 10% and at the same time the African subtype of STLV-I varies by only 5% (Watanabe et al., Virology 1986; 143:385-388). These estimates are based on comparisons of a highly variable region of HTLV, the LTR. When more conservative regions are analyzed, the Asian subtype of STLV-I varied by almost 10% and PNG-1 varied by approximately 6.5%. If one extrapolated the differences in the African subtype of STLV-I onto this dendrogram, it would branch off after PNG-1, implying that interspecies transmission between humans and nonhuman primates of African origin continued to occur after the Asian subtype of STLV-I and PNG-1 branched away from the rest of what is HTLV-I.

The dendrograms seem to reflect the entire genome, as the divergence pattern for the isolates other than PNG-1 is in complete agreement with dendrograms created for the HTLV family based on sequences of

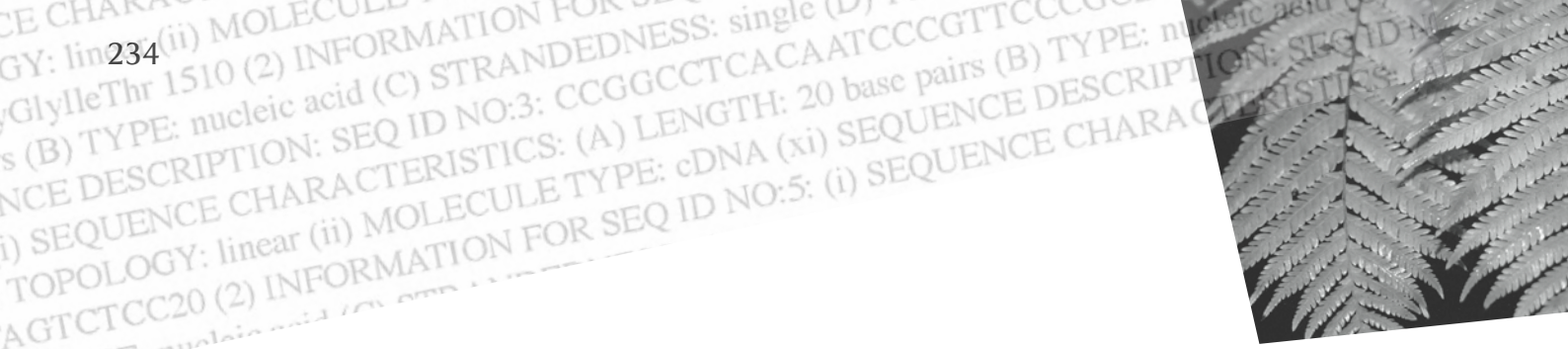
full-length clones and of clones of several kilobases in length.

The absence of nonhuman primates in Papua New Guinea and the Solomon Islands, both currently and in prehistoric times, indicates either that interspecies transmission occurred long before the introduction of HTLV-I in Melanesia or that HTLV-I Melanesia did not originate in monkeys. However, if the proto-Melanesian HTLV-I strain had its origin in nonhuman primates in Africa, the early and prolonged isolation of Melanesian populations are likely to have resulted in the evolution of a markedly different variant, since even the most divergent HTLV-I strains from Africa show .gtoreq.97% sequence identity with prototype HTLV-I (Paine et al., Virology 1991; 182:111-123).

All publications cited hereinabove are hereby incorporated by reference.

While the foregoing invention has been described in some detail for purposes of clarity and understanding, it will be appreciated by one skilled in the art from a reading of this disclosure that various changes in form and detail can be made without departing from the true scope of the invention.

SEQUENCE LISTING (1) GENERAL INFORMATION: (iii) NUMBER OF SEQUENCES: 26 (2) INFORMATION FOR SEQ ID NO:1: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 12 amino acids (B) TYPE: amino acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: peptide (xi) SEQUENCE DESCRIPTION: SEQ ID NO:1: Pro IleLeuSerPheTyrSerProSerCysCysThr 1510 (2) INFORMATION FOR SEQ ID NO:2: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 12 amino acids (B) TYPE: amino acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: peptide (xi) SEQUENCE DESCRIPTION: SEQ ID NO:2: LeuAlaIleGlyThrGlyIleAlaGlyGlyIleThr 1510 (2) INFORMATION FOR SEQ ID NO:3: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 24 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:3: CCGGCCTCACAATCCCGTTCCCGC24 (2) INFORMATION FOR SEQ ID NO:4: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 20 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:4: TGGCGGTCTGGCTAGTCTCC20 (2) INFORMATION FOR SEQ ID NO:5: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 24 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:5: AAACGTGGGAATTAGTGATGTTTA24 (2) INFORMATION FOR SEQ ID NO:6: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 22 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:6: CTTGTAGCGCCTTGCATAATCC22 (2) INFORMATION FOR SEQ ID NO:7: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 20 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:7: CAGACGAGGCCTTGATCTCC20 (2) INFORMATION FOR SEQ ID NO:8: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 24 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:8: CCGGCCTCACAATCCCGTTCCCGC24 (2) INFORMATION FOR SEQ ID NO:9: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 20 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS:



single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:9: TGGCGGTCTGGCTAGTCTCC20 (2) INFORMATION FOR SEQ ID NO:10: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 24 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:10: AAACGTGGGAATTAGTGATGTTTA24 (2) INFORMATION FOR SEQ ID NO:11: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 22 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:11: CTTGTAGCGCCTTGCATAATCC22 (2) INFORMATION FOR SEQ ID NO:12: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 21 base pairs (B) TYPE: nucleic acid (C ) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:12: ACAGGTACCTGCAGATCTAGA21 (2) INFORMATION FOR SEQ ID NO:13: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 21 base pairs (B) TYPE: nucleic acid ( C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:13: TACGAGCTCGCGAATTCATGA21 (2) INFORMATION FOR SEQ ID NO:14: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 36 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:14: TTTGAGCGGCCGCTCAAGCTATAGTCTCCTCCCCTG36 (2) INFORMATION FOR SEQ ID NO:15: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 34 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:15: ACTTAGAATTCGGAGGTGTCGTAGCTGACGGAGG34 (2) INFORMATION FOR SEQ ID NO:16: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 20 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (xi) SEQUENCE DESCRIPTION: SEQ ID NO:16: CAGACGAGGCCTTGATCTCC20 (2) INFORMATION FOR SEQ ID NO:17: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 159 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (ix) FEATURE: (A) NAME/KEY: CDS (B) LOCATION: 19..138 (xi) SEQUENCE DESCRIPTION: SEQ ID NO:17: CGGATACCCAGTCTACGTGTTTGGAGACTGTGTACAAGGCGACTGGTGCCC51
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CATCTCTGGGGGACTATGTTCGGCCCGCCTACATCGTCACGCCCTACT99
HisLeuTrpGlyThr MetPheGlyProProThrSerSerArgProThr 152025
GGCCACCTGTCCAGAGCATCAGATCACCTGGGACCCCATCGATGGACGC148
GlyHisLeuSerArgAla SerAspHisLeuGlyProHis 303540 GTTATCGGCTC159 (2) INFORMATION FOR SEQ ID NO:18: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 40 amino acids (B) TYPE: amino acid (D) TOPOLOGY: linear (ii) MOLECULE TYPE: protein (xi) SEQUENCE DESCRIPTION: SEQ ID NO:18: ValTrpArgLeuCysThrArgArgLeuValProHisLeuTrpGlyThr 151015 MetP heGlyProProThrSerSerArgProThrGlyHisLeuSerArg 202530 AlaSerAspHisLeuGlyProHis 3540 (2) INFORMATION FOR SEQ ID NO:19: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 186 base pairs (B) TYPE: nucleic acid (C) STRANDEDNESS: single (D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (ix) FEATURE: (A) NAME/KEY: CDS (B) LOCATION: 22..162 (xi) SEQUENCE DESCRIPTION: SEQ ID NO:19: CCCTACAATCCAACCAGCTCAGGACTTGTAGAACGC TCTAATGGCATTCTT51
GlyLeuValGluArgSerAsnGlyIleLeu 1510 AAAACCCTATTATATAAGTACTTTACTG
ACAAACCCGACCTACCCATG99 LysThrLeuLeuTyrLysTyrPheThrAspLysProAspLeuProMet

152025 GATAATGCTCTATCCATAGCCCTATGG ACAATCAACCACCTGAATGTG147
AspAsnAlaLeuSerIleAlaLeuTrpThrIleAsnHisLeuAsnVal 303540
TTAACCAACTGCCACAAAACCCGATGGCAGCTT CACCAC186 LeuThrAsnCysHis
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TYPE: protein (xi) SEQUENCE DESCRIPTION: SEQ ID NO:20: GlyLeuValGluArgS
erAsnGlyIleLeuLysThrLeuLeuTyrLys 151015 TyrPheThrAspLysProAspLeuProMetAspAsnAlaLeuSerIle
20 2530 AlaLeuTrpThrIleAsnHisLeuAsnValLeuThrAsnCysHis 354045 (2) INFORMATION FOR SEQ
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FEATURE: (A) NAME/KEY: CDS (B) LOCATION: 32..205 (xi) SEQUENCE DESCRIPTION: SEQ
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CTTGATCTCCTGTTCTGGGAGCAAGGAGGATTATGCAAAGCATTACAA100
LeuAspLeuLe uPheTrpGluGlnGlyGlyLeuCysLysAlaLeuGln 101520
GAACAGTGCCGTTTTCCGAATATTACCAATTCCCATGTCCCAATACTA148
GluGlnCysArgPheP roAsnIleThrAsnSerHisValProIleLeu 253035
CAAGAAAGACCCCCCCTTGAGAATCGAGTCCTGACTGGCTGGGGCCTT196
GlnGluArgProProLeuGluAsn ArgValLeuThrGlyTrpGlyLeu 40455055
AACTGGGACCTTGGCCTCTCACAGTGGGCTCGAGAGGCC235 AsnTrpAsp (2) INFORMATION
FOR SEQ ID NO:22: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 58 amino acids (B) TYPE:
amino acid (D) TOPOLOGY: linear (ii) MOLECULE TYPE: protein

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GlyLeuCysLysAlaLeuGlnGluGlnCysArgPheProAsnIleThr 202530
AsnSerHisValProIleLeuGlnGluArgProProLeuGl uAsnArg 354045 ValLeuThrGlyTrpGlyLeuAsnTrpAsp
5055 (2) INFORMATION FOR SEQ ID NO:23: (i) SEQUENCE CHARACTERISTICS:
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(D) TOPOLOGY: linear (ii) MOLECULE TYPE: cDNA (ix) FEATURE: (A) NAME/
KEY: CDS (B) LOCATION: 20..343 (xi) SEQUENCE DESCRIPTION: SEQ ID NO:23:
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TGTACTCTCACAATTGGAGTCTCCTCATACCACTCTAAACCCTGCAAT100
CysThrLeuTh rIleGlyValSerSerTyrHisSerLysProCysAsn 152025
CCTGCCCAGCCAGTTTGTTCGTGGACCCTCGACCTGCTGGCCCTTTCA148
ProAlaGlnProV alCysSerTrpThrLeuAspLeuLeuAlaLeuSer 303540
GCAGATCAGGCCCTACAGCCCCCCTGCCCTAACCTAGTAAGTTACTCC196
AlaAspGlnAlaLeuGln ProProCysProAsnLeuValSerTyrSer 455055
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SerTyrHisAlaThrTyrSerLeuTyr LeuPheProHisTrpThrLys 60657075
AAGCCAAACCGAAATGGCGGAGGCTATTATTCAGCCTCTTATTCAGAC292
LysProAsnArgAsnGlyGlyGl yTyrTyrSerAlaSerTyrSerAsp 808590
CCTTGTTCCTTAAAGTGCCCATACCTGGGGTGCCAATCATGGACCTGC340

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1510 15 GlyValSerSerTyrHisSerLysProCysAsnProAlaGlnProVal 202530
CysSerTrpThrLeuAspLeuLeuAlaLeuSerAlaAspGlnAlaLeu 354045
GlnProProCysProAsnLeuValSerTyrSerSerTyrHisAlaThr 505560 TyrSerLeuTyrLeuProHisT
rpThrLysLysProAsnArgAsn 65707580 GlyGlyGlyTyrTyrSerAlaSerTyrSerAspProCysSerLeuLys
85 9095 CysProTyrLeuGlyCysGlnSerTrpThrCysPro 100105 (2) INFORMATION
FOR SEQ ID NO:25: (i) SEQUENCE CHARACTERISTICS: (A) LENGTH: 520 base
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TCATAACTCCCTCATCCTGCCCCCCTTTTCCTTGTCACCTGTTCCCACCCTAGGATCCCG60


Blood collection Team processing Hagahai blood samples (Papua New Guinea Institute of Medical Health).

# Traditional Biological Knowledge, Innovations And Practices Act (2000)

## Analysis



## Traditional Biological Knowledge, Innovations and Practices Act 200x

An Act to protect the rights of owners of traditional biological knowledge, innovations, and practices.

### 1 Short title

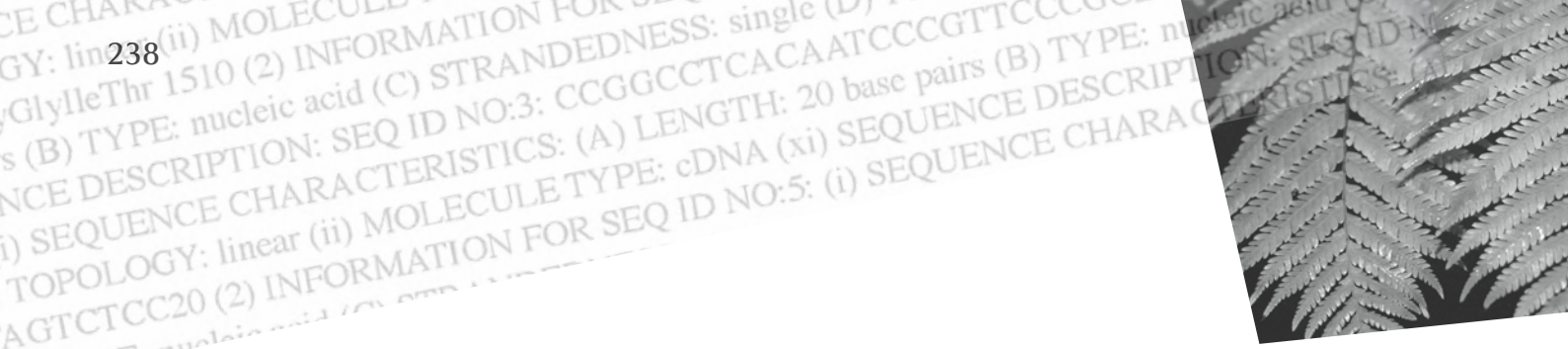
This Act may be cited as the Traditional Biological Knowledge, Innovations and Practices Act [date].

### 2 Commencement

This Act commences on [date].

### 3 Application

(1) Where there is an inconsistency with intellectual property laws, this Act, is to the extent of the inconsistency, to prevail.
(2) Section 9(1) of this Act (Moral rights) has retrospective effect.



## 4 Definitions

In this Act, unless the context otherwise requires:

**biological material** means any part of a plant, animal or microorganism.

**database** means the database of traditional biological knowledge, innovations and practices established under section 7 of the Act;

**innovation** means traditional biological innovation.

**knowledge** means traditional biological knowledge.

**own** in relation to knowledge, innovations and practices, includes the following:

(a) own as a trustee;

(b) own as a custodian;

(c) own as a steward;

and its meaning in any particular context is to be determined according to the history and traditions and customs and usages of the social group which claims ownership over that knowledge, innovation or practice.

**practice** means traditional biological practice.

**social group** means a family, clan, tribe, village or similar social organisation.

**traditional biological innovation** means a product, belonging to a social group, which has resulted from biological material whose usefulness has been enhanced by the application of traditional biological knowledge.

**traditional biological knowledge** means knowledge whether embodied in tangible form or not, belonging to a social group and gained from having lived in close contact with nature, regarding:

(a) living things, their spiritual significance, their constituent parts, their life cycles, behaviour and functions, and their effects on and interactions with other living things, including humans, and with their physical environment;

(b) the physical environment;

(c) the obtaining and utilising of living or non-living things for the purpose of maintaining, facilitating or improving human life.

**traditional biological practice** means a process, method or way of doing things, belonging to a social group and gained from having lived in close contact with nature.

**Tribunal** means the Traditional Ownership Tribunal convened under section 13 of the Act.

## 5 Competent National Authority

The Competent National Authority for the purposes of this Act is the [insert body] which shall carry out the functions described in this Act.

## 6 Ownership

(1) For the purposes of this Act, ownership by a social group over an item of knowledge or an innovation or a practice is established according to the history and traditions and customs and usages of that social group.

(2) The [Competent National Authority] may assert ownership over an item of knowledge or an innovation or a practice in either of the following situations:

(a) where it is satisfied there is no immediately verifiable owner of that knowledge or innovation or practice. The [Competent National Authority] will be considered to be the owner for the purposes of this Act of that knowledge or innovation or practice as trustee on behalf of the eventual owner.

(b) where it is satisfied, after having made extensive efforts to locate an owner of an item of knowledge or an innovation or a practice, that an owner will not be found. The [Competent National Authority] will be considered to be the owner for the purposes of this Act of that knowledge or innovation or practice as trustee on behalf of [the enacting country].

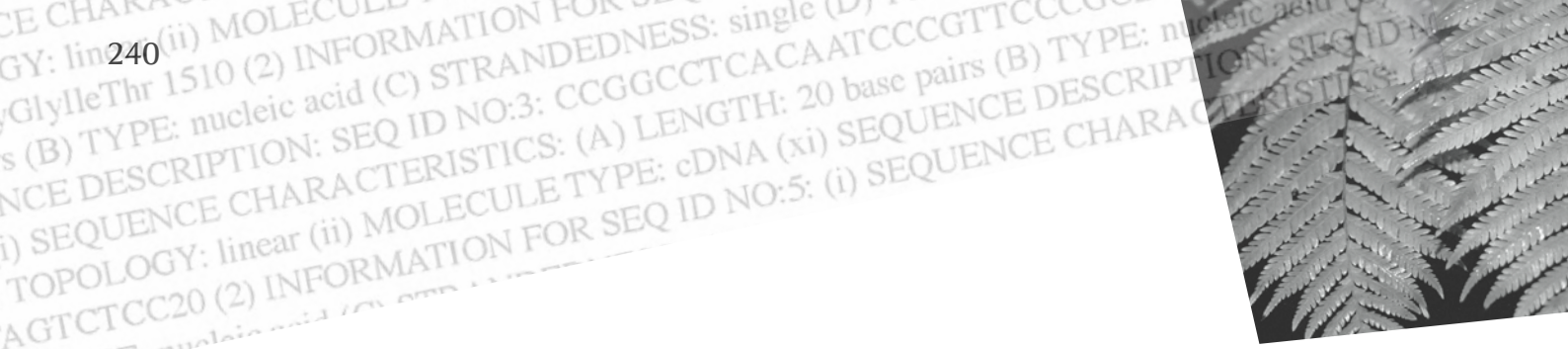
## 7 Database of traditional biological knowledge, innovations and practices

(1) The [Competent National Authority] is to establish and maintain a database of knowledge, innovations and practices and shall enter into it such information as it receives or collects pertaining to knowledge, innovations and practices.

(2) An owner may enter its knowledge, innovations and practices in the database.

(3) Where the owner does not specify who can access the information, access will be limited to the owner. The [Competent National Authority] may also access the information for the purpose only of seeking the identity of an owner pursuant to section 10 of this Act.

(4) Any person wanting access to information in the database must write to the [Competent National



Authority]. The [Competent National Authority] shall consider the request and may refuse access, grant access unconditionally or grant access with conditions attached.

(5) Any person who knowingly provides false information for entry into the database commits an offence and is liable upon conviction to a fine not exceeding [$].

## 8 Economic rights

(1) In addition to any rights available under applicable intellectual property laws an owner of an item of knowledge, an innovation or a practice has the exclusive right to use or to authorise the use of its knowledge, innovation or practice:

(a) for a commercial purpose, or
(b) for an activity that is likely to assist in achieving a commercial purpose.

(2) Any person other than the owner wanting to use an item of knowledge, an innovation or a practice for a commercial purpose, or an activity that is likely to assist in achieving a commercial purpose, must comply with sections 10 and 11 of this Act.

(3) Subsection (2) shall not apply to plant genetic resources for food and agriculture whose collection, holding, transfer and use are covered by a policy approved by the Secretariat of the Pacific Community.

(4) Any person who contravenes subsection (2) commits an offence and is liable upon conviction to a fine not exceeding [$].

## 9 Moral rights

(1) Owners of knowledge, innovations and practices have the following moral rights:
(a) the right of attribution of ownership in relation to their knowledge, innovations or practices;
(b) the right not to have ownership over an item of knowledge, an innovation or practice falsely attributed to them; and
(c) the right not to have their knowledge, innovations and practices subjected to derogatory treatment.

(2) Any person who, upon the commencement of this Act, contravenes subsection (1) commits an offence and is liable upon conviction to a fine not exceeding [$].

## 10 Identity of owner and prior informed consent

(1) A prospective user wanting to use an item of knowledge, an innovation or a practice for a commercial purpose, or an activity that is likely to assist in achieving a commercial purpose, must in all cases

apply to the [Competent National Authority] in the form prescribed by the [Competent National Authority].

(2) The [Competent National Authority] must give a copy of the application to the social group they believe to be the owner of the knowledge, innovation or practice applied for and at the same time publicise the application locally, or where warranted, overseas.

(3) Any social group claiming ownership must identify itself to the [Competent National Authority] within 30 days from the date the application is publicised and satisfy the [Competent National Authority] of its claim to ownership.

(4) Where the [Competent National Authority] is satisfied as to the identity of an owner it must inform the prospective user of the identity, publicise the identity nationally and enter it into the database along with the information used to prove ownership.

(5) After the expiration of twenty one days from the time the prospective user is informed of the identity of the owner he must ensure the owner is fully informed of the use proposed to be made of its knowledge, innovation or practice.

## 11 Access and Benefit Sharing Agreement

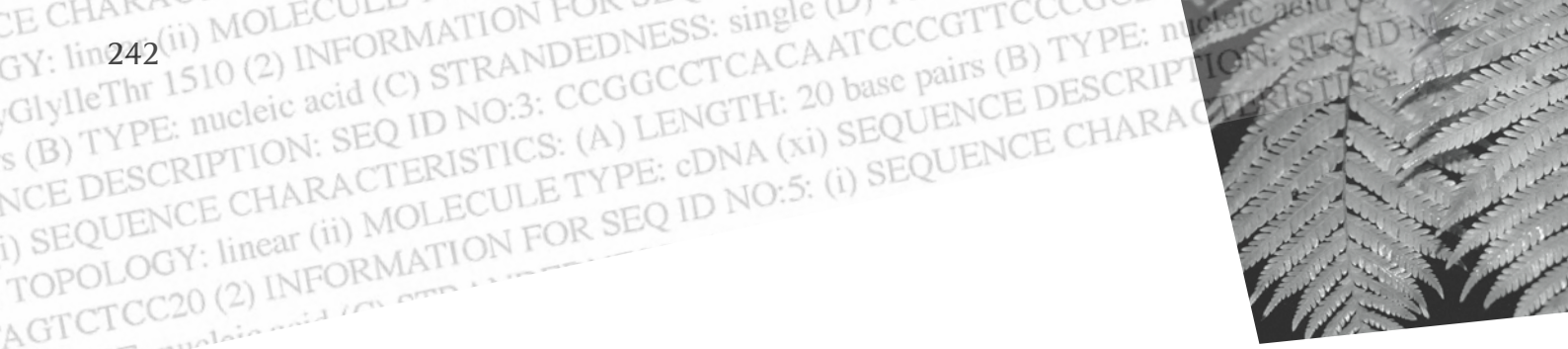
(1) Where the owner gives its prior informed consent to the proposed use, an agreement between the owner and the user, to be known as an Access and Benefit-Sharing Agreement, must be negotiated under the supervision of the [Competent National Authority] setting out the terms under which use is permitted and having regard to the following matters, amongst others:

### Knowledge, innovations and practices:

(a) restrictions on using knowledge in any other material form
(b) restrictions on reproduction, publication, translation, or broadcasting of knowledge
(c) restrictions on the quantity of an innovation to be obtained
(d) requirement for progress reports to be supplied at each stage of testing of an innovation
(e) rights regarding anything derived from research on an innovation.

### General:

(a) fees or compensation for using the knowledge, innovation or practice
(b) obtaining of relevant permits
(c) duration of the Agreement
(d) choice of law upon breach of a term of the Agreement
(e) options upon breach of a term of the Agreement
(f) limits on transfer to third parties



(g) restrictions on fixation through any process such as making a sound recording or taking a photograph
(h) intellectual property rights
(i) recognition of moral rights
(j) benefit sharing, monetary and non-monetary, on the successful commercialisation of any aspect of the knowledge, innovation or practice

(2) The [Competent National Authority] is to ensure that the Agreement is not to the detriment of the owner.

(3) Nothing in subsection (1) is to be construed as preventing the promulgation of more detailed access and benefit regimes for knowledge or for innovations or for practices or for any combination of these elements.

## 12 Ownership enquiry

(1) Any person may lodge an enquiry at any time with the [Competent National Authority] regarding ownership of an item of knowledge, an innovation or a practice. He must specify the owner of as well as the knowledge, innovation or practice being enquired about and the basis for the enquiry. He may present such other submissions as he considers relevant.

(2) The owner being challenged is to be given a copy of the enquiry by the [Competent National Authority] and must within thirty days provide a written reply along with any other submissions it considers relevant to the [Competent National Authority] and to the enquiring party.

(3) The [Competent National Authority] will publicise the enquiry in summary form and invite submissions from the public.

(4) The [Competent National Authority], acting as mediator, after it has considered all submissions and when it is satisfied that the issues in dispute have been clarified, must call a conference between the parties at which the following matters are to be discussed:

(a) whether there is any merit in the enquiry and if not, then the enquiring party is to be requested to withdraw its enquiry and where this is done then the enquiry will terminate upon the entry of that information in the database.
(b) whether the parties are owners of different items of knowledge, innovations or practices and if the parties agree that this is the case then the enquiry will terminate upon the entry of that information in the database.
(c) whether the parties are co-owners of the knowledge, innovation or practice in dispute and if the parties agree that this is the case then the enquiry will terminate upon the entry of that information in the database.
(d) whether only one of the parties is the owner of the knowledge, innovation or practice in dispute because the other party agrees that this is the case or does not answer the enquiry

then the enquiry will terminate and the appropriate information entered in the database.

(e) such other matters as the [Competent National Authority] or parties consider relevant.

## 13 The Traditional Ownership Tribunal

(1) In the event that a consensual decision pursuant to section 12, or any other additional means, is not reached either of the parties may then request the [Competent National Authority] to convene a body, to be known as the Traditional Ownership Tribunal, to adjudicate on the dispute.

(2) Where, pursuant to subsection (1), a party requests the [Competent National Authority] to convene the Tribunal, the [Competent National Authority] shall do so within 30 days.

(3) The Tribunal shall consist of three people with expertise in the area under dispute.

(4) The Tribunal shall:

(a) select a chairperson;

(b) model its rules of procedure as closely as practicable to those of the [principal] Court;

(c) hear all such evidence as it considers necessary to hear;

(d) consider the evidence and dispose of the dispute by deciding:

(i) that there is no merit in the enquiry, or

(ii) that the parties are owners of different items of knowledge, innovations or practices, or

(iii) that the parties are co-owners of the knowledge, innovation or practice, or

(iv) that only one of the parties is the owner of the knowledge, innovation or practice, or

(v) that none of the foregoing decisions can be made and that the matter will be referred back to the [Competent National Authority], and shall have all such powers as are required to carry out these functions.

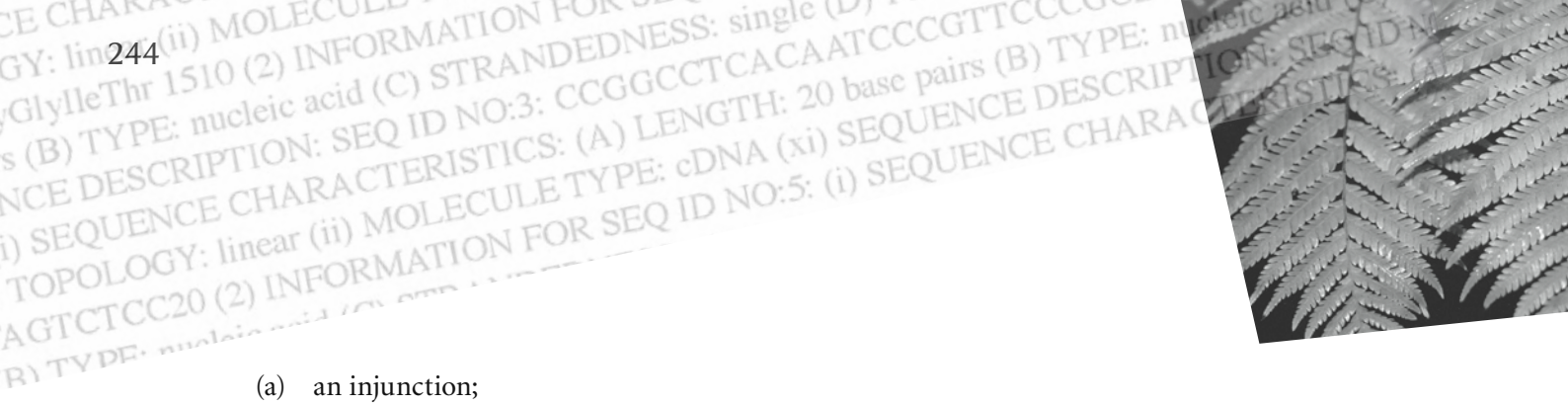
(5) The [Competent National Authority] shall make available all documents in its possession or control pertaining to the dispute to the Tribunal and shall act as the secretariat to the Tribunal.

## 14 Appeal

A party may, within twenty one days of having received the decision of the Tribunal, appeal against the decision to the principal [Court] whose decision shall be final.

## 15 Legal proceedings

(1) The [principal] Court shall have full jurisdiction to hear and determine any proceedings for infringement or otherwise relating to knowledge, innovations and practices in [the enacting country], and may grant in addition to any other relief any one or more of the following remedies:



(a) an injunction;
(b) damages;
(c) a declaration that a right has been contravened;
(d) an order for a public apology;
(e) an order that any false attribution or derogatory treatment cease or be reversed;
(f) an order for an account of profits;
(g) an order for the seizure of any object made contrary to this Act;
(h) an order for the impounding and destruction of any object used in the commission of an offence under this Act.

(2) The [principal] Court in deciding what relief is to be granted may take into account all or any of the following factors:

(a) whether the defendant was aware or ought reasonably to have been aware of the rights of the owner;
(b) the effect on the reputation of the owner resulting from the unauthorised use;
(c) anything done by the defendant to mitigate the effects of the unauthorised use;
(d) any cost or difficulty that may have been associated with identifying the owner;
(e) any cost or difficulty in ceasing or reversing any false attribution of ownership, or derogatory treatment of the knowledge, innovation or practice;
(f) whether the parties have undertaken any other action to resolve the dispute.

### 16 Offence by a company

Where a company commits an offence under this Act, any officer, director, employee or agent of the company who directed, authorised, assented to, or acquiesced in the commission of the offence is a party to and guilty of the offence, and is personally liable to the punishment provided for the offence, whether or not the company has been prosecuted or convicted.

### 17 Reciprocal agreements

In accordance with reciprocal agreements entered into with other countries or territories, this Act may provide the same protection for knowledge, innovations and practices originating in those countries or territories as it provides for knowledge, innovations and practices.

### 18 Regulations

The [insert] acting upon the advice of [insert] may make regulations for giving full effect to the provisions of this Act and for its due administration.

# Statement Of Bioethics Consultation Tonga National Council Of Churches Centre Nukuoalofa, Tonga (2001)

## Preamble

As peoples of the Aqua continent of Pacifica, equally created in the image of God and in fellowship with one another, we do thereby solemnly declare our faith and unity in the sovereignty of our Triune God, in whom we live, move, and have our being.

With God as the source of this life and that which is yet to come. Revealer of truth and sustainer of justice, faith and reasons; we make these pronouncements as guiding principles to all that we may do in the field of bio-ethics and intellectual property rights.

And as participants in this Consultation we pledge the following as our covenant by which we are bound.

We shall always endeavour to raise awareness and to take action regarding bioprospecting, bio-piracy, gene-mapping, human genetic engineering, patenting of plant, animal, microbial and human genetic resources and their possible impacts on Pacific Island Countries.

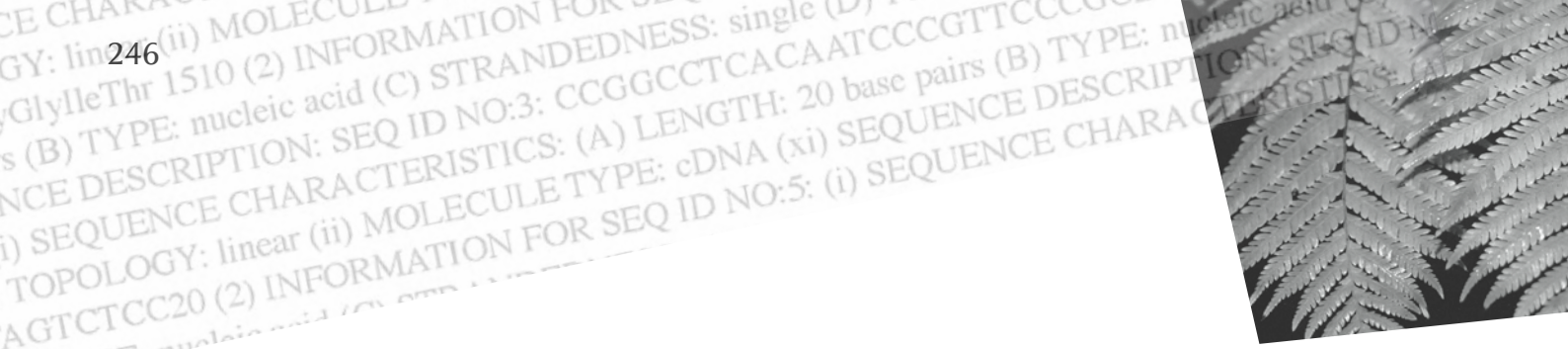
In the context of the proposed agreement between Autogen Ltd. (Aust.) and the Government of Tonga regarding genetic research on the people of Tonga. We are concerned as Christians about the requirement of prior informed consent and the right of people to information regarding any negotiations in the field of genetic research in the Pacific.

With fellow sojourners and friends everywhere, we do hereby pledge to support and uphold the following principles and recommendations to the best of our abilities _ so help us God.

## Principles

We believe,

(a) in God as the supreme creator of all living things;
(b) all human being are born equal in dignity and rights, and every human life has value;
(c) Christian values should be placed first and all other values evaluated according to these Christian values;
(d) the peoples of the Pacific should be respected and valued for their identity as distinct peoples;
(e) all lifeforms should be treated in a way that respects their intrinsic value as living generational manifestations of creation;



(f) the quality of life is based on the development of human relationships, spiritual fulfillment, and reverence for life and the natural world;
(g) commitment to the quality of life of the future generations is fundamental to the world view of the peoples of the Pacific;
(h) the peoples of the Pacific are the guardians of their heritage and have the right to protect and control dissemination of the heritage;
(i) the peoples of the Pacific have the right to manage their own biological resources, to preserve their traditional knowledge and to protect these from expropriation and exploitation by scientific, corporate, or governmental interests;
(j) in the rights of the peoples of the Pacific to live and practice their customary practices relating to communal existences as well as their God- given ethics and cultural heritage based on common values such as reciprocity, respect and sanctity;
(k) no person should be subjected to medical or scientific experimentation without that personÕs freely given prior informed consent;
(l) that cloning of human beings is wrong;
(m) the conversion of lifeforms, their molecules or parts, into corporate property through patent monopolies is counter-productive to the interests of the Pacific;
(n) that scientific and commercial advances should not be allowed to proceed past the deliberations necessary to provide for their social, moral and ethical control;
(o) that national laws and provisions in international agreements which encourage and facilitate the patenting of lifeforms _ such as the Trade Related Aspects of Intellectual Property Rights of the General Agreement on Trade and Tariffs _ should be repealed;
(p) that civil society is similarly concerned with these issues as reflected in: The Earth Charter, the Genetic Bill of Rights and the Treaty for a Lifeforms Patent-Free Pacific and Related Protocols(the Hagahai Treaty);
(q) all forms of genetic engineering of human genes should be rejected; and
(r) confirm our stand against the unauthorized collection and commercialisation of genetic resources from the Pacific.

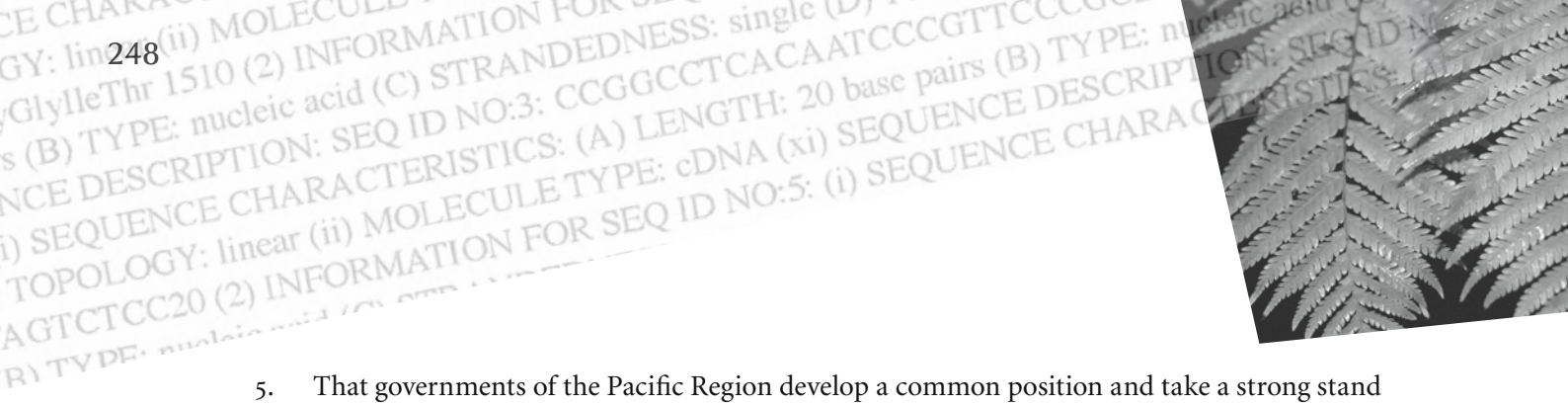
## Recommendations

We make the following recommendations to the Churches in the Pacific region, the National Councils of Churches, the Pacific Council of Churches, governments, and Councils of Chiefs, in the Pacific:

(a) That the Churches and Councils of Churches in the Pacific Region:
    1. Be informed, and where necessary speak out against, the following: bio-piracy, bio-colonialism, international intellectual property rights regimes, and genetic engineering.
    2. Educate and empower the Pacific people by providing relevant information on prior informed consent, bio-piracy, bio-colonialism,international intellectual property rights regimes, and geneticengineering.
    3. Provide such information via as many ,media as are available.
    4. Address issues of bio-ethics in order to provide to our church institutions a framework for ethical; and theological discussions concerning these issues.

5. Develop an Information Center to develop relevant, theologically-based information on informed consent, bio-piracy, bio-colonialism, international intellectual property rights regimes, and genetic engineering.
6. Continue to be at the forefront in promotion of human dignity, defending human rights, and protecting the environment which supports all of our lives. They must make sure that our human, animal, plant andmicroorganism species, and their genetic and other biological inheritance be safeguarded from exploitation and manipulation. Decisions in the field of genetic engineering should be based on the Precautionary Principle, which was agreed on by government at he Earth Summit in Rio in 1992 and reconfirmed in the Cartagena Protocol on Biosafety. The church must monitor developments in the field of biotechnology and act decisively if there is risk of serious harm.
7. Being an ecumenical effort in which all churches work together on all levels and within the National Council of Churches, Pacific Council of Churches, and World Council of Churches all continue to follow up on these issues.
8. Network with other agencies and organizations in order to increase their ability to understand and influence the complex ethical, economic, legal, and scientific processes involved. The Tongan Churches should accept the Tongan Minister of HealthÕs invitation to participate the newly-formed Research and Ethic Committee, and churches in other countries should seek to establish similar relationships.
9. Help and support the indigenous peoples and local communities of the region and the world to protect their biological resources, and to preserve their traditional knowledge and their right to live normally and free from genetically _ engineered environments.
10. Work to promote bio-diversity and sustainable practices within the Pacific region.
11. Support the Genetic Bill of Rights, the Earth Charter, and the Treaty for a Lifeforms Patent-free Pacific and Related Protocols, and work for realization of the principles expressed therein.
12. That the churches will remind scientists, when necessary, that science is only a tool, and that human beings should not be used as tools of science. Scientific research is at he service of the human persons, and not the other way around. The Kingdom of God which is here and now must continue to challenge the different scientific undertakings to further the growth and development of human beings who fare on pilgrimage towards the fullness of the Kingdom of God.

(b) To governments and Councils of Chiefs:
    1. When any genetic research project is proposed, there should be full public discussion and absolutely all relevant information disclosed by all parties involved, including financial interests and assessments of environmental, health, and socio-economic risks.
    2. Independent experts should be fully accessible to aid the public discourse, and to evaluate proposed research protocols in order to insure the full protection of the individual human and collective rights of the South Pacific peoples, and to ensure that all research is sound valid, and beneficial to the people and environment.
    3. Pacific regional legislation should be prepared, addressing issues of genetic engineering, bio-prospecting, and bio-piracy.
    4. The people should be consulted before any government signs any agreement impacting peopleÕs rights.



5. That governments of the Pacific Region develop a common position and take a strong stand in international negotiations relevant to these issues, such as
   - the review of the agreement on Trade-Related Intellectual Property Rights;
   - the negotiations on Access and Benefit-Sharing in the framework of the Convention on Biological Diversity; and
   - the International Undertaking on Plant Genetic Resources in the framework of the United NationsÕ Food and Agriculture Organization.

## Acknowledgement

The bio-ethics consultation wishes to acknowledge the initiative made by the Pacific desk/Justice, Peace & Creation unit of the world Council of Churches in visioning and facilitating this very important consultation. Without their support, we would not have achieved such an exciting but challenging event.

We are grateful to the Minister of Education in Tonga, Hon. Dr. Tutoatasi Fakafanua for his inspiring insights and sharing during the official opening of the consultation. The guidance and expertise of our international speakers were of invaluable assets to our meeting especially Ms. Christine von Weizsaecker of Germany, Ms. Debra Harry and Mr. Brett Shelton from United States, Mr. Clark Peteru from Samoa. Your untiring efforts we hope will be a milestone in our journey onwards with regards to bio-ethics in the region. Also our many thanks to our local resources, Dr. Taniela Palu, Sr. Dr. Keiti Ann KanongataÕa, Rev. Dr. Mohenoa Puloka, and Mr. Lopeti Senituli. We want also to highlight the important role and participation of the regional and national ecumenical organizations as well as churches in the Pacific and local organizations participating in raising awareness and responding to the issues of bio-ethics from ethical, moral and theological perspectives.

Last but not the least we wish to extend our very sincere appreciation to the Tonga National Council of ChurchesÕ secretariat and its Ecumenical CenterÕs staff and friends for helping out in the hosting and coordination of the consultation. Also the presence of Pacific Conference of ChurchesÕ Moderator, Mrs. Fuiva Kavaliku had been an encouraging gesture for the future follow up of the issue.

To God be all honor and Glory.

# Model Law For The Protection Of Traditional Knowledge And Expressions Of Culture (2002)

## Part 1 – Preliminary

### 1 Short title

This Act may be cited as the Protection of Traditional Knowledge and Expressions of Culture Act [Enacting country to insert year of enactment].

### 2 Commencement

This Act commences on [Enacting country to complete].

### 3 Application

(1) This Act applies to traditional knowledge and expressions of culture that:
  (a) were in existence before the commencement of this Act; or
  (b) are created on or after that commencement.

(2) This Act does not affect or apply to rights that exist immediately before the commencement of this Act, including intellectual property rights.

(3) This Act does not affect or apply to contracts, licences or other agreements entered into by traditional owners before the commencement of this Act in relation to the use of traditional knowledge or expressions of culture.

### 4 Definitions

In this Act, unless the contrary intention appears:

*authorised user agreement* means a written agreement entered into under Division 3 or 4 of Part 4.

customary use means the use of traditional knowledge or expressions of culture in accordance with the customary laws and practices of the traditional owners.

*derivative work* means any intellectual creation or innovation based upon or derived from traditional knowledge or expressions of culture.

*derogatory treatment*, in relation to traditional knowledge or expressions of culture, includes any act or omission that results in a material distortion, mutilation or alteration of the traditional knowledge or expressions of culture that is prejudicial to the honour or reputation of the traditional owners, or the integrity of the traditional knowledge or expressions of culture.

*expressions of culture* mean any way in which traditional knowledge appears or is manifested, irrespective of content, quality or purpose, whether tangible or intangible, and, without limiting the preceding words, includes:

(a) names, stories, chants, riddles, histories and songs in oral narratives; and (b) art and craft, musical instruments, sculpture, painting, carving, pottery, terra-cotta mosaic, woodwork, metalware, painting, jewellery, weaving, needlework, shell work, rugs, costumes and textiles; and
(c) music, dances, theatre, literature, ceremonies, ritual performances and cultural practices; and
(d) the delineated forms, parts and details of designs and visual compositions; and
(e) architectural forms.

*Minister* means the Minister responsible for this Act.

*moral rights* are the rights mentioned in section 13.

*prescribed* means prescribed by the regulations made under this Act.

*sacred-secret* means any traditional knowledge or expressions of culture that have a secret or sacred significance according to the customary law and practices of the traditional owners concerned.

*traditional cultural rights* are the rights mentioned in sections 7(2) and (3).

*traditional knowledge* includes any knowledge that generally:

(a) is or has been created, acquired or inspired for traditional economic, spiritual, ritual, narrative, decorative or recreational purposes; and
(b) is or has been transmitted from generation to generation; and
(c) is regarded as pertaining to a particular traditional group, clan or community of people in [Enacting country]; and
(d) is collectively originated and held.

traditional owners of traditional knowledge or expressions of culture means:
(a) the group, clan or community of people; or
(b) the individual who is recognized by a group, clan or community of people as the individual;

in whom the custody or protection of the traditional knowledge or expressions of culture are entrusted in accordance with the customary law and practices of that group, clan or community.

## 5 Customary use

The customary use of traditional knowledge or expressions of culture does not give rise to any criminal or civil liability under this Act.

## Part 2 – Traditional Cultural Rights

### 6 Holders of traditional cultural rights

The traditional owners of traditional knowledge or expressions of culture are the holders of the traditional cultural rights in the traditional knowledge or expressions of culture.

### 7 Meaning of traditional cultural rights

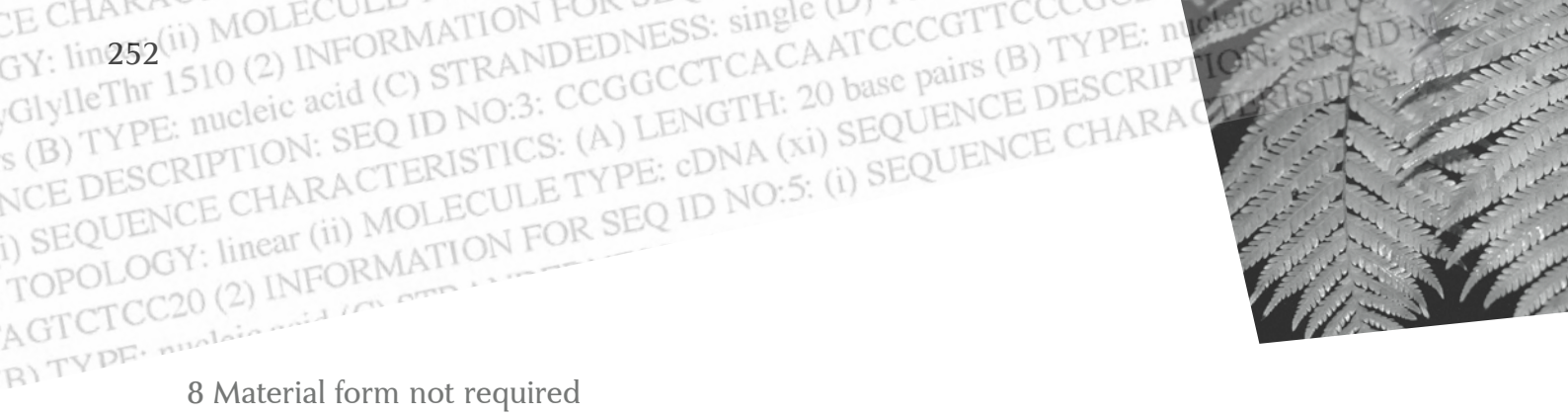
(1) Traditional cultural rights are the rights set out in subsections (2) and (3).

(2) The following uses of traditional knowledge or expressions of culture require the prior and informed consent of the traditional owners in accordance with section 23(1) or 25(5):
   (a) to reproduce the traditional knowledge or expressions of culture;
   (b) to publish the traditional knowledge or expressions of culture;
   (c) to perform or display the traditional knowledge or expressions of culture in public;
   (d) to broadcast the traditional knowledge or expressions of culture to the public by radio, television, satellite, cable or any other means of communication;
   (e) to translate, adapt, arrange, transform or modify the traditional knowledge or expressions of culture;
   (f) to fixate the traditional knowledge or expressions of culture through any process such as making a photograph, film or sound recording;
   (g) to make available online or electronically transmit to the public (whether over a path or a combination of paths, or both) traditional knowledge or expressions of culture;
   (h) to create derivative works;
   (i) to make, use, offer for sale, sell, import or export traditional knowledge or expressions of culture or products derived therefrom;
   (j) to use the traditional knowledge or expressions of culture in any other material form;
   if such use is a non-customary use (whether or not of a commercial nature).

(3) To avoid doubt, the traditional owners are entitled to use traditional knowledge or expressions of culture in the ways mentioned in subsection (2) in the exercise of their traditional cultural rights.

(4) Subsection (2) does not apply to the use of traditional knowledge or expressions of culture for any of the following:
   (a) face to face teaching;
   (b) criticism or review;
   (c) reporting news or current events;
   (d) judicial proceedings;
   (e) incidental use.

(5) A user of traditional knowledge or expressions of culture mentioned in paragraphs (4)(a) to (d) must make sufficient acknowledgement of the traditional owners by mentioning them and/or the geographical place from which the traditional knowledge or expressions of culture originated.



### 8 Material form not required

Traditional cultural rights exist in traditional knowledge and expressions of culture whether or not that traditional knowledge or those expressions of culture are in material form.

### 9 Duration

Traditional cultural rights continue in force in perpetuity.

### 10 Traditional cultural rights inalienable

Traditional cultural rights are inalienable.

### 11 Additional rights

The traditional cultural rights in traditional knowledge or expressions of culture are in addition to, and do not affect, any rights that may subsist under any law relating to copyright, trademarks, patents, designs or other intellectual property.

### 12 Derivative works

(1) Any copyright, trademark, patent, design or other intellectual property right that exists in relation to a derivative work vests in the creator of the work or as otherwise provided by the relevant intellectual property law.

(2) If a derivative work, traditional knowledge or expressions of culture are to be used for a commercial purpose, the authorised user agreement must:

  (a) contain a benefit sharing arrangement providing for equitable monetary or non-monetary compensation to the traditional owners; and

  (b) provide for identification of the traditional knowledge or expressions of culture on which the derivative work is based in an appropriate manner in connection with the exploitation of the derivative work by mentioning the traditional owners and/or the geographical place from which it originated; and

  (c) provide that the traditional knowledge or expressions of culture in the derived work will not be subject to derogatory treatment.

## Part 3 – Moral Rights

### 13 Meaning of moral rights

(1) The traditional owners of traditional knowledge or expressions of culture are the holders of the moral rights in the traditional knowledge or expressions of culture.

(2) The moral rights of the traditional owners of traditional knowledge and expressions of culture are:
  (a) the right of attribution of ownership in relation to their traditional knowledge and expressions of culture; and
  (b) the right not to have ownership of traditional knowledge or expressions of culture falsely attributed to them; and
  (c) the right not to have their traditional knowledge and expressions of culture subject to derogatory treatment.

(3) The moral rights of traditional owners in their traditional knowledge and expressions of culture exist independently of their traditional cultural rights.

(4) Moral rights continue in force in perpetuity and are inalienable, and cannot be waived or transferred.

## Part 4 – Obtaining Prior And Informed Consent From Traditional Owners

### Division 1 – General

#### 14 Overview

This Part sets out the procedure for obtaining the prior and informed consent of the traditional owners to use their traditional knowledge or expressions of culture for a non-customary use (whether or not of a commercial nature).

### Division 2 – Applications for use and identifying traditional owners

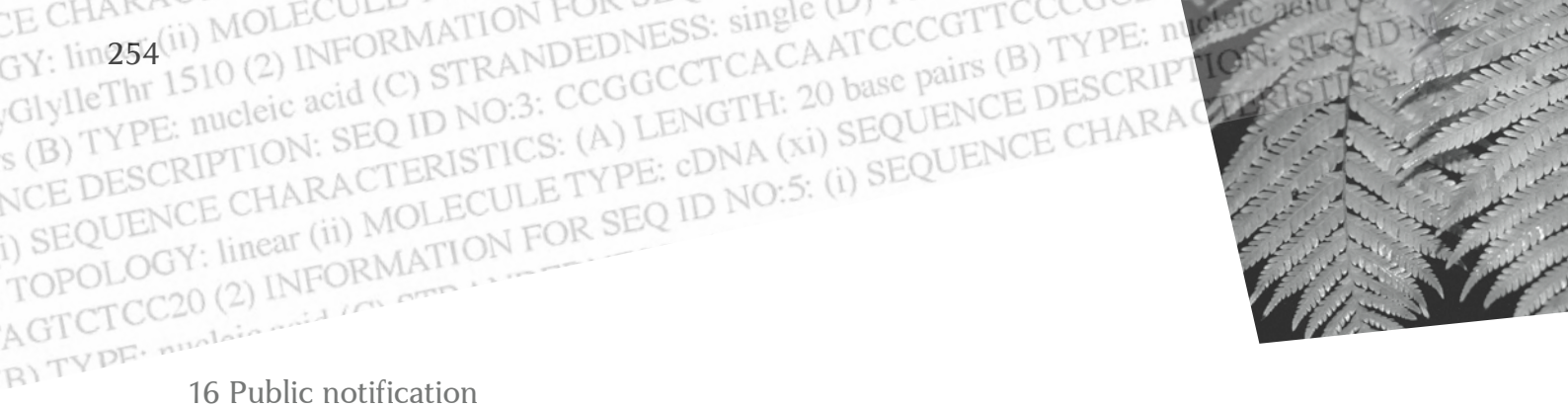
#### 15 Application

(1) A prospective user of traditional knowledge or expression of culture for a non-customary use (whether or not of a commercial nature) may apply to the Cultural Authority to obtain the prior and informed consent of the traditional owners to use the traditional knowledge or expressions of culture.

(2) The application must:
  (a) be in the prescribed form; and
  (b) specify the way in which the applicant proposes to use the traditional knowledge or expressions of culture; and
  (c) state clearly the purpose for which that use is intended; and
  (d) be accompanied by the prescribed fee.

(3) The Cultural Authority must finalise the application in accordance with this Part within [Enacting country to insert time period].

(4) If the Cultural Authority does not finalise the application within the period mentioned in subsection (5), the traditional owners are deemed not to have consented to the proposed use.



## 16 Public notification

(1) The Cultural Authority must:
  (a) give a copy of the application to those persons (if any) who it is satisfied are the traditional owners of the traditional knowledge or expressions of culture to which the application relates; and
  (b) publish a copy of the application in a newspaper having national circulation stating how interested persons may obtain a copy of the application; and
  (c) if appropriate, broadcast details of the application on radio or television stating how interested persons may obtain a copy of the application.

(2) Any person who claims to be a traditional owner of the traditional knowledge or expressions of culture to which the application relates must advise the Cultural Authority within 28 days after the application is published or broadcasted (whichever is the later). The advice may be given orally or in writing.

(3) The Cultural Authority must record in writing the details of any oral or written advice given under subsection (2).

## 17 Identification of traditional owners

(1) If the Cultural Authority is satisfied that it has identified all of the traditional owners it must make a written determination containing such details as to identify the traditional owners.

(2) The Cultural Authority must:
  (a) publish a copy of the determination in a newspaper having national circulation; and
  (b) if appropriate, broadcast details of the determination on radio or television.

## 18 Uncertainty or dispute about ownership

(1) If the Cultural Authority is not satisfied that it has identified all of the traditional owners or that there is a dispute about ownership, the Cultural Authority must refer the matter to the persons concerned to be resolved according to customary law and practice or such other means as are agreed to by the parties.

(2) When all of the traditional owners have been identified in accordance with customary law and practice or such means as have been agreed to, the traditional owners must advise the Cultural Authority, and the Cultural Authority must make a written determination containing such details as to identify the traditional owners.

(3) The Cultural Authority must:
  (a) publish a copy of the determination in a newspaper having national circulation; and
  (b) if appropriate, broadcast details of the determination on radio or television.

### 19 No traditional owners or no agreement about ownership

(1) If the Cultural Authority is satisfied that:
  (a) no traditional owners can be identified; or
  (b) no agreement has been reached on ownership within the period mentioned in section 15(3) after the application was made; the Cultural Authority may, after consultation with the Minister, make a determination that the Cultural Authority is the traditional owner of the traditional knowledge or expressions of culture concerned for the purposes of this Act.

(2) If the Cultural Authority enters into an authorised user agreement, any monetary or non-monetary benefits arising under the agreement must be used for traditional cultural development purposes.

## Division 3 – Authorised user agreements

### 20 Application to be rejected or negotiations for agreement

(1) The traditional owners must decide whether:
  (a) to reject the application; or
  (b) to accept the application and to enter into negotiations for a written authorised user agreement in relation to the application.

(2) The traditional owners must advise the Cultural Authority of their decision. The advice may be given orally or in writing.

(3) The Cultural Authority must advise the applicant in writing of the traditional owners' decision.

### 21 Proposed agreement to be referred to Cultural Authority

(1) Before entering into an authorised user agreement, the traditional owners must refer the proposed agreement to the Cultural Authority for its comments on the proposed terms and conditions of the agreement.

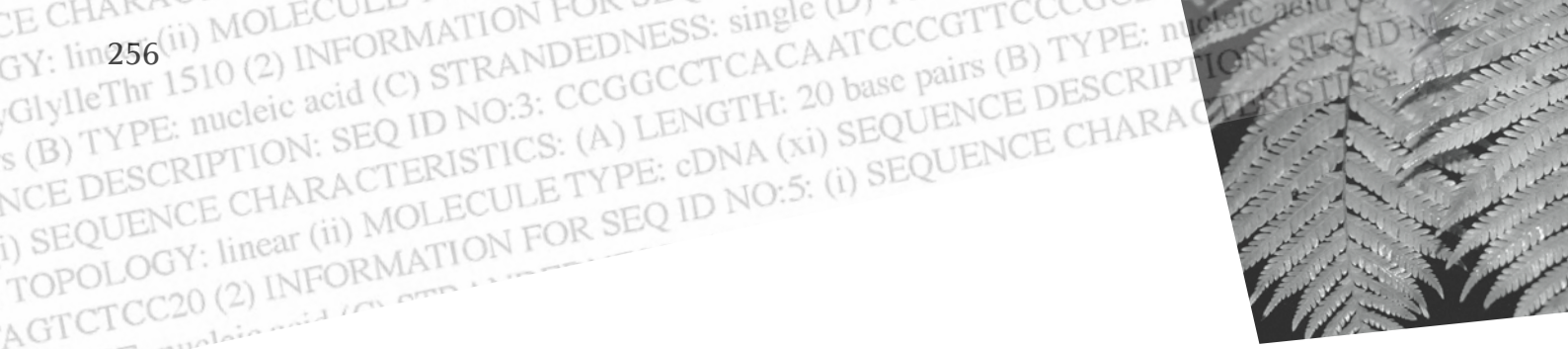
(2) The Cultural Authority may request the applicant and the traditional owners to meet with it to discuss the proposed agreement if the Cultural Authority is, after reviewing the proposed agreement, satisfied that:
  (a) the traditional owners do not have sufficient information to make a full and informed decision about the proposed terms and conditions of the agreement; or
  (b) the proposed terms and conditions of the agreement do not adequately protect the traditional knowledge or expressions of culture of the traditional owners.

(3) The traditional owners may accept, reject or modify any comments made by the Cultural Authority in relation to the proposed agreement.

### 22 Terms and conditions

An authorised user agreement should include terms and conditions about the following:

(a) sharing of financial and other benefits arising from the use of the traditional knowledge or expressions of culture;



(b) compensation, fees, royalties or other payments for the use;
(c) whether the use will be exclusive or non-exclusive;
(d) duration of the use to be allowed and rights of renewal;
(e) disclosure requirements in relation to the use;
(f) the possible sharing by the traditional owners of any intellectual property rights arising from the use of the traditional knowledge or expressions of culture;
(g) access arrangements for the traditional owners;
(h) education and training requirements for the applicant;
(i) controls on publication;
(j) specify whether the rights arising under the agreement can be assigned;
(k) choice of law in relation to disputes under the agreement;
(l) respect for moral rights of the traditional owners.

### 23 Authorised user agreement and prior and informed consent

(1) If a prospective user and the traditional owners enter into an authorised user agreement, the traditional owners are deemed to have given their prior and informed consent to the proposed use.
(2) The traditional owners must advise the Cultural Authority and forward to it a copy of the final agreement.
(3) The Cultural Authority is to keep a register of authorised user agreements. The register is to be in such form and contain such information as the Cultural Authority determines.

### 24 No authorised user agreement reached

(1) If the traditional owners and the applicant cannot agree on the terms and conditions of an agreement in relation to the application, the traditional owners must advise the Cultural Authority. The advice may be given orally or in writing.
(2) The Cultural Authority must advise the applicant in writing that the traditional owners have rejected the proposed authorised user agreement.
(3) The Cultural Authority must record in writing the details of any oral or written advice given under subsection (1).

## Division 4 – Applications not made under this Part

### 25 Procedure for applications

(1) Nothing prevents a prospective user of traditional knowledge or expressions of culture from obtaining the prior and informed consent of the traditional owners without applying to the Cultural Authority under section 15.
(2) The prospective user must advise the Cultural Authority that the prospective user has sought the prior and informed consent of the traditional owners.
(3) The prospective user must provide the Cultural Authority with a copy of the proposed authorised

user agreement between the prospective user and the traditional owners for comment, and advice about other prospective traditional owners.

(4) The prospective user must provide a copy of the signed authorised user agreement to the Cultural Authority to be entered in the register (refer subsection 23(3)) within 28 days after the agreement comes into force.

(5) If a prospective user and the traditional owners enter into an authorised user agreement, the traditional owners are deemed to have given their prior and informed consent to the proposed use.

(6) The prospective user cannot contract out of the obligation under subsection (3). If a copy is not provided under subsection (3), the authorised user agreement is null and void.

## PART 5 – ENFORCEMENT

### Division 1 – Offences

#### 26 Offence in relation to traditional cultural rights

If:

(a) a person makes a non-customary use of traditional knowledge or an expressions of culture (whether or not such use is of a commercial nature); and

(b) the traditional owners have not given their prior and informed consent to that use;

the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.

#### 27 Offence in relation to moral rights

If:

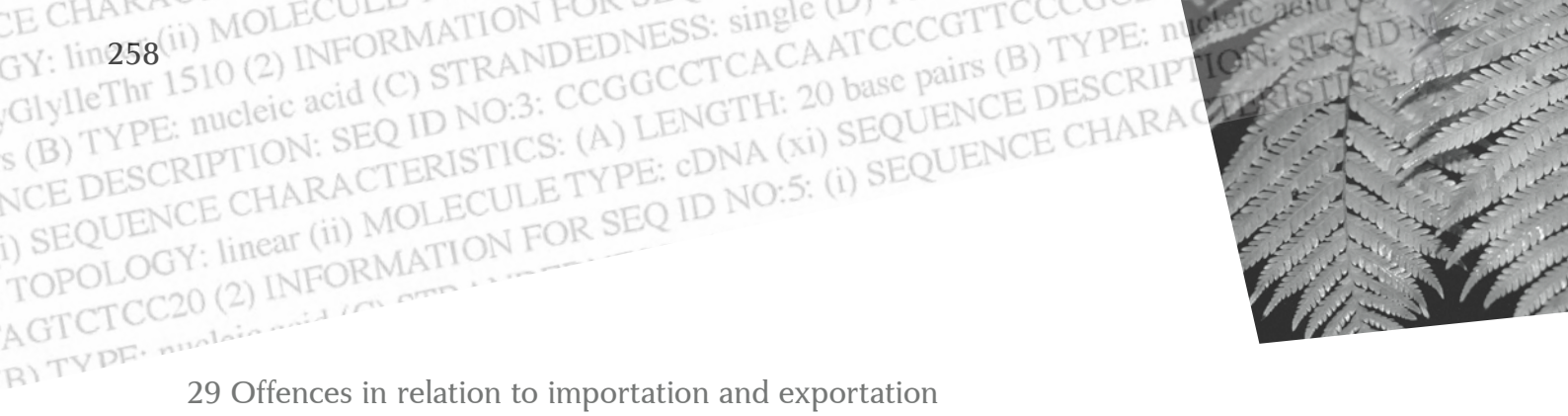
(a) a person does an act or makes an omission in relation to traditional knowledge or an expression of culture that is inconsistent with the moral rights of the traditional owners of that traditional knowledge or expression of culture; and

(b) the traditional owners have not given their prior and informed consented to the act or omission;

the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.

#### 28 Offence in relation to sacred-secret material

If a person uses sacred–secret traditional knowledge or an expression of culture other than in accordance with a customary use, the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.



### 29 Offences in relation to importation and exportation

If:

(a) a person imports an article or other thing into [Enacting country] that relates to traditional knowledge or expressions of culture of that country; and

(b) the person knew, or ought reasonably to have known, that the article or thing would have contravened the traditional cultural rights or the moral rights of the traditional owners had it been created in [Enacting country];

the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.

If:

(a) a person exports traditional knowledge or an expression of culture and the export is a non-customary use (whether or not such use is of a commercial nature); and

(b) the traditional owners have not given their prior and informed consent to the export of the traditional knowledge or expressions of culture;

the person is guilty of an offence punishable on conviction by a fine not exceeding an amount equivalent to [Enacting country to determine] or a term of imprisonment not exceeding [Enacting country to determine] years, or both.

## Division 2 – Civil actions

### 30 Civil claims

If:

(a) a person makes a non-customary use of traditional knowledge or an expression of culture (whether or not such use is of a commercial nature); and

(b) the traditional owners have not given their prior and informed consent to that use;

the traditional owners may institute proceedings against the person in the [ ] Court seeking all or any of the relief set out in section 31.

If:

(a) a person does an act or makes an omission in relation to traditional knowledge or an expression of culture that is inconsistent with the moral rights of the traditional owners of that traditional knowledge or expression of culture; and

(b) the traditional owners have not given their prior and informed consent to the act or omission;

the traditional owner may institute proceedings against the person in the [ ] Court seeking all or any of the relief set out in section 31.

### 31 Remedies

(1) The [ ] Court may grant all or any of the following in relation to proceeding instituted under section 30:

(a) an injunction;
(b) damages for loss resulting from the unauthorised use;
(c) a declaration that the traditional cultural rights of the traditional owners have been contravened;
(d) an order that the defendant make a pubic apology for the contravention;
(e) an order that any false attribution of ownership, or derogatory treatment, of the traditional knowledge or expression of culture cease or be reversed;
(f) an order for an account for profits;
(g) an order for the seizure of any object made, imported or exported contrary to this Act;
(h) such other orders as the Court considers appropriate in the circumstances.

(2) The Court in deciding what relief is to be granted may take into account all or any of the following:
(a) whether the defendant was aware or ought reasonably to have been aware of the traditional cultural rights and moral rights of the traditional owners;
(b) the effect on the honour or reputation of the traditional owners resulting from the unauthorised use;
(c) any thing done by the defendant to mitigate the effects of the unauthorised use;
(d) any cost or difficulty that may have been associated with identifying the traditional owners;
(e) any cost or difficulty in ceasing or reversing any false attribution of ownership, or derogatory treatment, of the traditional knowledge or expression of culture;
(f) whether the parties have undertaken any other action to resolve the dispute.

## Division 3 – Defences and other matters

### 32 Defences

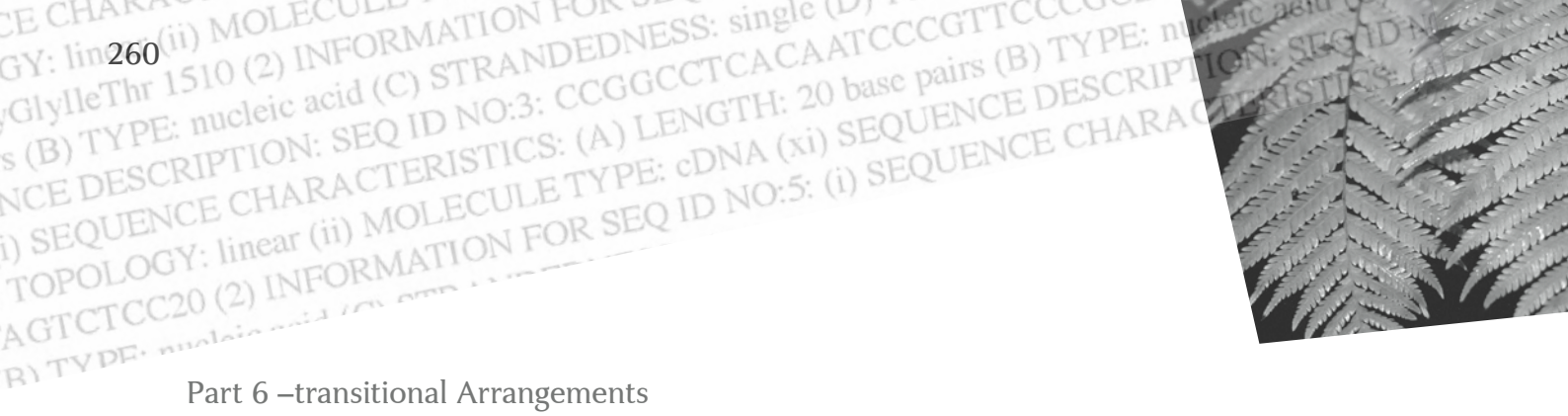
It is a defence to an offence against section 26 or 27, or an action under subsection 30(1) or (2), if a determination has been published under section 17 and the traditional owners specified in that determination have given their prior and informed consent to the use in question.

### 33 Other mechanisms to resolve disputes

Nothing in this Part prevents the traditional owner or the other person concerned from attempting to resolve a dispute using all or any of the following:
(a) mediation;
(b) alternative dispute resolution procedures;
(c) customary law and practices.

### 34 Other rights of action and remedies

This Part does not affect any rights of action or other remedies, whether civil or criminal, provided for under other Acts or laws.



## Part 6 –transitional Arrangements

### 35 Procedure for transitional arrangements

(1) Subject to subsections 3(2) and (3), this section applies to a person if, immediately before the commencement of this Act, the person was making a non-customary use of traditional knowledge or an expression of culture.
(2) The provisions of this Act do not apply to the person during the period of 60 days ("the application period") starting on the commencement of this Act.
(3) During the application period, the person must apply under Part 4 to the Cultural Authority to obtain prior and informed consent from the traditional owners to continue to use the traditional knowledge or expression of culture.
(4) If the person does not apply to the Cultural Authority in accordance with subsection (3), the Act applies to the person on and after the end of the application period.
(5) If a person has applied to the Cultural Authority in accordance with subsection (3), the Act continues not to apply to the person until the traditional owners reject the application or enter into an authorised user agreement with the person, whichever first occurs.

## Part 7 – Cultural Authority

### 36 Designation of Cultural Authority

The Minister may designate an existing [or new] body to perform the functions of the Cultural Authority in section 37.

### 37 Functions of the Cultural Authority

The functions of the Cultural Authority may include the following:
(a) to receive and process applications under Part 4;
(b) to monitor compliance with authorised user agreements and to advise traditional owners of any breaches of such agreements;
(c) to develop standard terms and conditions for authorised user agreements;
(d) to provide training and education programs for traditional owners and users of traditional knowledge or expressions of culture;
(e) to develop a Code of Ethics in relation to use of traditional knowledge and expressions of culture;
(f) to issue advisory guidelines for the purposes of this Act;
(g) to liase with regional bodies in relation to matters under this Act;
(h) to maintain a record of traditional owners and/or knowledge and expressions of culture;
(i) if requested to do so to provide guidance on the meaning of customary use in specific cases;
(j) such other functions as are conferred on it by this Act.

## Part 8 – Miscellaneous

### 38 Regulations

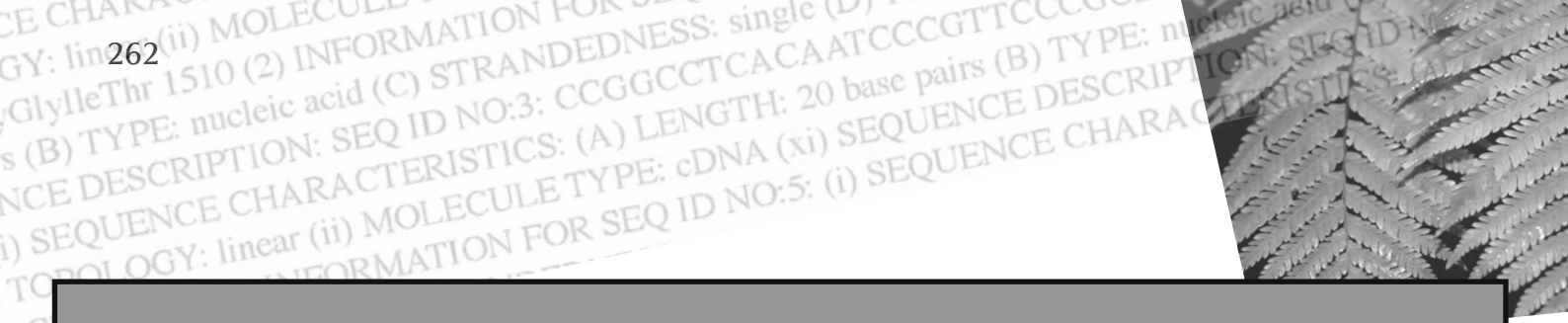
The Minister may make regulations prescribing all matters:

(a) required or permitted by this Act to be prescribed; or

(b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.

### 39 Recognition of other laws

In accordance with reciprocal arrangements, this Act may provide the same protection to traditional knowledge and expressions of culture originating in other countries or territories as is provided to traditional knowledge and expressions of culture originating in the [Enacting country].



# PAOAKALANI DECLARATION

# PALAPALA KŪLIKE O KA ʻAHA PONO PAOAKALANI DECLARATION

## BACKGROUND

On October 3-5, 2003, Kanaka Maoli of Ka Pae `Āina Hawai`i gathered at Ka `Aha Pono – Native Hawaiian Intellectual Property Rights Conference – and united to express our collective right of self-determination to perpetuate our culture under threat of theft and commercialization of the traditional knowledge of Kanaka Maoli, our wahi pana and nā mea Hawai`i.

Attending as participants were Kanaka Maoli who are Hawai`i's foremost kumu hula; elders skilled in lā`au lapa`au, traditional and contemporary artists; and individuals who engage in all cultural expressions, including spiritual and ceremonial practice, subsistence agronomy, marine economic pursuits, and the maintenance and transmission of Hawai`i's oral traditions; teachers and academics; and attorneys. Several non-Hawaiian participants made significant contributions throughout the conference.

## PREAMBLE

Inspired by this historical meeting at Paoakalani, upon the lands of our QueenLili`uokalani, we celebrate the mana of our akua, `aumakua, kupuna, `āina, and lāhui. Cognizant of our kuleana as guardians of our culture and land, we endorse the following Declaration as our collective responsibility to determine a pono future for Hawai`i nei, her culture, and indigenous peoples.

Throughout the Pacific Basin and Ka Pae `Āina Hawai'i, the territories, lands, submerged lands, marine resources and seas of our peoples are being subjected to commercial exploitation. This exploitation is perpetrated by state and national governments, international agencies, private corporations, academic institutions and associated research corporations.

Commercialization has profoundly and adversely impacted Kanaka Maoli spiritual practices, sacred sites, and associated objects, preventing our ceremonial undertakings, encouraging the selling of sacred ceremonial artifacts, and advertising the images of sacred ceremony and wahi pana. The creative cultural expressions of Kanaka Maoli are being stolen and commercialized for the advertising of commercial products and for the sale of our lands and natural resources in total disregard for and in derogation of our rights as creators of these artistic cultural expressions.

In Hawai`i, bioprospecting and biotechnology institutions and industries are imposing western intellectual property rights over our traditional, cultural land- based resources. This activity converts our collective cultural property into individualized property for purchase, sale, and development. The biogenetic materials of our peoples, taken for medical research for breast cancer and other diseases attributable to western impact, have been obtained through misrepresentation and without the free, prior and informed consent of our peoples. We view these activities as biopiracy and condemn these acts as biocolonialism.

In recognition of the Pacific `ohana and the global family of indigenous peoples who have previously produced unifying statements, we incorporate and support the statements contained in the Kari-Oca Declaration, Indigenous Peoples' Earth Charter, Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, UNDP Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights (Suva, Fiji, 1995), and the Treaty For a Lifeforms Patent-Free Pacific and Related Protocols.

## KAUOHA: DECLARATION

1. Kanaka Maoli have the right of self-determination. By virtue of that right we freely determine our political status and freely pursue our economic, social, and cultural development, which includes determining appropriate use of our traditional knowledge, cultural expressions and artforms, and natural and biological resources.

2. The lands, submerged lands, waters, oceans, airspace, territories, natural resources of Ka Pae `Āina Hawai`i and associated Kanaka Maoli traditional knowledge are, by our inherent birth right, the kuleana and property of Kanaka Maoli and the inheritance of future generations of our peoples. As such, the standards and criteria for consumption, development, and utilization of these rsources shall be there for Kanaka Maoli to promote our culture through principles of pono, aloha `āina and mālama `āina.

3. We reaffirm that colonialism is perpetuated through the intellectual property regimes of the west and call upon all peoples residing on our territories to acknowledge, adopt, and respect the cultural protocols of our peoples to maintain and protect Hawai`i and its great wealth of biodiversity.

4. We declare our willingness to share our knowledge with humanity provided that we determine when, why, and how it is used. We have the right to exclude from use those who would exploit, privatize, and unfairly commercialize our traditional knowledge, cultural expressions and artforms, natural resources, biological material, and intellectual properties.

## PAPA: THE FOUNDATION

5. According to the Kumulipo, a genealogical chant of creation, Pō gave birth to the world. From this female potency was born Kumulipo and Pō`ele. And from these two, the rest of the world unfolded in genealogical order. That genealogy teaches us the land is the elder sibling and the people are the younger sibling meant to care for each other in a reciprocal, interdependent relationship. Humanity is reminded of his place with the order of genealogical descent. The foundational principle of the Kumulipo is that all facets of the world are related by birth. And thus, the Hawaiian concept of the world descends from one ancestral genealogy.

6. From time immemorial, Kanaka Maoli have understood the evolution of the world, its life forms, and our cultural place within the cosmic worldview. All life forms of the honua, arising first from the kai with counterparts on the `āina, the naming of our `ohana and the identification of our mo`okū`auhau in the Kumulipo, impress upon our peoples the obligation to act as the kia`i of the honua and its life forms. Through pono behavior, we perpetuate the life of our lands and our peoples.

7. We emphasize that the Kanaka Maoli worldview is governed by the cultural principles of pono, mālama `āina, and kuleana. Within this worldview, the Earth and her myriad lifeforms (biological diversity) are kinolau, the earthly body forms of the Akua. Every life form possesses living energy that sustains each other creating a familial, interdependent, reciprocal relationship between the Akua, the `āina, and the kanaka in fine balance and harmony.

    7.1 Pono governs the cosmos, guiding and informing the behavior among the Akua, the `āina, and the kanaka, and their interaction at and between the microcosmic and macrocosmic levels, ensuring proper maintenance and development of our society, our culture, and ourexistence in all forms and in all dimensions.

    7.2 Mālama `Āina is the operating cultural principle that maintains pono. The people and the land are of the same integrated ancestral lineage, the `āina and all of her life forms, our ancestor, and the Hawaiian people, the younger.

    7.3 Each aspect of the trilogy of the Akua, the `āina, and the kanaka share familial, interdependent, and reciprocal responsibilities to each other expressed in kuleana. Kuleana encompasses both the rights and corresponding sacred responsibility with accountability to maintain, conserve, and protect the Akua, the `āina, and the kanaka in perpetuity.

8. As Kanaka Maoli, we maintain our inalienable rights to, jurisdiction over, and management of our `āina mai uka a i kai, mai kahi pae a kahi pae and assert our kuleana for future generations.

9. We maintain our inherent right of self-determination, despite the oppression of colonization and illegal occupation of our land base since January 17, 1893 when our sovereign Kingdom of Hawai`i was overthrown by the military force of the United States.

## TRADITIONAL KNOWLEDGE, CULTURAL EXPRESSIONS AND ARTFORMS

10. Our culture is living and evolves over time with the Kanaka Maoli peoples. The embodiment of Kanaka Maoli identity manifests in both traditional and contemporary artforms and cultural expressions. Authenticity, quality, and cultural integrity of Kanaka Maoli cultural expressions and artforms are, therefore, maintained through Kanaka Maoli genealogy.

11. Kanaka Maoli traditional knowledge encompasses our cultural information, knowledge, uses, practices, expressions and artforms unique to our way of life maintained and established across Ka Pae `Āina Hawai`i since time immemorial. This traditional knowledge is based upon millennia of observation, habitation, and experience and is a communal right held by the lāhui and in some instances by `ohana and traditional institutions and communities. The expression of traditional knowledge is dynamic and cannot be fixed in time, place or form and therefore, cannot be relegated to western structures or regulated by western intellectual property laws. We retain rights to our traditional knowledge consistent with our Kanaka Maoli worldview, including but not limited to ownership, control, and access. We also retain the right to protect our traditional knowledge from misuse and exploitation by individuals or entities who act in derogation of and inconsistent with our worldview, customs, traditions, and laws. Our traditional knowledge includes, but is not limited to, the following:

    a. knowledge of histories and traditions transmitted through Kanaka Maoli traditional and contemporary means;

    b. details of cultural landscapes and particularly sites of cultural significance;

    c. records of contemporary events of historical and cultural significance;

    d. sacred ceremonies, images, sounds, knowledge, material, culture or anything that is deemed sacred by the lāhui, `ohana, and traditional institutions and communities;

    e. cultural property, including but not limited to expressions, images, sounds, objects, crafts, art, symbols, motifs, names, and performances;

    f. knowledge of current use, previous use, and/or potential use of plant and animal species, soils, minerals, and objects;

    g. knowledge of planting methods, care for, selection criteria, and systems of taxonomy of individual species;

    h. knowledge of preparation, processing, or storage of useful species and formulations involving more than one ingredient;

    i. knowledge of ecosystem conservation (methods of protecting or maintaining a resource);

    j. biogenetic resources that originate (or originated) in Ka Pae `Āina Hawai`i and consistent with the Kumulipo;

    k. tissues, cells, biogenetic molecules, including DNA, RNA, and proteins, and all other substances originating in the bodies of Kanaka Maoli, in addition to genetic and other information derived therefrom;

12. Our oral traditions transmitted from generation to generation through our kupuna have sustained our people, culture and natural resources. Therefore, we must look to our kupuna for guidance to the rights and responsibilities inherited with this knowledge.

13. We recognize our traditional methods of expression, including oral modes, as valid forms of documentation.

14. The use of traditional knowledge is inseparable from the kuleana to comply with the Kanaka Maoli worldview, whether operating within traditional, contemporary, or western structures.

15. Kanaka Maoli, as the inherent owners and guardians of our traditional knowledge, are the rightful beneficiaries of the privileges of western intellectual property rights when our traditional knowledge is used. We retain all rights to the use of our traditional knowledge. Accordingly, western intellectual property rights holders who use such knowledge do not attain ownership rights to that knowledge. Those who use our traditional knowledge have the kuleana to properly accord Kanaka Maoli the benefits and rights derived from such use.

16. We oppose the theft of our traditional knowledge by entities, including the pharmaceutical, agricultural and chemical industries, the United States military, academic institutions and associated research corporations, for scientific and biotechnology research and further commercialization and granting of patents on all life forms.

## SCIENTIFIC RESEARCH

17. We have the right to free, prior and informed consent before research relating to our biological resources commences. Researchers, corporations, educational institutions, government or others conducting such research must fully and entirely inform Kanaka Maoli regarding the purposes of their research and recognize our right to refuse to participate.

18. Biological samples are being transferred, traded, bought, and sold without the agreement or consent of our peoples, in violation of our inherent human rights.

19. Although biological and genetic samples have been transferred, sold, patented or licensed, Kanaka Maoli never relinquished our rights to our biological and genetic materials and, therefore, call for the rightful repatriation of such samples and due compensation.

20. Kanaka Maoli human genetic material is sacred and inalienable. Therefore, we support a moratorium on patenting, licensing, sale or transfer of our human genetic material.

21. We further support a moratorium on patenting, licensing, sale or transfer of any of our plants, animals and other biological resources derived from the natural resources of our lands, submerged lands, waters, and oceans until indigenous communities have developed appropriate protection and conservation mechanisms.

## KŪ I KA PONO: ASSERTING THE BALANCE

22. In accordance with our right of self-determination, we are determined to take future action to bring pono and protect our culture, `āina and lāhui from exploitative use and commercialization of our traditional knowledge, cultural expressions and artforms, natural and biological resources, and intellectual properties. Recognizing that existing laws are insufficient to protect our cultural and intellectual property, we call upon Kanaka Maoli, our `ohana, and supporters to join in the following future action:

    22.1 Develop a code of conduct/standards for best practices, which private industries, academics and academic institutions, and government must observe before and during the use (such as visual, audio or written recording) of our traditional knowledge, cultural expressions and artforms, and natural and biological resources.

    22.2 Develop a sui generis system for protection of our intellectual property and related traditional knowledge and biological diversity and support its enactment into law.

    22.3 Advocate for adoption of a policy that recognizes our rights to our traditional knowledge, cultural expressions and artforms, or natural and biological resources and ensures a system of equitable benefit sharing by those conducting research relating to, or using or seeking to use our traditional knowledge, cultural expressions and artforms, or natural and biological resources.

    22.4 Continue to educate Kanaka Maoli, the public, the private sector and government about our cultural and intellectual property rights through Kanaka Maoli-produced forums, video works, and publications.

    22.5 Continue Ka `Aha Pono as an annual conference to gather, discuss, educate about, and take action to protect Kanaka Maoli intellectual property rights, traditional knowledge, culture, arts, and natural and biological resources.

23. We call upon government, the private sector, and the public to cooperate with the above future action and undertake to develop and implement policies and practices consistent with this Declaration in full consultation with Kanaka Maoli.

# GLOSSARY

## HAWAIIAN

`Āina: Land (lit. that which feeds)

Akua: Divine manifestations

`Aumakua: Deified ancestral manifestations

Honua: Earth

Kai: Ocean

Kanaka Maoli: Genealogical descendants born of Ka Pae ʻĀina Hawai`i

Ka Pae `Āina Hawai`i: Hawaiian archipelago from Kure to Kama`ehu, including waters, submerged lands, air and all life forms, minerals and other resources therein from the depths of the Earth to the zenith of the heavens from the rising of the sun to the setting of the sun.

Kia`i: Sacred guardian

Kinolau: Earthly manifestations of Akua

Kumu hula: Master teachers of Kanaka Maoli dance and chant

Kumulipo: Cosmogonic genealogy chant of creation

Kupuna: Kanaka Maoli elders, existing both physically and spiritually, who possess traditional knowledge and serves as conduits ensuring the present and the future of ka lāhui Hawai`i.

Lāʻau lapaʻau: Traditional process of Hawaiian healing incorporating the gathering, preparation, and use of Native plants in conjunction with prayer and the Kanaka Maoli worldview.

Lāhui: Collective being of Kanaka Maoli expressed through land, natural resources, and institutions

Mo`okū`auhau: Inherent Ancestral Genealogy

Mai uka a i kai, mai kahi pae a kahi pae: include lands, waters, submerged lands, air and all life forms, minerals and other resources therein, according to the cultural principle of mālama `āina.

Mana: Spiritual strength

Nä Mea Hawai`i: All things Kanaka Maoli

`Ohana: Traditional system of familial relations

Wahi pana: Sites of significance and importance to Kanaka Maoli

# GLOSSARY

## ENGLISH

Biogenetic materials: Biological and genetic resources, including plant material, animals, microorganisms, cells, and genes.

Biological diversity (biodiversity): The total variety of life in all its forms. It includes many levels that range from the level of alleles to the biosphere. The major elements of biodiversity include alleles, genes, populations, species, ecosystems, landscapes and the ecological processes of which they are a part.

Free, prior and informed consent: Principle of fully informed consent after full disclosure and consultation. Full disclosure is of the full range of potential benefits and harms of the research, all relevant affiliations of the person(s) or organization(s) seeking to undertake the research, and all sponsors of the researcher(s).

Sui generis: Of its own kind; unique. In the context of Kanaka Maoli, sui generis mechanisms are those we create for particular application to Ka Pae `Äina Hawai`i.

Western intellectual property rights: Includes copyrights, trademarks, and patents. Intellectual property is a legal concept used to "protect" the dissemination of information, derives from capitalism, and is commercial in nature. It is used to insure an author, inventor, or producer of a product the right to monopolize what they have created.

### Copyrights

Copyright law protects the expression of an idea, literary, artistic, commercial, or otherwise. The expression is protected when it is original, not copied and "fixed in a tangible medium of expression." An expression is fixed when it is written or recorded somehow so that it can be communicated again. "Original" means only that the author contribute something more than a mere trivial variation; in other words the author must contribute something recognizable as his own. Works that are protected by copyright law include literature, music, drama, dance, pictures, sculpture, and movies. Copyright does not protect ideas, concepts or procedure. Protection under copyright law lasts for the author's life plus 70 years. During that time, the author has exclusive rights to reproduction or copying, distribution, adaptation, public performance, and public display. When the term for protection expires, the work becomes part of the public domain and can be used by anyone.

### Trademarks

Trademarks are always linked to commercial activity. The purpose of trademarks is to identify goods and products in the mind of the consumer to gain a commercial advantage. Trademarks are often found in names and symbols that identify products.

### Patents

Patent law deals with inventions; any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement. Patents exist for things found everywhere: medicine, computers, and cars, just to name a few. Patents are not given for any natural phenomena or abstract ideas, for example mathematical formulas and calculation.


Participants of Mataatua Declaration Conference, Kokohinau Marae, Te Teko, Aotearoa NZ, June 1993 (ATP Mead)

Participants of Maori Congress Roundtable on Indigenous Self-Determination, Wahiao Marae, Whakarewarewa, Rotorua, Aotearoa NZ, 1995 (ATP Mead)

Participants of Pacific Workshop on the UN Draft Declaration on the Rights of Indigenous Peoples, Suva, Fiji, September 1996 (ATP Mead)

Participants of the UNESCO/SPC Symposium on the Protection of Traditional Knowledge & Expressions of Indigenous Cultures in the Pacific Islands, Noumea, 1999 – meeting that mandated the development of the Pacific Model Law for the Protection of TK. (SPC).

Participants of Pacific Dialogue on the use & Ownership of Genes, The University of The South Pacific (USP), Suva, Fiji, June 2005 (COE)


Demarcation Line
Xi'an
Seoul
S. KOREA
Tokyo
Osaka
JAPAN
Shanghai
North Pacific Ocean
San Francisco
Midway Islands (U.S.)
UNITED STATES
Hawaiian Islands
Honolulu
Tropic of Cancer
Guangzhou
Taiwan
Hong Kong (U.K.)
Macau (PORT.)
Hanoi
Vientiane
Philippine Sea
Northern Mariana Islands (U.S.)
Wake Island (U.S.)
Johnston Atoll (U.S.)
Manila
Saipan
Guam (U.S.)
PHILIPPINES
VIETNAM
CAMBODIA
Spratly Islands
FEDERATED STATES OF MICRONESIA
Koror
Trust Territory of the Pacific Is (Palau) (U.S.)
Kolonia
MARSHALL ISLANDS
Majuro
Kingman Reef (U.S.)
Palmyra Atoll (U.S.)
BRUNEI
Bandar Seri Begawan
MALAYSIA
Borneo
SINGAPORE
Tarawa
Howland Island (U.S.)
Baker Island (U.S.)
Yaren
NAURU
KIRIBATI
Equator
Jarvis Island (U.S.)
Jakarta
Java
INDONESIA
PAPUA NEW GUINEA
SOLOMON ISLANDS
Honiara
TUVALU
Funafuti
Tokelau (N.Z.)
KIRIBATI
Christmas Island (AUSTL.)
Port Moresby
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Apia
Wallis and Futuna (FR.)
Amer. Samoa (U.S.)
Cook Islands (N.Z.)
Ashmore and Cartier Islands (AUSTL.)
Darwin
Coral Sea Islands (AUSTL.)
VANUATU
Port-Vila
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Suva
TONGA
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AUSTRALIA
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South Pacific Ocean
Pitcairn Islands (U.K.)
Brisbane
Norfolk Island (AUSTL.)
Perth
Sydney
Canberra
Tasman Sea
Auckland
Wellington
NEW ZEALAND
Chatham Islands (N.Z.)
Tasmania
Auckland Islands (N.Z.)
Scale 1:88,000,000
0 500 1000 Kilometers
0 500 1000 Nautical Miles
Miller Cylindrical Projection
120
150
180
30
0
30