"A room of our own?"* Legal *lacunae* regarding genomic sovereignty in South Africa

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OPSOMMING

"A room of our own?" *Lacunae* in die reg rakende genomiese soewereiniteit in Suid-Afrika

Die artikel bespreek die kwessie van genomiese soewereiniteit en die regsregulering van genetiese en genomiese navorsing in Suid-Afrika krities in die lig van onlangse berigte oor die genomiese kartering van die genome van Aartsbiskop Desmond Tutu en 'n paar Khoisan-gemeenskapsleiers deur 'n buitelandse navorsingspan. Die belang van genomiese navorsing vir die Suid-Afrikaanse konteks word aangedui. 'n Oorsig van relevante internasionale instrumente en dokumente toon 'n onbevredigende en gefragmenteerde benadering tot hierdie kwessies. Ernstige *lacunae* in die reg blyk uit die bespreking van die huidige regsposisie rakende genetiese en genomiese navorsing in Suid-Afrika, wat ernstige implikasies vir die beskerming van Suid-Afrika se menslike genetiese erfenis inhou.

1 INTRODUCTION

The transition from *genetic* to *genomic* research in the field of biomedicine has been necessitated by a growing recognition amongst scientists that, in order to better understand the complexity of human health and the risk of disease, it is critical that studies of normal genomic variation be carried out across whole populations.[1] Traditional genetic research that has focused on inherited human

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* Proponents of genomic sovereignty policies rely on the idiom from the classic essay by Virginia Woolf, *A room of one's own* (1929), claiming that if genomics research is a house, developing countries should "create a room of their own". See Séguin, Hardy, Singer and Daar "Genomic medicine in developing countries: Creating a room of their own" 2008 *Nature* 487–493. Another article that utilises this idiom is that of Benjamin "*A lab of their own*: Genomic sovereignty as postcolonial science policy" 2009 *Policy and Society* 341–355.

1 The move from genetic to genomic research is explained by Gibbons *et al* "Governing genetic databases: Challenges facing research regulation and practice" 2007 *J of Law and Society* 165–167. Human "genetic research" can be described as a process that enhances

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disorders has employed a range of techniques to identify and examine specific genes implicated in monogenic diseases.[2] In genomic research, instead of examining specific genes, studies have focused on the whole genome.[3] Genetic markers such as single nucleotide polymorphisms (SNPs) and haplotypes[4] are used to identify genetic variations and, when combined with a careful analysis of other data,[5] are able to shed light on their relationship to disease. However, in order to undertake large-scale studies on genomic variation across whole populations (longitudinal and cross-sectional in nature) large collections of biological samples and data are required.

A recent report in *Nature*[6] entitled "Africa yields two full human genomes", describes a study published in the same edition. The report has attracted attention across South Africa for a number of reasons, two of which are highlighted here. First, one of the two fully sequenced genomes is that of Archbishop Desmond Tutu.[7] The study, "Complete Khoisan and Bantu genomes from southern Africa",[8] conducted mainly by American and Australian researchers and one South African from the University of Limpopo,[9] reports that the genetic structure of the indigenous hunter-gatherer peoples of southern Africa – the oldest known lineage of modern humans – is genetically divergent from other humans and hence important for the understanding of human diversity.[10] The aim was to compare genomic information obtained from four individual hunter-gatherers from the Kalahari Desert and that of Archbishop Tutu (who represents the Bantu peoples – Sotho-Tswana and Nguni – of southern Africa), with genomes of other individuals thus far sequenced (mainly of European origin) in order to address questions regarding the origins of modern humans in Africa. Another objective was to map human evolution and the accumulation of genetic variation.[11] The report claims that for the Africans of Southern Africa, the data may have additional

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our understanding of how genes and environmental factors interact to influence the health of individuals and populations, with the aim of generating knowledge that has the potential to improve individual and community health.

2 Examples include cardiovascular diseases, diabetes and some cancers.

3 "Genome" refers to the complete genetic information of an organism (DNA in the case of humans, RNA in the case of certain viruses). Genomics is required to study complex diseases that are the result of a combination of multiple genetic and environmental factors such as cardiovascular disease, obesity, diabetes, asthma, schizophrenia and cancer. Genomics provides an understanding of the pathogenesis of disease and offers new possibilities for their diagnosis and treatment. The major tools and methods required for genomic studies are sequencing and bioinformatics (including sequence analysis, measures of gene expression and determination of gene function). See *Genomics and world health: Report of the Advisory Committee on Health Research*, Geneva, WHO (2002).

4 Consisting of SNPs that are commonly inherited together. See Knoppers, Abdul-Rahman and Bédard "Genomic databases and international collaboration" 2007 *King's LJ* 291 292.

5 Eg geneology, medical history, lifestyle, physical examination and environmental information.

6 (2010) 463 857.

7 The other genomes come from four hunter-gatherers from the Kalahari desert in Namibia, each the eldest member of their respective communities.

8 2010 *Nature* 943–947.

9 Philippus Venter.

10 "Complete Khoisan and Bantu genomes from Southern Africa" 943.

11 "Africa yields two full human genomes" 857.

"tangible benefits" which may include insight as to why "some drugs designed to treat Europeans do not work well in Africans".[12]

Second, the study is noteworthy as it relates to pertinent legal concerns not obvious at first glance, namely, those relating to genomic sovereignty, access and benefit sharing. These concerns are addressed in the article. A growing concern internationally is that of an increasing tendency to undertake "safari research" or "helicopter research" projects that "drop" into communities to collect data, but leave without establishing any benefit for, or short or long term relationship with, the local community. (It should be noted that at the time of writing, the status of the abovementioned concerns in relation to the *Nature* paper cited above has not been established.)

Indigenous populations in Southern Africa, believed to be the most genetically divergent on the planet, are a very valuable source of genetic information. Hand-in-hand with this potential wealth of knowledge goes the potential for significant commercial exploitation and financial gain in the form of intellectual property protection (eg patents) and commercialisation of new health solutions.[13] South Africa, in addition, is in many ways an ideal setting for health research, offering a well-developed infrastructure with clinical and scientific expertise, academic institutions of good standing, and good laboratory facilities.[14] Despite the obvious advantages of genomic research, which include the possibility of more personalised medicine, a better and more accurate ability to predict illness and prevent disease, and the development of novel therapeutics which will be considered below, serious legal questions arise.[15]

The purpose of the article is to critically examine the present legal position relating to genomic research in South Africa, with specific emphasis on the concepts of genomic sovereignty and the access to and sharing of benefits gained from genomic research. The fact that developing countries may not be participating fully in genomics research (eg as a result of limited human and financial resources and lack of technical capacity, including bioinformatics) is problematic,[16] prompting the question as to how these countries may benefit from discoveries in this rapidly-developing field, particularly those that are done on genetic material gathered from within their borders. Although the article focuses on the human genome, it is important to recognise that the principles discussed here are equally relevant to genomes of animal and plant origin.

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12 *Ibid*. One of the "medical mysteries" referred to in this study is the question why the Khoisan and some other African populations are particularly susceptible to tuberculosis.

13 Jakobsson *et al* "Genotype, haplotype and copy-number variation in world-wide human populations" 2008 *Nature* 998–1003.

14 Van Wyk "Clinical trials, medical research and cloning in South Africa" 2004 *THRHR* 1.

15 See Harmon "DNA gatherers hit snag: Tribes don't trust them" *New York Times* 10 Dec 2006. Some of these DNA studies may also contradict specific indigenous cultural histories, potentially thwarting legal sovereignty arguments and other legal claims. DNA studies, in conjunction with other evidence, may corroborate claims relating to land, eg by suggesting, based on migration patterns, that one ethnic group occupied a given area prior to others.

16 Coloma and Harris "Molecular genomic approaches to infectious diseases in resource-limited settings" 2009 *PLoS Medicine* 1.

2 THE CONCEPT OF GENOMIC SOVEREIGNTY

In 1997, the United Nations Educational, Scientific and Cultural Organisation (UNESCO) declared the human genome "the heritage of humanity".[17] This statement was severely criticised on the grounds that it may lead to "biocolonialism" or "genetic piracy" of genetic samples in developing countries lacking the scientific capacity or resources to conduct the research themselves.[18]

Countries such as Mexico, India and Thailand were some of the first to recognise that the unique patterns of variation within their subpopulations may have implications for the development of genomic medicine and diagnostics and as such should be seen as the equivalent of sovereign resources.[19] Mexico, for example, was the first to introduce a specific provision into its General Health Law to protect the genomic sovereignty of Mexicans. As a result, both the sampling of genetic material, as well as its transport outside of Mexico without the prior approval of the Ministry of Health (SSP), is illegal.[20] This provision was inserted following reports of "safari research" where foreign researchers attempted to obtain blood samples from indigenous Mexican subjects without the prior approval of the Ministry of Health and local Mexican ethics committees.[21]

Although India does not have a specific provision regarding genomic sovereignty, efforts have been made to protect the Indian genome from foreign exploitation by preventing the use of human biological material without prior arrangement with the Indian government.[22] In Thailand, the need for explicit legal regulation of the export of human DNA samples is recognised, provided that such initiatives do not impede international collaboration and partnerships.[23] Two countries that have adopted specific national legislation to regulate genomic database projects in their jurisdictions are Iceland and Estonia. Iceland's Act on Health Sector Database 139/1998[24] and its supporting regulations,[25] protect confidentiality; access to data; transfer of medical data and intellectual property, whereas Estonia's Human Genes Research Act 2000[26] provides for data protection; the right to ownership of tissue samples and oversight.

The concept of genomic sovereignty is a recent one which can be described as "representing a nation's ability to capture the value of its investments in the field

17 See UNESCO, Universal Declaration on the Human Genome and Human Rights, General Conference Res 29 C/Res16, reprinted in Records of the General Conference, UNESCO, 29th Sess, 29 C/Resolution 19, 41 (1997) (adopted by the UN General Assembly, GA res 152, UN GAOR, 53rd Sess, UN Doc A/RES/53/152 (1999)).

18 See eg in general Cohen, Illingworth and Schueklenk (eds) *The power of pills: Social, ethical and legal issues in drug development, marketing and pricing* (2006) 203–215.

19 Séguin, Hardy, Singer and Daar 487.

20 See General Health Law of 1984 (*Ley General de Salud*), aa 100, 317, 317*bis* and 461. Research utilising genetic samples of Mexicans outside Mexico will need to apply for a permit from the Ministry of Health.

21 See "Genomics and benefits shared" *Parliamentary Gazette* IX, 1953 (2006).

22 *Guidelines for the exchange of human biological material for biomedical research purposes*, New Delhi, 19 November 1997, issued by the Ministry of Health. For a copy of the Guidelines, see http://www.icmr.nic.in/min.htm (visited 4 March 2010).

23 Séguin, Hardy, Singer and Daar 490.

24 *Lög um gagnagrunn á heilbrigðissviði.*

25 Regulation on a Health Sector Database, 32/2000 (*Reglugerð um gagnagrunn á heilbrigðissviði*).

26 *Inimgeeniuuringute seadus*, RT I (2000) 104 685.

of genomic medicine".[27] In other words, in the context of global research on genomics, it refers to the capacity of a people, a country or nation to own, to control both access to and use of, samples, data and knowledge concerning human genes. (Similar principles would apply to plant and animal material.) Genomic sovereignty is, as discussed below, much more than the notion expressed in article 15 of the Convention on Biological Diversity (hereafter referred to as CBD),[28] which recognises the sovereign rights of states over their natural resources, including their authority within their respective national jurisdictions, to determine access to genetic resources.[29] South Africa ratified the Convention in November 1995 and subsequently enacted the National Environmental Management: Biodiversity Act (hereafter the Biodiversity Act)[30] in 2004.

Access to genetic resources in terms of the CBD is determined by the various national governments and is subject to national legislation,[31] which, together with the access to, and sharing of, the benefits of genetic information, are two of the cross-cutting themes of the CBD. South Africa's Biodiversity Act is silent on the issue of genomic sovereignty, except to regulate activities described as "bioprospecting",[32] as well as access to and benefit sharing of indigenous biological resources. As may be noted from the definitions of "genetic material" and "genetic resources" in both the CBD and the Biodiversity Act, as well as from section 80(2)(b)(i) of the Biodiversity Act, genetic material of *human* origin is excluded from the scope of the CBD as well as from Chapter 6 of the Biodiversity Act that regulates access to and benefit sharing from indigenous biological resources in South Africa.[33]

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27 Hardy, Séguin, Ramesar *et al* "South Africa: From species cradle to genomic applications" (2008) *Nature Review Genetics* S20.

28 Signed by 150 government leaders at the 1992 Rio Earth Summit, dedicated to promote sustainable development. The Convention, negotiated under the auspices of the United Nations Environment Programme (UNEP), entered into force on 23 December 1993. The three goals of the CBD are to promote the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising out of the utilisation of genetic resources.

29 A 15 reads: "1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. 2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."

30 10 of 2004. The objectives of the Act, stated in s 2, *inter alia* are to provide for the management and conservation of biodiversity within the Republic; the use of indigenous biological resources in a sustainable manner and the fair and equitable sharing among stakeholders of the benefits that arise from bioprospecting that involves indigenous biological resources.

31 The CBD defines in a 2 ("use of terms") the phrase "genetic resources" as "genetic material of actual or potential value", whereas "genetic material" which is used in the latter definition is described as "any material of plant, animal, microbial or other origin containing functional units of heredity".

32 "Bioprospecting" is defined as "research on, or development or application of, indigenous biological resources for commercial or industrial exploitation".

33 S 80(2)(b)(i) of the Biodiversity Act states that "indigenous biological resources" excludes "genetic material of human origin". The chapter referred to is ch 6 (Bioprospecting, access and benefit sharing).

The legal regulation of both genetic and genomic research in South Africa is problematic, as will be discussed below. There are also no national guidelines governing genomic research and its legal or ethical ramifications that succeed in balancing the protection of human genetic information and the promotion of international collaboration that may increase the development of local scientific capacity. Genetic material may leave South Africa's borders virtually undetected and undocumented, as has already happened in some instances.[34] Sadly, the possible misuse of biological samples by foreign researchers is a reality, as indigenous populations such as the Havasupai Indians[35] and the Nuu-chah-nulth[36] have experienced.

South Africa should also take note of the growing number of countries that are successfully lobbying their governments to recognise the importance of protective ownership of the DNA of their populations. The result of this movement is the emergence of new bio-political entities, eg "Mexican DNA" or the "Indian genome", which, as one author asserts,[37] has the effect of strategically calibrating socio-political categories – nationality and race-ethnicity – with scientifically produced ones, such as genotypes.[38] Moreover, this trend asserts strong nationalist sentiments of self-determination by "branding" national populations – and even different ethnical groups within one population – as biologically distinct from each other and other populations.[39] In this sense, genomic studies of indigenous populations may be perceived as "race-based research" which is "highly political".[40]

Before the legal framework relevant to genetic research is examined more closely, it is necessary to turn to some of the genomic activities and the significance of these studies presently undertaken or envisaged in South Africa.

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34 See eg McGown *Out of Africa: Mysteries of access and benefit sharing* (2006) and *Pirating African heritage* (2009).

35 In November 2008, Havasupai Indians were granted permission by the Arizona Court of Appeals to proceed with legal action related to the misuse of biological samples taken by the Arizona State University and the University of Arizona. In the early 1990s, more than 200 genetic samples were consensually loaned for diabetes research. Years after the findings of this study were published the samples were used without the consent of the Havasupai to investigate schizophrenia, inbreeding and population migrations. For more detail, see Davenport "Court revises Arizona tribe's lawsuit over research" available at http://www.contracostatimes.com/nationandworld/ci_11101736 (visited 28 February 2010).

36 Further back in history (more than 25 years ago) more than 800 genetic samples were taken from the Nuu-chah-nulth tribe by researchers at the University of British Columbia. The Nuu-chah-nulth gave consent that the samples be used to investigate rheumatoid arthritis, which affects the tribe significantly. However, it appeared later that the samples were used and shared with other researchers across the world, without their consent, for a variety of different studies. The tribe never benefited in any way from any of these later studies. See Dalton "Tribe blasts 'exploitation' of blood samples" 2002 *Nature* 420. See also Pellekaan "Genetic research: What does this mean for Indigenous Australian communities?" 2002 *Australian Aboriginal Studies* 65–75.

37 Benjamin 341.

38 "Genotype" refers to particular alleles at specified loci on given chromosomes that define genetic traits present in an organism or a group of organisms sharing common genetic traits.

39 Benjamin 341.

40 See Harvey "Stirring up the gene pool" *New Zealand Herald* 29 July 2005.

3 SOUTH AFRICAN GENOMIC INITIATIVES

South Africa has a strong tradition in classical genetic research, and several scientists and research groups have made significant contributions to the understanding of diseases which affect our population. Many of the studies conducted to date have examined monogenic diseases in which heritability is determined by classical Mendelian genetics. In addition, most studies performed within the country have looked at single genes or groups of genes believed to be responsible for a given phenotype.

This approach, while laudable, suffers from two important drawbacks:

(1) Most of the common diseases that affect our society (all racial groups included) are polygenic rather than monogenic in nature. These diseases include, but are not limited to, cardiovascular disease, obesity and diabetes, the so-called "lifestyle" group of diseases. In addition, it has been demonstrated that there is a genetic predisposition to the major infectious diseases that currently ravage our society, namely HIV/AIDS, tuberculosis and malaria. The term "polygenic" implies, firstly, that several genes are involved, and secondly, that an environmental component, physical exercise and calorie intake, for example in the case of the lifestyle diseases, impacts significantly on the final phenotypic expression of the genetic predisposition to the disease in question. In the case of infectious diseases, the environmental component would be the infectious agent itself and the carrier.

(2) Important differences exist in the prevalence of several diseases in different racial and ethnic groups in the South African population. With these differences come different and specific approaches to treatment. In addition, of great significance with respect to our current knowledge on genetic risk factors for these diseases, is that most of the data generated thus far is from populations of European and North American origin.

Given therefore that little information exists on the genetic risk factors for these polygenic diseases in the different ethnic groups in South Africa and that there is an increase in the incidence of these diseases in our country, there is a critical need and a very important window of opportunity to undertake large scale multi-institutional genome-wide studies on carefully selected groups in the South African population.

Recently, a multi-institutional application (by 21 institutions in the public and private sectors) for the establishment of a Southern African Genome Programme was submitted to the Department of Science and Technology.[41] The initial aim of this Programme is to sequence whole genomes of several thousand individuals of African origin. The medium-to-long term objectives are to determine genetic risk factors and pathogenetic mechanisms of diseases that are important to the Southern African population (eg infectious diseases and diseases of lifestyle); and to build bioinformatic capacity across the country in order to be able to analyse data generated locally and also to access and analyse data published in the public domain that could have an impact on our local populations.

The notions of genomic sovereignty, access and benefit sharing will need to be carefully considered in the execution of the above Programme.

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41 Application submitted to the Department of Science and Technology in December 2009.

4 LEGAL FRAMEWORK RELEVANT TO GENOMIC RESEARCH

4 1 International context

Section 39(1)(b) of the Constitution[42] instructs that when the Bill of Rights is interpreted, a court, tribunal or forum must consider international law. The discussion will hence first examine international law relevant to genomic research, before turning to the domestic legal position. At the international level, the last ten years have seen the development of guidelines and statements of principle by various international bodies. Four different types of bodies are distinguished, eg those representing all countries, such as the UN in the form of UNESCO; the Council of Europe representing countries in Europe and others who have signed its conventions; various international scientific organisations, such as the Human Genome Organisation (HUGO);[43] and finally bodies that represent industrialised nations, such as the OECD.[44]

An overview of the various statements, guidelines and documents issued by these bodies shows that these documents address general principles and activities, and that none has a clear mandate or authority to formulate an internationally-accepted position or norms and standards to oversee the governance of international collaborative genomic research.[45] The status, authority, content and enforceability mechanisms of these bodies differ widely. The general approach is cautious, the result of public perceptions that researchers are "playing God" or tampering with God's creation, and of visions of clone farms, organ banks and the creation of robot-like beings.[46]

4 1 1 Universal Declaration on the Human Genome and Human Rights; the International Declaration on Human Genetic Data and the Universal Declaration on Bioethics and Human Rights

The Convention on Biological Diversity referred to above,[47] although recognising the territorial sovereignty of states over genetic resources within their jurisdictions, does not explicitly extend this to genetic resources of *human* origin.

UNESCO's Universal Declaration on the Human Genome and Human Rights[48] is prospective in nature and provides the basic ethical principles for the proper conduct of human genome research generally. The Declaration emphasises the inherent dignity of all persons, regardless of their genetic characteristics,[49] as well as the idea that the human genome – in its natural state – should not give rise to financial gain.[50] The Declaration states that no research applications relating to the human genome, specifically in the fields of genetics, medicine or biology should prevail over a respect for human rights, fundamental

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42 Of the Republic of South Africa, 1996.
43 See eg the official website at http://www.hugo-international.org.
44 Organisation for Economic Co-operation and Development, see http://www.oecd.org.
45 Knoppers, Abdul-Raham and Bedard 294.
46 Moore "Owning genetic information and gene enhancement techniques: Why privacy and property rights may undermine social control of the human genome" 2000 *Bioethics* 97 98.
47 See para 2 above.
48 Adopted on 11 November, 1997, text available at http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47 (visited 5 March 2010).
49 A 2 of the Declaration.
50 A 4.

freedoms and the dignity of individuals or groups of people.[51] Benefits gained from research on the human genome should be made available to all (the notion of "access"), and the applications of this research should seek to offer relief from suffering and aim to improve the health of individuals and humankind in general.[52] Although not legally binding, the Declaration represents the dynamic development of international legal norms and reflects the commitment of member states to abide by certain principles. As a form of "soft law", these principles may in time become entrenched as exacting standards, as there is no doubt that the Declaration has already significantly affected the *opinio iuris* of the international community.[53]

In 2003, UNESCO adopted the International Declaration on Human Genetic Data[54] which focuses on the protection of human genetic data under international human rights law. The aims of the Declaration are *inter alia* to ensure that the collection, processing, use and storage of human genetic data, human proteomic data and biological samples conform to requirements of respect for human dignity and the protection of human rights and fundamental freedoms.[55]

UNESCO's Universal Declaration on Bioethics and Human Rights, adopted in 2005,[56] reiterates similar principles and specifically aims to promote equitable access to medical, scientific and technological developments. It also emphasises the importance of the free flow and rapid sharing of knowledge concerning these developments, as well as the sharing of benefits, with particular emphasis on the needs of developing countries.[57] In the case of transnational research, the Declaration advises that this research should be responsive to the needs of host countries and to the alleviation of urgent global health problems.[58]

4 1 2 World Health Organisation: Indigenous Peoples and Participatory Health Research (2002)

The World Health Organisation's document on Indigenous Peoples and Participatory Health Research[59] provides useful instruction regarding the joint management of research by research institutions and indigenous peoples. The document captures the most significant provisions of an ideal agreement between research institutions and indigenous peoples, drawing on experiences in various countries and providing references to key literature. As explained in the document, the need for research agreements arises from the issues that many indigenous peoples feel are specific to their cultural and political situation, and which

51 A 10.
52 A 12.
53 See Francioni "Genetic resources, biotechnology and human rights: The international legal framework" (European University Institute Working Papers, EUI LAW No 2006/17) 8, text available at http://cadmus.iue.it/dspace/bitstream/ 1814/6070/1/ LAW200617.pdf (visited 5 March 2010).
54 Adopted 16 October 2003.
55 A 1.
56 Adopted 19 October, 2005, text available at http://portal.unesco.org/en/ev.php-URL_ID=31058andURL_DO=DO_TOPICandURL_SECTION=201.html (visited 5 March 2010).
57 A 2(f). See also a 15.
58 A 21(3).
59 The text can be accessed at http://www.who.int/ethics/indigenous_peoples/ en/print.html (visited 5 March 2010).

are not sufficiently covered by existing scientific or ethics guidelines, such as issues relating to the collection, ownership, and sharing of knowledge, benefits and information.

Although not legally binding, this document testifies to some of the problems relating to genomic sovereignty, particularly in instances where genomic research is undertaken with DNA samples of local indigenous populations without any regard to the balancing of the interests, benefits and responsibilities between the researchers and the indigenous peoples involved in the research. Mechanisms for ethical review may be weak or non-existent in some developing countries, whereas low levels of education and cultural or language barriers may increase the likelihood of exploitation of indigenous peoples and their genetic material.[60]

4 1 3 Recommendation on Research on Biological Materials of Human Origin of 2006

The Council of Europe's Recommendation on Research on Biological Materials of Human Origin,[61] the first instrument addressing genomic databases at a supranational level, provides in Chapter V for the regulation of and access to "population biobanks",[62] a term that denotes a large repository or collection of human DNA from which genomic databases will be derived. Tissue samples contained in these collections or banks can include a wide range of human biological materials such as extracted DNA, body fluids, cells and sections of tissue, and also information that may include molecular genetic data, standardised clinical data, genealogical data and information on the health, lifestyle and environment of an individual.[63] For interest sake, countries that have or are in the process of establishing large genomic databases are Iceland (eg the Icelandic Health Sector Database); Estonia (eg the Estonian Genome Project Gene Bank); the United Kingdom (UK Biobank); the USA (National Cancer Institute Biorepository); Scotland (the Generation Scotland projects) and Canada (the CARTaGENE Project). Databases of this nature, if established initially for African populations in Southern Africa, could ultimately serve the whole continent.

The Recommendation instructs that a proposal to establish a population biobank should be subject to an independent examination of its compliance with the

60 See para 1.4.

61 Recommendation Rec (2006) 4 of the Committee of Ministers to member states on research on biological materials of human origin (adopted by the Committee of Ministers on 15 March 2006), text available at https://wcd.coe.int/ViewDoc.jsp?id=977859 (visited 5 March 2010). Earlier in 1997, the Council of Europe adopted the Convention on Human Rights and Biomedicine (Oviedo, 4 Paris 1997, ETS 164) which, together with its Additional Protocol, addresses broadly the human rights implications of the applications of biology and medicine. The binding force of this Convention is limited to signatory states who have introduced national legislation aligned to the principles of the Convention. The aim of the Convention is to protect the dignity and identity of all human beings and to guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine (see a 1).

62 A 17 defines a "population biobank" as "a collection of biological materials that has the following characteristics: (i) the collection has a population basis; (ii) it is established, or has been converted, to supply biological materials or data derived therefrom for multiple future research projects; (iii) it contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated; and (iv) it receives and supplies materials in an organised manner".

63 See Lowrance "The promise of human genetic databases" 2001 *BMJ* 1009.

provisions of this recommendation,[64] and that each population biobank should be subject to independent oversight in order to safeguard the interests and rights of the persons concerned in the context of the activities of the biobank.[65] Despite giving general guidelines regarding transparency, accountability and quality assurance in the operation of population biobanks, the Recommendation does not address genomic sovereignty and related issues, such as access and benefit sharing.

4 1 4 HUGO's Statement on Human Genomic Databases of 2002

The Human Genome Organisation's Statement on Human Genomic Databases of 2002[66] recommends *inter alia* that: (1) human genomic databases are global public goods; (2) knowledge useful to human health belongs to humanity; (3) human genomic databases are a public resource; and that (4) all humans should share in and have access to the benefits of databases.[67] Despite the fact that this Statement is not legally binding on countries, HUGO has significant influence over the international scientific community.[68]

Knoppers, Abdul-Rahman and Bédard[69] rightly note that the description of a population biobank contained in the Council of Europe's Recommendation on Research on Biological Materials of Human Origin differs from that defined in HUGO's Statement on Human Genomic Databases of 2002.[70] Terms such as "biobank"[71], "gene bank"[72], "tissue bank" and "human genetic research databases" are interchangeably used in the context of population biobanks. It is also not clear whether these banks may contain samples alone, information alone, or linked combinations of the two.

The lack of universally-agreed upon terminology relating to population databases illustrates that there is still much confusion over the very nature of, risks and benefits relating to population (genomic) research, the latter being very different from those related to other databases (eg of residual tissue collections or bio-samples collected during clinical trials). This discrepancy makes it difficult to determine the present situation relating to genomic sovereignty; a situation already complicated by a range of different bodies issuing partly-overlapping

64 A 18.
65 A 19.
66 Adopted December 2002, text available at http://www.eubios.info/HUGOHGD.htm (visited 5 March 2010). The Human Genome Organisation (HUGO) was established in 1989 as an international organisation, primarily to foster collaboration between scientists around the world that are working on the human genome.
67 Rec 1.
68 Recs 1 and 2.
69 "Genomic databases and international collaboration" 296.
70 Which defines a "genomic database" as being simply "a collection of data arranged in a systematic way so as to be searchable". See HUGO Ethics Committee, Statement on Human Genomic Databases.
71 Eg used in the United Kingdom, eg the Biobank UK project, at www.ukbiobank.ac.uk, and in Sweden, the Swedish National Board of Health and Welfare biobanks in medical care, at http://www.privilegedproject.eu/projstages/stage-2-genetic-databases-and-biobanks/genetic-databases-and-biobanks-by-country/sweden (visited 6 March 2010).
72 As established via the Estonia Genome Project; see Human Genes Research Act 2000 (Estonia) s 2(10).

documents or guidelines in an unco-ordinated manner.[73] Despite the fact that these databases may differ in their intended uses, the unifying element is that they have been primarily created for the purposes of medical or other human research, unlike that of archived pathology samples, for example.

4 1 5 OECD and others

The Organisation for Economic Co-operation and Development (OECD), established in December 1960 by virtue of the Convention on the Organisation of Economic Co-operation and Development, has as one of its primary aims the promotion of policies designed to "achieve the highest sustainable economic growth and employment and a rising standard of living in Member countries". In 2009, the OECD Council issued the OECD Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs)[74] which, although not specifically referring to genomic sovereignty,, provides valuable guidelines relating to the establishment, management, governance, operation, access to, use and discontinuation of HBGRDs. It recognises that one of the fundamental objectives of an HBGRD is to foster scientific research. It specifically seeks to facilitate wide access to data and materials for biomedical research, as well as to ensure that research is conducted in a manner respectful of participants, and that it upholds human dignity, fundamental freedoms and human rights. The Guidelines make specific and culturally-sensitive recommendations regarding custodianship of HBGRDs and benefit-sharing.[75] South Africa is not a member of the OECD but is classified as an "Enhanced Engagement Country".

As already mentioned above, despite the fact that the OECD's guidance documents lack enforceability as membership is limited, these guidelines, via the OECD as a forum for reaching multilateral policy agreement, could assume potentially powerful, global norm-setting standards.

The Canadian Institutes of Health Research (CIHR) issued Guidelines for Health Research involving Aborginal People in 2007.[76] These Guidelines recommend the co-ownership of samples and data between researchers and Aboriginal people involved in research,[77] and that biological samples used by researchers should be considered "on loan" to the researchers unless otherwise specified in the research agreement. A researcher is considered to be a steward rather than as owner of the relevant samples.[78] The Guidelines recognise the importance of special protection for indigenous cultural (and also sacred) knowledge, but do not refer specifically to genomic sovereignty and ownership of genomic information identified for specific studies.[79]

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73 Other related HUGO Statements are eg the Ethical, Legal, and Social Issues Committee Statement on the Principled Conduct of Genetic Research of 21 March 1996; and the HUGO Ethics Committee Statement on Benefit Sharing of 9 April 2000.

74 The Guidelines can be accessed at http://www.oecd.org/dataoecd/41/47/44054609.pdf (visited 6 March 2010).

75 See Rec 9.

76 The Guidelines can be accessed at http://www.cihrirsc.gc.ca/e/documents/ethics_ aboriginal_guidelines_e.pdf (visited 6 March 2010).

77 A 12.5.

78 A 13.

79 Aa 7 and 8. A 8 states that any intellectual property claims should be addressed in the negotiations prior to the commencement of the research project.

Another instructive document that advises on genomic research is the Human Genome Diversity Project's Model Ethical Protocol for Collecting DNA-samples of 1997,[80] which provides detailed guidance on how to approach and plan genomic research, eg by learning as much as possible about the cultural, social and religious practices of the relevant population.[81] Although not explicit on the issue of genomic sovereignty, the Protocol states that the Project will not profit from any commercial uses of samples it gathers or knowledge derived from these samples, and that should commercial products be developed as a result of the Project's collections, a "fair share" of the financial rewards must return to the sampled populations. Researchers who take part in the Project must accept these two conditions.[82]

4 2 Preliminary conclusion

It is clear from the discussion above that there is no comprehensive and consistent legal network at an international level that governs, in a satisfactory manner, issues relating to genomic sovereignty, genomic databases, access and benefit sharing. It also appears that there is no global consensus on the issues of ownership, commercialisation, access and benefit sharing specifically. The haphazard manner in which a diverse range of international instruments and documents deal with these issues makes it extremely difficult for both researchers and the populations involved in genomic studies to define the legal, ethical and commercial boundaries within which to conduct research on the human genome. There seems, however, to be a strong awareness of the importance of the notions of access and benefit sharing with regard to communities, and the relevant human rights of individual participants, as well as the legal requirements relating to consent.

Many developing countries and indigenous populations share a history of underdevelopment and colonial exploitation that have left them politically and economically marginalised. Moreover, these peoples also suffer disproportionately from HIV/AIDS, tuberculosis, malaria and diarrhoea and are rapidly approaching prevalence levels in lifestyle diseases such as obesity, diabetes and heart disease seen in developed countries. As pointed out, a few national guidelines do recognise the special vulnerability of these peoples and caution against assumptions that all indigenous communities would spontaneously agree to participate.

4 3 The legal regulation of genomic research in South Africa

The South African Constitution contains a few provisions relating to scientific research. Section 12(2)(c) provides that "[e]veryone has the right to bodily and

80 North American Regional Committee. The text is available at http://www.stanford.edu/group/morrinst/hgdp/protocol.html (visited 7 March 2010). The Human Genome Diversity Project is an international effort to collect, preserve, analyse, and make available genetic and ethnographic information from people around the world.

81 In some societies, hair is secretly collected from intended victims to harm them through witchcraft. Consequently, these people may collect their own loose hair, fingernail parings, and other body products and bury them to avoid this danger. Researchers who ask such a population for hair may be perceived as intending to perform witchcraft. Blood is often intended to be used as a sacrifice, sometimes through special rituals. Donation of blood in some cultures is a serious issue that may require discussion and perhaps a neutralising ritual. Before approaching the population, researchers need to know as much as possible about its likely concerns about and reaction to their plans for sample collection. See para II of the Protocol.

82 Para IX of the Protocol.

psychological integrity, which includes the right ... not to be subjected to medical or scientific experiments without their informed consent". The issue of informed consent[83] in the case of indigenous populations, however, may not be straightforward, as the consent of community leaders or of the community as a whole may be necessary before individual consent is sought.[84]

Section 16(1)(d) of the Constitution on the other hand provides that "[e]veryone has the right to freedom of expression, which includes ... academic freedom and freedom of scientific research". Nowhere is the need for the full realisation of this right more clearly expressed than in the field of human genetics.[85] The specific inclusion of this right may be interpreted as a statement against suppressive scholarship and a constitutional acknowledgement of the value of science. The scope of what would be permissible under this provision will depend on many factors, including a consideration of justifiable limitations of this right in terms of the limitation clause of the Constitution,[86] as well as relevant international and foreign law.[87] The latter includes "soft law" and international ethical guidelines and norms that have emerged in relation to specific research activities, such as those discussed above, including the views locally of reputable members of a profession as to what activities in their fields or disciplines are proper or improper. All research involving human participants conducted in South Africa must be reviewed by a relevant ethics committee,[88] whereas the National Health Act (hereafter NHA)[89] provides that research on or experimentation with human subjects may only be conducted "in the prescribed manner" and with the written consent of the person after he or she has been informed of the objectives of the research or experimentation, as well as possible positive or negative consequences on his or her health.[90]

The Human Tissue Act[91] (hereafter HTA) and National Health Act provide the legal framework for issues relating to the sampling, retention and use of human tissues and organs from adults and children. Chapter 8 of the NHA, which deals with the "control of use of blood, blood products, tissue and gametes in humans" has to date not been promulgated, except for section 53, which was enacted in June 2008.[92] The result is that all matters pertaining to human tissues are

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83 The issue of consent will not be discussed due to the limited scope of the article.

84 See, in general, Schueklenk and Kleinsmidt "North-south benefit sharing arrangements in bioprospecting and genetic research: A critical ethical and legal analysis" 2006 *Developing World Bioethics* 122–134.

85 Also in respect of pre-embryo experimentation; in this regard, see Jordaan "Science versus anti-science: The law on pre-embryo experimentation" 2007 *SALJ* 618–634.

86 S 36.

87 See s 39(1) of the Constitution.

88 It is envisaged that all studies approved by ethics committees (the latter registered with the National Health Research Ethics Council by virtue of s 73 of the NHA), will be issued a national study number, to be included in the database of the National Health Research Ethics Council (NHREC). Guidelines also relevant to research involving humans are the Department of Health's Guidelines for good practice in the conduct of clinical trials in human participants in South Africa (2000), text available at http://www.doh.gov.za/docs/policy/trials/trials_preamble.html (visited 8 March 2010) and the MRC's *Guidelines on ethics for medical research: General principles* (4th ed).

89 61 of 2003.

90 S 71 of the NHA.

91 65 of 1983.

92 S 53 provides for the establishment of a national blood transfusion service.

presently regulated by the HTA, an act promulgated more than 25 years ago. As a consequence South Africa is operating in a regulatory vacuum in which the rules and guidelines concerning human tissue are fragmentary and inadequate.[93]

The Department of Health has published a range of unco-ordinated and inconsistent draft regulations pertaining to chapter 8 of the NHA for public comment,[94] covering activities such as artificial insemination; the use of human DNA; use of human stem cells, to name but a few.[95] None of these regulations are presently in force.

The HTA provides *inter alia* for the donation of human bodies and tissue for the purposes of medical or dental training, research or therapy or the advancement of medicine or dentistry in general;[96] the removal of tissue, blood and gametes from the bodies of living persons and the use thereof for medical or dental purposes;[97] and for the regulation of import and export of human tissue, blood and gametes.[98] Similar provisions are contained in the (to date not yet enacted) chapter 8 of the NHA.[99] At the time of writing, extensive revision of chapter 8 in its entirety (and accompanying regulations) is underway, as the limited prevailing provisions are inadequate to effectively regulate the control and use of tissues, organs, stem cells, gametes, DNA and blood in view of the many new advances in the fields in which they are employed.[100]

Determining the scope of the legal regulation of genetic (and genomic) research from these provisions is no easy task. Section 4 of the HTA makes it clear that (donated) tissue from deceased persons may in addition to other purposes, be used for "research" and the "advancement of medicine or dentistry",[101] whereas tissue or gametes removed from living persons may only be used for "medical and dental purposes" (section 19). In the case of the latter, placenta, foetal tissue and umbilical cord may only be used for these purposes if the Minister consents

93 See Pepper "The stem cell regulatory environment in South Africa – A cause for concern" (99) *SAMJ* 505.

94 The long time delay between the publication of the initial versions of these regulations (on which submissions have been made) and their enactment, means that many new advances in these fields have arisen, necessitating that the legal regulation of these issues be revisited and revised. See Pepper 506.

95 See Draft regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics *GG* 29526, 5 January 2007; Regulations regarding artificial fertilisation and related matters *GG* 29527, 5 January 2007; Regulations relating to research on human subjects *GG* 29637, 23 February 2007; Regulations Relating to Human Stem Cells *GG* 29840, 4 May 2007.

96 See ch 1 of the Act.

97 Ch 2 of the Act.

98 Ch 4.

99 See eg s 55 (on removal of tissue etc from living persons); s 56 (use of tissue etc from living persons); s 60 (payment in connection with the importation, acquisition or supply of tissue, etc); and s 64 (purpose of donation of tissue etc of deceased persons).

100 Wide consultation of stakeholders in seven areas has been undertaken: blood transfusion and related matters; assisted reproductive technology (including in vitro fertilisation; cell-based therapy (including stem cells); organ transplantation; genetic services; tissue banks; and forensic pathology and use of tissues for teaching purposes.

101 S 4(1) read together with section 3(1) limits the donees in this provision to a hospital; university of technikon; an authorised institution; medical practitioner or dentist.

thereto.[102] The question arises whether "medical and dental purposes" in section 19 includes medical or health research, as well as genetic research. The explicit omission of "health research" from section 19, in contrast to its inclusion in section 4, is curious.

The position is similar in chapter 8 of the NHA. Neither the HTA nor the NHA defines "medical or dental purposes". Section 56(1) of the NHA provides that tissue or gametes from living persons may only be used for "such medical or dental purposes as may be prescribed", whereas section 64(1)(b) and (c) state that donated tissue from deceased persons may only be used for five purposes of which two are "the purposes of health research" and "the advancement of health sciences". "Medical or dental purposes *as may be prescribed*" (emphasis added) in section 56(1) directs us to relevant regulations, which in this instance appear to refer to the draft regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics of 5 January 2007,[103] which have thus far not been promulgated.

Before these regulations are examined more closely, it should be noted that the HTA in section 39A expressly prohibits "genetic manipulation outside the human body of gametes or zygotes",[104] whereas the NHA in section 57(1) prohibits the manipulation of any genetic material, including genetic material of human gametes, zygotes or embryos, as well as any activity, including nuclear transfer or embryo splitting, aimed at the reproductive cloning of a human being. Therapeutic cloning utilising adult or umbilical cord stem cells may be permitted in terms of the same section, subject to prescribed conditions.[105] Research on stem cells and zygotes not older than fourteen days may be permitted under certain circumstances.[106] Finally, payment for human tissue is unlawful in terms of both the HTA and the NHA, except that the NHA permits the reimbursement of reasonable costs incurred to the person who has donated the tissue, gamete, blood or blood product.[107] No tissue, gamete, blood or bloodproduct may be imported or exported without a permit issued by the Director-General[108] in terms of the HTA and the NHA[109].

The draft regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics of 5 January 2007 obscure the position regarding genetic research even further. Draft regulation 3(1) on the removal of biological material from living persons, states that a person may not remove "biological material" from a living person for, *inter alia*, "health research", unless this is done with the relevant person's informed

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102 S 19(iv).
103 *GG* 29526.
104 See Van Wyk "Clinical trials, medical research and cloning" 2004 *THRHR* 1–21.
105 S 57(2).
106 S 57(4), eg if the application is in writing; the applicant undertakes to document the research for record purposes and prior consent needs to be obtained from the relevant donors of these cells or zygotes. S 57(6) defines both "reproductive cloning" and "therapeutic cloning".
107 S 60(4)(a) of the NHA. See s 28 of the HTA.
108 Of Health and Population Development (s 1 of the HTA).
109 S 25.

consent. This would imply that the phrase "medical or dental purposes as may be prescribed" contained in section 56(1) of the NHA does include "health research". "Biological material" is defined in these regulations as "any material from a human being, including blood, cells, tissues, DNA, RNA, polar bodies, blastomeres, embryos and gametes".[110] Draft regulation 4 lists the permissible activities for which DNA, RNA, cultured cells, stem cells, small tissue biopsies, and such, may be used. "Health research" is again mentioned, but this time "health research" as referred to in section 69(3) of the NHA, the latter providing for the responsibilities of the National Health Research Committee,[111] which in turn are limited to public health research activities.

This brief overview of the relevant provisions relating to genetic research in legislation that has been enacted as well as that which is pending, sketches a very confused picture.[112] The regulatory vacuum and the inconsistencies between the draft regulations and the relevant provisions of the NHA, as well as the outdated provisions of the HTA, place South Africa in a very vulnerable position as far as genomic research is concerned, particularly that which is undertaken beyond our borders on material derived from South Africa. The Minister's authority to permit or prohibit specific activities in terms of chapter 8 of the NHA is granted in the absence of sufficient guidelines as to how this power is to be exercised.[113] As Swanepoel[114] rightly points out, section 36(1) of the Constitution directs that rights may only be limited if the limitation takes place by law of general application and the limitation is "reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors". If these conditions are not satisfied, a constitutionally-entrenched right may not be limited.[115] She questions the manner in which freedom of scientific research, guaranteed by section 16 of the Constitution, is curtailed by some of the provisions of the NHA, particularly the specific limitation in the form of ministerial permission, and not the permission of health research ethics committee (registered with the National Health Research Ethics Council by virtue of section 73 of the NHA).

Although guidelines or policy statements regarding biological research and the commercialisation thereof (eg biotechnology) do not constitute law, they are legally relevant, as courts of law, in the absence of express legislation on a specific topic, will have recourse to the common law, characterised by a set of principles ("beginselstruktuur"), which may provide some direction.[116] Relevant ethical

110 Draft reg 1.

111 Which is established by the Minister in terms of s 69 of the NHA.

112 The draft regulations also refer to ownership of excess embryos, umbilical cord blood, stem cells and aborted foetuses vesting in different parties (draft regs 9 and 1), which is directly in conflict with the traditional "no property" notion against ownership in the human body. This complex issue will not be addressed here, suffice it to say that human tissues can be considered as "property" in law in specific and well-circumscribed settings.

113 See Swanepoel *Embryonic stem cell research and cloning: A proposed legislative framework in context of legal status and personhood* (LLM UP 2006) 284.

114 *Ibid*.

115 S 36(2) of the Constitution.

116 "Beginselstruktuur" is the term used by Strauss in "Legal aspects of genetic manipulation" in Hattingh (ed) *Genetic engineering in ethical perspective* (1992) 63 and 65. See also See Slabbert "Are the human embryo and the foetus *extra uterum* sufficiently protected in terms of South African law" 2001 *TSAR* 495 498.

guidelines provide guidance on what members of the relevant professions regard as proper or improper in their respective fields.

The MRC's Guidelines on Ethics for Medical Research: Reproductive biology and genetic research[117] provide no clarity in respect of genomic sovereignty, except for a reference to the Human Genome Diversity Project (HGDP)[118] and the endorsement of the HGDP's guidelines for their researchers. The concern is expressed that if the aim of research is to test for disease (such as HIV) in South Africa, whether proper pre- and post-counselling of participants would be included and whether this creates an obligation to provide treatment to participants. The issue of technology transfer as part of benefit sharing in developing nations is specifically mentioned.

The HPCSA Code of Ethical Practice for Medical Biotechnology Research in South Africa[119] refers to gene mapping and sequencing[120] and emphasises that in South Africa, the potential for abuse of vulnerable participants is great, requiring that "culturally appropriate ways" be used to communicate information to indigenous participants.[121] The Code advises that research first be directed at those technologies with the greatest potential to directly benefit South Africa's health care, with areas such as HIV/AIDS, tuberculosis, tropical diseases and malnutrition as priority areas. The Code strictly states that "biopiracy" may not be practiced in any form.[122]

4 ACCESS AND BENEFIT SHARING

The notions of access and benefit sharing are central to discussions relating to genomic medicine, as has been repeatedly highlighted in the discussion of relevant international documents above. Access and benefit sharing are relevant in two areas: biobanks (DNA and the data derived from the sequencing thereof) for the purpose of pharmacogenetics and pharmacogenomics as well as population genomics research, and the use of traditional knowledge from indigenous communities to develop new products (eg in the pharmaceutical industry, involving non-human genetic resources). It is in the case of human genetic material, ironically, where the principles of access and benefit sharing are nowhere explicitly and consistently mentioned,[123] despite UNESCO's incorporation of the principle into the International Declaration on Human Genetic Data.[124] Access and benefit sharing may take the form of access to medical care or new drugs; financial payment; technology transfer; capacity building; the wide dissemination of knowledge; and the accessibility of research results to the biobank or database.

117 Book 2 (4th ed).

118 Para 3.6.

119 Adopted in 2005 by the HPCSA, developed by Dhai, Msomi and McQuoid-Mason, available at http://www.hpcsa.co.za/downloads/conduct_ethics/rules/general ethical_guide_ biotechnology_research.pdf (visited 6 March 2010).

120 Para 1.3.1.

121 Paras 3.2 and 3.3.

122 Para 9. "Biopiracy" is defined as the "appropriation of developments or discoveries in the area of biological resources, by another party without consent".

123 This principle is firmly established in the Convention on Biological Diversity as well as the South African Biodiversity Act in respect of non-human genetic material.

124 A 19(a) states that "[b]enefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community".

Benefits may not be immediate or tangible, as some studies are conducted over extended periods, with benefits accruing in the future and not for the immediate direct benefit of the participants themselves.[125] Not addressed in this article is the issue of commercialisation and intellectual property rights relating to information derived from genetic sequencing. These issues may inhibit the translation of genetic discoveries into health benefits and require detailed consideration in their own right.

5 CONCLUSION

The protection of genomic sovereignty and the legal regulation of genomic research (both privately and publicly funded), including the protection of South Africa's genomic resources, are concerns that need to be addressed seriously. The current regulatory framework for medical research, including genetic and genomic research, is deeply inadequate and such research is impossible to monitor. Many more genomic studies involving thousands more individuals from Southern Africa[126] are underway, specifically targeting Southern Africa's indigenous populations, such as the Zulu, Xhosa, Herero, San and the Sotho-Tswana. In the absence of a clear regulatory framework and no specific insistence on access and benefit sharing, there is nothing to protect the genomic information of the South African population from exploitation beyond our borders. It will be important for all genomics-based research projects to be combined with clearly-defined and rigorously-applied education programmes in order to prevent further division based on the misuse and/or abuse of genetic information. Whether the Biodiversity Act should be extended to provide for human genomic research and the protection of genomic sovereignty, or whether separate legislation (with a Human Genetics "Authority" overseeing this) should be instituted, perhaps under the NHA or a revised HTA, is a question that needs to be debated as a matter of urgency. Finally, the protection of genetic privacy is another concern, as it is unclear to what extent the Protection of Personal Information Bill[127] will protect genomic information in the contexts described above.[128]

125 Knoppers, Abdul-Rahman and Bédard 304.

126 See Anderson "Kalahari bushmen genome project underway" (26 October 2009) GenomeWeb Daily News, available at http://www.genomeweb.com/print/926414.

127 [B9-2009]. See also the South African Law Reform Commission *Privacy and data protection* (Discussion paper 109, project 124) ch 9.

128 See Slabbert "Genetic privacy in South Africa and Europe: A comparative perspective" (Part I) 2007 *THRHR* 622; (Part II) 2008 *THRHR* 81. It will regulate access to personal information held by private and public bodies, however.