Roger Scarlin Chennells

Equitable Access to Human Biological Resources in Developing Countries

Benefit Sharing Without Undue Inducement

Springer

Equitable Access to Human Biological Resources in Developing Countries

Roger Scarlin Chennells

Equitable Access to Human Biological Resources in Developing Countries

Benefit Sharing Without Undue Inducement

Springer

Roger Scarlin Chennells
Chennells Albertyn Attorneys
Stellenbosch, Cape Town
South Africa

ISBN 978-3-319-19724-1 ISBN 978-3-319-19725-8 (eBook)
DOI 10.1007/978-3-319-19725-8

Library of Congress Control Number: 2015943038

Springer Cham Heidelberg New York Dordrecht London

Printed on acid-free paper

Springer International Publishing AG Switzerland is part of Springer Science+Business Media (www.springer.com)

I would like to dedicate this book
To Jono, Sparks, Bids, Miah and Jilly.

Endorsements

Indigenous peoples' genes are precious resources for research and innovation. Yet, no binding international law governs access and benefit sharing for human DNA. In this in-depth ethical and legal study, Chennells makes a convincing case for benefit sharing. With his engaging style, he succeeds in bringing a complex area to life and provides valuable advice for indigenous peoples, policy makers, ethics committees, academics and NGOs. Strongly recommended reading.

Prof. Doris Schroeder
Director of the Centre for Professional Ethics, UCLAN, UK

Genomic studies to date have shown quite convincingly that the San from Southern Africa have retained some of the oldest genetic signatures found among living people throughout the world. Consequently, their genetic material is much sought after by researchers conducting genomic studies to understand the molecular evolutionary processes that have contributed in generating the genetic diversity seen among living people today. How do we balance scientific curiosity for knowledge with social issues related to good ethical practice, respect for research subjects, and acknowledgment of the plight of indigenous communities, engaging with, and educating the public around science? Roger Chennells has worked with the San and represented them on legal issues in the past. In this book, he brings the humanitarian issues into focus, reminds us about governance as stipulated in the legal framework, but most of all, raises our collective consciousness and awareness to sensitive issues, which when addressed respectfully through engagement, has the potential for win–win outcomes for all.

Prof. Himla Soodyall
Division of Human Genetics
National Health Laboratory Service
and University of the Witwatersrand
Johannesburg, South Africa

Since the Convention on Biological Diversity was adopted in 1992, much has been written on access to genetic resources and benefit sharing, and the international rules are now in place. Human biodiversity is another source of genetic material of potential value, but we have no clear guidelines on how to regulate fair and culturally appropriate exchange transactions involving indigenous peoples, government, and industry. This excellent volume forms a practical and philosophical basis to meet the ethical, legal, and regulatory challenges, benefiting from the author's unique insights as a legal representative of indigenous groups in Southern Africa.

Prof. Graham Dutfield
Professor of International Governance
University of Leeds, UK

Acknowledgments

This book is based upon my Ph.D. thesis during which I was ably supported by my supervisors Doris Schroeder and Peter Herissone-Kelly, as well as funded by a bursary from the Wellcome Trust.

I wish to also acknowledge and single out certain San leaders with whom I have worked for many years as their lawyer, and who have been a source of wisdom, inspiration, occasional despair and regular humour. They are Andries Steenkamp, Mario Mahongo, Collin Louw, Zeka Shiwarra, Leana Snyders and Mathambo Ngakaeaja. Their individual and collective struggles over decades to advance the rights of the San provided me with concrete reasons to write this book.

Finally, my children Rebecca, Guy, Oliver, Clara and Sebastian were often bemused but always supportive during this project, Bex pouring encouraging cups of Earl Grey tea, and David reminding me that 'retreat is not an option.' Biddy and Andrew provided generous home comforts and a safe corner in London, and my partner Judy Beaumont's loyal motivation and support contributed hugely towards the eventual completion.

Contents

1 Introduction 1
1.1 Genetics, Genomics and Human Biological Resources 4
1.2 Human Population Genetic Research 8
1.3 Population Bio-Banks 10
1.4 Global Biomedical Research 12
1.4.1 Funding and Collaborations in Research 13
1.4.2 Indigenous Peoples in Genetic Research 15
1.4.3 Setting Research Priorities 17
1.5 Perceived Unfairness in the Exchange of Human Genetic Samples? . . . 18
1.6 Concerns About the Fairness of Exchanges of Genetic Material 23
References 25

2 Exploitation 31
2.1 Everyday Use of the Word Exploitation 32
2.2 Attempts at Understanding the Concept 33
2.3 Legal Approaches to Exploitation 34
2.4 Non-legal Approaches to Exploitation 35
2.5 Mayer's Three Forms of Exploitation 37
2.6 Conclusions 39
References 40

3 Common Heritage of Humankind 41
3.1 A History of the Concept 42
3.2 The Convention for Biological Diversity, State Sovereignty and Benefit Sharing 43
3.2.1 Bioprospecting or Biopiracy? 43
3.2.2 Bioprospecting Case Studies 44
3.2.3 The International Response to Exploitation and the CBD . . . 45
3.2.4 State Sovereignty Over Resources 46

3.3 Human DNA Governance Following Exclusion from the CBD 47
3.3.1 The First Five Years Following the CBD Exclusion 47
3.3.2 Benefit Sharing for Research Participants Introduced 48
3.4 The Profile of Bioprospecting: Non-Human and Human Genetic Resources..... 51
3.4.1 The Genetic Resources, Human and Non-Human 52
3.4.2 The Utilisation of Genetic Resources..... 53
3.5 Conclusion 56
References 57

4 The Altruism Argument 61
4.1 Altruism 62
4.2 Solidarity 64
4.3 The Altruism/Solidarity Argument Examined 66
4.3.1 Is a Call for Altruism and Solidarity in Research Appropriate in the Developing World or Is It Exploitative? ... 66
4.4 Summary and Conclusion 68
References 69

5 The 'No Value Added' Argument..... 71
5.1 An Economic Argument..... 72
5.2 The Prospecting Argument..... 74
References 77

6 Justice and Exploitation in Bilateral Exchanges 79
6.1 The Concept of Justice 80
6.2 Global Justice and International Law..... 81
6.3 Justice and Domestic Law 83
6.3.1 Thomas Pogge's Conceptual Analysis of Justice..... 83
6.3.2 Procedural and Substantive Justice 85
6.3.3 Aristotle's Distributive and Corrective Justice..... 86
6.4 The Law of Equity 88
6.5 The Law of Contract, and Commutative Justice 91
6.6 Exploitation in Contract Law 95
6.6.1 Unconscionable Dealing..... 97
6.6.2 Duress (Coercion)..... 100
6.6.3 Undue Influence 103
6.7 Conclusion 109
References 110

7 Undue Inducement and Coercion 113
7.1 Background to Undue Inducement and Coercion in Bioethics 115
7.2 The Ethical Guidelines..... 119
7.2.1 Exploitation in the Guidelines 120
7.2.2 The Central Concerns of the Guidelines 122

7.3 Vulnerability . . . 122
7.3.1 Definitions and Categories of Vulnerability . . . 124
7.3.2 Desperate Need and Low Baselines . . . 125
7.4 Autonomy . . . 127
7.4.1 Overview . . . 128
7.4.2 Limits on Voluntariness of Consent . . . 130
7.4.3 Inducements . . . 132
7.4.4 Extreme Inducements and Needy Offerees . . . 134
7.4.5 Is Authentic Consent Possible Under Extreme Conditions? . . . 135
7.5 Risk and Beneficence/Non-maleficence . . . 137
7.5.1 Risks and Harms . . . 137
7.5.2 Risks in Genomic Research . . . 139
7.5.3 Assessment by RECs . . . 141
7.5.4 Concerns About Functioning of RECs . . . 143
7.6 The Case Studies . . . 145
7.7 Summary and Conclusions . . . 149
References . . . 152

8 Risks to Indigenous Peoples as Vulnerable Populations . . . 157
8.1 Who Are Indigenous Peoples? . . . 158
8.2 What Are the Risks Faced by Indigenous Populations? . . . 162
8.3 How to Engage with Indigenous Groups? . . . 168
8.3.1 Informed Consent . . . 168
8.3.2 Collective Consent . . . 170
8.3.3 Specific Guidelines and Principles for Indigenous Peoples . . . 171
8.3.4 Guidelines on Consultations and Negotiations . . . 173
8.3.5 Group Consent and Community Review . . . 174
8.3.6 The Southern African San Case . . . 175
8.4 Research Ethics Committees: Roles and Concerns . . . 177
8.4.1 Attitude . . . 178
8.4.2 Capacity . . . 178
8.4.3 Representation . . . 179
8.4.4 Process . . . 181
8.5 Conclusion and Proposals . . . 181
References . . . 183

9 Closing Chapter . . . 189
9.1 Fair Treatment . . . 192
9.2 A Fair Deal . . . 193
9.3 Research that Entails no Harm . . . 194
9.4 Closing Remarks . . . 195

List of Legal Cases . . . 197

Abbreviations

ACUNS	Association of Canadian Universities on Northern Studies
AIATSIS	Australian Institute of Aboriginal and Torres Straits Islander Studies
CBD	Convention on Biological Diversity
COHRED	Council on Health Research for Development
DNA	Deoxyribonucleic Acid
EC	Ethics Committee
EPO	European Patent Office
GWAS	Genome-Wide Association Studies
HGDP	Human Genome Diversity Project
HPGR	Human Population Genetic Research
HUGO	Human Genome Organisation
ICESCR	International Covenant on Economic, Social and Cultural Rights
IHS	Indian Health Service
IPACC	Indigenous Peoples of Africa Coordinating Committee
IPCB	Indigenous Peoples Council on Biocolonialism
IPHRC	Indigenous Peoples' Health Research Centre
IRB	Institutional Review Board
IWRI	Indigenous Wellness Research Institute in America
LMIC	Low Middle Income Country
NBAC	National Bioethics Advisory Commission
NHGRI	National Human Genome Research Institute
NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health
REC	Research Ethics Committee
SPEAR	Social Policy Evaluation and Research Committee
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNOOSA	United Nations Office for Outer Space Affairs
UNPFII	United Nations Permanent Forum on Indigenous Issues
USPTO	United States Patent and Trade Office

WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WMA	World Medical Association
WIMSA	Working Group of Indigenous Minorities in South Africa

List of Tables

Table 6.1 Three doctrines of contractual exploitation 108
Table 9.1 Research questions, main ethical principles, two forms of enquiry 190

Abstract

The overall question examined in this book is, how can cross-border access to human genetic resources, such as blood or DNA samples, be governed to achieve equity for developing countries?

Access to and benefit sharing for human biological resources is not regulated through an international legal framework such as the Convention on Biological Diversity, which applies only to plants, animals and microorganisms as well as associated traditional knowledge. This legal vacuum for the governance of human genetic resources can be attributed (in part) to the concern that benefit sharing might provide undue inducements to research participants and their communities.

This book aims to show that:

(a) Benefit sharing is crucial to avoiding the exploitation of developing countries in genetic research.
(b) With functioning research ethics committees, undue inducement is less of a concern in genetic research than in other medical research (e.g. clinical trials).
(c) Justified concerns remain regarding genetic research involving indigenous populations. These concerns are debated, and some recommendations are provided.

In addressing the above highly pressing topics in global bioethics and international law, the book combines bioethical argument with jurisprudence, drawing on the law of equity as well as the legal concepts of duress (coercion), unconscionable dealing, and undue influence. Recommendations are made towards more ethical genetic research involving indigenous peoples.

Chapter 1
Introduction

Abstract The introductory chapter places the topic of exchange of human biological resources within the parameters of modern human population genetic research (HPGR). In doing so it traverses the legal and ethical landscape pertaining to population wide genomic research, including population bio-banks and global bio-medical research, describing the types of cases that have aroused persistent perceptions of unfairness. These cases lead to brief discussions on the issues raised in more depth during the book. In particular the topic of exploitation encountered during genetic and genomic research is introduced, and institutional legal recommendations for benefit sharing are described in the context of theories in bioethics that oppose benefit sharing in principle. Finally ethical concerns about the dangers of undue inducement are described, as well as the specific problems pertaining to genomic research which is conducted on vulnerable and in particular indigenous research populations.

Keywords Human biological resources · Human population genetic research · Research ethics · Benefit sharing · Indigenous research populations

Humans have since ancient times sought to unravel the mysteries of life. This quest, involving fields of knowledge ranging from life science to philosophy, has a mysterious and even existential component, delving as it does into the very heart of the human condition. Human DNA has been at the centre of relevant research endeavours since the 20th Century. This book examines the equity or fairness of the exchange of human biological resources, in particular DNA samples, across national borders. This exchange is very important for scientific and health research; yet it has been described as highly exploitative of developing countries (Macklin 2004, p. 68).[1] How to enable scientific and medical research using

[1]The commonly used descriptive adjectives, *developed* and *developing* countries are utilised throughout this book rather than, 'first and third world', 'north and south', or other formulations currently in use.

R.S. Chennells, *Equitable Access to Human Biological Resources in Developing Countries*, DOI 10.1007/978-3-319-19725-8_1

human biological resources without exploiting individuals, and in particular vulnerable populations such as the indigenous or Aboriginal peoples frequently targeted for genetic research, is the main question of this book.

In order to resolve this question, a number of sub-topics have to be examined, in particular:

1. How does the putative exploitation of donors of human biological resources manifest itself at the beginning of the 21st Century?
2. What is the legal and ethical landscape governing this area of enquiry? That is are there existing legal or ethical frameworks, which aim to protect relevant groups from exploitation? If so, what are their deficits given on-going exploitation claims? And how can these be addressed?
3. Working towards answering these questions requires clarity on the concepts used. In particular it needs to be clear what I mean by genetic and genomic research, and by human biological resources. In addition, other terms such as benefit sharing, exploitation, equity, common heritage of humankind, altruism, solidarity, indigenous peoples, international customary law, commodification, and undue inducement will become important as the book progresses and will be explained as they arise.

At the same time a number of questions fall outside the scope of this investigation. For example, questions about the legitimacy of genomic research. To illustrate this point, one might argue that the public funds spent on genomic research on malaria could be better used to distribute bed-nets.[2] However, I shall assume with Gro Harlem Brundtlandt the former Director General of the World Health Organisation (WHO 2002) that, "it is clear that the science of genomics holds tremendous potential for improving health globally […] the specific challenge is how to harness this knowledge and have it contribute towards health equity, especially amongst developing nations" (ibid, p. 3).

Other important questions such as the potential exploitation of clinical trial participants or researchers, of forensic databases created by governments for purposes of resolving crime and enforcing law and order also fall outside the scope of this book. Broader questions about the human right to access to health care as well as major issues in global distributive justice (Pogge 2008) cannot be ignored and will be used for context, but will also not be addressed in full depth.

Finally and with moral emphasis I intend to address the question of the fair and equitable treatment of indigenous peoples in genomic research, and to provide convincing arguments to persuade or counter the beliefs of an imaginary sceptic whose views, a composite of various authors who will be referred to below, could be condensed and expressed as follows,

[2]Question from the floor at the Human Heredity and Health (H3) Conference, Cape Town 3–6 March 2011.

Exploitation is not a problem in genetic research, for indigenous peoples or any other communities. Benefit sharing is inappropriate for a number of reasons, including the fact that human genetic resources are part of the common heritage of humankind. In addition, individuals should share willingly out of altruism, and they have done nothing to add value to their DNA. If benefit sharing were to be allowed, (which we do not concede) it would run the risk of unduly influencing or coercing poor research participants. Finally, indigenous peoples are but one of many types of genomic research communities, and their concerns are adequately addressed by mainstream research ethics guidelines.

In order to achieve the objective set out above and to counter the views of the imaginary sceptic, the origin of the notion of benefit sharing will need to be broadly examined in this introduction, this mechanism having been proposed in order to prevent exploitation during the exchange of genetic materials for research. Three leading questions will be specifically addressed in the book, namely firstly whether and in what circumstances benefit sharing is appropriate for human genetic research, secondly whether such benefit sharing runs the risk of unduly inducing or coercing research participants, and thirdly whether the particular concerns of indigenous peoples are adequately met by the current research practice and guidelines.

For the remainder of this introductory chapter one shall describe the field of genetic and genomic research involving human biological resources, proceeding to a description of global research today.[3] Problems occurring in the exchange of human genetic samples for research purposes will then be described, with reference to a number of cases that have been viewed as exploitative or unfair in various ways, which form the backdrop to and motivation of the research questions. The chosen cases involve communities described as indigenous peoples, whose concerns about and responses to these issues will be examined as a priority in this book. Apprehensions about the fairness of genomic research encounters with such communities in the developing world will then be examined, leading to a description of proposals for benefit sharing to be introduced as a mechanism to counter the potential unfairness in the exchange of genetic material for research. The chapter will close with an outline of how the research questions will be addressed during the remainder of the book.

[3]The term genomic research is used more often in this book for the reason that it is broader in scope and includes genetic research. In some contexts the words are used as being more or less interchangeable.

1.1 Genetics, Genomics and Human Biological Resources

In 1794, Erasmus Darwin, grandfather of the more famous Charles, a renowned polymath poet and physician of his time, predicted the discovery of a single basis of all organic life, one that was later to be termed as DNA.[4]

> As the earth and the ocean were probably peopled with vegetable productions long before the existence of animals: and many families of these animals long before other families of them, shall we conjecture that one and the same kind of living filaments is and has been the cause of all organic life? (Darwin 1794, p. 244)

Exponential advances in biotechnology over the past decades have exposed the essential building blocks of nature, termed by some, "God's blueprints for life" (Ridley 1999, p. 8), in their fascinating complexity. Popular authors such as Dawkins (1995) and Matt Ridley have contributed towards placing the idea firmly in the public domain, and human genetic resources have become a new and valuable commodity, their exchange fuelled by and contained within a rapidly transmuting intellectual property rights system.

Exploration of the human genome has proceeded apace, triggered by the discovery of the structure of DNA by Watson and Crick in 1953, and characterized by a dynamism and breadth that has transformed the paradigms previously underpinning science and public health. Watson and Crick's discovery of the DNA double helix can be equated with Darwin's theory of natural selection as a milestone in human history in its presaging of a new era of biological and scientific exploration. The heightened importance of human genetic resources over the past decades has contributed towards an explosion in genomic research, has forced states to revisit their laws, and has given rise to fresh ethical and legal challenges.

The term *human biological resources* refers to all and any parts of the body including tissue, bone and fluids, whereas *human genetic resources* is a more narrow term denoting the components of human DNA. The latter comprises the raw material utilised by the vast biomedical research industry, the appropriate utilisation of which is the intended subject of this book. A brief description of human DNA commences with cells, which exist as the basic working units of every living system, and with the chemical deoxyribonucleic acid (DNA) within each such cell which contains the full instructions to create that entire individual (Mehlman and Botkin 1998). These instructions are located within the chromosomes, namely twenty-three pairs of individual DNA strands, which in humans contain an

[4]According to the Joy of Knowledge Encyclopedia DNA or deoxyribononucleic acid is a long strand of matter too fine to be seen with the most powerful optical microscope, arranged in the form of a twisted rope ladder with millions of rungs—the double helix. The struts are made up of alternating units of phosphate and deoxyribose sugar. Each rung contains a linked pair of chemical compounds called nucleic acid bases.

estimated thirty thousand encoded genes (The International Human Genome Sequencing Consortium).[5] Genes provide codes for proteins, which in turn determine the structure and characteristics of all life forms (Ridley 1999, pp. 6–9).

Genes used to be regarded in abstract form as the unit of inheritance that transferred characteristics from parent to child, but have now with the advancement of molecular biology become physically observable units, sequences of DNA which when converted into strands of what is called messenger RNA become the basis for building the associated proteins. As Richard Dawkins explains in his book *The Selfish Gene*, in which he describes the central role played by genes in evolution, "genes are denizens of geological time: genes are forever." This message was recorded more playfully in the following verse form

> An itinerant selfish gene
>
> Said, 'bodies aplenty I've seen.
>
> You think you're so clever,
>
> But I'll live forever,
>
> You're just a survival machine (Dawkins 2004, p. 630).

Genetics, the study of heredity in general, and genes in particular (Jones 2009, p. 3) is an exploding field, described by some as not only the science of the 21st Century but also and in equal measure as big business, with applications from medical diagnosis to drug production, law enforcement to chicken breeding (Jones 2009, p. ix). The genome contains the sum total of genetic information of an individual, which information resides in each cell of the body and is encoded in the structure of the DNA (ibid, p. 28).[6] The DNA sequence of each organism consists of the particular arrangement of bases along the DNA strand, and the science of genomics, as described by one commentator, now allows the *metaphor* of life-as-information to become *material* reality, that can be commodified (Rajan 2006, p. 16). How this specific form of information is utilised by research for eventual commodification is discussed in more detail below.

Genetic information, which relates to families as well as to individuals, is the research target of all genetic research, and has been differentiated by Zhou into three different types. Firstly, non-differential human genetic information, secondly, individual human genetic information, and thirdly, group/collective human genetic information (Zhou 2006, p. 113). Non-differential human genetic information is the genetic information shared by each human being, namely the approximately

[5]This number has been estimated as being closer to 20,000 genes by the National Human Genome Research institute. [online] Available at http://www.genome.gov/DNADay/q.cfm?aid=2&year=2012.

[6]The Human genome, like the genome of all other living animals, is a collection of long polymers of DNA. These polymers are maintained in duplicate copy in the form of chromosomes in every human cell and encode in their sequence of constituent bases (G, A, T and C) the details of the molecular and physical characteristics that form the corresponding organism. The sequence of these polymers, their organisation and structure, provide the genome with the capability to replicate, repair, package and maintain itself.

99.8 % of the information on the human's approximately 30,000 genes that is entirely uniform. Neither states nor individuals could claim any proprietary rights over this wealth of shared information, which is potentially of great benefit to humankind, and could aptly fall into the category of common heritage of humankind, which will be discussed later. Individual human genetic information refers to the 0.02 %, which determines the diversity of the human race, from outward appearance to susceptibility to diseases, and is unique to each human. Bio-banks collect this type of genetic information, and it is highly prized, being the particular focus of forensic databases, relationship testing and genetic research on diseases (Richards 2001, p. 674). According to Annas, this form of personal information is, in some countries at least, the subject of a right to privacy (Annas 1999, p. 7).

With regards to community or group/collective perspectives human genetic information is a combination of the first two types described above, namely non-differential and individual human genetic information, but in addition concerns the genetic properties of groups. As McGregor explains, a group of people living together for a sufficiently long period of time are likely to share genetic properties, which become a research tool to explore variations that can lead to knowledge about genetic disorders, and the origins and migration patterns of peoples (McGregor 2007). These communities can become dispersed, such as the Ashkenazi Jews who share genetic mutations predisposing them to certain diseases, but nevertheless retain their collective association as a genetic group (Weijer 1999, p. 502). This form of genetic information is the research target of human population genetic research (HPGR) and is arguably the subject of certain group as opposed to individual rights (Wang 2011, p. 10).

Genetic research examines how genes relate to environmental factors and the health of humans, whilst genomic research studies focus on the whole genome, usually across selected populations (Gibbons et al. 2007). As might be anticipated, the rapid expansion of the interrelated fields described below has exposed the need for regulatory systems relating to research use of human tissue to adapt to changing circumstances (Slabbert et al. 2010). According to Knoppers et al. (2007), there has been a move in biomedicine from genetic to genomic research, which operates at the level of the whole genome, and studies 'normal' genomic variations across whole populations (Knoppers et al. 2007, p. 291).

Functional genomics aims to characterize the many different genes that constitute these genomes and their variability of action (WHO 2002, p. 4). Pharmacogenomics aims to develop therapeutic interventions individually tailored to the biochemical makeup of the patient. Monogenic diseases resulting from mutations from a single gene, such as the most common forms, Thalassemia and sickle cell disease, provide particular challenges as they are generally incurable and require a lifetime of medical treatment.[7] Techniques have been developed for

[7]There are about 5000 diseases classified as monogenic, such as inherited haemoglobin disorders, cystic fibrosis, haemophilia, with the global prevalence being about 10 per thousand at birth (WHO 2002, p. 43).