Genomic Sovereignty in South Africa:
Ethico-Legal issues

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Abstract

With the completion of the Human Genome project, advances in bioinformatics, computational biology and scientific techniques, human genetic research has established itself as a leading focus of study for many involved in the biological research world. However with all forms of research comes the relevant ethical procedure to guide these studies. Human genetic studies are especially intricate in their ethics evaluations as not only do they require biological material to be obtained from an individual or group of individuals but it in turns gives a researcher access to one’s own personal genetic code, i.e. DNA sequence. Such information has become extremely useful in identifying predispositions and causative factors for certain diseases, identifying possible phenotypic traits, clues into one’s ancestry as well as the overall potential for commercial gain by pharmaceutical companies in drug and gene therapy research and development through acts of gene patenting. Thus with the biological world completely open to exploitation, the need for various control regulations and guidelines to be further developed to address these issues persists. The main questions addressed in studies such as these are those of ownership - who does the sample belong to - access and benefit sharing should any product be developed from information gathered from these samples, consent for use of these samples outside its intended purpose as well as protection of vulnerable groups for unique genetics studies. There are four main sections in this report. First the concepts of Genomic Sovereignty and Common heritage are discussed. Following this, some philosophical theories of ownership are investigated to provide justification toward the concept of ownership with regard to the human body and international bioethical guidelines are then discussed with regard to research involving samples of human genetic material from population groups. The third section is an analysis of the law with regard to ownership, patenting and benefit sharing from research using human genetic material. The
fourth section synthesizes the information of the previous 3 sections to produce an alternate approach in dealing with research involving human genetic material from population groups.
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Ethics waiver

The method or inquiry used in this research thesis is not subject to the problems of confidentiality or informed consent as no human participants were involved. Ethical issues which are appropriate to this research include 1) a careful analysis of facts while remembering that facts may change in the light of new knowledge, 2) the obligation of fairness – to ensure that I give the oppositional position equal consideration to my own, 3) the duty to ensure I reference my sources properly and completely to avoid any thought of plagiarism, 4) the obligation to keep an open mind, and 5) the duty to continue to learn. I have therefore applied for a waiver of ethical review. Please see Appendix I.
1. Introduction

The study of human genomic diversity is nothing new to the world of science. From the days of Darwin to Mendel and even today, scientists all around the world are constantly seeking the scientific quest to find the answers that lay in our DNA\(^1\). Some of these include determining which among the many populations around the world is the oldest, tracking human evolution as well as searching for causative agents in one’s genes that cause or predispose oneself to certain diseases and disorders\(^{1,2}\). The valued effort to provide the scientific community with the complete sequence of the human genome has led to an even greater influx of research into the questions mentioned above.

The complete sequencing in 2003 of the human genome, funded by the US Department of Energy and the National Institutes of Health\(^1\), came with the hope of establishing new information and links between the estimated 20 000 – 25000 genes and how their malfunction/ mutational events can cause disease\(^1\). An overview of post human genome project possibilities into disease prediction and improving their related therapeutic interventions are found on the website.

The ultimate goal is to use this information to develop new ways to treat, cure, or even prevent the thousands of diseases that afflict humankind. But the road from gene identification to effective treatments is long and fraught with challenges. In the meantime, biotechnology companies are racing ahead with commercialization by designing diagnostic tests to detect errant genes in people suspected of having particular diseases or of being at risk for developing them\(^1\).

While studies into these various research areas has provided us with immense understanding into who we think we are and what we are capable off, recently questions have arisen as to how this type of population based genomic research is being undertaken. Much discourse around this topic relates to the manner in which samples are attained, who controls what
happens to these samples, where research is done, who is involved and what the benefits and access to these studies are there to the populations involved.

The purpose of this research is therefore to examine the ethical and legal issues that should be considered by researchers before, during and after the commencement of genetic research. The paper deals primarily with the ethical and legal concerns regarding the nature of ownership that should be determined before bodily samples/DNA can be collected from specific groups or populations through analysis using two concepts, namely Genomic Sovereignty and the Common Heritage concept.

### 1.1 Genetic background

Since the complete sequencing of the human genome and the discovery that human beings of all ethnic backgrounds share ~99.9% of their genomic sequence with one another, the need for individual research has become somewhat phased out with the second phase of mapping known as genome-wide association studies (GWAS) coming into focus. Thus moving away from the traditional Mendelian approach, which dealt primarily with single gene disorders, scientists and researchers are now able to look deeper into the ways in which genes interact with each other as well as the influence of environmental factors in disease phenotypes. But sequencing a whole human genome whilst being knowledgeable of the vast similarities between all individuals would be scientifically wasteful of both time and resources, hence a faster method to analyse the 0.1% variation in all populations needed to be established. This resulted in the formation of the HapMap initiative in 2002, which uses Single Nucleotide Polymorphisms (SNPs) as markers for genetic variants associated with a disease in question. These SNPs are then grouped together to form haplotypes.

A haplotype can be defined as ‘a set of DNA variation or polymorphisms that tend to be inherited together’ on a region of a chromosome that is not commonly altered by
recombination events such that they are highly conserved regions on a chromosome that one can use as a genetic marker. These haplotypes can span large regions of a chromosome such that the in-between regions are capable of recombination events.

The HapMap project then makes use of these SNPs by producing catalogues of linked variants for disease profile associations thus making analysis for specific diseases or phenotypes easier and quicker to research. This reduces the amount of time spent on such research, leading to a more rapid increase in the knowledgebase as well as making such genomic research endeavours more cost-effective. For the HapMap project to be sustainable it required samples be collected from individuals of different ancestry, namely, Asian, European and African. The project has gained much popularity in providing a well-informed database for those involved in genomic research as well as pharmaceutical research and development with specific interests in personalised medicine. However some controversies have arisen in relation to the means in which populations were engaged, consent obtained and the manner in which these individuals were defined during sample collection.

In response to the issues above mentioned, the emergence of the concept of genomic sovereignty has been brought to light.

1.2 Defining the concepts

In this chapter the concepts of Genomic Sovereignty and Common Heritage will be defined and discussed. The aim of this section is to provide an overall understanding of how these two concepts are related to ownership of human genetic material as well as providing background information into each concept with regard to their origination, significance and use in issues relating to ownership from an ethical as well as a legal perspective.
Genomic Sovereignty is a concept described as “the capacity of a people, country or nation to own, to control both access and use of samples, data and knowledge emanating from genetic material”.\(^5\) The definition stems from a reaction to a statement made in 1997 by the United Nations Educational, Scientific and Cultural Organisation (UNESCO)\(^6\) which declared the human genome “the heritage to humanity”. The UNESCO statement has been subjected to both severe criticism on the grounds of ‘bio-colonialism’ or ‘genetic piracy’\(^5\) as well as support on the grounds of the ‘Common Heritage Concept’.

Bio-colonialism refers to “the unpermissioned appropriation or exploitation of indigenous peoples’ genetic resources, traditional-medical or ceremonial-knowledge or cultural and human rights by practitioners of the new biotechnology”\(^7\). Bio-piracy refers to “the practise of commercially exploiting naturally occurring biochemical and genetic material, especially by obtaining patents that restrict its future use, while failing to pay fair compensation to the community from which it originates”\(^8\).

Proponents of genomic sovereignty attempt to dispel such negative views of bio-colonialism by advocating that through some form of national/local regulation, misappropriation, exploitation and social justice can be acted upon with greater vigour and strength owing to national protective measures that aim to protect its people\(^5\) as well as secure some amount of benefits for the people or community contributing their biological samples. It is therefore assumed that those who advocate for the concept of genomic sovereignty base their supporting argument on having a level of structure to control how genetic research is conducted on a people, nation or state. Providing a guideline as to how such research should be undertaken within a community therefore ensures that benefits of a study and a certain amount of economic gain is rightly awarded to the contributing community.
Contrastingly, proponents of the common heritage concept welcome UNESCO’s declaration with regard to the human genome. Those who advocate for the common heritage of the human genome do so with the vision that all knowledge should be shared and that, for genetics/genomics, the fact that we share the same DNA from one human being to another makes us connected to each other through genetic heritage and linked to each other through genetic diversity. It is likely that common heritage supporters would suggest that the sharing of knowledge between one another should be considered a kind of global communitarianism, from which the donation of genetic material for research purposes should be altruistic in nature. The common heritage concept therefore debases the notion of bio-colonialism and bio(genetic)-piracy and instead promotes the creation of open source platforms for all to be able to obtain genetic/genomic information and therefore use it freely in research. Overall the common heritage concept promotes the idea that makes ownership of any genetic material a universally applied rule, such that it is owned by everyone in the world. However this does not imply that one may have an ownership right over any other person but themselves.

As shown the concepts of genomic sovereignty and the common heritage bring to light seemingly opposing frameworks from which to consider the ownership of genetic material, data and knowledge. Ownership is an important issue which requires resolution in terms of its ethical dimensions in order to provide grounds upon which the law regarding ownership can be clarified.

1.2.1 Defining Genomic Sovereignty

The term genomic sovereignty was coined by Mexican legislators as a means to ensure ownership over Mexican human genetic resources as well as to stifle the growing concerns of bioprospecting of these human genomic resources by foreign entities based on the premise
that such resources and their related data hold both significant and commercial value. The concept of genomic sovereignty aims to protect the genomic material of a nation, state or people; in doing so, those belonging to that land or who fall within its boundary lines are presumed to be protected from bioprospecting and bio-piracy as well as encouraging benefit sharing. Furthermore, by implementing a level of protection over genetic material it in turn provides a platform for better co-operation between a research body and the nation state.

An example of a sovereign claim to genetic material is that of the lawsuit of the Havasupai Indian tribe V Arizona State University, over improper research use of DNA from that community. The research study was initially done in efforts to search for a genetic variant that might be a contributing factor to the increasing rate of diabetes in the Havasupai people. Consent was obtained prior to collection of the samples of the initial study on diabetes research. At the end of the study, DNA and blood samples still in possession of that state university was used without consent of the Havasupai people in other genetic studies such as schizophrenia, ancestry and inbreeding. Upon the Havasupai discovering what other studies the university had used their peoples DNA for, the tribe filed a lawsuit against the state university for improper use of DNA from members of the tribe. The six year case was eventually settled in April 2010. The settlement included $700 000 in compensation to the Havasupai tribal members, funds for a clinic and school and the return of the DNA samples to the tribe.

Although the lawsuit was based on improper use of DNA from the tribe and lack of fully informed consent, the final verdict which ordered that the state university return the DNA samples to the tribe exhibits a form of ownership in which sovereignty over genetic material was claimed by the Havasupai tribe. By claiming their genetic heritage as sovereign, they therefore are able to claim ownership and control over the use of such biological material as well as dictate the conditions under which such samples can be utilised. The misinterpretation
and failure to obtain fully informed consent from the Havasupai tribe with regard to the intended use of their genetic material can be seen as the causal factor from which genomic sovereignty and genetic heritage are able to control both access to and use of those samples, curbing bioprospecting.

The concern that bioprospecting presents is particularly relevant in a sub-Saharan context, such that in sub-Saharan Africa, as well as much of the rest of Africa, genomic diversity has been relatively understudied, despite scientific evidence promoting the high proportion of human genetic diversity within the continent\textsuperscript{12}. South Africa, in particular hosts a wealth of different population groups, such as the indigenous Khoi-San, Xhosa, Zulu, Venda, as well as the Afrikaners, Asians and Coloureds, the latter being a uniquely admixed population of immigrant Europeans, Asians and indigenous peoples\textsuperscript{13}. According to the ‘Out of Africa’ hypothesis\textsuperscript{14}, Sub-Saharan Africa is believed to be the area in which modern humans arose\textsuperscript{14,15}. Thus the populations here are considered to hold in them a wealth of human genetic, linguistic and cultural diversity\textsuperscript{14}. There is a lot to be learnt from understanding and investigating human genetic variation from this part of Africa.

Proponents of genomic sovereignty would argue that protecting these resources from biopiracy and bioprospecting enables South African researchers to maintain a competitive stake in the global genomic research arena, such that it allows developing countries such as South Africa the opportunity to leverage their ‘unique’ genomic variations within their respective population(s), so as to, “encourage local innovation and participate as equals in the global knowledge economy”\textsuperscript{16}.

In Mexico, Thailand and India, investment in genomic medicine has played a significant role in these nations participation in a global knowledge-based economy\textsuperscript{13}. In South Africa the innovation within the biotechnology sector, which included genomics has started to develop,
insofar as to promote economic growth and stand firm as a formidable competitor in the global market\textsuperscript{13}.

Sustainability of economic growth through knowledge-based works is highlighted in South Africa’s Department of Science and Technology report entitled “Innovation toward a knowledge-based economy: Ten-year plan (2008-2018) for South Africa”\textsuperscript{17}. The report highlights genomics as an economic investment, which South Africa should use so as to position itself as a “major producer in the pharmaceutical and nutraceutical industries through the development of appropriate technology platforms that would be based on local strengths”\textsuperscript{13}(p599). However since the release of this report, South Africa currently still has no national genomic platform comparable to Mexico’s National Institute of Genomic Medicine (INMENGEN)\textsuperscript{18} with its focus on commercialization of locally generated knowledge.

In countries such as South Africa, the potential to improve and build upon skilled resources are regarded with high importance as a necessity to build such skills locally\textsuperscript{19}. It can be understood that research initiatives undertaken within local indigenous communities stand a better chance of community co-operation if the researchers involved in the study are native to that land. This would allow both compensation and dissemination of information to be executed much more efficiently. The National Biotechnology Advisory Committee’s (NBAC) position statement on genomic sovereignty in South Africa\textsuperscript{20} advocated the use of locally skilled individuals as well as locally developed resources as a fundamental component in retaining genetic/genomic material within the countries boarders. The statement although promoting local innovation, does not exclude such research being undertaken through collaborative partnerships with outside partners of that country thus promoting national research capacity.\textsuperscript{19}
In summary proponents of genomic sovereignty would argue that it is an important concept which could play a role in ensuring that the benefits of the genomic research conducted using genetic material obtained from a specific people, nation or state would be more likely to accrue to that people, nation or state. Thus it would go some way in protecting developing countries from being exploited by developed countries in this field of research.

1.2.2 Defining the Common Heritage Concept

The first introduction of the common heritage concept (CHC) was during the 1960’s in an effort to regulate the material resources that were deemed to be of global responsibility, such as the ocean seabed, outer space, Antarctica and the moon.\textsuperscript{21,22} In the 1970’s the concept was then expanded to include culture and cultural heritage.\textsuperscript{23} This expansion lead to the formulation that the world and humanity itself is a global village, linked to each other through our history and ancestry\textsuperscript{23}. Cultural heritage is expanded to beyond local cultures throughout the world so as to emphasise the cultural heritage that humanity overall exhibits thus making it common to all. Emphasising cultural togetherness promotes the need for global solidarity and management to protect and utilize certain property equally and with benefit to all.\textsuperscript{23}

In wasn’t until the late 1990’s that the concept of common heritage was uttered within the field of genetics\textsuperscript{23} followed shortly after in the 2000’s by global bioethical frameworks being drafted around the topic by organisations such as UNESCO\textsuperscript{6} for example.

From a common heritage point of view, UNESCO’s declaration of the human genome being “heritage to humanity” can be used as defence for preserving and equitably distributing this resource for the benefit of Mankind\textsuperscript{6}. Heritage simply defined is provided as a “property that is or can be inherited – denoting or relating to things of architectural, historical, or natural value that are preserved for the nation”\textsuperscript{24}. The concept of common heritage for mankind has its foundation set in the doctrines \textit{Res communis}, also referred to as \textit{Res communis}
The doctrine states that all human beings are members of the human race regardless of whether they live in the developed or developing world, and that “things” cannot be appropriated such that everyone should have access to its use. The use of a resource is allowed only if it is not held in monopoly or within exclusivity to one person or company insofar as one’s use for this resource should not impede its use for the next.

The common heritage concept, while pre-dating that of sovereign resources up until today continues to lack a universal definition among those of the ethical and legal world. However in its absence there are 5 principles that those of the legal fraternity propose as guides towards such definition.

The first is that there will be no private or public appropriation as the commons belongs to all; the second is that all nations should manage the resource since the ‘common’ belongs to all. Third, all nations should share in each others benefits acquired from exploitation of the common resource. The fourth principle refers to weaponry or military installation in a common area, however since the human genome cannot be delimited to a region or singular landmark, the fourth principle could be consider under the conditions of bioterrorism. Fifth, the commons should be preserved for the benefit of future generations, insofar as to prevent a “tragedy of the commons” scenario.

Following from UNESCO’s declaration that the human genome in its natural state should not give rise to financial gain, the idea of common heritage in light of bio-piracy has been used as a defence against any patenting laws with regard to the human genome. Much of the common heritage concept has been used as a flagship in debates around DNA patenting and commercialisation. Whilst opponents to this concept attempt to prove that patenting and commercialisation in certain forms are morally acceptable, they still acknowledge...
UNESCO’s statement of the human genome as ‘heritage to humanity’ but choose to view it as a symbolic rather than literal interpretation.²⁷

Maintaining some level of symbolism with regard to the human genome being considered a heritage to humanity allows for those who oppose the absolute literal interpretation to provide a means in which they can re-interpret its current understanding in an effort to sway opponents of the concept of genomic sovereignty to become more lenient to the idea. One such way may be to use the words “heritage to humanity” as a means of marketing by campaigning the potential idea that in protecting one’s genetic material, one’s genetic heritage is also protected and that to save humanity, one must start on home ground, so as to say that, if you protect your own and preserve your local heritage it in turn continues to maintain its valued position as a contributor to our overall heritage and all of humanity.

However those who advocate for common heritage employ the notion that whatsoever findings in the form of diagnosis, therapeutics, or drug development that one might have should belong to all people and all nations. For example, the Convention on the Law of the Seas²⁸ states that, “all rights in the resource of the area are vested in Mankind as a whole, on whose behalf the authority shall act”.

The concept of common heritage within its doctrines has no explicit prohibitions that prevent economic exploitation of a common heritage resource.⁹ Therefore all resources that are declared to be a common heritage resource can be ‘mined’, such as the moon, sea bed and even the human genome. However the principles of common heritage stipulate that if such actions are undertaken on a resource regarded as common heritage, then “all nations and all peoples should still have access to that resource and be able to all share in the benefits derived from it”.²⁸
By sharing both the resource as well as the benefits accrued from research involving genetic material, the acts of bio-colonialism and bio-piracy are diminished. From a socio-economic point of view, developing and low income countries are also able to gain from any benefits gained from a common heritage resource.\textsuperscript{28} This is especially important for developing countries where their indigenous peoples’ (genetic) knowledge has been subjected to acts of bio-piracy and safari research.\textsuperscript{5} The common heritage concept therefore provides a means through legal governance, a structure that promotes bidirectional flow,\textsuperscript{28} from those doing the research to those whose resources are being used, of knowledge, resources and technology transfers, thus ensuring that those who give, or rather provide biological genetic materials receive comparable benefits.

Proponents of the CHC base their arguments on several standings, such as, the high degree of DNA sequence commonality between individuals and by extension associated populations\textsuperscript{29}. In addition, genes are hereditary genomic blueprints of a population, or group of individuals that share a common ancestor (notion of the ‘Out of Africa Hypothesis’). Those who advocate for this concept appear to do so with the intention to stifle and seize acts of bio-colonialism or bio-piracy\textsuperscript{5}, insofar protecting genetic material capitalised on mainly by western developed countries while taking into account the technological disadvantage some developing countries, such as South Africa, may have. Thus many of these developing countries rely on the scientific capacity being aided by developed nations.\textsuperscript{30}

For example, GWAS requires access to laboratory facilities that are capable of processing large scale genotyping of the samples in the study, additionally there needs to be available the statistical expertise to aid in interpretation and analysis of the GWAS data produced. These necessities are only available in a limited number of countries, most being within the developed northern hemisphere nations.\textsuperscript{30} Thus samples for such studies are often exported to these sophisticated centres for processing, genotyping and statistical support.

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For developing countries, who send their genetic samples to these institutions; the concern is raised that once the samples have left the country’s borders, control over its use is limited. This plays into the notion of dual use for these samples, such that while the intended data will be obtained for the study purpose in the developing country, secondary use of those samples is possible outside the focus of the intended study by researchers in these sophisticated labs.

The lack of control over samples in genetic research poses a key challenge for research on populations from the developing countries and builds a general lack of trust between the researcher and the population under investigation. For a country like South Africa, rich in genomic diversity within its populations, the situation isn’t very different. The study conducted by Sathar, Dhai and van der Linde investigated if researchers and a research ethics committee at a South African Institution addressed ethical issues pertaining to human biological materials in collaborative research with developing countries. Their findings indicated that “researchers and the Research Ethics Committee did not adequately address the inter-related ethical and regulatory issues pertaining to human biological materials and that there was a lack of congruence between ethical guidelines of developed countries [and] their actions which are central to the access to human biological materials in collaborative research. Human biological material may be leaving South Africa without export permits and material transfer agreements during the process of international collaborative research”.

Ownership of common heritage resources, including genetic/genomic materials, information and data, is seen as universal, such that every person on this world has a property interest in that resource. Common heritage in its entirety only considers benefits that should be accessed by everyone irrespective of whether you are from the developed or developing world. However the common heritage concept can be seen as being too broad in its approach with regard to its application to a common heritage resource and only completely applicable if defending such a resource against a foreign nation not of this world.
The common heritage concept does however suggest that governance on how a resource should be utilised and how the benefits be distributed, globally. It also provides legal governance with regard to those whom invest largely in research and development of a common resource in efforts to produce a product useful to all. The Convention on the Law of the Sea,\(^{28}\) which stands firm as the strongest example that, exemplifies the common heritage concept, calls for ‘equitable sharing of financial and other economic benefits’. This is executed through an international committee that includes a representative of every country. The issues of financial and other economic benefits are discussed and allocation of benefits decided upon based on a one-country-one-vote approach.\(^{29}\)

Alternatively, those who are opposed to the notion that the human genome be classified as common heritage propose that it be valued as a common resource rather. Arguments supporting the common resource ideology suggest that if the human genome is actually to be considered Mankind’s common heritage, then it implies that every human being, whether in acknowledgement or not, has an ownership interest in the genome.\(^{27,32}\) This would make it virtually impossible to gain consent for any genomic related research as every living human being would have to provide consent.\(^{27}\) Thus under Common Resource modelling, the understanding would be that research, patenting and commercialisation can be morally acceptable provided that moral duties toward such a resource are maintained. Such duties can be borrowed from Aldo Leopold’s Land Ethic\(^{33}\) which emphasises the duties of stewardship and justice.

It is clear that these two concepts of Genomic Sovereignty and Common Heritage seem to present incompatible views with regard to ownership of genetic material with one claiming that it should belong to the nation or people from whom it came from and the other stating that the human genome is the common heritage of all and so the concept of sovereignty should not apply to it.

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2. Ethical Framework associated with Genomic Research and Related issues of Ownership

In this chapter various theories relating to ownership will be discussed. The purpose of this chapter is to present a link between the theories as well as explain, analyse and propose how ownership of genetic material can be associated to them. The theories outlined in this chapter include Kantianism, John Locke’s theory of ownership, and global bioethics with a communitarian approach in conjunction with African philosophy. The aim of this chapter is to formulate the philosophical underpinnings with regard to ownership that will later be used in relation to the concepts of genomic sovereignty and the common heritage concept.

2.1 Understanding Ownership: Defining property

Ownership by general understanding relates to the some form of property and by defining the level of ownership rights to property rules, can be created that govern access to and control of that property. Ownership of anything is to lay claim over some form of property, therefore by association ownership rights are considered analogous to property rights.34

Ownership of property has 3 categories. These are common property, collective property and private property.34 In common property “resources are governed by rules whose point is to make them available for use by all or any members of society”. This type of property ownership allows for open access to resources, such as a street or park. Common property employs the notion of equal access and use of that resource, but places a restriction for its use. The restriction is to prevent any type of hoarding that might occur with use of that resource such that the use of that resource by one does not impede in its availability and use for another at the same time.26,34 Common property like a recreational parks are usually state controlled, that is, it is the responsibility of the state in which the common property exists to
maintain it for continued and future use. Collective property varies slightly from that of common property by advocating that “the community as a whole determines how important resources are used”. This type of ownership is decided upon through communal discussion and or debate. This can be either national or more local where by collective decision making is made by the people of that area, such as, the community chief or king, their cultural and spiritual leaders as well as regular members of the community.

Overall common and collective property apart from the variation mentioned above share the same principle of ownership. Therefore due to the similarity between these two property types, these shall be jointly referred to as collective property throughout this section.

Private property in contrast to collective property provides for the acquisition and autonomous rule of individual ownership over a resource. In this way a person is free to make decisions regarding the use, conditions for use as well as defining who may have access to the use of that resource. Based on this description, private property can be thought of as the key element of private ownership on which intellectual property rights are based, such as patenting.

The rules of private property allow for decisions of self-interest to be made without the need for justification from the public. However even though one might hold private ownership of a property, that person is within limits only allowed to use that property. The most likely restriction or limitation to a privately owned resource would be that its use or destruction does not amount to any amount of maleficence to those outside private ownership of that resource. For example a person who owns a factory cannot decide to release harmful gases into the air from his company because air is breathed by everyone and this would endanger the lives of others.
In private ownership the right to reserve access and control of a resource can be prescribed by the owner.\textsuperscript{34} That person also has the option to trade that resource as a form of commodity such that he/she may sell the resource completely to another or even gift it to that person, in which case the new owner shall acquire all the controlling rights to that resource from its previous owner. Alternatively the owner may even allow a ‘buy-in’ of that private resource, making it a shared resource between a selected few.

Overall the greatest contrast between collective property and private property is the restriction placed on each. Collective property affords everyone equal access to a resource provided one’s use of it does not impede on the next person. Private property on the other hand restricts access and use of a resource to only those who own it. Thus collective property from a philosophical point of view portrays a state of communitarianism displaying an altruistic nature, whereas private property embodies the principlistic nature of autonomy as well as rights based ethics with regard to personal freedoms, such as the freedom of choice.

\textbf{2.2 A philosophical overview of property and ownership}

Philosophical discourse surrounding the issues of property and ownership revolve between the self-interest of private property and communal value of collective ownership. For example, Plato argued in favour of collective ownership ideals, proposing that if property was collectively owned, everyone has a property interest in the resource, and that it would then create and maintain a form of social togetherness between people by each person sharing in a common interest.\textsuperscript{34}

Aristotle argues the opposite, advocating for private ownership on the basis that it promoted virtues like prudence and responsibility, stating that, ‘when everyone has a distinct interest, men will not complain of one another, and they will make more progress, because everyone will be attending to his own business’.\textsuperscript{35} Furthermore Aristotle takes on a counter-intuitive
approach with regard to altruism. While many might correlate being altruistic with striving to achieve a common good, Aristotle uses altruism as a means of drawing a parallel to that of one tending his own private property rather than questioning its acquisition by others. This is akin to ‘minding one’s own business’ whereby the common good to be achieved is not to intrude or interfere with the personal relationship between property and freedom of others and to have a sense of ownership over a thing invokes a status of liberty, whereas to be owned is by nature to be owned by another. Aristotle portrays this using the concept of slavery of a person as an example. In this example, the slave loses his entitlement to self-ownership as an autonomous being because it is claimed by another, to whom the slave owes servitude. Autonomy refers to the respect of an individual to make independent decisions and choices. In western culture, the term denotes the boundaries of the singular, to put into context then the phrase ‘to each his own’ is apt.

Aristotle’s example of the slave highlights the philosophical challenge with regard to self-ownership. As embodied beings, believing that our spirit is linked to our bodies provides for an intimate pre-legal relationship to exist with our own bodies. We are therefore born with the freedom and senses to enable us to continue living our lives. Thus if our range of motion is restricted or limited we are then put in a position that renders us incapable of living a full life since control and/or manipulation of our bodies are regulated by someone other than ourselves. Self-ownership forms a discursive pattern that authors such as John Locke and Immanuel Kant have attempted to provide clarity on.

2.3 Lockean theory of ownership

The Lockean theory of ownership can be used as a form of justification for the right to private ownership to things that currently have no private owner. Locke argues that if one has a property in himself then he rightfully also has a property and by association ownership right
to his own labour, which he demonstrates using the example of private ownership over pieces of land that is common to all. In his theory, Locke imposes two restrictions in claiming private ownership\textsuperscript{37}. The first is that there is ‘enough and as good’ left of that property for others to appropriate and the second restriction is the ‘spoilage limitation’, which stipulates that one should only take that which he is able to maintain and to sustain him without wastage, such as growing of vegetables and having too much for oneself that it spoils.

Locke’s uses this theory of ownership not only for issues related to land but also towards the ownership of the human body. A passage from \textit{The Second Treatise on Government} illustrates this,

\begin{quote}
Though the earth and all inferior creatures be common to all men, yet every man has a property in his own person. This nobody has any right to but himself. The labour of his body, and the work of his hands, we may say, are properly his. Whatsoever then he removes out of the state that Nature hath provided, and left it in, he hath mixed his labour with, and joined to it something that is his own, and thereby makes it his property (Locke, 1978, p.130).
\end{quote}

And in the same book:

\begin{quote}
From all which it is evident, that though the things of Nature are given in common, man (by being master of himself, and proprietor of his own person, and the actions or labour of it) has still in himself the great foundation of property;... (Locke, 1978, p.158).
\end{quote}

Locke argues that humanity can in itself, both of person and of physical body, have ownership of himself and therefore claim oneself as a form of property by virtue of acquiring ownership of things unowned in nature. However in acquiring such ownership, Locke, like Kant, prohibits acts of slavery, prostitution and suicide, but based on religious grounds that Man is not the complete owner of himself but rather the property of God, who created Man.

While Locke’s theory does not explicitly mention genetic material, it can be assumed that in his argument of private ownership of the human body, that biological materials that yield genetic information, such as blood and tissue, are also considered a state of private ownership based on the premise that they belong to the body that is producing work.
2.4 Kantianism

Immanuel Kant, in his teaching of morality emphasised that a moral act is one that is done autonomously. He states that, “Autonomy of the will is the sole principle of all moral laws and of duties in keeping with them”\(^{38}(p150)\). Kant’s view of autonomy is one that aims to hold all living persons to their duty to respect the intrinsic value, worth and dignity of other human beings.

Kant emphasises the point of unconditional worth and ability to be in control of one’s own behaviour because they are rational human beings in saying,

“The capacity to set an end-any end whatsoever- is what characterises humanity (as distinguished from animality). Hence there is also bound up with the end of humanity in our own person the rational will, and so the duty, to make ourselves worthy of humanity by culture in general by procuring or promoting the capacity to realise all sorts of possible ends, so far as to be found in a human being himself”\(^{38}(p154)\)

Based on these qualities he argues that all persons are deserving of dignity and respect on the basis of freedom and equality. He states. “The lawgiving itself, which determines all worth must for that very reason have a dignity, that is an unconditional, incomparable worth; and the word respect alone provides a becoming expression for the estimate of it that a rational being must give. Autonomy is therefore the grounding of the dignity of human nature and of every rational nature.”\(^{38}(p436)\) Law giving in the context of this statement made by Kant alludes to the requirement to have one’s maxim universalised. Therefore, if the law provides that one’s maxim should be universalised then participating in lawgiving gives one the unconditional worth of a morally good will.

Kant’s moral code sets a precedence that depicts the worth of humanity as immeasurable and infinite, thus Kant argues that because of such worth appropriation or ownership of a person or their actions is unobtainable. If ownership of one’s body by another could be allowed, it
would then reduce the worth/value of that person or their actions to a mere quantifiable state or property that can either be sold, exploited or destroyed if one wished to do so.\textsuperscript{38}

### 2.4.1 The Categorical Imperative

“Humanity is free and exercises that freedom through moral action”\textsuperscript{38}

Our duties are derived from a categorical rule, which Kant calls the Categorical imperative and so defines as, “Act only according to the maxim by which you can at the same time will that it should become universal law.”\textsuperscript{(p18)} The maxim employed must therefore be absolute such that that the duty which is imposed on one person is imposed to all universally. In this case the universal norms must exist without contradiction to all. For example, the act of lying is not universalisable because the act of lying requires that the person being told the lie is under the impression that you are telling them the truth. The second categorical imperative states that one should, “Act in such a way that you treat humanity, whether in your own person or in the person of any other, always at the same time as an end and never merely as a means to an end.”\textsuperscript{(p150)}

These 2 maxims can be used in formulating a guideline for making moral decisions. Like a chemical formula, a moral code also requires certain steps to be followed in an attempt to determine if a maxim is universally valid or not. Johnson identifies four steps in this decision making procedure\textsuperscript{50}. Firstly, formulate a maxim that enshrines your reason for acting as you propose. Secondly, recast that maxim as a universal law of nature governing all rational agents, and so as holding that all must, by natural law, act as you yourself propose to act in these circumstances. Third, consider if your maxim is even conceivable in a world governed by this law of nature, if yes, then fourth, ask yourself whether you would or could rationally will to act on your maxim in such a world. If after assessing these four tenants in view of your maxim, and make the decision that your maxim is indeed valid, then the action becomes
morally permissible. The actions then of a morally permissible act, supported by the four tenants that make it so then alludes to the moral standing that all human beings capable of rational thought should always be considered the end product of a moral act and never as an instrument or means to that end.

Thus Kant argues that the moral duty to humanity should be without ulterior motivation and without reward that would not be of universal standing. These “self-regarding” duties include refraining from committing suicide, engaging in voluntary servitude, or failing to develop one’s own talents.38 In staying in focus with the topic of discussion of this research, it would be assumed that Kant would support the maxim that rational beings ought not to sell one’s organs or any other biological material or have it taken without compensation as those body parts do not belong to that individual as a form of property in the same way that their house or furniture does. These acts do portray a form of self-regarding duties and therefore forbids the right to sell it.

However whilst Kant’s philosophy is highly applicable to self regarding duties, should Kant be alive today it would be interesting to see how he might have reconstructed this theories to the current day and age requirements. This is something that Taylor39 tries to do as discussed below.

2.4.2 Commodity and Self-ownership

Kant’s understanding of what self-ownership entails is characterised by the principle of self-ownership not being able to be universally accepted. Taylor39 alludes to Kant’s categorical imperatives with regards to self-ownership, stating, “In Metaphysics of Morals, Kant asserts that someone can be his own master but cannot be the owner of himself, still less can he dispose of others as he pleases – since he is accountable to humanity in his own person.”(p71)
However self-ownership is a concept that can be interpreted in more than one way. Some might find Kant’s view on accountability to humanity difficult to merge with autonomy in the foreground of self-ownership. If you consider that your actions must reflect that of humanity then at which point does one attain a sense of self, individuality? By constantly aiming to do what humanity expects of you, appears to induce coercion or a form of ethical imperialism or a paternalistic maxim.\textsuperscript{39} Taylor applies Kant’s categorical imperative to the issue of a paternalistic maxim in determining its validity as a universal law. The argument made by Taylor notes that for self-ownership to be valid for a rational being, that being must execute his duties as an autonomous agent capable of self-control; otherwise he will risk substituting his own wills for those whom he aids.\textsuperscript{39} This can be thought of as a similar reaction that Kant would have to the notion of voluntary servitude. Aristotle also makes reference to the application of self-control in relation to self-ownership in his example of the slave where he refocuses the concept of self-ownership on a ‘natural slave’ who as interpreted from Aristotle’s work is someone who enslaves oneself because he is unable to control his own desires and because he cannot control these desires he is regarded as ‘unfree because his reason could not prescribe a rule to his bodily appetites’.\textsuperscript{34}

Robert Nozick\textsuperscript{40} extends Kant’s argument of human worth and dignity with that of Locke’s argument that humankind should be allowed to have private property, using the second categorical imperative (that people are ends in themselves) as a mode of rationale for moral justification of self-ownership. Nozick submits that Kant’s categorical imperative is just but advocates that individual liberties, that is, being able to make decisions about oneself should be made without external influence, and thus holds to the ideal that one may treat oneself as an object of property. Nozick however falls short in trying to provide a clear understanding as to why, apart from acknowledging Locke’s theory towards ownership. Nozick does however provide an entitlement theory for acquiring property. He defines the theory as follows:\textsuperscript{40}
A person who acquires a holding in accordance with the principle of justice in acquisition is entitled to that holding.

A person who acquires a holding in accordance with the principle of justice in transfer, from someone else entitled to that holding, is entitled to that holding.

No one is entitled to a holding except by applications of the first two definitions.

Nozick therefore advocates that things held in private ownership/property can be transferred or bequeathed from one to the next provided that such a transfer is done in a way that portrays the act of legitimacy and that the state should not interfere if the transfer or acquisition of that property is just.40

Halewood41 then takes on the concept of self-ownership even further. He argues that there is a link between self-ownership, commodification (property) and personal liberty rights. He posits that “the universal commodification of the person produced by biotechnology can actually democratise and broaden the applicability of rights of self-ownership.”41(p133) In his argument, Halewood plays on the duality in which he proposes self-ownership can be used to describe not only “autonomy or a right to maintain the sacred wholeness of one’s person or body, but also the opposite, that is, the capacity of a person as a transactor to deal in his own body or person as a commodity.”41(p134)

He defines his argument by pointing out that commodification of the body (and its parts) are without a direct link to identification and does not allow for discriminatory ethos, which he uses as a paradox in extending self-ownership to commodification. His defence also includes a necessary need for checks and balances to be in place as a means to prevent ‘new forms of oppression’.41 One method of doing this, advocated by Halewood is through ‘partial-market inalienability’ of human genetic material and tissue. He mentions that self-ownership extends further than the self [body] as property but also includes all parts that make up that self and
that these elements need always be thought of as individual items or property and are thus not always able to transfer to new ownership.\textsuperscript{41}

Furthermore, Halewood points out that in the age of such advanced biotechnology, the human body, genetic material and information have become part of a ‘post-modern property’ and ‘hyper-reality’ such that the body no longer only exists as a physical object consisting of matter but has now taken on the role as a ‘body of information.’\textsuperscript{41}

This, ‘body of information’, has in the post genomic age, led to an increase in intellectual property rights, creating more control over segments of genetic and other biological material. This increased grasping at intellectual property rights, specifically in the form of patents has led to what has been described as a ‘body fragmented by technology’ and so deeply analysed that these fragments have become “discrete exploitable reservoirs of molecular and biochemical products.”\textsuperscript{41(p140)} Hence any application of the concept of personhood to these products is completely removed. This very conception where no person truly exists can be assumed to be the driving force behind intellectual property rights such as that of patents on genes and gene fragments becoming ever more prominent.

Halewood uses the increased commodification though biotechnology to enforce Lockean theory and self-ownership based on the maxims that the biotechnology industry applies both universally and without discrimination. He therefore provides for Nozick an argument that supports his notion that one should be able to treat oneself as an object.

The philosophical discussions made in this section reflect a strongly western influence which portrays a strong emphasis on the autonomous being and is therefore regarded as being too individualistic. An approach that caters to philosophical challenges with regard to population groups and communities needs to be considered. This approach is known as global bioethics.
Global bioethics was introduced in the 1970’s as a means to bring to the scientific community, beyond that of pure medicine, a more global moral insight. The extension of medical ethics to bioethics is said to be mediated by the view that medical ethics was too narrowly focused (doctor-patient) to deal with the now ethical issues of humankind, some of which include genetic research, genomics and large population group studies.

Global bioethics is used as a means of discourse due to widespread technology transfer internationally as well as the increase in the recruitment of research subjects for biological material from developing countries.

Potter argued that there are three stages involved in the development of ethics. These three stages he describes through Aldo Leopold’s environmentalist theory, ‘The Land Ethic’. The first stage investigates the relationship between individuals, the second stage looks into the relationship between the individual and society and the third stages attempts to show a reciprocal relationship between humanity and his environment. Only the first two stages will be considered in the research paper in efforts to stay in context within the research topic.

Potter envisions global bioethics as a platform to address the fundamentals of the word ‘global’, such that the understanding of the system of ethics can be universal and comprehensive, by illustrating that bioethics or ethics overall for that matter is shared by all throughout the world. Not only does it transcend national boundaries but it also affects each and every person universally. He therefore translates universal ethical behaviour into the theory that there is interdependence among people all around the world.

The need for global bioethics becomes imperative so as to prevent interdependence leading to exploitation or bullying with specific mention of those of the developing world being of
greatest risk of such possibilities. Potter understood that the opportunity to take advantage of those ‘smaller’ than you is an ever-present risk and thus promotes the unification of everyone in the world as a global community geared towards a practise in morality that allows for both access and benefits of biomedical progress to be shared equally, removing the risk of lower-income countries being excluded.

The concept of global bioethics highlights the significance of the community. Henk ten Have points out two reasons why community has such relevance in global bioethics. He states firstly, “that global bioethics necessarily reaches beyond the western individualistic perspective of traditional ethical systems… ethical systems of different cultures need to be examined and moral values analysed and applied in specific context”. The second reason he proposes is that, “awareness that individuals are embedded in relationships, communities and the wider world is moving contemporary bioethics to a broader social setting.”

These points of reasoning relate to Potter’s first 2 stages mentioned above for the development of ethics.

Overall the application of global bioethics necessitates an adaptation of conventional bioethical concepts, such that, issues of autonomy and informed consent may be interpreted differently between western and non-western cultures.

The concept of global bioethics can be associated with issues surrounding genomic sovereignty, as well as the common heritage concept. The ethical concept advocates for distributive justice or a collective duty to provide some level of benefit to a community (population group), either through the action or contribution of the community as a whole or by an individual member representing that community.

In the African context, the theories of communitarianism in combination with African philosophy such as that of Ubuntu can be used in promoting proper ethical conduct in
It is common-place in African tradition that decisions made, particularly when these affect said populations directly, are made by public discussion and deliberation. Unlike western majoritarian political structures, most African customs promote discussion between communities, leaders and elders in efforts to find a compromise rather than choose one option over another. This approach may prove more beneficial in opening up a more participatory discourse between researchers and respective communities, in principle at least.

The example above provides for discourse regarding global bioethics principles to be dealt with from a community and cultural based approach. Therefore it may be of the opinion that western bioethical ideals appear to autonomous and culturally insensitive to non-western populations. However the perception may appear too harsh and critical of western centric approaches due to a lack of understanding or interpretation of a western approach and vice versa.
3. Discussion: Ownership of Genetic Material

Using western philosophy, one can easily associate guidelines to genomic research with individualism. It denotes a person’s willingness to participate in a research study and allow the use of his/her biological material and thus decide independently how to regulate its use, benefits and access. But genomic sovereignty and the common heritage concept are based on genomic research of populations (greater than one person). Thus such bioethical concepts need to be revisited and re-interpreted in order to compensate for a ‘greater than one’ scenario.

3.1 Group ownership and Genomic Sovereignty

As a general form of understanding a group can be broadly defined as a number of people that share a common characteristic or interest. In genetic research, the context in which such definition is understood becomes a little more specific. Two types of genetics groups are defined here. The term “Demes” is used to describe or identify a set of people that share relevant genetic information. The other group is identified as the “ethnoi”, which are described as being self-identified or other-identified social groups based on categories such as culture, language, race, territorial occupation, etc.

For those identified as ‘demic’, it is difficult to assert any claim as a group over their genetic information, such that these individuals are unidentifiable as a set group until research and analysis has been completed. Therefore while autonomy and respect for persons can be maintained on an individual level, as a group their moral standings appear to not exist, thus making claims over genomic sovereignty obsolete. Thus classification as demic in genetic research provides little or no protection over the genetic information discovered.
To help understand this concept, consider the example of blood groupings. Globally human beings are either one of 4 blood types (A, B, O or AB) with a corresponding rhesus factor (positive or negative). Having a specific blood group is not unique to oneself, even if one is classified as a having a rare blood type, that person will still fall within the lowest percentile for an entire population. Thus whilst such a blood type may be difficult to find, it is in no way unique to a specific person but rather he/she would belong to a group that is classified as having such a blood type.

The point illustrated here is that one cannot claim control or sovereignty for that characteristic simply because the members of such a group are too large a number and dispersed globally, thus further removing the issue of national sovereignty. This seems to be the case for those of the demic grouping. However such research subjects are rarely a focus of a genetic study. It is rather those of the ethnoi grouping who are the most common subjects of genetic research.

The ethnoi as previously mentioned are self-identified or other-identified social groups, which although classification for this group may not be of genetic connotation, these varying factors are still considered critical components that drive genetic research within such groups.

Thus these specific groups are able to impose or leverage their genetic data for claims over genetic control of both sample and data, i.e. sovereignty. Research involving ethnoi groups are usually selected based on a “unique” externally unknown genetic characteristic that allows them for example, to metabolise faster, show immunity to a specific disease or conversely make them more susceptible. Such research is generally conducted in a localised environment thus prompting the need for sovereign control over such data. Since researchers have a vested interest in a specific set of people, it stands to reason that there is something of specific interest within them that researchers wish to explore further.
As Juenst portrays it⁴⁸, “it is the history, migration and relative disease burdens of humanity’s many socially defined groups, not our anonymous demes that derives most descriptions and defences of population-genomics research”(p675). Thus the assumption made here is also central to genomic sovereignty. These are the assumptions that the genetic information within a set population is unique and of commercial and symbolic value.

However it is known that there is <1% genetic variation between individuals, thus implying that most of the genomic sequences found from one individual to the next are almost the same¹. Hence it stands to reason that what researchers may perceive as a unique variant within a specific population group is indeed flawed. One can accept the fact that such variation can occur in a higher frequency within a population set due to certain factors that they hypothesise but in any case their findings for genomic uniqueness falters as individuals with the same variant could always be found in another population.

In the age of Genome Wide Association Studies (GWAS), microarrays and next generation sequencing, genetic markers that confer risk profiling and predictability testing use more than one variant as a mean of determining one’s at risk profile, thus in order to gain greater insight into one’s disease risk, haplogroups/types are generated that can be used as predictive markers. It can also be assumed that whatever the research is focused on, there will always be a patient with such ailment outside of the sample size for such study.

Thus if the quest for genomic sovereignty is to protect genetic information of a unique population group, then scientific evidence tends to lend itself to the converse, weakening the argument for genomic sovereignty⁴⁷.

Therefore, one needs to consider what other motivation there might be for seeking genomic sovereignty for a people, nation or state. If the argument towards unique genotypes cannot
substantiate for a strong enough argument to claim genetic information as a sovereign resource then other mitigating factors need to be brought in to support such argument.

One motivation for claiming genomic sovereignty and perhaps the greatest contributing factor are the tangible profits that could be made from such research. If those concerned (people, nation or state) do not enforce some level of remuneration for contributing to the science that has led to the breakthrough down the line then the doors for exploitation are free to open and take from the people as they see fit. This also ties in with the notions of access and benefit sharing.

Another motivation for promoting genomic sovereignty is that of increasing the knowledgebase of the country involved. For developing countries such as South Africa, research initiatives that involve collaboration with more developed countries such as the United States or the United Kingdom allow local scientists the opportunity to be recognised in a volatile field where it’s either publish or perish. Furthermore it allows those in developing countries the opportunity to sharpen their skills, by working with international collaborators and technologies that are unavailable to the developing world. If these ideas can all be used together it may be possible to create a strong motivation that would allow a nation or state to regulate genomic research in their country.

### 3.2 Group ownership and the Common heritage concept

The common heritage concept is used as an argument against the ideals of genomic sovereignty, such that the common heritage concept takes on a more utilitarian argument (greatest good for the greatest number). The argument made for common heritage is that the group in question here isn’t that of an indigenous group or of people of certain terrestrial land but rather all of humanity.
From an ethical point of view the argument stems from the concepts of global bioethics, in that we are all part of a global community, if people within this group are found to have certain genetic characteristics that would be beneficial to the understanding of a disease or aid in developing a therapeutic intervention then these findings should be shared with the rest of that group, that is, the global community\textsuperscript{23}. If we consider Kant’s theory on moral duty then, overlooking the point that Kant does not consider commodification of the body as morally just, the act of sharing knowledge and information is a maxim that can easily be associated to the categorical imperative thus making it universal in nature\textsuperscript{50}.

The role of common heritage has a duality in its understanding and comprehension. While the literal interpretation invokes property, ownership to all of humanity, the level of ownership is dependent on the doctrine that is used to define it. There are two doctrines that can be used that relate to regulating the commons, these are \textit{res communis} and \textit{res nullius}.\textsuperscript{26,27,29}

\textit{Res communis} as previously defined above states that all human beings are part of the collective known as the human race and that no person is to be excluded at all irrespective of colour, creed or social background\textsuperscript{26}. It allows for appropriation of a resource for the use of all of humanity, such that no individual may own it exclusively and that such a resource should be shared equally.

\textit{Res nullius} employs the same tenets but juxtaposed with \textit{Res communis} delivers a different outcome with regard to ownership, such that the global commons is said to belong to no one (which indirectly implies ownership by all) but allows for alienation to an individual if the mode and reasoning for such acquisition is both ethically and legally valid.\textsuperscript{23,26}

Based on the description of these two doctrines, it is most likely that the UNESCO Declaration, stating that the human genome is to be considered ‘heritage to humanity’ was employing the doctrine of \textit{res communis}. However the current landscape towards ownership
paints a rather different picture more reflective of *res nullius*. Evidence of this can be found throughout the world, more so in the developed countries, by appropriation of patents for genes found in the human genome\(^3\). It is likely that the *res nullius* doctrine is employed by intellectual property agents through claims that those who succeed in isolating a gene should be allowed to claim ownership over it based on the understanding that since no one owned it before despite it being present in everyone, then now that it has been discovered, extracted and isolated by an individual (group of individuals, biotech and pharmaceutical companies) it then can be rightly claimed by that individual as his own property\(^23,26,29\). Additionally, there is far greater economic growth and returns on investment based on the exclusivity of a resource such as a gene patent rather than having to share profits on a global scale, all of which cannot be possible in the absence of property rights.

It is of noteworthy importance to state that the opinions with regard to patenting in this section are generalised based on the US approach before the 2013 *Myraid Genetics*\(^76\) law suit was concluded and that the omission of a European approach within this section is due to size constraints of this report.

UNESCO’s Declaration of humankind’s common heritage in consideration of the doctrines mentioned above is more likely to be interpreted metaphorically, where all are urged to unite and act as one, but is more likely to be of greater impact in issues such as global warming rather than that of genetics. Despite this current situation with regard to ownership, property rights and patenting, the idea of common heritage still remains a force that some still continue to use as a means to influence ethical and political debates regarding commercialisation of the human genome and its genes.

The common heritage principles mentioned in the section above highlighted five points that can be used to build a definition for common heritage. The first four are fairly simple to
interpret with the fifth principle requiring further elaboration. To reiterate, the fifth principle states that the commons should be preserved for future generations, so as to avoid a ‘tragedy of the commons scenario’.

The ‘tragedy of the commons’, made popular by Hardin highlights the risks and consequences of over-exploitation of a common resource through unrestricted control and access, concluding that ‘freedom is the recognition of necessity’, and that the abuse of that freedom is the primary cause for a tragedy of a commons. The question remains: could there ever be a tragedy of the commons scenario with regard to genes?

Logically it seems impossible, for as long as human beings exist, access to the human genome from a biological point of view will always be available. Furthermore, in a technology driven age, gene sequences are capable of being immortalised through digital storage of their sequence data. I therefore argue that in trying to define the human genome and its genes thereof as common heritage that a tragedy of the commons scenario lacks sufficient evidence to support the common heritage principle. Instead an ‘anticommons scenario’ is more likely to occur, which is discussed further in the legal component of this research report.

While it is understood that the common heritage concept is meant to protect resources deemed common heritage and ensure global benefits to all, such as the efforts made toward that of the human genome and its genes, it falls under criticism in its lack of protection of group ownership on a more local scale.

For example, Sandel argues the moral claims to a “cosmopolitan citizenship”. In his paper he advocates for the role of the community to be scaled down and identified as individual groups. He emphasises that the moral relevance and importance of community are those which are located throughout the world and that the global community fails to protect
everyone equally. ten Have\textsuperscript{23} tries to offer a counter argument in which he bases his premise on the linkage between global and local communities. His defence is that “the global sphere is not a domain in itself, separate from other domains. It includes them all, and at the same time, manifests itself in each. That means that there is no opposition between the global and the local. The global is produced in the local; what we understand as global is constituted within the local. The global escapes the communities of its creations and at the same time manifests in them”.

Common heritage employs the ethical teachings of utilitarianism by making the assumption that the interest of the many outweigh the interests of the few.\textsuperscript{46} This however is not the case, as not everyone can or will have genetic testing nor can any person be forced to do so or join a medical research study even if the potential benefit would be for the greater number of people. Thus while the common heritage concept in principle employs a utilitarian ethic, it can be limited in its reach.

Although one might argue for a supreme emergency where individual or group rights are sacrificed for a perceived greater good, and where testing and research is coerced and mandatory. However owing to the possible rarity of such extreme circumstances, it may appear that in the current setting of genomic research and testing that the former argument holds greater poise.

3.3 The common resource argument

There are those who rather than view the human genome as common heritage or even a token of national sovereignty, motivate for it to be thought of more as a common resource. Proponents advocated for the common resource argument based on the following tenets; firstly, it removes the common property right in the genome, secondly, global ownership interest is also reduced to only those who have a specific interest in the genome and/or its
segments. It thus allows for commercialisation of that resource by individuals, companies or countries. By allowing the human genome to be considered a common resource it thus allows for both moral duties as well as legal platforms to be imposed in a more specific and focused manner as there would now be a smaller focus group to concentrate on rather than trying to control such concerns on a global scale.

The concept of ownership in view of the common resource argument also requires a paradigm shift where ownership of the human genome isn’t seen as the most suitable means in protecting itself. Where exclusivity is found there is room left for exploitation and selfishness in withholding the resource to one’s self. Rather the ideals of stewardship are promoted as an alternative. Furthermore, the five principles used to define a common heritage appear to fit in better with the common resource model as stewardship requires that those who undertake such responsibility do so with the intention to take care of such a resource and treat it with significant worth such that, in tune with the fifth principle, it be preserved for future generations.

### 3.3.1 Duties of stewardship

A steward in absolute simple terms is someone who is given the duty or put in charge of taking care or overseeing something for someone else, in other words, being made the trustee. From an environmental ethic point of view, those afforded the role of the steward are to, as part of their duties, not only take care of the item but also prevent harm from coming to it, in other words prevent a tragedy of the commons scenario. From a genetics point of view this would entail protecting the human genome and by association its genes from act of maleficence, such as the loss of genetic diversity, creation of harmful genetic mutations or negative eugenic practices.
Stewardship can be seen as a means of merging the ideals of genomic sovereignty, common heritage and the common resource argument, specifically with regard to group ownership. As previously mentioned the common resource model allows for appropriation of a resource by an individual, company or country\textsuperscript{5}. If one excludes the term company from this definition then the common resource argument starts to show a similarity to the definition of genomic sovereignty described earlier. Within genomic sovereignty heritage is spoken for as well in its definition by the terms ‘nation’ and ‘people’. A nation or people of a country carry with them inherent and inherited indigenous knowledge, perceived as a common resource to those in that area\textsuperscript{83}. Thus those who carry with them this indigenous knowledge have a duty to pass on the information from one person to the next both inter and intra generationally. Hence the information is preserved, transferred and shared from one to the next generation. Each person is therefore incidentally an honorary steward whether aware of it or not.

The act of stewardship provides for those of specific groups to allow the use of their genetic material without handing over exclusive rights to such materials. In this way, a research initiative that aims to use a specific population group is afforded the opportunity to decide whether they are willing to submit to the researchers their biological samples and state the terms and conditions under which their samples are used so as to address the cultural needs and sensitivities of their community\textsuperscript{23,27}. Furthermore a stewardship model allows for such communities to set more specific terms and conditions to access and benefit sharing to their communities. From an African perspective, the foundations of stewardship reflect similar findings to that of the way of Ubuntu\textsuperscript{45}. 

\textsuperscript{23}
3.4 Ethical conclusion: Ownership and Property

Kant’s philosophy in essence would agree that freedom from interference is necessary as it forms an implicit and fundamental component of autonomy but still affirms the duty to treat one’s self with the same respect and dignity that is to be afforded to others.\(^{38}\)

For example, helping a fellow Man in some ways does have moral worth. Thus if we consider Kant’s Maxim\(^{38,50}\), that a person cannot be used as a means to an end, but as an end in itself, then, under current bio-prospecting understandings, using one’s populations resources to benefit another with no ‘reward’ to the contributing donors is ethically flawed. However, if such samples were collected through the proper channels such as informed consent from the population, with the notion and intent that they too would benefit, such that intrinsic value, dignity and worth for human life is maintained by providing adequate mandates such as that of informed consent and benefit sharing.

Although Kant’s stance on self-ownership is a negative one, a defence of self-ownership can be made on the ideal of a *duty of physical non-interference*, that is, the duty to respect the bodily integrity of other persons.\(^ {39}\) This in turn produces a limitation right for that person, that is, the right not to intrude or interfere or trespass on one’s own person. This limitation right consequently provides for an autonomous person to be able to not only forbid actions against themselves but also allow temporary level of use.

For example if we consider the right to use common property such as a recreational park, where a person lays down a picnic blanket\(^ {34}\) on a certain area of the park, that person executes their right to use that portion of the park, thereby limiting that area’s use by others. It is a temporary claim that can be removed. Assuming that the picnic blanket only covers a portion of the area not obstructing anyone else from enjoying the park, this temporary claim can be permitted. This example relates to the common heritage concept principle whereby use
of a common resource, such as human genetic material, is permitted provided it does not impede on its use by others.

Another example is the right of transfer\cite{footnote} which can be applied as an indirect derivative of the right of exclusion. If we consider the scenario of people working out at the gym, when I am using one item of equipment, I am exercising my right to exclusion. I am using it now and therefore no one else can use it. However once I am done using the equipment it should be passed over to the next person requesting its use, that is, transfer the item from me to another party.

This example represents a duality of ownership in property. The first is one of common property. Since the gym is communal is can be shared by all who visit it. It is important to note that in a gym there is usually more than one machine or equipment of the same type thus allowing more than one person to use the same machine all at once. Again this type of environment does display a form of common property, such that we have many people in a common area utilizing the same work space and sharing it among their fellow gym partners.

Hence all the equipment in that gym is for common use. The equipment is owned by no one who works out there therefore temporary ownership can be recast again upon opening the gym again the following day. This form of ownership can be associated with the common heritage concept doctrine of *Res communis*,\cite{footnote} which has been previously described as, all human beings are members of the human race regardless of whether they live in the developed or developing world, “things” cannot be appropriated such that everyone should have access to its use. The use of a resource is allowed only if it is not be held in monopoly or within exclusivity to one person or company insofar as one’s use for this resource should not impede its use for the next\cite{footnote}.
Using this example, if we widen the lens a little, ownership of property takes a turn from common to sovereign. We understand that sharing the equipment in a gym is to be considered communal, but a gym is a business in which, overall, the equipment within that building sole ownership is awarded. Hence those who choose to use these types of gym equipment do so with the consent of the gym’s owner. Therefore the gym acts as a sovereign resource for which all rights of use of its equipment are reserved with the gym owner.

A gym like all businesses also needs to gain some form of income to sustain and maintain it so that it continues to provide a service to those who want to use it. This is done by charging patrons a membership fee which in turn grants the patron access to and use of the gym and its equipment. In the same way, a country (gym owner) that regards its resources such as genetic material (equipment) as a sovereign resource has the option and the freedom to decide on what grounds their genetic material can be used for and what the benefit to that country supplying such material is likely to gain.

It should be noted that the scenario depicted above is portrays the idea that national sovereignty is the accepted norm. It however does not take into account an individual’s right to own his/her own genetic material and use it as he/she wishes.

This now presents a dilemma in which a property type, such as a gym or human genetic material, can be represented as both common and sovereign. The question then to be answered is how we justifiably harmonise these to concepts that tend to present varying ideals with regard to ownership?
4. International Bioethical guidelines associated with genomic research

Guidelines with regard to ownership of biological samples and genetic data involve looking into how research is conducted in developing countries, such as South Africa.

Many of the bioethical guidelines, such as the Canadian Institute of Health Research guidelines, UNESCO’s Universal Declaration on Bioethics and Human Rights, and the Organisation for Economic Co-operation and Development (OECD), provide for ethical considerations when conducting genomic research. Much of what is stated in these guidelines, while not legally binding, are still capable of guiding legislature into protective laws, thus they can be considered to hold some degree of quasi-legal standing.

The notion of stewardship and justice as advocated for by Leopold in the form of access and benefit sharing is made evident in many of the research guidelines surrounding genetics. For example, the CIHR issued guidelines for health research involving aboriginal people in 2007 which infers the notion of co-ownership and stewardship in their research, such that samples used in research are to be considered to be ‘on loan’ to the researcher unless otherwise agreed upon.

Justice, access and benefit sharing are provided for in the OECD guidelines. Whilst these guidelines are not specific to genomic ownership the principles therein can be applied to the issue at hand.

For example the OECD guidelines with regard to Human Biobanks and Genetic Research Databases (HBGRD) present culturally sensitive recommendations with respect to custodianship/stewardship as well as benefit sharing. Furthermore, under the issue of access (fairness and transparency) one of their “best Principles” points out requirements for
researchers to set out policies that allow participants to view or get information regarding themselves in research involving their biological contribution. They also make the recommendation that participants consent to the type of research that their sample and data can be used for.

In terms of benefits, these same guidelines suggest that before any study can commence, policies and contracts should be drawn up and agreed upon by both researcher and research participant, particularly in the case of population level studies, where there may be vulnerable populations or unique concerns. These guidelines also include statements made with regard to commercialisation or resources or lucrative gain in commercial products obtained from research activities as stated in section 9D of the principles of custodianship, benefit sharing and intellectual property. This section states that “the operators of the HBGRD should have clearly articulated policy that is communicated to the participants relating to the commercialisation of its own resources, research results derived from those resources, and/or commercial products, if any that may arise from research using its resources”.

Whilst many of the guidelines with reference to genetic material are widely available internationally. The degree to which they are enforced differs broadly around the world. Furthermore, even though existing guidelines, such as, UNESCOs Declaration of the Human Genome and Human Rights or the CIHR or OECD, they aren’t legally binding documents but do play an important role in affecting legislature and policy making decisions.

4.1 Community benefit

Once a researcher and a community have reached an agreement with regard to the research being undertaken a relationship between the two parties is then formed. This relationship is to be maintained, especially in developing countries, even if an individual is used from that community - as he is positioned to act as a representative of that community. The relationship
formed should reflect a supportive and caring nature to the community with a sense of solidarity to the community based on the benefits stipulated within the community.\textsuperscript{23,54}

Benefit sharing stipulates not only that an individual benefit from research participation but also the community he belongs to. The ‘rewards’ in the form of some benefit to a community first emerged in the 1980’s as a principle to try and alleviate the amount of bioprospecting and biopiracy that was happening during that time. In 1992 the UN Convention on Biodiversity noted that the principle of benefit sharing should be used as a means to ‘appropriate access to and use of genetic resources’.\textsuperscript{55} The required access to communities implies that both the community itself as well as the indigenous knowledge that they carry is worthy of producing benefits. The principle therefore states, “that in return for access to genetic resources and the use of the traditional knowledge associated with these resources, benefit sharing agreements should be negotiated with the local community”.\textsuperscript{23}

Traditional knowledge is regarded as a property type of a community\textsuperscript{9,69,71}, such that all who belong to such a community, in whatever way that they are defined, own that knowledge. On a local scale, the shared knowledge between community members is regarded as common heritage\textsuperscript{23}. Thus discussions and agreements with regard to benefit sharing should be all encompassing of the local communities needs and, in doing so, reach an agreement which allows the researchers to obtain the required genetic resources and the providers of such material within a community to be adequately compensated for. It is imperative that such an agreement does not become misconstrued with any form of sale or transaction that makes one or the other out to resemble that of a buyer and seller relationship.

Conflating the human body with economic market value, as Sandel\textsuperscript{49} explains, is said to infer a form of corruption to the inherent moral value of a human being for “certain moral and civic goods are diminished or corrupted if bought or sold for money”. Sandel argues that to
assign monetary value to a human body, makes it’s a commodity capable of being, bought, sold, or destroyed as one sees fit and thus creates a shift of worth of the human body from intrinsic to instrumental. Sandel’s argument therefore on the basis of ethical principles echoes the moral standings and principles found in Kantianism.

ten Have, in his argument towards benefit sharing raises the concern of how a community worthy of receiving these benefits are defined\textsuperscript{23}. He advocated for an approach that emphasises ‘social ties, shared interests, common perspectives and joint actin besides geographical location’ above that of shared disease conditions, race and ethnicity. He also emphasises the need to clearly define the target community from whom research requires participants. It needs to be understood that biological material and genetic resources tie into the community that research chooses to focus on and thus the principle of benefit sharing requires proper identification of these communities so as to prevent any act of biopiracy or non-essential extraction of genetic materials from those not specific to the target community. Most notably, identification of a community allows for any benefits that are accrued to be distributed equally among those rightly deserving of it.

In addition the Human Genome Diversity Project’s Ethical Protocol Model for Collecting DNA samples of 1997\textsuperscript{56}, like the guidelines mentioned above also provide for detailed approaches as to how to approach and plan genomic research. In addition to the standard procedures of informed consent, privacy and confidentiality, it is recommended that researchers, who are to approach various groups, are to make an effort to first find out about social, cultural and traditional concerns with regard to sample collection.

“In many societies around the world, hair is secretly collected from intended victims to harm them through witchcraft. Consequently, people collect their own loose hair, fingernail parings, and other body products and bury them to avoid this danger. Researchers who asked such a population for hair might be seen as intending to perform witchcraft. Blood is often intended as a sacrifice, sometimes through special rituals. Donation of blood in such cultures is a serious matter that would require discussion and perhaps a neutralizing ritual.”\textsuperscript{56(p1437)}
This would appear greatly helpful so as to avoid disrespecting population’s cultural practices as well as that, by gaining insight by researchers into such cultures; they may be able to avoid insulting those populations or find alternative ways to collect samples from them that would not be of offense or possibly culturally misleading.
5. Legal Framework around Genomic Research in South Africa

Based on current legislation, biological samples capable of yielding genomic information can under certain circumstances be owned and have rights attached to them. This section will explore the ownership of human biological materials, DNA and the information derived from such research.

Ownership with regard to biological human material is addressed to some extent within South African law, specifically in Chapter 8 of the National Health Act\textsuperscript{59} and its regulations\textsuperscript{65}. However, those of the legal fraternity struggle in conceptualising ownership of such materials without objectifying a person or people thus laying risk as reducing such individuals as a state of property\textsuperscript{57}. This infers a reduction in human dignity by rendering one-self or parts of that same self as a commodity. The complexity of the issue raises much debate both legally as well as ethically.

The human body and its parts are traditionally classified as \textit{res extra commercium} (things outside of commercial value)\textsuperscript{64}. With regard to the body as a whole, ownership according to South African law bequeaths ownership status to the person to whom the body is still attached to, based on the interpretation of one’s constitutional right to bodily integrity\textsuperscript{58}. On the other hand, bodily material that has been separated from its owner (assuming the owner is aware and informed consent has been given) lies in a rather grey area legally. Current understandings are that of the \textit{Res nullius} doctrine, which if simply interpreted states that materials under this doctrine are said to belong to all due the conditions set out within the doctrine that suggest that such property belongs to no one but can be acquired through certain means\textsuperscript{21,25,57}. Therefore for samples of human biological material, once separated from the body, the original owner of that material loses his right to it and it becomes eligible to
become ‘property’ of the first person to claim ownership and use of it. The practise *res nullius* with regard to separated bodily materials is borrowed from the legal understandings of Roman-Dutch law upon which South African law is based.\(^{57}\)

\[\text{5.1 The Constitution, National Health Act 61 of 2003 and Relevant Regulations}\]

The Constitution of South Africa\(^{58}\), section 12(2) states that “everyone has the right to bodily and psychological integrity, which includes the right… not to be subjected to medical or scientific experiments without informed consent”. This advocates for the control over one’s own body and mind\(^{58}\), such that that person has the right to their own autonomy prior to medical or scientific experimentation. When applied to the issue of ownership it would seem that once someone decides to participate in any form of research, in this case, involving biological specimens then ownership of such samples should be re-discussed and agreed upon by both the researcher and individual/group through the proper informed consent protocol channels. Overall however, apart for inferred interpretations of the constitutional laws, ownership of human bodily material is blaringly silent.

Section 16(1)(d) of the Constitution\(^ {58}\), states that “everyone has the right to freedom of expression, which includes… academic freedom and freedom of scientific research”\(^{1249}\). Interpretation of such legislation is open and can be used as a means of exploitative methods to undergo research endeavours. However under limitation of rights, section 36,\(^ {58}\) this law can be restricted to certain rules and conditions through the limitation clause stated within the Constitution. It is important to ensure that an ethically justified balance is maintained between protecting individuals and promoting scientific research. Justification for limiting the freedom of researchers in the field of genetics and genomics can be motioned for by local
and international ethical guidelines, but it is important that the laws of the country provide a foundation from which to regulate these issues accordingly.

Therefore, on the one hand, whilst the Constitution can be seen to indicate that one’s own bodily materials belong to oneself, on the other hand it promotes freedom of scientific research, which in the case of genomic research requires human biological materials.

Research on or experimentation with human subjects and associated biological specimens obtained are covered by chapter 8 of the National Health Act No. 61 of 2003 (NHA) and its regulations, which deals with the “Control of use of blood, blood products, tissue and gametes in humans”\textsuperscript{59}. The National Heath Act defines tissue as ‘… human tissue that includes flesh, bone, a gland, an organ, skin, bone marrow or bodily fluid, but excludes blood or a gamete’\textsuperscript{59}. The regulations relating to the Use of Biological Material defines biological material as ‘… material from a human being, excluding DNA, RNA, blastomeres, polar bodies, cultured cells, embryo’s, gamete, progenitor stem cell, small tissue biopsies and growth factors from the same’\textsuperscript{60}. Additionally the regulations relating to Tissue Banks define tissue as ‘… a functional group of cells. The term is used collectively in regulations to indicate both cells and tissue’\textsuperscript{61}. Lastly, the regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes define a substance as, ‘… tissue, blood, blood product or gamete’\textsuperscript{62} and the regulations regarding the Clinical Forensic Medicine Services define a body specimen as, ‘… anybody [sic] sample which can be tested to determine the presence or absence of HIV infection’\textsuperscript{63}.

Judging from the various definitions toward human biological material mentioned above, it is quite evident that their lack of cohesion between one another leaves room for ambiguity and
thus lays the possibility for exploitation of such materials, especially from genomic research. Genomic research requires some form of genetic material as a means to conduct a research study, to obtain it biological material is required as in all of these sources genetic material (DNA and/or RNA) and be extracted. From a legal perspective, the contradictions between these definitions hinder the ability to provide a legal classification for human tissue, which in turn leads to a variation in what type of samples can be obtained for genetic studies.

Researchers may choose to define their proposed sample type based on a definition that offers them the greatest amount of freedom in obtaining the types of sample they require. Furthermore, with a lack of cohesion between these definitions, the rationale to limit the expressions of academic freedom and freedom of scientific research becomes difficult to impose, leaving room for exploitation. Equally so, the contradictions of these definitions make it difficult for those who wish to perform genetic research in South Africa, to dutifully state the specificity of what sample type is required for their form of genetic research and may thus cause problems in interpretation when seeking ethics approval for the study, in turn delaying the study.

5.2 Understanding Ownership: Legal Perspective

The description of ownership stems mainly from common law. Ownership is described on a case by case basis in South Africa, and has been defined in various decisions as ‘the most complete real right which gives the owner the most complete and absolute entitlement to a thing. Even so, it is a right which can be limited by objective law and by the rights of others’. A ‘thing’ is defined ‘in terms of characteristics, as a corporeal or tangible object external to persons and which is, as an independent entity, subject to judicial control by a legal subject, to whom it is useful and of value’.
Genetic material in this sense is reflective of what a ‘thing’ would be. Genetic material meets the criteria that are used as definable characteristics of a thing. It is corporeal, as being belonging to a physical body and tangible, as being a material that can be made visible, of definite substance and can be quantified.\textsuperscript{64}

According to regulation 180(S26) of chapter 8 of the NHA, ownership of human tissue obtained via informed consent is considered the exclusive property of the researcher or research institute\textsuperscript{65}. This is stated as “Any person who acquires the body of a deceased person or any tissue, blood or gamete by virtue of any provision of the Act and these regulations, shall, subject to any restrictions in terms of the Act or any other law and provided she or he uses the body, tissue, blood or gamete for the purposes for which it has been donated, handed over or supplied to her or to him, on receipt of that body, tissue, blood or gamete acquire exclusive rights in respect thereof”. Such regulation pertaining to biological material capable of yielding genetic material within the NHA portrays a sense of exclusive property rights from donor to donee, that being a researcher, doctor, or research institute for example\textsuperscript{59}.

This transfer of ownership therefore implies that when elements of the human body are separated from a person, the material gained loses its identity and is to no longer be considered a biological material that no longer has relatedness to the person whom has donated it. This may be true for biological material removed from a person as it can be coded or anonymous but the genetic information within those materials are capable of identification. For example if a population group under genetic investigation if found to hold in their genomic sequence a rare variant or SNP that specifically clusters within that group, it then acts as an identifiable marker to that population. Depending on the type of genetic association predicted to be linked to that SNP a population can become vulnerable to further genetic exploitation and cultural intrusion. Thus, while national regulations display ownership of
biological and genetic materials as a property that can be transferred from one person to another, the intimate nature of genetic material begs the question of, to whom does such material truly belong?
6. Genomics and Gene Patenting

Prior to the recent international ownership issues relating to genetic material such as that of patent laws, the common understanding was that such material was an open source with no one having exclusive rights to ownership over any piece of it thus allowing all countries to share their genetic resources freely. An example of open source in genetics is that of the Human Genome Project, an endeavour that required the collaboration of a number of different institutes sharing their information and data, therefore forcing each of them to decide on flexible research standards.

Safrin refers to the “legal enclosure of genetic material”, which she attributes to two developments: Firstly, the patenting of genetic material by predominantly developed countries and, second, a response to the privatisation of genes through the patent system the extension of sovereignty over genetic resources by developing countries. This action has then led to a reaction by many states of the developing world to begin implementing state sovereign rights or a form of national control over genetic resources within their borders. The interaction between the patent system and the sovereign-based system is described by Safrin as a “corrosive interplay” eventually leading to a system she describes as “hyperownership” of genetic material to the anticommons trap.

The anticommons is a concept introduced by Micheal Heller as ‘the mirror image of common property’. Whilst the Tragedy of the Commons is a philosophical idea expressed by Hardin that sets fort the consequences of overuse of a natural resource, such that access to that resource is overrun, the anticommons proposes the opposite: a tragedy is likely to arise “when these individuals or entities employ their rights to veto the use of a given resource and in so doing waste the resource by it’s under consumption compared with the social optimum”.

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Hardin’s Tragedy of the Commons represents over-consumption and exploitation of a resource without giving back to the entity from which it was taken. Heller's anticommons approach aims to identify the lack of willingness to allow others access and share in the benefits of that resource. From a genomics point of view this represents the effects of safari/helicopter research, whereby genomic samples were collected from communities without proper consent or fair compensation, that has happened in the past consequently leading to many nations seeking sovereign mandates over their genetic materials. In either case the action of both these groups incurs both social and economic repercussions.

Additionally, the development of excessive sovereign control or ownership of genetic material is likely to lead to over-regulation\(^6^6\), with bureaucratic red tape impeding important genetic research.

Although UNESCO’s declaration that the human genome in its natural state should not give rise to financial gain\(^5^3\), it does not offer any protection over segments of the human genome. Many of the developed countries allow for genes that have been isolated, extracted and functions determined to become a commodity, gain commercial value and allow for its patenting\(^6^6\). In South Africa, current laws, such as the Biodiversity Act\(^6^9\), restrict access to genetic material for the purpose of acquiring remuneration but its exclusion of human genetic material from the Act once again leaves a gap for exploitative means.

Globally, many of the developing countries such as Mexico, Brazil and India for example have in place regulatory guidelines\(^5^,1^0,6^6\) that view human genetic material as a natural resource based on the concept of Genomic Sovereignty as described above as “the capacity of a people, country or nation to own, to control both access and use of samples, data and knowledge emanating from genetic material”\(^5\text{(p436)}\).
Thus with the awakening of the wealth of genetic data available in their respective countries the so-called traditional distinctions in legal understanding between human and non-human genetic resources is slowly being eroded, with international bodies calling for amendments to the Convention of Biological Diversity to be made that govern access to human genetic material as well.

**6.1 What is a patent?**

A patent provides inventors, who have undertaken some form of research or experimentation, the means to make a financial gain from their invention for a set period of time (usually 20 years) thus preventing others from exploiting their invention unless prior consent is given.

The main objective of having a patent granted over a specific invention is to be able to recoup costs that were involved in creating and testing the invention as well as to make a profit through commercialisation. It is therefore assumed to be a justifiable system whereby innovation is encouraged and rewarded accordingly. Patenting rights are viewed as negative rights such that they restrict public access and control over a product in the form of preventing sales, use, distribution or manufacturing without approval of the patent holder.

While it is understood that a patent holder, should be allowed to recoup his costs from research and development initiatives and make a profit as well, the patent system must still balance the interest of the public and private sector, such that the benefits enjoyed by the patent holder should also filter down to society or more specifically a community for their contribution in developing a patentable product. However, the question that remains to be answered is whether, the benefits of the patent holder be equal to that which the community receives or should the benefits be skewed, if so, how skewed and in who’s favour?

For the patent holder, the benefits accrued are manifold, with specific interest on economic sustainability for companies. Holding a patent not only allows the patent holder to make
money but also provides an incentive and encourages investment in turning acquired knowledge through genetic resources into a form of marketable and helpful product.\textsuperscript{23} This investment further allows then for greater efforts to be made in the development of other products that could benefit a community or society as a whole.

From a genetic material ownership point of view, those who acquire patents due to genetic research involving population groups or communities have a duty to compensate those who have contributed to the research and development of that product by their population.\textsuperscript{52} This may be in the form of profit sharing, for example where the community may receive a certain percentage of all sales for that product; but this may take months or more realistically years before any remuneration back to the community can be seen. Thus a patent holder should also prior to obtaining a patent in this case, compensate the community involved.\textsuperscript{54}

These are short term benefits, made before a research study can begin and can include the research body improving the community’s healthcare facilities or educational resource contributions or even providing them with the means to increase their agricultural capacity. It is important to note that the benefit obtained from a research body/patent holder to a community need not be limited to only things related to healthcare as this may not always be the greatest concern for that community.

For something to be patentable there are criteria which must first be met. Section 25 (1) of the Patents Act\textsuperscript{72} states that: “A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture”. The Act further stipulates that “The duration of a patent shall, unless otherwise provided in this Act, be 20 years from the date of application …, subject to payment of the prescribed renewal fees by the patentee concerned or an agent” (S 46(1))\textsuperscript{72}. Once the patent has expired, the patent holder is required to disclose to the public
the invention in full so that the invention can be put into practice as well as the information used to increase the public knowledge-base and thus promote further research.\textsuperscript{70,71,72}

Therefore: “a patent is a grant of a property right to the inventor of an invention by the government acting through the Patent Office …. A patent, like any other form of property, can be sold, bought, rented or hired”.\textsuperscript{73(p87)} However, it is important to note that: “Patents are territorial rights and a South African patent will only give the holder rights within South Africa”.\textsuperscript{73(p87)}

6.2 Patenting of DNA in Biotechnology

The influx of companies applying for patents of genes or gene segments continues to increase. A report issued by the United Nations Development Programme states that industrialised countries hold 97\% of all patents globally. In addition, 80\% of the patents granted in developing countries are owned by multi-national companies that belong to the industrialised world. It is estimated that only 0.1\% of the patents filed by the United States Patent and Trademarks Office were by developing countries for a variety of patents, mainly in sub-Saharan Africa.\textsuperscript{74}

The risk then in patenting genetic material such as gene sequences is that the exclusive ownership of that sequence while relevant to the derived biomedical and genetic findings prevents downstream developments of medical treatments and therapeutics based on the patented data.\textsuperscript{74}

An example of this is the much cited case involving Myraid Genetics and its patenting and licensing of the \textit{BRCA1} and \textit{BRCA2} genes that have been found to be associated with breast and ovarian cancer in women. In countries, in which the Myraid Genetics patent holds, companies and research institutes not affiliated with Myraid could not, without prior
permission, perform research that could refine, improve and validate claimed genetic tests, nor could they identify new test and diagnostic approaches.75

However on the 13th June 2013 Justice Thomas made a United States Supreme Court ruling regarding the patenting of human genes based on the case against Myraid Genetics regarding the patents obtained for naturally occurring BRCA genes76. It was decided that it was the opinion of the court that “we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring”76. Based on this ruling the patent rights of BRCA1 and BRCA2 currently held by Myraid Genetics were lifted thus allowing other companies and research institutes where the patent was held to conduct biomedical research and diagnostic testing without infringing on patent laws. The court ruling was made by determining what constitutes being a “new invention” for biological material such as DNA, for which the conclusion of naturally occurring DNA is not eligible to be represented by such condition. However the eligibility of complementary DNA (cDNA) as a patentable invention was determined on the grounds that “cDNA cannot be isolated from nature, but instead must be created in the laboratory . . . because the introns that are found in the native gene are removed from the cDNA segment”.76

Before a patent can be claimed it is important to distinguish between an invention and a discovery, of which the latter cannot be patented. Finding a definition that separates these two is difficult but can be commonly distinguished by ‘what exists “in nature”, and what is the product of human labour, or at a minimum, human intervention’.75 In the field of biotechnology, this distinction becomes a lot more blurred as the content in which such work is done on is of “natural” existence. Hence there is much controversy over the patenting of DNA (genomes, genes, DNA sequences).
According to the United States Patents and Trademark Office (USPTO) “a patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature”. The European Biotechnology Directive 98/44/EC, article 5(2) states that, “an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention; even if the structure of that element is identical to that of the natural element”.

South Africa is silent with regard to patenting any form of human genetic material. South Africa has in place laws, regulations and guidelines such as the Biodiversity Act No. 10 of 2004 as well as the guidelines for South Africa’s Bioprospecting, Access and Benefit Sharing Regulatory Framework issue by the Department of Environmental Affairs. Within these laws, issues surrounding patenting of biological resources are mentioned but make explicit mention that these laws and guidelines exclude human genetic material. Nonetheless extrapolation of relevant information from such legal documents is still relevant in relation to human genetic material and thus could be used as a stepping stone in an effort to set into motion regulatory legislature for human genetic resources.

For instance, the Biodiversity Act defines indigenous biological resources as “any living or dead animal, plant or other organism of an indigenous species, any derivative of such animal, plant or other organism and any genetic material of such animal, plant or other organism”. Despite the exclusion of humans from this Act one does have the option to play with the interpretation of this definition. For example, if one considers evolution it is easy to assume that humans themselves are animals, given an elevated status based on our cognitive abilities to think and analyse before reacting to a situation, but in essence still animals. No greater evidence can be found in genetic studies which use various animal models as comparisons to humans in identifying homologous genes and deducing their possible function through such
association. For example the whole genome sequencing of the Fugu Puffer Fish has helped to identify close to 1000 human genes.\textsuperscript{79}

Another extrapolation can be taken from the terms ‘other indigenous species’. Firstly “other indigenous species” is not defined in the Act leaving room for interpretation. Thus if one chooses not to classify humans under the category of animals then it is by default assumed that the species should fall under ‘other’. Secondly, human genetic studies have continuously claimed that the indigenous people of southern Africa including South Africa, namely the Khoi-San\textsuperscript{14}, are our closest link to our most common ancestors\textsuperscript{12,14}.

6.3 South Africa’s Intellectual Property system - Patent Act No. 57 of 1978

In 2005, section 2 of the Patents Act No. 57 of 1978\textsuperscript{72} was amended to include certain definitions as well as stipulating the requirement for an applicant, for a patent, to furnish information relating to any role played by an indigenous biological or genetic resource or traditional knowledge. Those who wish to file an application to the Patents Office using indigenous knowledge, are obligated to disclose their source and thus work out an equitable and fair compensation to that relevant community.

However while this amendment is promulgated, the Act\textsuperscript{72} on its own is still active, as section 25(1) of the Act states that a patent is granted for any new invention, which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture. For human genetic material patents, the definition itself poses major challenges.

a) “Patent is granted for any new invention”

A specific gene sequence or partial thereof is not novel. Such sequence data has existed prior to its scientific investigation thus taking into account the Supreme Court ruling on Myraid
Genetics, DNA isolated in its natural form cannot be patented nor classified as a “new invention”.

b) “Which involves an inventive step”

This statement implies that something new was created or an inventive step arose out of a process. For genetic information such as targeted gene isolation and expression it is difficult to prove as such biological processes already occur in nature, whether it be ancestral or mutant. Additionally research, that finds evidence of a gene or other genomic data that is or could be linked to a specific disease or disorder, constitutes more an event of discovery rather than an invention. Furthermore, the scientific theory applied to such a discovery is also not eligible for patenting under the condition of an inventive step. This is justified by the need for scientific research to be continuously validated through reproducibility and proven robustness of a technique in order to either support or disprove a scientific theory.

c) “being used in trade or industry or agriculture”

Generally South African law exclude discoveries, scientific theories and any human or animal treatment method including surgery, therapy or diagnostics as patentable inventions. Such methods shall not be capable of being used or applied in trade, industry or agriculture if patented, but the law would grant a patent to a product consisting of a substance or composition being deemed to be capable of being used are applied in trade, industry or agriculture, even though it was invented for use in any such method. Hence section 25(1) of the Act does not define what a patent is not, but rather only provides clarification of what is cannot be.
The Patent Act overall leaves one with a feeling of having missed information relevant to genetic resources, but upon review it was found here to general lack of regulation for such material. However the amendment requiring disclosure of the use of indigenous knowledge is noteworthy as this provides for a means to ensure fair compensation to the relevant communities through various acts of benefit sharing.

6.4 Benefit sharing

Connected to the question of ownership and property and patenting lies the question of how those who contribute their genetic material to a study are compensated before collection, during the study and at the end of a study. This is known as benefit sharing.

Benefit sharing with regard to research involving genetic material is not adequately provided for in the NHA. While S83 of the Biodiversity Act No. 10 of 2004\(^ {80}\) does offer some form of guidance on benefit sharing contracts, by specifying the following conditions:

83. (1) A benefit-sharing agreement must-

(a) be in a prescribed format;

(b) specify-

(i) the type of indigenous biological resources to which the relevant bioprospecting relates;

(ii) the area or source from which the indigenous biological resources are to be collected or obtained;

(iii) the quantity of indigenous biological resources that is to be collected or obtained

(iv) any traditional uses of the indigenous biological resources by an indigenous community; and

(v) the present potential uses of the indigenous biological resources;
(c) name the parties to the benefit-sharing agreement;

(d) set out the manner in which and the extent to which the indigenous biological resources are to be utilised or exploited for purposes of such bioprospecting;

(e) set out the manner in which and the extent to which the stakeholder will share in any benefits that may arise from such bioprospecting;

(f) provide for a regular review of the agreement by the parties as the bioprospecting progresses; and

(g) comply with any other matters that may be prescribed.

However, the explicit mention that the Act does not include biological samples of human origin makes it difficult to use as a means of protective legislature within human genomic research. Hence there appears to be a regulatory vacuum within the context of genomic research in relation to ownership (sample and data) with regard to samples of human origin. This therefore leaves room for acts of bioprospecting and biopiracy to continue within the country without a proper means of repudiation.

6.5 Legal conclusion: Ownership and property

From a sovereignty point of view, without a clear definition with regard to human tissue, it becomes difficult to impose such a right over genetic material bearing in mind that all biological material obtained from a person is of potential genetic worth. Furthermore Mahomed et al mentions that “Although South African legislation seems to adequately deal with the issue of informed consent for the removal of human biological material from living and deceased persons for research purpose, informed consent relating to the participation in the research should be distinguished from specific consent relating to the future use of the human biological material. This is an issue that is often over-looked”.

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In a study Nienaber\textsuperscript{82} addresses the issue of consent and authorisation of human tissues after its primary use in research. Her findings lead to the conclusion that despite the existence of international Research Ethics documents and conventions governing the future use of human biological materials, “South Africa’s framework does not address informed consent for the future use of human biological material, unlike other African countries like Nigeria and Kenya” \textsuperscript{81(p17)}\textsuperscript{82} In relation to ownership and property rights this leaves little if any possible legal regulation for such samples if control over them is not determined at the beginning.

Thus if sovereignty is to be achieved then these issues need to be dealt with first beforehand. Future use of these samples outside the scope of the primary study must be included in the proposal for ethics clearance as well as being included as part of the informed consent processes. In this way, protection for people contributing to these studies is protected and future benefits from other studies utilising these sample sets can be secured.

Sovereignty essentially stands for being able to hold final decision making power in a system of government, thus by extension, genomic sovereignty would imply the same description with regard to genomic material. However for natural flora and fauna assigning sovereign rights is less complicated\textsuperscript{83} as opposed to genetic material of human origin which is often debatable between that of national governments and the people/communities of that area. The assumption made usually is that national government exclusively is the best option to protect the interests of its population groups within its borders.

To reiterate, according to South African law at present everyone has a right to their own body as a whole, pertaining to freedom of the persons\textsuperscript{58}; once biological material has been separated from its source, authority over that material becomes ambiguous especially with regard to ethnic indigenous groups. These communities are representative of people whom have chosen not to be associated with the current, modern and primarily western running’s of
the world today. From a genetics point of view, this makes them a valued ‘asset’ as they are viewed as valuable genetic resources that have been untainted by today’s physical and environmental stresses of life. Therefore when such a population group displays a certain disease or characteristic that could benefit all of humanity through research purposes, they become prime genetic material resource targets.

These indigenous peoples, owing to their choice not to conform to modern society, in turn place themselves at risk of submitting to having these genetic tests done without a clear scale of the potential impact it may have on such a community, both positively in the form of benefits and negatively through studies that may contradict traditional and cultural belief systems of those communities. Researchers may play on this vulnerability, reducing the study to a notion in which the community is viewed as objects of curiosity rather than forming a relationship with the research participants. Evidence of such things happening to indigenous populations is illustrated by the controversial genomic research that was conducted on the Havasupai Indians by the University of Arizona.

Ethnicity stands ill-defined. Such that it is defined as ‘relating to a population subgroup (within a larger or dominant natural or cultural group) with a common national or cultural tradition, further relating to ‘national and cultural origins’ is defining for example a population based on linguistics or by ‘denoting origin by birth or descent rather than by present nationality. To add to this, there is the issue of self-identification and the creation of new groups that emerge due to changing socio-economic developments. For example, an Indian person born in South Africa has various ways to identify himself. He could be considered an African, been born on this continent or Indian South African on a national scale or even South African
of Indian descent. Each of these are functionally acceptable to the individual but can cause greater misinterpretation of genetic data due to self-classification and ethnicity.

Another challenge that faces the concept of genomic sovereignty is that of ethnicity across boundaries. For example, on a ‘local’ scale the San people of Southern Africa are a population spread over three boundaries, namely, South Africa, Namibia and Botswana\textsuperscript{47}. On an international scale there are those individuals having ancestry linked to the African continent that were taken across to the United States of America and Europe during the years of colonialism and slavery. In these cases sovereignty over genomic material seems difficult to attain, such that access to individuals of a specific group can always be found in another country with less restriction and regulation. It therefore seems that if the concept of genomic sovereignty is to be promulgated into any type of protective law then such law needs to be agreed upon by all countries in order to protect those populations groups. Without such collaboration genomic sovereignty as a law in a specific nation seems fruitless against any measure of bioprospecting.\textsuperscript{46,47}

Thus if one looks at the regulations associated to the NHA with regard to this issue, it appears that current regulations and legislature paint a picture that denotes an ideal that relates more to the Common Heritage Concept. Evidence within the regulations mentioned above attempt to provide protection of population groups, whilst their genetic material is still freely available to leave South Africa with little or no benefit to them\textsuperscript{31}. Thus leaves room for speculation that researchers of the developed world may choose to do research in a less developed country to obtain samples that have better use in a greater research study on the developed side of the world. While this may seem a bit over imaginative, the possibility in hindsight for such events occurring from all research done in less developed countries does exist if one considers Nienabers’ report\textsuperscript{82} with regard to future use of human biological material.
Blurring the lines: The common-sovereignty compromise approach

Common heritage describes that genetic material like other common resources should always be shared, that it is excluded from privatisation and sovereignty, thus being made available for scientific research initiatives. But these genetic materials such as genetically modified organisms and human genetic material are being sifted through and absorbed into privately owned entities and/or sovereign nation states. The justification for these occurrences is attributed to biodiversity conservation. This is apparent in the International Convention on Biodiversity, which provides more for a nation state to apply sovereign rights over their natural resources. Thus the question then is, for samples of human genetic material, how can these concepts of common heritage and genomic sovereignty together with the ideals of intellectual property, namely patenting work in a collaborative and mutually beneficial way?

The first approach is to down scale the level at which common heritage is applied so that it can fit in with that of genomic sovereignty ideals. The way this can be achieved is to look more locally with regard to heritage. It is understandable that we are all human beings of the same earth living on different pieces of land separated by mountains, valleys, deserts, rivers and seas and it is to that degree of separation that populations localise their culture and traditional identities and knowledge systems. Therefore to each of these communities there is a shared heritage amongst themselves irrespective of their existence to the global community that they also belong to. Therefore genomic sovereignty can be employed to protect the local and indigenous heritage of a people within a land.

The second approach aims to look at the way human genetic material is regarded within both concepts. Both the common heritage concept and genomic sovereignty provide clear understanding that when dealing with human genetic material, such material removed from
the human body still maintains intrinsic worth. Thus if such material is capable of commodification that can be accessed by all, either through the common heritage concept ideals of universal sharing or through genomic sovereignty legislation granting access, then such a commodity can no longer be regarded as heritable but rather as a resource for common use.

It is interesting to note that even as a ‘common resource’ the guidelines of genomic sovereignty in its ability to control access to the human genetic material of that nation consequently provides a level of protection to such resources deemed common heritage under the assumption of the first approach, localising common heritage.

Based on the two approaches mentioned above it is noticeable that although the common heritage concept and genomic sovereignty are generally said to have opposing views with regard to human genetic material, there are levels of commonality that could allow them to work together. Hence the common-sovereignty compromise approach aims to utilise these levels of commonality in efforts to provide a global service (common) with regard to genomic research as well as national security (sovereign) by protecting its people from exploitation though bio-prospecting and bio-piracy thereby ensuring justifiable research agendas and benefits be negotiated.

The common-sovereignty compromise approach objectives are firstly to provide for ownership of human genetic material to reside at all times with the people from whom such samples are collected from a defined land, such as, a village or local town. This allows for better control over the type of research that can be undertaken with the population specific identifiable materials and data. Secondly, I propose that the responsibility for controlling access to and use of samples and data be devolved to the research institutions in the collection thereof, in a stewardship or custodian model. This fits in nicely with the research guidelines.
that allow a person, in this case their genetic material, to withdraw from a study without prejudice.\textsuperscript{6} Thus research, based on the agreement between the research body and the population involved, may either require the materials be destroyed or returned to the population group depending on cultural belief systems.

It should be noted that the common-sovereignty compromise approach is only valid for genetic material and data that contains identifiable data and information linking it to a nation state or specific population group. Should the research body indicate that the samples and data gathered will be anonymous, ownership rights to those samples by the population asked to provide it are no longer valid. This type of approach is valid for studies that employ a ‘double blind’ approach to their study, whereby the research body may have a disease or disorder in question which they would like investigate further but enter the study with a blind approach as to what may be the cause other than the idea of a few candidate genes. Then random sampling of populations to further investigate those genes is possible provided it remains anonymous. This is equivalent to studies involving ‘demic’ populations\textsuperscript{19} as explained in the group ownership and genomic sovereignty section above.

The common-sovereignty compromise approach overall provides for the possibility of ownership to be interpreted in more than one way, as opposed to the common heritage concept that can be regarded as too broad or genomic sovereignty that can be associated as sometimes being too restrictive. The common-sovereignty compromise approach provides the option of flexibility and therefore leaves room for compromise with regard to ownership of human genetic material.

Therefore the common-sovereignty compromise approach provides for 3 levels of ownership possibilities, that is, 1) exclusive ownership of human genetic material by a people within a nation state, 2) shared ownership between a people and research body in which researchers
are limited to certain ownership rights regulated by the terms of used agreed upon by a people or nation and 3) complete ownership of human genetic material by researchers provided all demographic information linking it to a specific population is erased and/or destroyed.

Furthermore the common-sovereignty compromise approach aims to incorporate a collective property approach with regard to deciding how a peoples resources in a nation, state should be used, as opposed to common property, which within a given area is state determined and controlled.

For a group of people to have collective ownership over their genetic heritage, one must consider the reasoning behind conducting a focused study on a specific population. The issue of collective heritage brings to light the definition of genomic sovereignty. For example the Canadian Institute for Health Research (CIHR)52 issued guidelines for health research involving aboriginal peoples. The guideline recommends co-ownership of both sample and data generated between the aboriginal people of that area and the researchers involved. These guidelines advocate that samples contributed to a study should be considered ‘on loan’ to the researcher unless otherwise specified in the research agreement, invoking a state of stewardship over those samples by the researchers involved. These guidelines also provide for a special protection for indigenous peoples cultural and sacred knowledge. This knowledge type although not explicitly mentioned can be used to infer the notion of collective ownership over genomic samples and data.

Following from these guidelines, the common-sovereignty compromise approach ensures that although a nation, state will protect its people from bioprospecting and bio-piracy that nation governance cannot coerce its people to participate in any form of study including genetic research if they choose not to. In this way the people’s autonomy and respect for persons is maintained and prevents a government from taking a more autocratic approach whilst making

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the assumption that such research is something that the people of that nation are willing to agree to without proper consultation, as this can been seen as a violation of rights based ethics – right to privacy.

Furthermore indigenous populations are fairly homogenous in their genetic makeup as well as small in number. This places them as a vulnerable group subject to certain group harms. Specifically with regard to the issue of ‘patented DNA’. The act of patency can lead to the exploitation of a peoples genetic heritage thus highlighting the issue of non-maleficence by invoking a social harm to these people by simply removing or disregarding their humanity in terms of who they are as a community as well as what makes them so culturally distinct. This could render them or part of them (genetic material) as a mere commodity item that can be used for commercial gain or other research without benefit to that population.

The statement above pertains to the risks involved in patenting DNA at a population or group level. Although this is of significant value and must be addressed accordingly, there is another side for which patency poses a problem. This is at the institutional level, where research on genes can be stifled due to companies in that area holding patent rights over that gene. Thus the third approach is to provide genomic information on an open source network.

In this way the distribution of human genetic material is shared equally by all of those who wish to make use of it. For example, the SNP Consortium, which is a project dedicated to elucidating and providing the global scientific community with information of DNA sequence variation within genomes and in providing this information freely entered into an agreement not to patent their sequence maps.\(^87\) Another example of open source information sharing is Alfred Gillman’s ‘Cellular Signalling’ project.\(^88\)

What makes both these projects noteworthy is that they are both open source information centres that are supported institutionally and financially by major institutions in genomics,
such as the National Institute of Health (NIH) as well as large corporations in biotechnology, such as, Eli Lilly, Merck, Aventis, Johnson & Johnson and Novartis. The Cellular Signalling initiative is further supported by international scientific journal Nature. Interestingly, the biotech firms associated with these initiatives allow for copyleft policy, that is, allow access to the information generated by these two projects, freely. The objective of the copyleft approach demonstrates the notion of altruism by providing genomic data with no actual return to the project except for the desire that other researchers like themselves follow through with this act of altruism and share their genomic data with everyone as well, invoking a state of commons. Gillman’s cellular signalling project goes even further with regard to open source by not only providing information but also modelling quantitative virtual cells by interactive peer reviews of genetic information outside journals or patents.

Thus it becomes fairly noticeable that contributors, specifically those of the biotech industry aren’t completely interested in just acquiring financial dividends or patents rights over sequence variations. It is more likely that economic gain for these stakeholders are to be acquired through alternative means, such as, patents of products derived from sequence variation data as well as marketing and sales of those products.

Providing genomic information in an open source network thus provides a means to share genomic information with fellow researchers while still allowing acts of patency to continue on products derived from its information but not on the genomic data itself. Furthermore, in the age of technological advancement, providing genomic information through electronic means ensures that the actual samples remain locally retained, respecting a community’s right not to have their DNA samples exported without consent. This approach also provides a means to anonymise the data being released, further protecting both a community and person. Lastly, should information about the data be requested that is of an identifiable nature, its release can be locally controlled at the institutional level but determined at the community
and individual level. Therefore the dissemination of information and what type of information can and cannot be released provides a method of maintaining the control of their genomic information. Communities are therefore able to actively determine the access and benefit sharing agreements between researcher and nation-community.

With regard to benefits, between the concept of common heritage, genomic sovereignty and the common-sovereignty compromise approach, the distribution of knowledge is regarded as a global benefit that should be universally distributed. However other benefits should be evaluated based in the contribution to research and the level of necessity to that nation. For example, a developed nation may choose financial rewards for their contribution to research, whereas those of the developing world may opt for technology transfers, access to other resources or aid in development of healthcare and education infrastructure in that state.

It is important to note that this ‘end point’ benefit option is aimed at a national level for which the nation receiving such benefits is to be held responsible for its distribution and use locally. The research group when working with a population must prior to beginning the study define the type and level of benefits that a population will receive before, during and after a study as stipulated within bioethical guidelines.
8. Conclusion

Ownership with regard to human genetic material provides for discourse that is both complex and fairly unsettled. For the last three decades or so there has been a shift in thinking towards resources considered common heritage to humanity to it becoming an item of appropriation and commodification that is subject to intellectual property rights and national sovereignty. This shift has led to efforts to protect against exploitation of peoples for their genetic resources but has also lead to unequal sharing and access to these resources such as genomic material, information and biotechnology. Ownership further highlights the disparities between developed and developing countries as well as those between national governments and its people, more specifically its indigenous people, with regard to access to these genomic samples and information, levels of intended use and benefit agreements.

To argue one concept over another seems fruitless when the end result for the common heritage concept and genomic sovereignty are the same. These are to conduct good research in human genetics whilst still providing a common good to the people involved and overall create a benefit to all mankind. Thus a blended approach of these two concepts would appear of greater use by using the commonalities of both concepts to work through their differences.

Moreover the question of ownership of genetic material undoubtedly raises the need for re-evaluation of how the concept of property is understood, interpreted and defined with regard to human genetic material. This in turn should provide a link between open source data and biotechnology as well as genomics as a whole with humanitarian objectives. Therefore the potential to re-negotiate and re-design biotechnology with regard to human genetic material and information does exist through a means of an open source approach.
The common-sovereignty compromise approach presented in this research aims to provide a foundation that exemplifies an ‘access to all’ understanding, whereby one cannot claim exclusive ownership, but also prevents others from claiming the same and to ensure that should revenue be made off these genetic material, that there is a framework for distribution of those resources. It must however be noted that the common-sovereignty compromise approach is merely a concept upon which myself and others may use to build upon so as to further investigate and draw our own conclusions towards the issues of ownership of human genetic material. Thus further investigation into this approach is necessary in efforts to further develop it, something that could not be done due the size limitation of this research report.

Therefore this normative analysis of the concept of ownership is important as various ethical guidelines and legal regulations need to be further developed and entered into socio-economic and political discourse with greater vigour, so as to provide a sound framework from which to address issues associated with genomic research- such as ownership, access and benefit sharing, as they arise in the practical aspects of genomic research, in regard to sample collection, data generated and commercialisation.

It is without dispute that for any genetic research to be done or development of some therapeutic measure to be implemented, sample donation of biological/bodily or DNA samples are imperative. However, in knowing this, the ethical questions involved in such research initiatives still need to be addressed in greater depth. The views, statements and recommendations made in this research report are an attempt to highlight the surrounding concerns mentioned above as an essential aspect of research to ensure that scientific integrity be maintained and that human intrinsic value and worth be respected at all times. If these two aspects can be made to work together in a mutually beneficial state, it may then make genetic research initiatives appear less inimical to individuals. Once the shroud of the unknown is
made clear it is with hope that participants will feel safe, comfortable and secure and thereby more willing to participate in such research.
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Appendix I

University of the Witwatersrand, Johannesburg

Ref: W-CJ-130909-2
09/09/2013

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from
the Human Research Ethics Committee (Medical).

Investigator: Mr K Mahesh (student no 329505).

Project title: Genomic sovereignty in South Africa; ethico-legal issues.

Reason: This is a analysis of information in the public domain. There are no
human participants.

Professor Peter Cleaton-Jones
Chair: Human Research Ethics Committee (Medical)

copy: Anisa Keshav, Zanele Ndlovu, Wits Research Office