2020

Genomic Justice: The Distribution of Human Flourishing

Robert Flores
Claremont Graduate University

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Approval of the Dissertation Committee

This dissertation has been duly read, reviewed, and critiqued by the Committee listed below, which hereby approves the manuscript of Robert Flores as fulfilling the scope and quality requirements for meriting the degree of Doctor of Philosophy in Philosophy.

Darrell Moore, Chair

Claremont Graduate University

Associate Professor of Cultural Studies

Patricia Easton
Claremont Graduate University
Professor of Philosophy
Executive Vice President and Provost

Shelley L. Hurt
Cal Poly, San Luis Obispo
Associate Professor of Political Science

Abstract

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Genes are functional cell segments of DNA within an organism, as well as basic physical units of biological inheritance, which have consequences for human dignity and public interest. Genes and genetic material (DNA strands of nucleotides, genetically altered plants and animals e.g., see Appendix B) are patentable. In the US and around the globe, governments grant genetic patents for new, non-obvious, and useful gene inventions. A wide range of interest groups such as religious leaders, scientists, biotech pharmaceuticals, medical practitioners, health care providers, venture capitalists, medical patients and persons have interests in defining what is subject to patents. Yet, it is at least questionable that genetic inventions, and the ownership of discoveries of gene mutations leading to possible diseases, should be subject to influence by interest groups. Although some genes (cDNA) are currently legally patentable, the question in this examination is whether gene patents should be legally and morally justified.

In this work I examine whether gene patents should legally and morally be justified, given the principles of biomedical ethics such as human Beneficence /Autonomy and Justice. I argue that gene patenting is not justifiable, and I consider what can be done to create a system that delivers access to genetic information in the current genetic Intellectual Patent system.

This interdisciplinary work is more complex than whether bio-science researchers and corporate entities should hold gene patents, or differentiating the legal question of whether genes are an invention or a discovery in the human genome. Mere responses to these questions would not ultimately solve the genetic justice problem. The justification for genetic appropriation is more complexity, since it is grounded in axiological claims about human dignity and public interest set in an ever changing biomedical/biogenetic technology. To address this complexity, I will draw upon the ideas of "the capability approach" to genetic justice found in the work of Nussbaum and Sen.

This work is an interdisciplinary examination of the proper appropriation of natural genetic material and its impact on human dignity. It is argued that genetic material and information should be accessible to all, via heath care, for example. We must look to new ways to achieve genetic justice that promote human flourishing as a public good.

Dedication

I want to acknowledge my indebtedness to my wife Teri Chesterman for her patients, grace, and support throughout the completion of this work.

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1.0 Introduction

Genes are in fact patentable in the United States. Should genes—cell segments of DNA and basic physical units of biological inheritance—be patented? Should disease genes and or the information encoded in genes be patentable? Ultimately, is the patenting of genetic information and material justified? This question is essential to all life, not just a human concern, since genes function as basic physical cell segments in human DNA and all biological inheritance of life. The effects of genetic information and material are far-reaching. The use of genetic information affects the future of humanity as it is used to genetically engineer and create future generations. However, the use and ownership of genetic information and material must address human dignity when considering whether we are to commodify access of genetic enhancements or distribute genetic information in an equitable manner (genetic justice). That is to say, genetic justice questions whether the commodification of human DNA makes humanity subject to ready exchange like grain and corn or exploitation within a market.

Moreover, genetic information and material can be used by patent holders to genetically altered plants, animals, and synthesis human proteins, for example. Genetic patent holders determine the future of genetic search and all that genetic information effects. Gene patent issues cover a wide range of groups such as: scientists, researchers, medical practitioners, health care providers, venture capitalists, religious views, political public policy, patients and persons. Some particular concerns focus on the basic patent criteria differentiating genetic inventions from none-patentable discoveries. In the US and around the globe governments grant genetic patents for new, non-obvious and useful gene inventions. Some human health concerns address gene mutations leading to possible diseases (see Appendix C, D and E).

Given the immense influence of genetic information, are gene patents morally justified? In this work I argue that, since genetic patents cannot be justified, genetic information and material ought not to be patented. I argue gene patents cannot be morally justified, given the principles of biomedical ethics, justice and the inconsistency of the Supreme Court's decision on genetic patents.

In examining the justifications for the appropriation genetic material, I look at distributive justice, biomedical/biotech genetic material and information, and moral ramifications as genetic justice. I consider the justifications for the genetic appropriation in connection with social access to genetic material/information and what might be new ways to develop genetic justice. Moreover, in light of the US Supreme Court's determination to patent genetic information, unlike the US

Supreme Court, and to enable genetic equity I propose a Nussbaum and Sen[1] capabilities form of genetic justice which entails human dignity.

Method

This work can be seen as a transcendental argument *simpliciter*. My transcendental argument *simpliciter* goes as follows: we start with a proposition we take to be true or known to be true in some sense or some range of application. Next we determine the conditions that must be fulfilled for our proposition to be possible. The proposition we take to be true is that human flourishing or wellbeing is a desired public good as identified by Locke. We next consider the conditions that must be fulfilled for human flourishing to be possible, which are the moral principles of beneficence, autonomy and justice; we find that in order to achieve human flourishing we must adopt the "Capability Approach" to genetic justice which has been championed by Martha Nussbaum and Amartya Sen.[2] Additionally, this work is interdisciplinary in that we will be exploring genetic justice not only with regard to moral issues, but in light of legal and scientific considerations. The shadow of philosophical ethics looms large in biomedical research and gene patents. To this end, I look to Locke[3], Hume[4], and others for their historical moral contribution to patenting genetic material. However, it is an assumption of this work that when

[1] Martha C. Nussbaum, *Sex and social justice*. Oxford University Press, 1999.
[2] Martha C. Nussbaum, *Sex and social justice*. Oxford University Press, 1999.
[3] John Locke: *Two treatises of government student edition*. Cambridge University Press, 1988
[4] David Hume, *Enquiries Concerning Human Understanding and Concerning the Principles of Morals* (1777), 2nd. ed., ed. L.A. Selby-Bigge, rev. P.H. Nidditch. (Oxford: Clarendon Press, 1975).

addressing biomedical issues, one must additionally have legal and genetic knowledge (see appendices on genetic topics).

The nature of this interdisciplinary work aims to give a holistic view regarding the question whether the patenting of genetic information and material is justified. This requires that one be generally acquainted with the history of property rights, patent law and biomedical research as well as biomedical ethics. Although economics, property rights, patent law, biomedical research and biomedical ethics may seem to all be independent issues, they are in fact the creators of the edifice that sets freedoms and limits on human dignity and flourishing.

This interdisciplinary work is asking questions more complex than whether bio-science researchers and corporate entities should hold gene patents, or legal issues such as differentiating genes as an invention as opposed to discovery in the human genome. Mere responses to these questions would not ultimately solve the genetic justice problem. The justification for genetic appropriation is more complex, since it is grounded in axiological claims about human dignity and public interest which are set in a context of ever changing biomedical/biogenetic technologies. To address this complexity, we will draw upon the capability notion found in Nussbaum and Sen, regarding our notion of genetic justice [5].

These chapters unfold as an interdisciplinary ancestry in support of the appropriation of natural genetic material and its impact on human dignity. To assist the reader in acquiring this interdisciplinary view, in Chapter Two, we look to Locke for the beginnings of property rights to set the foundation of human flourishing or wellbeing as a public good. To acquaint the reader with legal issues we examine

[5] Martha C. Nussbaum. *Sex and social justice*.

patent law in Chapter Three, and in Chapter Four we provide a general review of arguments for and against gene patents. In Chapter Five we look to the moral dimensions of gene patenting and what follows regarding the legal patent system. In Chapter Six we examine theories of justice and their justification for the appropriation of genetic material. The final chapter, Chapter Seven looks to current and future problems that may result from the court's decision to patent genetic material with an eye to possible ways to reconcile these problems. All of these chapters will be fleshed out in more detail at the end of this chapter.

In general, when we talk about genes we are referring to a unit of DNA. DNA consists of four chemical bases called nucleotides: adenine (A), thymine (T), guanine (G), and cytosine (C). Genes are the carriers of instruction for the production of specific proteins and heredity (see Appendix A). Although genes are contained in the chromosomes of each cell and produce proteins some do not code for protein, but are quite important, since they function to control genetic activity. The genes or DNA that we (will use interchangeably) are concerned with refer in part to the genes in the human genome. This distinction is important because many genes found in the human genome are shared with non-human organisms. A genome is an organism's complete DNA content. That is, the term genome applies to the complete (DNA) set of genes, information and content of a species. A genome contains all the genetic instructions needed to build an organism, to sustain grow, and ensure its future development (see Appendix B).

In order to grasp the importance and basic understanding of the relationship between a gene mutation and a possible cancer gene phenotype, we can look to the connection between gene protein production and cancer. BRAC1 and BRCA2 gene

mutations will give us some understanding of disease genes and their connection to protein production. For example, we can look to gene protein production and their connection to “breast cancer 2 onset” BRAC2 and BRCA1 (BRCA 1/2) genes.

We all have BRCA 1/2 genes. BRCA genes contain the instructions for the production of a tumor suppressing protein. The protein produced by BRCA1 and BRCA2 genes assists in preventing abnormal cell growth and division. Normal BRCA genes repair and help control normal breast growth. However, when BRCA 1/2 genes become abnormal or develop mutations the risk for breast cancer, ovarian cancer, and other cancers increases. BRCA gene mutation undermines the stability of the genetic information needed for proper cell growth. Identifying gene protein mutations and their monopolies is at the center of the gene patent debate.

Due to the successful development of genetic information, such as, BRCA1 and BRCA 2, the financial value of new gene therapeutics, and gene mutation diagnostics, some say that gene patents and gene commercialization is justified. Others argue that methods used to isolate genes or DNA do not constitute a patentable invention and should not be commercialized.

As early as 1997, Merz, Cho, Robertson, and Leonard[6], opposed disease gene patents (see chapter 4). Some disease genes, for example, are genetic mutations and can increase the possibility of Alzheimer’s or cancer. Merz et al. argued that identifying a disease gene is merely observing a gene segment and its association with a phenotype expression. Identifying disease genes, their instructions for building proteins that control the structure and function of cell growth, is not an

6 Jon Merz F., Mildred K. Cho, Madeline J. Robertson, and Debra GB Leonard. "Disease gene patenting is a bad innovation." *Molecular Diagnosis* 2, no. 4 (1997): 299-304.

invention and hence not patentable. As we will see later, the job of the U.S. Patent and Trademark Office is to patent novel and useful inventions—not to patent natural phenomena.

Against Merz, McGee[7] argues that in the act of determining the order of a DNA segment and identifying the gene sequence relationship as a gene, one creates a useful invention. The useful invention is diagnosing the correlation between a gene sequence and a phenotype, hence predicting the susceptibility of a possible future disease. This gene susceptibility correlation can have a specific purpose, say, to be developed as a commercial diagnostic test for future disease states. McGee calls this invention a patentable diagnostic utility in that it may identify a gene susceptibility correlation to cancer, for example. According to McGee, based on this hitherto unknown correlation between a particular sequence of a gene and cancer susceptibility, gene sequencing is more than merely observing a gene segment. For McGee, one has discovered a gene association with a phenotype expression, thus creating a patentable invention.

The acceptance of gene identification as an invention, diagnostic process or product of utility, by the United States Patent and Trademark Office (USPTO), led to the proliferation of gene (DNA) patents of all kinds. Some patents were for disease genes but others were just gene segments based on possible future genetic use. From 1980 to 2003, approximately 16,000 DNA sequence patents were granted

7 Glenn McGee. "Gene patents can be ethical." *Cambridge Quarterly of Healthcare Ethics* 7, no. 4 (1998): 417-421.

worldwide. Almost ten times more patents were granted by the USPTO compared to either the European or Japanese patent offices[8] .

Proponents for a liberal patenting system argue that genomic patents are necessary to fulfill the US Constitution mandate "To promote the progress of science and useful arts..." and serve the public interest.[9] Critics counter that gene patents violate human dignity and U.S. patent law does not allow the patenting of naturally occurring products. These naturally occurring products include: "laws of nature, natural phenomena, and naturally occurring animals, plants, and chemical compounds"[10]. Genetic patent proponents argue that it is up to the courts to determine a natural or non-natural phenomenon. Furthermore, the USPTO should only be concerned with legal issues not moral issues, as stated in Constitution, since patenting is governed by Congress (in the US) and case law via the judiciary. Given this view, gene patents as such are intended to promote the progress of science and useful arts, hence, gene patenting is not a moral issue. The USPTO's patent decisions show that they exclude moral issues and the patenting of product of nature. The USPTO's patent decisions, also support inventiveness and the commodification of human DNA.

On the other hand, Caplan argues that there is more to the commodification of human DNA than naturally occurring product vs. artificial inventiveness, "that keeping the human body and its parts off limits to the...market is an important way

[8] Subhashini Chandrasekharan, and Robert Cook-Deegan. "Gene patents and personalized medicine-what lies ahead?" *Genome medicine* 1, no. 9 (2009): 92.
[9] U.S. CONST art. I, § 8, cl. 8.
[10] David B. Resnik. *Owning the Genome: A moral analysis of DNA patenting*. (SUNY Press, 2004), 39, 84.

to make a moral statement about who we are."[11] The biotech industry, in contrast to gene commodification opponents, see DNA sequencing as a patentable invention. As is well known, the stakes are high (in the billions) for the biotech industry. Likewise, the public moral interest, gene (DNA) autonomy, and genetic ownership is immense.

Merz, McGee and Caplan are all correct in that genetic patent appropriation is more than issues of discovery or commodification; and that is what this work aims to make clear. Although the USPTO grants gene patents, based on legal precedence, gene (DNA) ownership cannot be isolated from moral concerns. Doing so leads to the disfranchisement of persons from their natural biological essence. Incorporating moral and legal values with gene patents do not render patent law non-judicial. Although there may be cases in which moral and legal issues are said not to influence each other, moral considerations are unavoidable. For example, genetic patents will determine person's access to genetic information and genetic enhancement—the use of genetics to improve humanity.

Locke

In Chapter Two, via Locke, I first look to the beginnings of property rights. Here I show Locke's property rights foreshadow the United States Patent and Trademark Office (USPTO) requirements for patents, e.g., Utility as useful for human flourishing. Although Locke is not known for his moral theory, Lockean property rights are built on the moral principle of human flourishing which I liken to the

[11] Arthur L. Caplan. "What's so special about the human genome?". *Cambridge Quarterly of Healthcare Ethics* 7, no. 4 (1998). 424.

public good. Rights of appropriation are given to man, over natural object, by God for the best advantage of life and convenience. I argue that gene appropriation cannot be justified based on Lockean property right, as first allowed by the USPTO. Early patents on genetic material were given without a description of genetic function or use[12]. The patenting of genetic material without a function or use disclosure violates a Lockean proviso. To appropriate natural objects one must add some labor that contributes to human flourishing. The appropriation of genetic material that does not disclose function, use and support open access to ensure the proviso that others are not worse off does not add to human flourishing. One reason we begin with Lock is not just based on his arguments on property appropriation; but, that the Lockean notions of human flourishing or convenience of life will be a recurring theme as expressed by topics such as Rawls' rational plan of life[13] and Nussbaum's Bodily Health[14].

United States Patent and Trademark Office (USPTO)

As a legal entity, the USPTO only grants inventors patent rights to prohibit others from commercializing their invention by way of production or use for twenty years. The USPTO legal authority is derived from the Constitution: "To promote the progress of science and useful arts..." (U.S. CONST art. I, § 8, cl. 8). To this end the USPTO has its patent criteria. In order to have an informed understanding of

[12] Mark A. Rothstein,ed. *Pharmacogenomics: Social, ethical, and clinical dimensions*. John Wiley & Sons, 2003.
[13] John Rawls. *A theory of justice.*
[16] Martha C. Nussbaum, *Sex and social justice*. Oxford University Press, 1999. Nussbaum addresses the human characteristics that are so central that they seem definitive of a life that is truly human. Number 2 on the list is: Bodily health**.** Being able to have good health, including reproductive health; being adequately nourished…; being able to have adequate shelter.

the gene patenting debate, it is important to have a general understanding of patent laws and what is not patentable is considered.

In Chapter Three, I present the general guideline for patenting. But as I argue, there is more to DNA patenting than legal issues. These additional issues are presented as the purpose of patents, as influenced, I argue, by Locke. The argument in essence is that Lockean human flourishing is consistent with the Constitutional mandate that patents must promote the progress of science and useful arts. Next I present and discuss the legal guidelines for gene patenting, namely, patentable genes must be novel, non-obvious and have utility (a useful composition of matter). Chapter three ends with a discussion on the principle of nature as it applies to patents. The principle of nature states that things discovered in the world may not be patented.

Arguments For and Against Gene Patents

Chapter 4 reviews standard genetic patent and court arguments for and against gene patents. A distinction between discovery vs invention is presented by differentiating a patentable "invention" from a non-patentable "discovery" of nature. I do this via McGee's[15] 1998 position that the detection of disease genes is a patentable invention; and the opposition to McGee by Merz[16] that the discovery of disease genes is no more than a non-patentable observation of natural phenomena.

We do additional groundwork addressing some justification topics regarding early court decisions allowing gene patents and the original intent of the human

[15] Glenn McGee. "Gene patents can be ethical." *Cambridge Quarterly of Healthcare Ethics* 7, no. 4 (1998): 417-421.
[16] Merz, "Disease."

genome project. Moreover, in examining the early intended value placed on the human genome project, we gain some understanding of the moral or social arguments supporting and challenging human gene patenting. Standard gene patent arguments are large in scope. Gene patenting proponents appealing to the USPTO mandate stating patents are given for the advancement of scientific knowledge and economic growth. Gene patenting opponents express their concern for personal medical privacy abuse arguing that gene patents do not necessarily support scientific knowledge and economic growth. In reviewing supporting arguments for and against gene appropriation we gain an understanding of the complexity of gene patent issues.

More to the point, we find the perils of arguing or taking a stand on genetic patents in a technology in flux. Both gene patent proponents and opponent use many of the same arguments to support their view. Gene patent proponents use the growth of scientific knowledge to support their views. Gene patent opponents argue gene patents stifle scientific knowledge and growth. This argument makes it clear that we need to look to new ways to support scientific knowledge and genetic access. We explore this issue in chapter 6 on justice and chapter 7.

Moral genetic patenting issues run from patent support via the promotion of scientific and technological development by way of economic growth, to the prevention of ill health and genetic enhancement access; however, the courts try to avoid moral issues. The courts only consider the legal issue whether DNA is a patentable "invention" or a non-patentable "discovery" of nature. Although moral concerns have been a bone of contention for legal and non-legal groups, the courts do not address moral concerns as seen in the US Supreme Court's 2013 decision.

The US Supreme Court allowed only the patenting of cDNA (complementary DNA)—cDNA is patentable because the Court considered it man manipulated DNA. The Court's only issues was whether DNA is a natural or non-natural phenomenon. The US Supreme Court concluded that natural DNA was not patentable (we challenge the Court's decision in the final chapter). Since gene patents affect the wellbeing of persons, we next take into account the moral issues relating to gene appropriation.

Moral Grounds

In Chapter Five I take up the moral dimension of gene patenting and what follows regarding the legal patent system. I accept a one system picture of law. This requires that both legal and moral principles be taken into account. The failure of the legal system to consider moral principles leads to the loss of personal Autonomy for persons. A system of pure axiology with no concern for the legal system can lead to the lack of moral action on the part of the patent system. An amoral patent system lacking moral consideration leads to a legal system unconcerned for personal self-governance and self-determination. Both moral and legal principles are needed when considering gene patenting policy.

When one ignores moral principles and is only considered with a pure application of case law for the promotion of technology and commodification, one violates the moral biomedical principle of "human dignity." When moral concern for persons is excluded and gene parenting is profit driven patents enable violations of human dignity or lack of concern for the respect of persons. This violation entails "Autonomy," self-governance, and justice: the self-determination for person's

present and future wellbeing. My argument turns on the warrant that patent law void of axiology issues hinders world public health and wellbeing.

Although the current patent system plays a role in promoting biomedical progress, "useful arts" and contributes to the public interest, it is also essential to address its lack of moral public interest. Hence, moral principles and biomedical research, via patent law, must promote each other. I examine and apply patient autonomy principles to the question: can gene patenting be justified on the principle of autonomy? For example, I present and apply paternalism to gene patents to show that patent holders unlike physicians do not have the expertise to decide who and which research projects should have access to their patents. The application of autonomy to gene patents shows that patent holders should abide by accepted recommendations given by medical groups. Patent holders should comply with the principle of autonomy; noncompliance leads to adverse consequences.

In this chapter we consider a number of biomedical moral principles, such as, the moral principle of Autonomy and Beneficence and who decides the direction of biomedical research. How does the current patent system hold up with regard to a person's freedom to control genetic information?

We examine the question of Beneficence, that is, what compels us to respect moral principles when confronted with the USPTO patent criteria and biomedical research? Regarding Beneficence and the USPTO, Hume is helpful. We apply Hume's concept of reciprocity to the USPTO and biomedical research. Beneficence is based on humanity's obligation to reciprocity. Our experienced reciprocity through social interaction compels us to act morally. We argue that since the USPTO patent

system is part of our social reciprocity, it has a responsibility to be mindful of moral principles, such as Beneficence and Autonomy (Dignity).

We move on to a discussion on Dignity and the USPTO's lack of concern for moral principles. Dignity bring us to the questions regarding genetic similarities and differences in animals, universal human rights, and bodily rights. The discussion leads us to David Resnik's[17] argument on the violate human dignity

David Resnik [18] argues that gene patenting does not violate human dignity. However, Resnik argues the patenting of a complete human genome would violate human dignity. In opposition to gene patenting David Koepsell[19] argues that human genes should not be permissible because the human genome is a common, owned and to be used by all. But the real work supporting gene patent is done by Resnik. Resnik argues that DNA patents only violate human dignity if patents treat people as complete commodities, analogous to human servitude.

We examine whether DNA parts of a person can in fact effect a complete person's autonomy. We look to Kant for an account of persons as autonomous and rational. We look to Aristotle[20] for an account of persons as blameworthy and praiseworthy. The point here is that rationality and morality, blameworthy and praiseworthy are foundational qualities of personhood; genetic information and research will affect these foundational qualities. We conclude this chapter by examining how pharmaceutical (a large force in genetics) research impact autonomy and quality of life.

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[17] Resnik. "*Owning,"* 120.
[18] *Ibid*, 120-129.
[19] David Koepsell. *Who Owns You?: The Corporate Gold Rush to Patent Your Genes*. John Wiley & Sons, 2009.
[20] Richard McKeon. "Nicomachean ethics." *The basic works of Aristotle* (1941): 935-1126.

Theories of Justice

In Chapter Six we look to theories of justice as justification for the appropriation of genetic material. The distribution of genetic technology and information is taken to be an issue of the ownership of genetic material. A just ownership of genetic material is an issue of distributive justice. It is one's self interest and social issues with access to genetic research and information to foster our future wellbeing. Our libertarian justification begins with Locke[21] and Nozick's[22] arguments applied to genetic ownership. We reexamine Locke and Nozick's [23] libertarianism here, since it is the standard torchbearer for property rights and supports human flourishing as a life that is as good as, or better off than we currently have.

We consider the justification for the appropriation of property and whether the appropriation of property is consistent with its supporting foundational principles. That is, the justification for the appropriation of property must be consistent with its foundational principles.

One theory of justice supporting genetic patents is Nozick's brand of libertarianism. We critically exam Nozick's concept of a "Lockean proviso" in which patents are allowed, given that others are not made worse off by the appropriation of some object. Although Nozick's Lockean proviso makes a moral stand to avoid creating a less advantageous position for others, we show some problems with Nozick's brand of libertarianism. Subsequently, finding Locke and Nozick's libertarianism unsatisfying, we move on and examine a genetic distribution of

[21] John Locke: *Two treatises of government student edition*. Cambridge University Press, 1988.
[22] Robert Nozick. *Anarchy, state, and utopia*. Vol. 5038. New York: Basic Books, 1974.
[23] *Ibid*

justice technology in light of Rawls's more robust theory of justice. We consider possible alteration to Rawls and the distribution of genetic technology, not just to combat genetic diseases, but to have access to genetic enhancement.

Some proponents of gene patent projects, Adam Moore,[24] use of public money claim that research in genetic engineering should first give genetic access to the wealthy. Moore argues historically technologies first available to the wealthy spurred the development and access to society as a whole. Early access to the wealthy will open the way to greatly contribute to a genetically based health care system, public health benefits that would free us from our hitherto biological limits, and the creation of personal genetically based medicine. We challenge Moore's argument and find it problematic[25]. Finding Libertarians and others problematic, Locke[26], Rawls,[27] Moore[28] and Farrelly,[29] we consider and support a Nussbaum and Sen Capabilities[30] as a genetic theory of justice.

[24] Adam D. Moore. "Owning genetic information and gene enhancement techniques: why privacy and property rights may undermine social control of the human genome." *Bioethics* 14, no. 2 (2000): 97-119.
[25] For an additional arguments challenges Moorean positions, see Hilary Rose, and Steven Peter Russell Rose. *Genes, cells, and brains: The promethean promises of the new biology*. Verso Trade, 2014. Solomon R. Benatar and Peter A. Singer. "Responsibilities in international research: a new look revisited." (2010): 194-197.
[26] Locke. *Two treatises*.
[27] John, W. "Rawls's Theory of Justice." (1971).
[28] Moore. "Owning."
[29] Colin Farrelly. "Genes and social justice: A Rawlsian reply to Moore." *Bioethics* 16, no. 1 (2002), 72-83. Colin Farrelly. *Biologically modified justice*. Cambridge University Press, 2016.
[30] Nussbaum, "*Sex."* Theo Papaioannou*. "New life sciences innovation and distributive justice: rawlsian goods versus senian capabilities." Life sciences, society and policy 9, no. 1 (2013): 5.*

Challenging the Supreme Court and Possible Future

In the final chapter Seven, I present possible ways to deal with current problems that may result from the court's decision to patent genetic material. But first I examine and argue against the US Supreme Court's decision to patent genetic material. I argue that the Court fails to see that both DNA and cDNA, at their essence, are products of nature and not patentable. Next, I need to consider possible ways to reconcile human access to gene heath care and the promotion biomedical research. So, since both legal and moral principles are needed, I explore and develop a compulsory patent pool DNA system (CPPS), a commons biobank system and prize fund system to insure competition. One main ethical worry is that research companies or individuals may not use patented intellectual property without the consent of the holder. In our scenario patents may be used when deemed to be in the best interest of society and open for use for others. I consider compulsory patent pool systems, a commons biobank system and prize fund systems as types of open source biology.

These funding systems are used to resolve some genetic technology patent system vs. morality problems such as: pharmaceutical accesses for the poor, accesses to personal DNA information and DNA research availability.

Ultimately, with regard genetic justice, as a call to arms, I suggest a way to move forward. Since prior attempts to justify genetic material (DNA) patents failed, I present a general outline for a Nussbaum and Sen Capabilities genetic justice. The final way to move forward is a call to arms, precisely because, these technologies are in their embryonic stage and capabilities genetic justice guidelines can be constructed to evolve with biotech/biomedical strategies.

Although this work is, for the most, philosophical in that its focus is on arguments from Locke to logical inconsistency in the PTO and courts, I want to acknowledge that the development and connection between culture, economics, technology, and politics is essential for a full understand of genetic patents.[31] Additionally Bioethics (philosophers, theologians, ethicists, and others) can be seen, in some cases to be in alliance with commercial or scientific players such as pharmaceutical companies dependent upon grants, recognition, a professional vocation, and a public role. Bioethicists "seem to be for sale: when bioethicists, in taking subsidies for their educational activities, accepting grants, and acting as consultants to biotechnology and pharmaceutical companies."[32] Nikolas Rose in the following passage captures this cultural, economic, technological, and political evolution:

> The management of health and vitality, once derided as narcissistic self-absorption, has now achieved unparalleled ethical salience. The tensions between the intensifying demand for the products of the bio economy - organs, embryos, pharmaceutical products, and the like in the West - and the inequities and injustices of the local and global economic, technological, and biomedical infrastructure required to support such a somatic ethic seem to

[31] Catherine Waldby, *The visible human project: Informatic bodies and posthuman medicine*. Routledge, 2003. See also Catherine Waldby, "Stem cells, tissue cultures and the production of biovalue." *Health:* 6, no. 3 (2002): 305-323.
[32] Carl Elliott, "Pharma goes to the laundry: Public relations and the business of medical education." *The Hastings Center Report* 34, no. 5 (2004): 18-23

> me to be a constitutive feature of contemporary biopolitics - and one in which the differential value of life is very much at stake.[33]

Rose's term "somatic ethic" refers to human beings working to make themselves better physically, as well as better persons by addressing their health, vitality, and morbidity of their bodies in this bioeconomy. As I stated this work is philosophical and will focus on arguments from Locke to inconsistency in the PTO and the courts, however our ultimate aims are the same. That is ultimately this work addresses and attempts to alleviate what Rose identifies as "the inequities and injustices of the local and global economic, technological, and biomedical infrastructure" by way of a Nussbaum and Sen Capabilities genetic justice. Before starting with Locke in chapter 1 we acknowledge Biopolitics, give a sketch of Nussbaum and Sen Capability Approach.

Sketch of Biopolitics Nussbaum and Sen Capability Approach

What follows is an acknowledgement that biopolitics plays a vital part in the evolution of genetic patents. I present a thumbnail sketch of biopolitics. Next I give an account of how my new approach may work. I begin with a short reiteration of biological and genomic information access from public to private control. What began as shared genetic knowledge with all humanity, as proclaimed by President Bill Clinton and British Prime Minister Tony Blair, is now privatized to be managed

[33] Nikolas Rose. "The value of life: somatic ethics & the spirit of biocapital." *Daedalus* 137, no. 1 (2008): 36-48.

by the free market and World Trade Agreement on Trade-Related Aspects of Intellectual Property Rights. Genomic information is now valued as bio capital[34].

Historically it was in the 18th century, according to Michel Foucault, that politics and power began to connect technology and society to the body for intervention and management. That is, historically, this is the first time that biological existence reflected political existence. Foucault showed that:

> For the first time in history ... biological existence was reflected in political existence; the fact of living was no longer an inaccessible substrate ... emerged from time to time ... part of it passed into knowledge's field of control and power's sphere of intervention. Power would no longer be dealing simply with legal subjects over whom the ultimate dominion was death, but with living beings, and the mastery it would be able to exercise over them would have to be applied at the level of life itself ... If one can apply the term bio-history to the pressures through which the movements of life and the processes of history interfere with one another, one would have to speak of bio-power to designate what brought life and its mechanisms into the realm of explicit calculations and made knowledge-power an agent of transformation of human life[35].

It is not the case that biopower is used solely for biological purposes, it is necessary for the development of capitalism. Life forms are controlled through political

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[34] Patricia H.Hynes. "Toward a Laboratory of One's Own: Lesbians in Science." Women's Studies Quarterly 28, no.1 1nd 2 (2000), 158-64.
Timothy Caulfield, and Roger Brownsword. "Human dignity: a guide to policy making in the biotechnology era?." *Nature Reviews Genetics* 7, no. 1 (2006), 72.

[35] Foucault, Michel. "The history of sexuality, vol. 1." *New York: Pantheon* (1978), 242-143.

construction, regulated as objects of technology and power to commercialize and capitalize. Through this new political construction of life forms, the status of "intellective subjects or objects" changes. The courts have expanded the scope and power of intellectual property rights for capitalist production. Paving the way for major bioengineering patent expansion, for example, Diamond v. Chakrabarty (1980) ruled that modified life forms are patentable. In Moore v. Regents of the University of California, John Moore, research participant, was denied property rights on his own cells irrespective of the fact that he allowed researchers to patent a line of cells derived from his tissue[36].

The United States, through the courts and policymakers, constructed a legal patent system that combines academic genetics research, capital investment, and the biotechnology industry. Congressional policies promoted institutional relationships with the biotechnology industry for government sponsored intellectual property rights in research[37]. We see Congress in 1980 passing two laws that enhanced the patent system. The first law, Stevenson-Wydler Technology Innovation Act transfers technology research and development to the responsibilities of federal laboratories. The second law, the Bayh-Dole Act enabled businesses to patent government funded discoveries[38]. As argued by bio politics scholars, to foster bio capital patent law is "a juridical tool and mechanism of

[36] Moore v. Regents of the University of California, 793 P.2d 479, 493-97 (Cal. 1990). See also James Boyle. *Shamans, software, and spleens: Law and the construction of the information society*. Harvard University Press, 2009. Sheila Jasanoff, Ordering Life: Law and the Normalization of Biotechnology, 62 POLITEIA 34 (2001).
[37] Rebecca S. Eisenberg, Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research, 82 VA. L. REV. 1663 (1996).
[38] Stevenson-Wydler Technology Innovation Act, 15 U.S.C. §§ 3701-3717 (2000). Bayh-Dole Act, 35 U.S.C. §§ 200-211,301-307 (2000)

neoliberalism where biological and genetic material are privatized for the development of capitalist production"[39].

Bio capital studies examine relationships between forms of life and their value; for example, they examine genetic phenomena use and the market value of body organ attempts to patent genetic material. These studies include slavery and human trafficking, the market value of reproductive material services, and clinical trials of pharmaceuticals[40] Bio capital studies also examine the making of products and pursuit of profit by converting "biotic material" and its information into value markets for wealth and profit.

Some opposing the marketing of genetic material and lack of access due to patents can be seen in the Association for Molecular Pathology v United States Patent and Trademark Office, and Myriad Genetics, Inc. Additional opponents expressed their opposition as briefs for the United States as Amicus Curiae. Amici curiae National Women's Health Network, for example, argues that isolated DNA is a product of nature and unpatentable[41]. The patenting of isolated DNA harms women as it stifles innovation and interferes with patient medical testing and

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[39] Laura A. Foster. "Patents, biopolitics, and feminisms: Locating patent law struggles over breast cancer genes and the hoodia plant." *International Journal of Cultural Property* 19, no. 3 (2012): 371-400

[40] Dumit, Joseph. *Drugs for life: how pharmaceutical companies define our health*. Duke University Press, 2012. Kaushik Rajan. *Biocapital: The constitution of postgenomic life*. Duke University Press, 2006. Nikolas Rose. "Molecular biopolitics, somatic ethics and the spirit of biocapital." *Social Theory & Health* 5, no. 1 (2007): 3-29. Catherine Waldby and Robert Mitchell. *Tissue economies: Blood, organs, and cell lines in late capitalism*. Duke University Press, 2006. Stefan Helmreich. "Species of biocapital." *Science as culture* 17, no. 4 (2008): 463-478.

[41] Ass'n for Molecular Pathology v. Uspto. 702 F. Supp. 2d 181 (S.D.N.Y . 2010) Decided Mar 29, 2010. See also. Shobita Parthasarathy. *Patent Politics: Life forms, markets, and the public interest in the United States and Europe*. University of Chicago Press, 2017. Additional Reading Brief of Amici Curiae.

treatment access. Moreover, Amici curiae National Women's Health Network also argues that the human gene and information is part of the common heritage of humanity, whose patenting is "contrary to both international law and treatises as well as the public trust doctrine". The fight for woman the poor continues[42].

Given that historically the US Biotech industry and government legal systems worldwide restricted genetic information to the poor, how might we present a more ethical patent system for the public good? First, let's reverse engineer this problem. How have we in the past supported the public good scientifically? This question does not exclude new radical ways forward. One ethical expression or action of public good was to give a scientific discovery or invention to mankind. On April 12, 1955, Jonas Salk gave the polio vaccine to mankind. We can start by thinking of ways to extend genetic information and treatment of the disadvantage and mitigate their lack of access. Some can argue that to give genetic information to all of mankind would slow or stop scientific progress.

I argue that genetic open access does not necessarily stifle genetic research, but let's accept this as true for now. Alternatively, we can exercise beneficence and give genetic access to some in return for patents. Some might argue that giving access to genetic material would create financial hardship. In cases of financial hardship governments can assist. After all, governments already assist biotech and corporations financially through tax breaks and access to government scientific

[42] Ibid.

information. As has been shown by Shelly Hurt early funding in chemistry and biology was crucial to the development of the current biotech industry[43] .

Let us return to our focus on the central question, how do we make genetic patents ethically justified? Succinctly put, in order for one to get a genetic patent one must do some ethical research, and/or make that research accessible to the poor or disenfranchised. What kind of ethical standard shall we use? Here is where we look to Nussbaum's capabilities. As a Nussbaum index capabilities test we can know that a genetic patent is morally justified when:

i. The patent complies with one of Nussbaum's Capabilities,

and

ii. The patent does some ethical research.

In order to satisfy i, for an example, we will consider Nussbaum's Capabilities 1:

> Life: Being able to live to the end of a human life of normal length; not dying prematurely, or before one's life is so reduced as to be not worth living.

Our actions are justified when we enable people to live a natural expected life span. Take the historical BRCA1/2 case. Woman in the BRCA1/2 case, for example, are at a disadvantage when it comes to genetic information and access to new genetic treatments worldwide. Many women were unable to pay the costly amount

[43] "From the early 1950s to 1969, controlling for inflation, the budget allocation for the chemical and biological warfare (CBW) program increased by more than 2,000 percent from $10 million to $352 million, with most of the change coming during the Kennedy administration." Shelley Hurt. "The military's hidden hand: examining the dual-use origins of biotechnology in the American context, 1969–1972." In *State of Innovation*, pp. 39-64. Routledge, 201.

for the BRCA1/2 test, and those who could afford the high cost were not give the opportunity for a second opinion. Giving that BRCA1/2 genetic information and treatment would mitigate a premature life span and foster a better quality of live for the disadvantaged (disenfranchised and poor), biotech patent holders can choose to do research that promotes the natural life span of BRCA1/2 patients.

One can argue that currently natural DNA is not patentable. Since natural DNA is not patentable, DNA and genetic technology is more accessible for biogenetic companies to create more genetic information and treatment availability. Moreover, the cost of genetic sequencing has dramatically dropped and has made the sequencing of genes and its studying possible for many countries. It is the case that there has been a drastic reduction in the cost of genetic sequencing. Nonetheless, for many in the developing countries the cost is still prohibitively expensive for many of the average income-earners[44]. Not patenting genetic information that extends genetic information and treatment to developing countries is consistent with our view, since it supports biogenetic companies that create more genetic information and treatment availability. Giving access to genetic information and treatment to developing countries and the US, to mention just a few, will save countless lives.

The historic BRCA1/2 case is one example of the capabilities method I propose. Nussbaum's Capabilities 1: Life[45] is fixable enough to be extended to ethical research on the prevention, control and cure of diseases and viruses.

[44] Frontier Technology Quarterly: Playing with genes: The good, the bad and the ugly 15 May 2019.
[45] Martha C. Nussbaum, *Sex and social justice*. Oxford University Press, 1999.

Another case in point is malaria. Every two minutes one child dies from malaria[46]. It is estimated that 219 million malaria cases accrue worldwide and 435,000 deaths. Death from malaria are clearly premature death that can be avoided with a cure.

Here again someone can argue that tech companies would be hard pressed to financially support ethical research. At this point it is important to put corporate finances in perspective:

> Some 60 companies reported in their 2018 federal tax rates amounted to effectively zero, or even less than zero, on income earned on U.S. ... according to ... the Institute on Taxation and Economic Policy. The number is more than twice as many as ITEP [*Institute on Taxation and Economic Policy*] found roughly, per year, on average in an earlier, multi-year analysis before the new tax law went into effect[47].

Corporations in 2018 did not have to pay $16.4 billion in taxes[48]. In fact, Amazon.com Inc., Netflix Inc., global oil giant Chevron Corp., and pharmaceutical manufacturer Eli Lilly & Co., for example, received a tax rebate of $4.3 billion. These tax rebates amounted to $20.7 billion in the federal budget last year. Government corporate tech funding has never been a problem, the problem is the will to fund moral research. By mandating corporate genetic patent holders to perform some ethical research, making genetic information and treatment

[46] Frontier Technology Quarterly.
[47] You Paid Taxes. These Corporations didn't. The Center for Public Integrity. https://publicintegrity.org/inequality-poverty-opportunity/taxes/trumps-tax-cuts/you-paid-taxes-these-corporations-didnt/
[48] Ibid.

available, and perhaps allowing some ethical research outcomes to be marketable to those who can afford it, creates incentive for public and private gain.

2.0 Lockean Property, Human Flourishing and Genetic Patents

Historical

All moral, political and legal justification for genetic intellectual property (IP) patents start with property rights. Historically, property rights were seen as a way to avoid social discord. These early views had a moral dimension. Plato argued for a communal ownership of property to support common goals, interest and avoid social strife[49]. Aristotle argued private ownership promotes prudence and responsibility in everyone's "distinct interest" and avoids social strife, because private owners will attend to their own business[50].

We begin with Locke's justification for property rights. Our goal in this chapter is not simple to show Locke's justification for property rights, but to also underscore Locke's commitment to human flourishing as a public good. Central to this work on axiological justification for IP is human flourishing. An additional reason we begin with Locke is that he has one of the three general forms

[49] Plato *Republic*, 462b-c.
[50] Aristotle, *Politics*, 1263a.

supporting moral justification for intellectual property[51]. With regard to human flourishing, how and when individuals acquired the right to property, we look to John Locke.

For John Locke, earth in the state of nature was given by God as a common belonging to mankind. The earth and all its resources are given to assist and comfort mankind. Given that God gave "earth to the children of man" in common presents the following challenge:

> it seems to some a very great difficulty, how anyone should ever come to have a property in anything...upon a supposition that God gave the world to Adam, and his posterity in common, it is impossible that any man...should have any property upon a supposition...exclusive of all the rest of his posterity...how men might come to have a property in several parts of that which God gave to mankind in common...[52].

Since God gave the earth to all mankind, an account of individual property rights must be given. Locke proposes to show how it is possible that one can possess parts of the common as personal property. An important point of interest here is that Locke emphasizes the commons. Whether one finds property in the state of natures by way of the Devine, or otherwise we find ourselves having access to nature freely. We must set limits as to what we can and cannot have justly, if we are to live in harmony with others.

[51] The three general forms are personality-based, utilitarian, and Lockean (Hughes 1988; Moore 2008).
[52] Locke: *Two treatises*, 1988, II, V.

First, in contrast to Locke and some contemporary views, Hobbes[53] contends property in the state of nature is that which every man can acquire and is his for as long as he can keep it. In the state of nature, prior to property rights given by the sovereign, the world was in a state of war each man against every other man to appropriate what he can. Property rights were given by sovereign power to create peace:

> all men had right to all things, which necessarily causeth war: and therefore, this propriety, being necessary to peace, and depending on sovereign power...[54].

Whichever position one takes, property in the state of nature given by the Divine, or natural state of war, an account of individual property rights must be given. One way to answer Locke's challenge in the Second Treatises of Government[55] that individuals cannot possess property if God gave the earth to all mankind, or we find property in common, is that one can acquire appropriation consent from all other property owners.

One possibility by which individuals acquired property is that over time the owners of the earth in common gave their consent to others to appropriate and use segments of the common. If this was what Locke had in mind, he would have to produce or present a mechanism by which holders of the common would allow their consent. The consent of all the world's stakeholder must in some way be obtained.

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[53] Thomas Hobbes, and Edwin Curley. *Leviathan: with selected variants from the Latin edition of 1668*. Vol. 8348. Hackett Publishing, 1994.
[54] Hobbes, T., 1651, *Leviathan*, in E. Curley (ed.), *Leviathan, with selected variants from the Latin edition of 1668*, Indianapolis: Hackett, 1994
[55] Ibid, 148.

To reach each and every stakeholder would be prohibitive; at the very least unmanageable, without some worldwide mechanism or political system. Such a worldwide system would have to regulate consent over all other owners to appropriate the use of the common. Since Locke does not present a mechanism by which all individuals can consent to relinquish their rights, we take it to be the case that Locke assumes all holders of the common needn't consent to relinquish their rights. However, Locke does recognize that in order for one to realize and utilize what one is given, there must be prior conditions.

Locke assumes, and it stands to reason, that a deity in giving dominion over "the world to men in common" would additionally give them a purpose for the gift:

> given them reason to make use of it [fruits of the earth] to the best advantage of life, and convenience... and nobody has originally a private dominion, exclusive of the rest of mankind...yet being given for the use of men, there must of necessity be a means to appropriate them some way or other, before they can be of any use, or at all beneficial to any particular man[56].

This is the important bit: it is in this Lockean reason or purpose that we see the moral dimension of the appropriation of the common. The moral dimension is that the appropriation of the common by individuals is intended to benefit human flourishing (implies human dignity we will take up latter), hence human flourishing presents the beginning of individual property rights. Human Flourishing can be seen as the beginning of individual property rights in that in order for humanity to

[56] Locke: *Two treatises*, (II, V) 26.

flourish, one must transform or do some work on the common. Intern, in order for one to transform or do some work on the common, one must appropriate some part of the common as property.

At the very least for Locke, God would not give the earth to mankind without also a purpose or ability to transform or do some work on the common. Again, whichever position one takes, God given dominion over the earth to mankind, or property acquired by war man "against every man"[57] appropriation of the commons is necessary. Here Locke considers the fundamental conditions for personal property in that, if nature is to provide for the "support and comfort" (flourishing) of mankind, mankind must somehow appropriate these fruits from the common:

> ...being given for the use of men, there must of necessity be a means to appropriate them some way or other, before they can be of any use, or at all beneficial to any particular man[58].

Locke continues, the appropriation of "meat and drink, and such other things" provided by nature cannot be consumed or used, if not taken out of the common. In what way are we to know which parts of the common are appropriate to remove in order to support human flourishing? Surely one cannot appropriate any part of the natural common at any time for any purpose that suits one's perceived benefit. Locke needs to establish a system or conditions by which one may appropriate the "earth or its products."

[57] Hobbes, T., 1651, *Leviathan*.
[58] Locke: *Two treatises*, 26

Locke presents man as his own property and the conditions by which he comes to possess parts of the earth in common. Locke introduces the notion of labor and work to establish private property rights over parts of the common in the state of nature:

> ...every man has a property in his own person: this no body 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[59].

In this passage Locke presents the means by which individuals can appropriate parts of the natural earth commons and fulfill their purpose to flourish. Individuals can fulfill their purpose and support wellbeing, if they are able to remove parts of earth or its products from the common. By removing something from the common and working on it, one has "by this labour something annexed to it" and excludes the rights of others. By mixing or joining labor to something one brings about exclusive "unquestionable property" rights "of the labourer...at least where there is enough, and as good, left in common for others"[60]. In "cultivating the earth, and having dominion, we see are joined together" give man the authority to appropriate and "introduces private possessions"[61].

[59] Locke: *Two treatises*, 27.
[60] *Ibid*.
[61] *Ibid*. 35.

I gather three key claims form Locke's argument. First, one can create something new from the commons. Second, one can acquire rights over to the commons. Lastly, the commons and be created to be of more value.

From Locke's first claim, when one removes the common from nature and adding labor one creates something new[62]. From Lock's second claim, by removing the common from nature, adding labor and creating something new one acquires a right to the new created parts of the common. Lastly, labor improves the common and improves the common as a "value-adding activity" fulfilling the Divine purpose for man to use the earth as his support and comfort[63].

On the one hand, in the state of nature, land in common that yields or produces nothing for one to eat or use has little value. It is clear, for example, that in cultivating the earth or transforming the common into useful products or improvements one increases the value of the common[64]--labor creates value.

We now bring all the above results together and call the aggregate conclusions, from i-iii, above the CRV Provisos in the following way:

> From i. we get (Proviso C) one creates something new by removing the common from nature and adding labor;
>
> From ii. we get (Proviso R) one creates the right to appropriate the new created common by removing the common from nature and adding one's labor;

[62] *Ibid*. 27.
[63] Stephen Buckle. *Natural law and the theory of property: Grotius to Hume*. Oxford: Clarendon Press, 1991.
[64] Locke: *Two treatises*, 43, 45.

> From iii. we get (Proviso V.) labor improves the common as a "value-adding activity" fulfilling the Divine purpose for man to use the earth as support and comfort – the benefit for human flourishing .
>
> Hence, we have (CRVP) The Creation of Rights and Value Provisos.

For Locke, labor and the CRVP transforms common property into individual property rights. That is, one extends the ownership of one's body to the ownership of parts of the once common, when the common is "annexed" or "mixed" with one's body via labor. So, labor and human flourishing are the foundation by which the appropriation of the common is justified. Labor and human flourishing provide the justification for one to appropriate the common, "makes it his property" creating individual property rights.

Problem of Waste

Locke, quite rightly, anticipates a possible problem in using labor as a foundation for individual property rights. Can one acquire property of the common and squander it away, since one has, in the past, commingled one's labor with the acquired property? The appropriation of the common does not include the wasteful use of the common:

> It will perhaps be objected to this, that if gathering the...the earth, &c. makes a right to them, then any one may engross as much as he will. To which I answer, Not...[65].

[65] Ibid (988, II, V), 31.

There are natural limits on the amount one can own of the common. For Locke, the natural limits are contingent on the Divine, and "set by reason" as a theological end. One can acquire only as much of the common that one can use (and labor) to one's advantage. One cannot spoil or waste that which the Divine or nature has given for humanity to flourish.

Locke's view on the natural limits of personal appropriation of the earth's common is based on "unquestionable property" rights "of the labourer...at least where there is enough, and as good, left in common for others"[66]. This Lockean no worse off condition, I will call the No Worse Off Proviso - also known as the Lockean Proviso[67]. Not Worse Off Proviso (NWOP) contends that individual property rights will not make others worse off.

Via the above Lockean provisos, Locke for now, has resolved the problem he presented in the Second Treatises of Government). Locke's resolution, as to how one can possess parts of the common, given the purpose for all mankind to use and have dominion over the earth, sets the foundation for a theory of property rights. Much of these provisos can be seen in the United States Patent and Trademark Office criteria for gene patens.

Lockean Provisos and Intellectual Property

Locke's provisos, (CRV) and (NWO), can be seen as the foundational forerunners of some of the United States Patent and Trademark Office (USPTO's) criteria; and patent IP (intellectual property) rights which we will consider in the

[66] *Ibid* (II, V) 25
[67] Nozick. *Anarchy.*

next chapter. Moreover, we will explore whether Locke's provisos support and are consistent with USPTO's patent criteria for gene patents.

Locke in the Second Treatises of Government recounts the industrious use, invention and arts used to support a flourishing life as follows:

> industry provided and made use of [the common] before it came to our use...iron, wood...stone, bricks, coals, lime, cloth, dying drugs...all the materials made use of ...which made up the great part of what he applied to the support or comfort of his being, when invention and arts had improved the conveniences of life...[68].

In this passage we see the beginning of what will be called patents on intellectual property. There is a symmetry in what "industry" provides between "Locke's state of nature and the public domain" of information[69]. The creators of IP draw from the public domain of information as does the creators of Locke's day draws from the common to create property rights. Locke's relevance to IP can be seen at a deeper "level, the logic of his thinking applies to intellectual products ... at least as well as to the objectives of physical properties."[70] This is analogous to Locke's appropriation of iron or wood from the state of nature. Labor grounds "claims over intellectual assets as well as tangible items such as land, crops, and the like"[71]. Moreover, IP corresponds well with NWOP because not making others worse off entails not spoiling or wasting the common. IP may not be easily wasted or used up to the point in which there is not "enough, and as good, left in common for others."

[68] *Ibid* (II, V), 43-44.
[69] Merges P. Robert *Justifying intellectual property*. (Harvard University Press) 2011, 33.
[70] Ibid.
[71] Merges. *Justifying*, 36.

For example, authorizing copyrights for cookbooks or Goethe's Faust does not directly deprive anyone from food or their souls.

As a parallel to Locke's state of nature we take intellectual property to be the human creations of ideas applied, at least, to the conveniences of life and its flourishing. Locke can be seen not just interested in tangible items that can only be appropriated via physical work. His property rights arguments are consistent with intellectual assets improving life and contributing to human flourishing. It is here that Locke may be seen to have the foresight to include more than appropriating objects. That is, Locke makes it clear that human flourishing is produced by the conveniences of life that are created by the application of "invention and arts". That is to say, ideas of invention and arts are necessary for the actualization of actions that bring about human flourishing through the industry of work and appropriation. Human flourishing is achieved via the appropriation of tangible objects or IP. That is not to say that harm cannot come from the appropriation of the common. But it is the preview of patent rights, the appropriation of the common, as seen by Locke, to support human wellbeing by way of invention and arts.

Locke's theory of property and human flourishing via appropriation and the industry of work lends itself nicely as a justification for IP as argued above. Locke's property rights and human flourishing (moral theory) apply to some US patent requires; for example, Utility and Novelty, since Utility and Novelty can improve human life. We will take up human flourishing (moral theory) and US patent requirement issues in the next section. We now turn to Locke's property rights, human flourishing, and the presupposition that support Locke's property rights.

Lockean Provisos, Patents and Human Flourishing

Although the US and other countries patent (property rights in general) requirements primary focus on novelty as originality, one can see Locke's discussion of Proviso C, creating something new and perhaps novel by removing parts of the common from nature and adding labor. The focus of Locke is not necessarily that each appropriation is novel or an original invention, but that the work one imposes on the common creates something new or different in use than that found in the original common of nature. Furthermore, Locke in the Second Treatises promotes the use of the industrious as "invention and arts" to support a flourishing life. That Locke's proviso C, creating something novel that supports human flourishing, can also be seen in the US's mandate by the US Constitution to promote the progress of "Science and useful Arts" (Constitution is Article 1, section 8, clause 8). As we know the sciences and useful arts contribute to human flourishing, whether it be to achieve health, self-actualization or scientific knowledge within a larger community of individuals.

The patents, in the US and other countries allow for the patenting of inventions when they promote the progress of "Science and useful Arts". In promoting the progress of "Science and useful Arts" via patents, one can additionally promote social economics (human flourishing) as well as individual rights to property.

The more fundamental dimension of Locke's property theory is the foundation for which property rights are intended and the conditions needed for its actualization. Locke's foundation for property, which is not always emphasized, is

grounded in the moral concept human flourishing. It is the intent and conditions that bring about human flourishing, creates individual property and freedom to control one's environment and future. Human flourishing protects and fosters basic human needs or interests. However, human flourishing is contingent on some additional conditions and these conditions are important in understanding a moral justification for property rights.

Some Presuppositions to Proper Rights

Human flourishing assumes that human basic needs and interests can and will be fulfilled. This leads to the following question; namely, what are some important presuppositions that emerge in the pursuit of human flourishing? In order for one to fulfil one's basic needs and interests, one must have access to the fruits of nature's bounty. Quite simply, without food one cannot survive, without trees one cannot build boats or weapons to hunt. So, the appropriation of nature is needed. Here we have the need for personal property via the appropriation of nature. There must be open access to nature for appropriation to fulfill personal need.

The open access to the common as well as appropriation is a necessary condition for the fulfillment of one's personal needs. Action as labor and reason (to understand what is needed) alone are not sufficient to brings about the appropriation of nature. Open access to the common comes before action (work) and acquisition. Open access may also be seen as limits to appropriation when it stifles the fulfillment of one's need. Open access to the common allows for the

acquisition or appreciation of nature and the action needed to bring about one's personal needs.

Action implies some work, but not just any work. The work must be creative such that it brings about or creates, some new, useful produce for mankind. The need for open access to nature as well as utility will be important to latter discussions on patents. Here utility based on promoting human flourishing and, as we will see, human flourishing will be used as support for IP and gene patents. For Locke and the USPTO, inventions that provide a well-defined and particular benefit to the social and economic future justify the appropriation of segments of nature.

To the extent that intellectual property supports science, useful Arts and human flourishing, intellectual property rights seem to be supported by Locke. This chapter is more than an historical recap of Locke's views on the appropriation of property. As we will see Locke sets some fundamental moral principles found in patent law and society that express a moral justification for genetic patens. What we find in this chapter is that parts of nature must be open to individuals to appropriate nature, yes, but also open contingently. Nature must be accessible to all but appropriated only when it does not create a life worse off for others and stifles human flourishing. But without access to nature we cannot start to flourish. We find in this chapter that through Labor, avoidance of the problem of waste, open access for individual liberty and well-being human flourishing provide the moral justification for one to appropriate the common. We also incorporate in the no worse off proviso that flourishing as wellbeing is a public good with the two properties of Nonrivalry and Non-excludability. As Nonrivalry, human flourishing as wellbeing is seen when one person's opportunity for wellbeing is not diminish by

another people's opportunities for wellbeing. As Non-excludability, human flourishing as wellbeing is seen when nobody can be excluded from opportunities for consuming wellbeing once it is produced. We will revisit gene patents and human flourishing latter, for now we look to Patent Law as it stands in the US.

3.0 Patent Law Overview

> The first argument I shall make use of is deriv'd from the vulgar Definition of justice. Justice is commonly defin'd to be *a constant and perpetual will of giving every one his due*. (Hume THN III (ii) 6)[72].

The Purpose of Patents

In this chapter we examine US (PTO) criteria for patent law. Patents can be seen as monopoly rights. Patent monopoly rights are granted by governments to patent holders to promote science and technology. The purpose of these grants is to encourage patent holders to disclose their inventions as opposed to keeping the invention secret. Ultimately, as I have shown through an interpretation of Lock's property rights, appropriation and monopolies are grounded on more than work. The inception of the patent is also grounded on the principle that the public must benefit. This view is clearly expressed in the USPTO.

The moral or axiological justification for IP rests on the US Constitution (Article 1, section 8, clause 8) authorizing Congress to enact laws for the purpose of promoting "the progress of Science and useful Arts." The United States Patent and Trademark Office (PTO) is also authorized to issue 20 years patents to inventors promoting Science and useful Arts. The 1966 Supreme Court fleshed out this axiological justification as follows:

[72] Emphasis Hume's. David Hume, *Enquiries Concerning Human Understanding and Concerning the Principles of Morals* (1777), 2nd. ed., ed. L.A. Selby-Bigge, rev. P.H. Nidditch. (Oxford: Clarendon Press, 1975), 526.

> The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society—at odds with the inherent free nature of disclosed ideas—and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly.[73]

Accordingly, the 1966 US Constitution created IP to "reward, induce and foster new knowledge. It follows that IP also promotes human flourishing to the extent that it advances new and useful human knowledge by promoting Science and useful Arts. That is, the US Constitution in promoting human knowledge, "and were new and useful" also promotes human flourishing to the extent that IP knowledge creates medical and economic inventions that support human freedom, as autonomy/dignity. The US Constitution promotes human flourishing and human freedom as autonomy/dignity, since these are the outcomes of genetic medical and economic technology inventions currently see as dominant technologies. We take up additional biomedical ethical principles in latter chapters.

Although the legal justification for patenting is not the specific concern of this paper, a general understanding of the USPTO patent criteria as well as the general tenor of the non-legal arguments (which we take up in the next chapter) well help set the background for the gene patenting debate. USPTO patent applications must have three components: *Utility*, *Novelty*, and *Non-obviousness*. In addition to the

[73] *Graham* v. *John Deere Co.,* 383 U.S. 1, 9 [1966]

USPTO patent criteria *Utility*, *Novelty*, and *Non-obviousness*, the *Principle of Nature* addresses what is not patentable, i.e., products of nature cannot be patented. I take up the above three patent applications components and what is not patentable in turn.

USPTO Criteria for Patenting

Utility

> Whoever invents or discovers any **new and useful process**, machine, manufacture, **or composition of matter**, or any new and useful improvement thereof may obtain a patent therefor, subject to the conditions and requirements of this title. [74] (My emphases)

The axiological justification for the Utility standard is found in creating something new and useful. The Utility standard sets the condition that an invention must be useful. Under this standard, patentable subject matter must be: "specific", "substantial", and "credible."[75] Its usefulness must be *specific* to the subject matter of the invention—not to inventions of a broad class. Its utility must also be *substantial*: the invention must "provide a well-defined and particular benefit to the public."[76]

For one to claim an idea for future heart disease treatment would not suffice for a utility patent. The would-be patentee cannot simply say, "I have the idea for

[74] See section 101 of Title 35 of the U.S. C. The U. S. C., United States Code. This is the law and regulations under which the Federal government and USPTO conduct their work. These USPTO guidelines were first visited in the 1999s for new amendments see: https://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#al_d1fbe1_234ed_52

[75] The PTO Utility Guidelines Training, p. 3 online version: http://www.uspto.gov/web/menu/utility.pdf

[76] Manual of Patent Examining Procedure (MPEP), Eighth Edition. August, 2001. Latest Revision July, 2008 §2107.01 (a).

treating heart problems, but I have not worked out how it will solve heart problems". If an artificial heart had not shown a heart valve treatment connection, it would fail the substantial Utility standard. Pure research is not sufficient to obtain a patent.

> Materials to be used for research, or methods of using those materials for research, raise issues of whether the utilities require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use... wherein a research utility was not considered a "substantial utility."[77]

The Supreme Court defined substantial Utility as a beneficial invention having a "current available form"[78].

Let's take the case of the artificial or mechanical heart valve invented by Dr. Charles Hufnagel in the early 1950s. Human hearts are divided into four chambers. Sometimes due to diseases, age, or birth defects heart valves do not open and close properly. Heart valves beat to allow blood flow in only one direction. Human heart valves that do not open or close fully can cause serious problems. Surgery or drugs can treat some defective heart valves, but others can only be treated by replacing the heart valve. The invention of an artificial heart valve would be of substantial utility for patients with heart valve problems.

If our artificial heart valve invention was created solely for research purposes and produced no particular benefit, it would fail the specificity Utility standard for substantial use or function. This would constitute a case of pure research that is

[77] Uspto.gov Revised Interim Utility Guidelines Training Materials
[78] Brenner v. Manson, 383 U.S. 51, 1966.

non-patentable subject matter but passes a general utility standard. Likewise, the discovery of the inner workings of genetic material to expand scientific understanding satisfies utility (useful for scientific knowledge), but the knowledge acquired from such research may not be patentable if it does not include substantial use or function.

In addition to failing substantial use or function, inventions "that are not patentable subject matter are mental processes, naturally occurring articles or scientific principles"[79]. We address non-patentable subject matter below in Principle of Nature.

Finally, although an invention's claim to Utility need not be conclusive, it must be *credible*. Creditability, also, turns on the invention's acceptance by "a person of ordinary skill in the art." New vaccines, for example, using a process understood by bacteriologists would satisfy the credibility Utility standard for anyone in immunology.

The Axiological and Human Flourishing and Genetic Patents

The value of Utility can be found in its connection to our axiological human flourishing and genetic patents. We found in Locke a number of criteria that set the justification for the appropriation of the natural common through human flourishing. We can see human flourishing in the Utility standard as substantial use or function. With regard to genetic biotechnology and/or patents human flourishing can be seen as protecting and fosters basic human needs or interests. The Supreme Court defined substantial Utility as a beneficial invention having a "current available

[79] Rockman, 2004, .72.

form." Moreover, according to the Manual of Patent Examining Procedure a patent's utility must also be *substantial* in that the invention must "provide a well-defined and particular benefit to the public". We now move on to the Novelty standard for patents.

Novelty

> A person shall be entitled to a patent unless - (a) the invention was known or used...in this country, or patented or described in a printed publication in this or a foreign country...or (b) the invention was patented or described in printed publication in this or a foreign country or in public use or on sale in this country...for patent in the United States...[80]

The axiological justification for Novelty is that the invention is new; and does not infringe on another issued patent. The patent standard of novelty requires that an invention not be previously published or patented**,** and that the inventor is the first inventor. This coincides with the first part of the Utility standard above: "Whoever invents or discovers any new and useful process...or composition of matter..." can patent their invention. In applying this section (as in Utility), the Supreme Court found that products of nature are not new compositions, whether living or non-living, and are not patentable.[81] Critics of human gene patenting contend that because human genes are naturally found in the human body, they are not novel inventions and hence are not patentable. In earlier replies to such critics, the USPTO cites the US Constitution, which allows for the patenting of

[80] See section 102 of Title 35 of the U.S. C. The USPTO is less concerned with ethics than with novelty requirements. We will return to the question of novelty later when considering the identity argument.

[81] Strictly speaking novelty requires that one be the original inventor. That a product of nature is not patentable applies to all patentable subject matter; however, since a product of nature is a claim of originality I consider it in novelty as a criterion of exclusion.

discoveries and inventions when they promote the progress of "Science and useful Arts" (Constitution is Article 1, section 8, clause 8)[82] and it is up to the courts to give guidance on what accounts for a novel invention.

Again, patent law is based on the Constitution, with the intent "To promote the Progress of Science..." It is the courts and Congress however, that determine what is patentable. Ultimately, it is my understanding that the patenting of genetic and biomolecular material is an open question. The courts ultimately ruled on what counts as non-patentable phenomenon of nature and invention on June 13, 2013, yet genetic patents have not found closer. On Tuesday, June 4, 2019 the Senate opened a new hearing on patent eligibility reform. Although Utility is the main issue in the Senate committee, we see that most of the central players are represented by the biotech companies continuing their dominance on access to genetic information[83].

Non-obviousness

> (a) A patent may not be obtained... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.[84]

[82] United States Patent and Trademark Office: Utility examination guidelines. Federal Register, 5 Jan 2001; 66(4):1092–99. URL: http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf.
[83] The Senate committee can be accessed at: https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-i
[84] (MPEP) 2141 Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 [R-6] (a). For a discussion of Utility, novelty, and non-obviousness see Mark A. Chavez, pp. 258-260. An additional way to understand this concept is as a description that an invention that can be described in sufficient detail to enable someone who has been trained in the relevant disciple to construct and make use of the invention.

The axiological justification for Non-obviousness is ingenuity that goes beyond the current patents known to a person of ordinary skill in the art. The non-obviousness requirement states that the invention's reproducible details not be known or easily knowable by someone skilled in the field. Given what is already patented or known at the time of the invention, one cannot simply perform trivial alterations to the known patented subject matter. For example, given a patented invention, simply changing the material, color or size of the invention would not result in a new patentable product.

One difficulty in satisfying the non-obviousness requirement is that the patent process may take many years to complete. An invention may seem non-obvious given the state of the art at the time the inventor began the patent application process. The invention may be a non-obvious invention given the lack of knowledge at the early state of the invention but be obvious years later when examined by the USPTO. Allowing non-obviousness technical patents harms useful patents when trivial patents do not make their new useful inventive step clear. Philosophically the appropriation of genetic information should be a limited right. That is, genetic information must be treated, truly as an exception to access the human genome – to foster the betterment of humanity.

Principle of Nature

> [P]atents cannot issue for the discovery of the phenomena of nature...like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes[85].

[85] Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 1948)

Given that patents must be novel, non-obvious and have utility, the PTO allows for a large range of patents. These patents include engineered bacteria (Diamond v. Chakrabarty, 1980, owned by General Electric), living and non-living inventions. There are, however, limits to what can be patented. For centuries (over 150 years) the Supreme Court maintained that nature is not patentable. The "USPTO is bound by the Supreme Court's interpretation"[86] is bound by the Supreme Court's interpretation[87] which excludes laws of nature, natural phenomena, and abstract ideas.

Natural things discovered in the world may not be patented. The laws of nature, natural phenomena, and abstract ideas are not patentable because they "are the basic tools of scientific and technological work' and lie beyond the domain of patent protection" (Ibid). To tie up these tools via patent protection would inhibit future innovation. Non-patentable examples cited by the Supreme Court (as above in Funk Brothers) are abstract ideas, physical phenomena, discovered minerals and new plants found on earth. Consequently, "Einstein could not patent … $E = mc^2$; nor could Newton patent the law of gravity."[88]

We can think of patent limitation as discovery vs. invention. Discoveries are not patentable. Given this view, discoveries are not novel and exist independent of human manipulation, even though, discoveries can be used in novel ways. $E = mc^2$ is used for understanding our universe. Via $E = mc^2$ we understand that energy and

[86] 35 U.S.C. § 101
[87] The US Constitution, 35 U.S.C. § 101 and the Association for Molecular Pathology v. Myriad case. See also Ingram, Tup. "Association for Molecular Pathology v. Myriad Genetics, Inc.: the product of nature doctrine revisited." *Berkeley Tech. LJ* 29 (2014): 385.
[88] Ibid.

mass (matter) are interchangeable, for example, or that $E = mc^2$ is used in building a nuclear reactor to generate electricity or a bomb. Inventions on the other hand are patentable. An invented nuclear reactor design can be patented. Inventions are the result of human creation and not found in nature. For example, Thomas Edison invented the phonograph, a device not found in nature. The examples from Einstein and Edison clearly differentiate discovery from invention.

As we will see, the old mechanical examples do not help us with differentiating the patentability of new genetic discoveries or inventions. One cannot patent for example a wild mouse found on a college campus. However, if one creates an animal that is prone to developing cancer, a quality not found in natural animals, that animal can be patented.

The discovery and research of the human genome, however, did reignite the discovery vs. invention debate. Whether something is a discovery vs. invention is of enormous ethical concern. The discovery vs. invention debate is of ethical importance, since supporters of genetic research first claimed all humanity should have access to nature's genetic material and set the conditions by which one can have appropriation over parts of nature by way of invention. Patents are not to be issued to things observed or merely identified as discovers in nature. In this chapter we endeavored to make a philosophical or ethical connection between patent law criteria, human flourishing and the public good. The USPTO is only concerned with procedural criteria and not with moral and social order. The discovery vs. invention debate by Jon Merz and McGee is examined in the next chapter.

Problems with Public and Private Goods

Patent criteria can determine public and private accessibility and interests. Private patent access and interest can be stifled, given that patent requirements can be a difficult hurdle to overcome. Notwithstanding private concerns, patent information can become less accessible to the public when the patent system favors private biotech to achieve their commercial interests. Although patent criteria can be seen as quite technical it affects the interest of the public good. For example, although genetic technology has automated much of its methods and the connection between specific genes can be made obvious, knowledgeable public access to genetic testing that reveal genetic prone phenotypes leading to diseases is not. Looking beyond the technical issues of non-obviousness, emphasizing genetic access to phenotypes support public wellbeing. The public good is best served when private interest is balanced with public interest, and more genetic information is made available to the public. We take up this issue later throughout the chapters**.**

4.0_Discovery vs. Invention, Arguments for and Against Gene Patenting

Gene Discovery vs. Gene Invention

Whether genes are invention or discovery is a fundamental issue in the patenting of genetic material. As we know, via the USPTO and the Supreme Court, if something is discovered it is not patentable. If something is invented it is patentable. In this section I examine arguments addressing whether disease genes are commercial objects or just natural discoveries. This lays the groundwork for understanding the complex underpinning that many use to justify the patenting and ownership of genetic material. Glenn McGee[89] argues that disease genes are inventions (commercial objects) and patentable. Jon Merz, [90] in contrast to McGee, argues that disease genes are discoveries, hence not patentable. I begin with the

[89] McGee Gene 417-421.
[90] Merz, "Disease."

importance of disease genes and Merz's view that disease genes are not innovations.[91]

Disease gene patents make claim to segments or position of DNA on a chromosome that may develop into a disease. Some disease gene patents, in 1997, were genetic mutations associated with phenotypes such as Alzheimer's diseases.[92] Some current disease gene patents include breast and ovarian cancers (BRCA1 and BRCA2), colon cancers (HNPCC, FAP), cystic fibrosis (CFTR) and hemochromatosis (HFE), a blood disorder (see Appendix C and D). The commercial use and epistemic importance of disease genes is enormous.

Tests and treatments can be created once one identifies a gene segment that may lead to a possible disease. In the case of BRCA genes, for example, genes help repair damaged DNA in the breast and other tissues. BRCA1 and BRCA2 are normal genes that produce a tumor suppressing protein that aid in preventing abnormal cell growth and division. When BRCA genes are damaged a mutation accrues. The damaged DNA hampers cell growth and natural repair. Since discovery of the connection between BRCA1 and BRCA2 genes to cancer, Myriad Genetics has developed a test to identify persons with the BRCA genes. In the case of BRCA12 owning a patent or possessing knowledge of the phenotype leads to financial gain and/or information that enables one to make informed future health care decisions.

In "Disease gene patenting is a bad innovation"[93], Jon Merz challenges, on legal grounds, disease gene patents. Disease genes are discoveries, hence not

[91] Ibid
[92] Kathakali Addya Y. Lynn Wang, and Debra GB Leonard. "Optimization of apolipoprotein E genotyping." *Molecular Diagnosis* 2, no. 4 (1997): 271-276
[93] Merz."Disease."

patentable. The identification of a disease genes is "merely an observation of a state of nature or "nature's handiwork"[94] (ibid) and not an invention. In order for a gene (segment of DNA) discovery to qualify as patentable, the gene must be changed or altered from its natural state to an invention (Novelty). Observation of genes, per say, does not include "human alteration of an existing organism or naturally occurring entity"[95]. Moreover, the knowledge one acquires by observing these genetic discoveries creates no new diagnostic methods that may be patented. According to Merz, those who discover disease genes all use the same known methods to identify these genes.

Merz's argument has merit with regard to some similarities in identifying different genes and locations in which one observes the naturally occurring disease gene. Say, one discovers the position of some item of interest in nature, or a new item of interest in nature. One can refuse to disclose their discovery to others, but surely, one cannot assert that others are prohibited from looking at one's discovered locus. One cannot assert that no one can look at their discovered locus, unless one is compensated. Nor can one prohibit the use of one's discovered locus, unless one gives a license to others to do so. There is no patent monopoly provision for non-invented discoveries, i.e. locating a gene segment in nature and relocating (separating) it from a cell to a lab unaltered.

For example, consider a case in which all claimed inventors use the same known methods to identify genes. In this case an inventor invents a device, say a Gscope, to examine, inspect or locate genetic items. The Gscope is the state of the

[94] *Ibid*.
[95] Merz,"Disease," 300.

art available and used freely by all geneticists. Each time one views a new genetic locus or discovers a possible new phenotype, using the Gscope, one cannot claim that that position or phenotype has been invented. The gene located by the Gscope is not patentable. Since all one is viewing is a natural occurring phenomenon and all viewers are using the same methods used by others—there was no inventive step. All that occurred is the viewing of a new discover gene.

One difficulty with Merz's argument regarding observation (identifying diseases genes is nothing over and above viewing nature) is that it does not specifically take into consideration the process used in general. Nor, in our case, the process used in identifying the connection between a gene and its phenotype.

Glenn McGee takes issue with Merz's discovery argument. Glenn McGee in "Gene Patents Can Be Ethical"[96] argues that the process of sequencing and identifying a "disease gene" is more than just discovery, and hence patentable. For McGee, a gene's usefulness and worth (Novelty), "as a commercial object is not discovered but rather invented." The inventive or innovative aspect is in "creating a diagnostic process." To consider the process of identifying a "disease gene" as no more than observation of nature is to believe in "genetic essentialism." Genetic essentialism is the view that genes are only a "self-evident library of data …in everyone and responsible for all aspects of human embodiment and disease."[97] Genetic essentialism fails to address the particular relationship between genes and their particular environment. It ignores an epidemiological study of causes, and the population distribution of genes and the environment.

[96] McGee, "Gene."
[97] Ibid., 418

The inventive process of disease gene identification goes beyond the mere examination of a natural form by considering possible utility. The utility is in altering the nature of the gene to become a diagnostic method. For McGee, genes serve a new purpose in identifying the correlation between a gene and its disease phenotype. Genes can have a close degree of correlation with diseases. This correlation does not necessarily make the disease "genetic". McGee continues, a phenotype as with a gene disease expression, and the grouping of organisms meriting medical intervention "is in part a matter of social and scientific convention"[98]. It is our medical, social and scientific communities that determine what is and what is not a disease. The correlation between discovering DNA segments and creating a diagnostic process is one innovative step for McGee.

An issue with McGee's argument is that when one scientifically categorizes genetic correlations, based on our social concerns, the outcome of the process is not necessarily an invention. Social concerns can express what is manifested in nature. Identifying the correlation between genes and phenotypes can be in part a matter of social and scientific convention when one states, for example, they like blue eyes. It can be true that we categorized DNA based in part on our social preferences and scientific concerns. Yet, the DNA phenotype, having blue eyes, is expressed naturally in our body independent of our categorizing blue eyes as something we like; or categorizing something as a disease, for that matter. That which is claimed to be a biological invention and a created correlation between genes and phenotype, is naturally embodied in us as organisms. Discovering one likes blue eyes and creating a category of things one likes is subjective and can be

[98] Ibid., 419

socially constructed with others. The phenotype, however, of having blue eyes is a biological phenomenon between the appropriate DNA and blue eyes.

Let's consider the science of genetics and blue eyes more closely. Originally, according to Professor Hans Eiberg[99], the Department of Cellular and Molecular Medicine, University of Copenhagen, we all had brown eyes. A mutation changed some of our brown eyes to blue. Even if one accepts that the science of genetics is a social invention, the mutation and protein affecting blue eyes is not. A genetic mutation affected the OCA2 gene in our chromosomes producing the so-called P protein, turning off "… the production of melanin in the iris diluting brown eyes to blue"[100]. The OCA2 mutation or phenomena is not invented. Blue eyes and their connection to a genetic mutation is a description given by geneticists of nature embodied in us. In order for there to be an invention/discovery distinction (as described by the USPTO criteria) inventions must be created from a natural source somewhere down the line. Everything cannot be an invention or socially constructed.

In the next section we endeavor to understand additional justification for the patenting of genetic material such as political and philosophical and the human genome project's original intent.

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[99] Hans Eiberg. Jesper Troelsen, Mette Nielsen, Annemette Mikkelsen, Jonas Mengel-From, Klaus W. Kjaer, and Lars Hansen. "Blue eye color in humans may be caused by a perfectly associated founder mutation in a regulatory element located within the HERC2 gene inhibiting OCA2 expression." *Human genetics* 123, no. 2 (2008): 177-187.

[100] www.sciencedaily.com/releases/2008/01/080130170343.htm

Some Justification for the Patenting of Genetic Material

Gene discovery vs. gene invention, legal, political justice and philosophical arguments all address modes of justification for genetic material patents. The scope of these justifications ranges from: the courts on genetic life and the US patent system, financial reward for inventors, sharing of genetic information to utilitarian and libertarianism as social justice. In this section we continue to lay the historical groundwork addressing the topic of gene discovery vs. invention with regard to the courts and gene patents. Moreover, we examine the early intended value placed on the human genome project, arguments for and against patenting DNA as stated above and some ramifications of genetic material patents. These original values justified global support and ethical concerns regarding the patenting of genetic material. In the case of public financial support, without public financial support gnomonic research as we now know it would be hard-pressed to go forward.

The Early Courts and Gene Patents

What is known as genes may refer to segments of DNA nucleotides that code for human proteins and nonhuman proteins, and their phenotypes. These segments of DNA nucleotides were patentable[101] prior to the Supreme Court ruling of June 13, 2013[102]. For example, genetically altered animals, recombinant biological living organisms and DNA segments in general were all patentable based on court rulings.

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[101] Early DNA gene sequencing methods of manipulation were considered sufficient for legal patenting. These sequencing methods can be any of the following:
...isolating DNA, purifying DNA, removing a small segment of the DNA from its place in the genome and connecting it to bacterial DNA (termed 'cloning' DNA...), chemically unwinding DNA, and constructing radioactive or florescent copies of the genomic DNA, fragment (Ossorio, 2002, p.412).

[102] The Supreme Court Rule on June 13 that genes as found in nature as part of the human genome are not patentable (see below for summary).

The Supreme Court ruled in Diamond v. Chakrabarty 1980[103] that genetically engineered bacteria, in particular "an oil-eating microorganism bacterium genetically modified to dissolve crude oil, is a patentable invention." Diamond v. Chakrabarty allowed patents for "anything under the sun that is made by man," including living and non-naturally occurring creations. This patent was allowed, since the court deemed Chakrabarty's bacterium inventive (Novel) and useful (Utility). This, some claim, opened the door for the patenting of animals, manufactured human DNA and perhaps human's and human proteins. For example, the US legal system later allowed for the patenting of genetic life as well as isolated Complementary DNA (cDNA). Complementary DNA unlike natural DNA only contain coding sequences for proteins, for example.[104] That is cDNA (exons) the coding information for the production of proteins, are separated from non-coding DNA (introns) and are now considered invented genetic material.

With regard to patenting animals, in 1988 the OncoMouse, engineered to grow malignant tumors, was the first animal given patent protection by the United States Patent and Trademark Office (USPTO or PTO). The OncoMouse is patentable given PTO standards. The Onco-gene (OncoMouse) that allows for malignant tumors is considered novel and inventive by the PTO. The Onco-gene's utility is in cancer research as a new genetic tool. This patent was based on the PTO's interpretation that the OncoMouse with Onco-gene was man made.

[103] Diamond v Chakrabarty. 447 U.S. 303 (1980)
[104] See The Supreme Court 2013 decision Summary Chapter 5 below.

On June 13, 2013, the Supreme Court ruled against the patenting of DNA, because the discovery of DNA is a product of nature. Despite the fact that DNA is taken out of the body or organism and has utility, it is not patentable. Essentially, DNA occurring in the body is a product of nature. Only man-made inventions are patentable. Moreover, patenting isolated genes or DNA sequence present in nature violates the principle of Utility. Patenting isolated genes violates the principle of Utility, since the patenting of sequenced products of nature are not created, a "new and useful process... or composition of matter." To recap the conditions of non-patentable discoveries vs. inventions, take for example, discovering the inner working of a gene to expand scientific understanding of biological organisms. This knowledge may be useful, but the knowledge acquired from such a discovery is not patentable, if it does not include some substantial, "specific" and "credible" use (see Chapter 3).

In contrast to un-patentable products of nature, such as acquiring pure scientific knowledge (non-substantial use) of biological organisms, the genetically altered OncoMouse and oil-eating bacterium have new utility and are patentable. CDNA is also patentable. That is, the court ruled that because cDNA does not naturally occur, it is not a product of nature.

Part and parcel to the courts and USPTO support for patents, the defenders of bio-patents, on DNA and life, understand that they must give additional compelling reasons for patent monopoly rights. For example, although Locke's position on the appropriation of nature implies a discovery vs. invention distinction in line with the courts and PTO criteria (manmade), Locke argued above (Chapter 2), persons have a natural entitlement to the fruits of their labor. Locke's argument

is examined below in (this Chapter) Arguments For and Against Genetic Patenting. Over and above the courts and USPTO support for patents, patents proponents must address public funding.

Since public funds are used for genetic research and development leading to bio-patents, the use of public funds for bio-patents on DNA and life also needs to be addressed. I address this issue below in Persons and Moral Dimension Revisited. The patenting of genetic material goes beyond the legal concerns of the courts and the USPTO with regard to addressing genetic mutations and medical therapies. Yes, these patents affect genetically modified oil-eating bacterium able to dissolve crude oil, but also affect public funded discoveries of genes prone to developing cancer, C-reactive proteins as a test marker for the treatment of cardiovascular disease, and new chemical compounds that produce therapies.

Intent of the Human Genome and Gene Patenting

Before addressing additional gene patenting arguments, it is important to remind the reader of the original intent of the human genome project. Unlike our current push to patent genetic material, the human genomic data was originally intended to be placed in the public domain. The genetic fruits of the genome project were considered the common heritage of humanity.[105] This is important because early in the development of the biotech industry, proponents of human gene patenting understood the need to place the human genomic data into the public domain. Addressing new human genome raw data, US President Bill Clinton and the

[105] Jean Buttigieg. "The common heritage of mankind: from the law of the sea to the human genome and cyberspace." (2012), 88.

British Prime Minister Tony Blair acknowledged the importance of making the human genome 'freely available to scientists everywhere'[106]. Here US President Bill Clinton remind us of our duty to share genetic knowledge with all humanity:

> [A]s we consider how to use new discovery, we must also not retreat from our oldest and most cherished human values. We must ensure that new genome science and its benefits will be directed toward making life better for all citizens of the world, never just a privileged few..., we must work simultaneously to ensure that new discoveries never pry open the doors of privacy..., we must guarantee that genetic information cannot be used to stigmatize or discriminate against any individual or group...the human genome must never change the basic belief on which our ethics, our government, our society are founded... Increasing knowledge of the human genome must never change the basic belief on which our ethics, our government, our society are founded. All of us are created equal, entitled to equal treatment under the law...the great truths to emerge from this is that in genetic terms, all human beings, regardless of race, are more than 99.9 percent the same.[107]

The above address was given in June 26, 2000 by President Clinton, Prime Minister Tony Blair and others (via satellite) to assure the US, England and the world that the human genome, among other things, is founded on human values such as ethics, open access and human flourishing. It is up to genetic organizations and

[106] https://www.genome.gov/human-genome-project
[107] Ibid. And here is the speech from the NY Times. https://www.nytimes.com/2000/06/27/science/reading-the-book-of-life-white-house-remarks-on-decoding-of-genome.html

anyone having access to public funds for human genomics, to act on the human values of ethics, open access and human flourishing.

Proponents and critics of genetic material patents both claim to make genomic access easier. As early as 1996, some genetic organizations promoted the patenting of new "processes and products using genes," but other genetic organizations promoted placing all human genome data into the public domain. Many institutions, scientists and individuals understood that the human genome was part of the common heritage of humanity. By placing mankind's genetic common heritage in the public domain, we make the common heritage of humanity accessible to all for "research and development of new products." As stated by Gerald Dworkin, in February 1996, the principle genetic organizations endorsing placing the human genome in the public domain were all Human Genome Organization (HUGO) participants:

> …including officers from, and scientists supported by the Wellcome Trust, the UK Medical Research Council, the USA National Institute of Health, the National Center for Human Genome Research, the US Department of Energy, the German Human Genome Programme, the European Commission, HIGH and the Human Genome Project of Japan[108].

Moreover, in the early days of the gene patent conflict, the Industrial Biotechnology Association (125 companies of which 80 percent members investing in 1992 US biotechnology) opposed the patenting of genetic sequences by the National Institutes of Health (NIH). The reasoning given by the Pharmaceutical

[108] Gerald Dworkin, "Should there be property rights in genes?" Philosophical Transactions of the Royal Society of London B: Biological Sciences, 352.1357, (1997): 1083.

Manufacturers Association was that the licensing of gene sequences would "impede the research and development of new medicine"[109]. To insure all biotechnologies have access to new genomic knowledge, when government support was crucial for the advancement of scientific knowledge, the biotech industry understood the need for open source genetic information.

The intent of the original human genome project can be seen as lost or ignored by the current genetic patent debate; it is parliament for a reasonable understanding of this debate that we explore both interests. As philosophical groundwork, and to better understand the different views, we examine arguments for and against genetic patents where possible. Whether one is or is not a proponent of human gene patents, we need to be reminded that the goal of the human genome project was to make genomic information freely available to scientists and to place all human genome data into the public domain. That is why we need compelling arguments that support the public good, if we are to support patent exceptions to gene patent. In the next section, we return to the justification for genetic patents, beginning with the appeal to the USPTO Guidelines.

Arguments for Genetic Patenting

Now that we have laid out some of the historical groundwork for genetic patents—e.g., the historical views of the courts and the USPTO decisions on patenting DNA and life—we will look at some standard arguments for gene patents.

[109] Rebecca S. Eisenberg, "Genes, patents, and product development". *Science*, *257*.5072, (1992): 907.

There are several standard arguments for human gene patenting. The arguments we will examine next in support of gene patenting are: Appeal to the USPTO Guidelines, Appeal to Utilitarianism and Economic Growth.

Appeal to the USPTO

Some proponents of human gene patents appeal to the USPTO Guidelines for the Examination of Patent for support:

> The requirement for an adequate disclosure ensures that the public receives something in return for the exclusionary rights that are granted to the inventor by a patent. The grant of a patent helps to foster and enhance the development and disclosure of new ideas and the advancement of scientific knowledge. Upon the grant of a patent in the U.S., information contained in the patent becomes a part of the information available to the public for further research and development, subject only to the patentee's right to exclude others during the life of the patent[110].

This passage supports gene patent proponent's appeal to the USPTO claim that patenting promotes science, technological development and discloses new information that may not be available without patents. Patenting, when making genetic material available via the patent process, prevents corporate monopolies on gene information. Some claim that publishing patent information, for example, genetic patent information, shares information that otherwise would not be readily available.

[110] USPTO Guidelines for the Examination of Patent Applications 2162 Policy Underlying 35 U.S.C. 112 (a) or Pre-AIA 35 U.S.C. 112, First Paragraph [R-11.2013], http://www.uspto.gov/web/offices/pac/mpep/s2162.html

A reply: It is true that patents do in fact share patent information via the USPTO process, but does it follow that sharing information significantly advances scientific knowledge for the public? The above phrase "subject only to the patentee's right to exclude others during the life of the patent"[111] make it clear that future scientific advancement is subject to the discretion of companies that are not necessarily interested in the promotion of science, technological development and the sharing of such information. In fact, patents are de facto monopolies whose interests are first and foremost the company or patent holder, not science, technology or the public.

Other gene patent supporter, Sung, claim that intellectual property rights are not concerned with whether inventors gain financial reward. Those who support patents for more than financial reward claim that patents promote "national creativity and innovation … and the public disclosure of the seeds of individual imagination to grow the fruits of societal knowledge"[112].

Reply: There are clear short comings in Sung's position. One shortcoming in Sung's position is that Sung seems to emphasize the distribution of genetic knowledge, which implies that genetic research supports the sharing and expansion of this knowledge. Yet the sharing and expansion of genetic knowledge is not a prominent goal of those wanting to patent genetic material:

> the current environment of corporate contracts (themselves often confidential), trade secrecy, and academic entrepreneurism has changed the

[111] *Ibid*.
[112] Sung, Lawrence M. "It Is Ethical to Patent or Copyright Genes, Embryos, or Their Parts." *Contemporary Debates in Bioethics* 25 (2013): 143.

ethos of science, reducing its ability to contribute unbiased knowledge to public interest matters such as law, policy, and public health[113].

It is well known that, genetic patents are primarily the concern of companies that want to commercialize, monopolize and grow their bottom line. Those concerned with the distribution of genetic knowledge, for the most part, take on careers in pure research. The fruits of pure research, based on the PTO's guidelines, are not patentable.

On the other hand, Research from patents does not just share information, it shares new understanding of the causes and effects of diseases that were misunderstood. Lekovic's view can be used to support Sung's short-coming. Genetic research contributes to our understanding of the causes and effects of diseases that were believed to be non-genetic, e.g., infectious disease. This knowledge is central to the creation of novel therapies that have the potential to prevent, cure or treat previously untreatable conditions[114]. Diagnostic testing increases our understanding and ability to predict late-onset disorders. Knowledge and a basic understanding of possible future disorders can help us determine present choices that will affect our wellbeing. So even in the case of pure knowledge sharing, without patents and patent financing, our understanding of these new causes and effects of genetic diseases would not be shared.

An example of the kind of information, for gene patent proponents, that may not be shared without a patent might be an adult-onset disorder such as Cystic

[113] Krimsky, Sheldon. *Science in the private interest: Has the lure of profits corrupted biomedical research?*. Rowman & Littlefield, 2004.
[114] Lekovic, Gregory P. "Genetic Diagnosis and Intellectual Property Rights: A Proposal to Amend The Physician Immunity Statute." *Yale J. Health Pol'y L. & Ethics* 4 (2004): 275-276.

Fibrosis. Specific information on Cystic Fibrosis (CF) is presented below to underscore the important details of a disease gene that might be held back and not distributed, some say, without patents. The gene that causes CF is a mutation of the Cystic Fibrosis Transmembrane Regulator (CFTR) gene. CF causes a thick, sticky mucus that clogs the lungs. Clogged lungs lead to infection and blocks the pancreas. The blocked pancreas stops digestive enzymes, required for digesting food, from reaching the intestine. The gene was discovered in 1989:

> In normal cells, the CFTR protein acts as a channel that allows cells to release chloride and other ions. But in people with CF, this protein is defective and the cells do not release the chloride. The result is an improper salt balance in the cells and thick, sticky mucus. Researchers are focusing on ways to cure CF by correcting the defective gene or correcting the defective protein[115].

Genetic testing can be used to predict future genetic disease and assess pre-symptomatic disorders like CF in population-based screening. The CF example also underscores the importance of protein production (regulating human health) by genes and the desire by many to control gene patents for future commercialization.

The knowledge gained by biological research is unquestionable and diagnostic testing for late-onset disorders is supported by both proponents and non-proponents of gene patenting. The substantive question is whether, not scientific patents as a whole, but specifically genetic research, protein production and public health concerns can be developed and distributed justly without patent

[115] National Institutes of Health, Accessed December 27, 2013 https://www.genome.gov/10001213/learning-about-cystic-fibrosis/

monopoly. The above arguments supporting genetic patents have not shown nor have they addressed whether science, technological or the public advancement cannot be developed independent of the patent system.

Appeal to Utilitarianism

The utilitarian justification for commercialization and patents on genetic material is based on patents that result in maximizing social benefits (utility) and minimizing non-utility. Some Utilitarian genetic patent proponent[116] argue that gene patents will foster additional future social benefits with good health that promotes happier and more satisfying lives. For example, healthier individuals pay less for health care[117]. The assumption here is, given these current patent law benefits, the patenting of new therapeutic processes or products will not only lead to illness or disability treatments but will promote the public good in that it will produce happier and more satisfying lives.[118] Here again gene patent proponents claim that future social benefits can only come via the protection of the patent system. Consequently, we should allow patents to be extended to human genetics.

Reply: The Utilitarian arguments fail in their claim that future social benefits can only come via patent protection. Although it is true that genetic patents can produce future social benefits, the *healthier individual* argument has not shown logical necessity nor necessary causal connection to positive human gene patenting.

[116] David Resnik, B. "The morality of human gene patents." *Kennedy Institute of Ethics Journal* 7, no. 1 (1997): 43-61.
[117] *Ibid*., 43-61.
[118] Ibid.

Scientific research funding by the National Science Foundation (NSF), for example, is granted independent of the USPTO legal protection via patenting.

Another utilitarian, Lawrence Sung, referring to patents as government grants, acknowledges it is not the case that "government grants conjure creativity and invention where none would have existed"[119]. What genetic patents facilitate is the placing of genetic knowledge and innovation in the public domain. This supports the use of technological information after the "temporary period of exclusivity,"[120] given via patent rights, and not complete ownership.

Reply: Sung's point is well taken on intellectual property as a way to facilitate accesses to genetic knowledge and innovation in the public domain. Sung, however has not advanced the patent proponents position regarding why genetic patents are the best recourse to advance social benefits and technological innovation. Why for example is it not the case that placing all genomic information, say, online for universal access is more effective than patents?

Economic Growth

Some gene patent proponents appeal to economic growth by way of genomic R & D companies. These genomic R & D companies will also discover and create new technologies for gene sequencing, identify disease gene connections to common illnesses and advance biotechnologies (See Appendix E for some examples of Biomedical Applications of Genomics and Human Genome Sequencing). These gene patent supporters maintain public-private partnerships of genetic patents are

[119] Sung, It Is Ethical, 150.
[120] Ibid.

central to human genetic innovation and invention; and will improve the well-being of those suffering genetically based diseases. Public-private partnerships will also improve our economy via biotech markets. For example, Genomic R & D, as with other companies, have invested billions of dollars to obtain genetic patents. Investments by companies like Genomic helps spur medical, pharmaceutical, and agriculture advancements.[121]

Evidence for genomic R & D companies and economic growth can be seen as early as the 1990, where we have seen molecular technology investment improve the world economy. These molecular technology investments spurred growth in agribusiness, biotech and pharmaceutical companies. The year "…1997, provided eight times more capital to U.S. biotech companies than did initial public offerings"[122].

Reply: Genomic R & D and economic growth arguments have their foibles, however. Some examples with companies geared for profit that harm the public good are products manufactured by Monsanto. These include the biochemical weapon Agent Orange and DDT, a chemical commonly used in pesticides, both linked to cancer[123].

In addition to producing products geared for profit, there is delaying research information for profit. An early survey showed that one in five medical scientists delayed research results for publication, by at least a half a year, for financial

[121] Rifkin, Jeremy. *The biotech century*. Sonoma County Earth First/Biotech Last, 1998.
[122] Juan Enriquez. "Genomics and the World's Economy." (1998), 925.
[123] Ali Kanso, M. "World's "Most Evil Corporation"? Evaluating Monsanto's Public Relations in Response to Intense Negative Media Coverage." *QRBD* (2015), 251.

interests[124].The current patent system leaves the use of biotech information to the discretion of the patent holders. By and large, patent holders are indebted to shareholders controlling exclusive rights on who is allowed to make, use, sale or produce the objects from their patents. Patents for profit may foster economic growth but as shown historically with Monsanto, will harm the public without some oversight.

Arguments against Genetic Patenting

Opponents of human gene patenting have many standard objections. First, they argue that the potential for abuse by insurance and health care companies is great. Information acquired from biotech testing is controlled by patent holders and those given the rights to use their patents. Genetic information can be shared and used to discriminate against possible job applicants or to deny health care. The specific concern with regard to genetic patents and discrimination stem from patent holder's control over information gathered from their patients. Patent holders have exclusive control over patient's access to their own genetic information. When an individual participates in clinical research trials genetic information can be shared or restricted. When patent holders grant researchers the rights for genetic research and testing, the results are usually not available to patients or their healthcare providers[125]. For example, "Myriad used its gene patents for 15 years to stop all other labs from offering clinical testing of [their BRCA] genes to determine cancer

[124] David Blumenthal, Eric G. Campbell, Melissa S. Anderson, Nancyanne Causino, and Karen Seashore Louis. "Withholding research results in academic life science: evidence from a national survey of faculty." *Jama* 277, no. 15 (1997): 1224-1228.
[125] NIH Genetic Testing Genetics Home Reference, Oct 24, 2017) *https://ghr.nlm.nih.gov/primer/testing.pdf*

risk" and denied women second opinions from non-Myriad labs[126]. Myriad disallowed the use of its BRCA patent, even in cases where the non-Myriad labs revealed more information than the Myriad labs.

Genetic information is a concern, since the control of personal genetic information and the possible healthcare products derived from a particular person does not reside in the original bearer of the genetic material. The patent system will have to show that gene patent control benefits outweigh the possible costs of abuse. This criticism has been taken seriously by all sides.

Reply: GINA (Genetic Information Nondiscrimination Act of May 21, 2008)[127] legislation has been passed to limit insurance companies and employer discrimination to address genetic information concerns. This Act is intended to ensure that employees etc., not suffer discrimination based on genetic information. GINA legislation bars employers from using genetic information to hire or fire individuals. It also bars health insurance companies from charging higher premiums that are based exclusively on genetic predisposition information that may cause some future disease. The statute and the final rules say that, "genetic information" includes:

- Information about an individual's genetic tests;
- Information about the genetic tests of a family member;
- Family medical history;

[126] ACLU, 2 12, 2015, https://www.aclu.org/blog/speakeasy/myriad-genetics-relents-gene-patents-will-patent-office-stop-issuing-patents-products

[127] Information on Nondiscrimination Act can be found at: http://www.gpo.gov/fdsys/pkg/PLAW-110publ233/html/PLAW-110publ233.htm

- Requests for and receipt of genetic services by an individual or a family member; and
- Genetic information about a fetus carried by an individual or family member or of an embryo legally held by the individual or family member using assisted reproductive technology.[128]

It is important to note that there are tests not covered under GINA. These include "HIV tests, cholesterol tests, and tests relating to drugs or alcohol"[129].

GINA does not cover complete "blood counts (CBC, or blood panels) that do not detect genotypes, mutations, or chromosomal changes." Moreover, HIV tests are not covered:

> Although it is a retrovirus that inserts itself into human DNA, HIV is not itself human DNA, and measuring the presence of infectious agents such as bacteria, viruses, and fungi does not constitute a generic test under the law's definition[130].

The above exceptions have the potential for abuse by insurance companies, since GINA does not cover life-insurance, education and employers[131]. Genetic information not covered by GENA, can be used as "genetic discrimination." Take the case, in 2012, of a school district in Palo Alto California. Colman Chadam was required to leave the school based on his DNA. In this case, the boy was pulled out of class because, when younger, he had tested positive for the cystic fibrosis gene.

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[128] The U.S. Equal Employment Opportunity Commission https://www.eeoc.gov/laws/regulations/gina-background.cfm
[129] Ibid.
[130] The Genetic and Public Policy Center. (2002). http://www.councilforresponsiblegenetics.org/pageDocuments/UZFZDKF4OQ.pdf
[131] Sarah Zhang. "The loopholes in the law prohibiting genetic discrimination." *The Atlantic, March* 13 (2017): 2017.

Cystic fibrosis is a concern for schools because it is a contagious infection. Yet having the genetic markers is no guarantee that one gets the disease. Colman did not have the disease. Nonetheless, Colman was treated has if he had the disease. GINA does not apply in this case because it does not involve employers or health insurance.[132] This is a case for the courts to decide. Given the Colman Chadam case, insurance companies can acquire genetic test information from patent holders. Based on this information, insurance companies can require persons with genetic disease markers to pay higher premiums and or question their eligibility.

Some opponents of gent patents challenge the current system contending that patenting could stifle openness and cooperation, since many companies would be required to pay for patent use and companies are often quite secretive during the patenting process. This can be the case, since the patenting process may take many years.

The arguments for and against gene patenting show the complex nature of genetic patenting. Both supporters and opponents used many of the same arguments. Gene patenting, for advocates of gene patenting, promotes economic and scientific progress. Economic and scientific progress occurs, gene patent advocates contend, because patents create the essential financial investment needed in economic growth, scientific development and healthcare discoveries. Opponents for gene patenting use the same argument.

For opponents of gene patenting, patents stifle economic progress, scientific research and healthcare discoveries and inventions. Economic growth, health and scientific progress are restrained due to patents limiting essential access to genetic

132 Ibid.

information. So, patenting can stifle openness and conversely expand cooperation, knowledge and healthcare discoveries and inventions. Since biotech science is quite new it becomes difficult to know which view will ultimately hold true, if at all. Or whether other views will prevail.

Other gene patent opponents (Koepsell) contend that genetic material and information should be seen as a public "common" and owned by all[133] benefits and information from the human genome should be shared by all humans, since these genes contain characteristics and potentialities derived from one's ancestors. The marketing of genetic information and research creates, for the most part, a for-profit culture. The advantages of genetic research, in a for-profit culture, typically benefit the powerful and affluent (whether they are wealthy individuals, corporations or countries) over the poor and disenfranchised. As seen above, patent arguments from opponents and proponents lack cogency; we need to look elsewhere for axiological guidance on genetic patents.

Moreover, legal patent advocates do little in the way of considering specific overriding moral principles that come into play, irrespective of DNA or any other genetic patentable item. I look to moral reasoning and biomedical ethical arguments such as personal autonomy and human dignity for persons in the following chapter.

The above arguments for and against gene patenting may extend to newfound genes or products. They attempt to distinguish between artificial invented genes and natural occurring genes to support economic and scientific progress.

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[133] David Koepsell, *Who Owns You?: The Corporate Gold Rush to Patent Your Genes*. John Wiley & Sons, (2009), 127-131.

Artificial genetic material is patentable and natural genetic material is not. The artificial vs. natural gene distinction is the patent issue the Supreme Court ruling addressed on June 13, 2013. We will assess the Supreme Court ruling in later chapters. So, in cases in which one finds a new process for creating an artificial (synthetic) gene, the arguments given earlier (McGee above) in favor of gene patenting, may allow for the patenting of both components—the new process and the new artificial gene. However, whether we are considering artificial genes (inventions), natural gene information (discovers), patent law and artificial gene research will have a profound affect to many species as well as persons. The consequences of human genetic research and the protection of personal body rights and genetic material must be considered.

Some Ramification of Genetic Material Patents

The patenting of genetic material has consequences. For example, the outcome of patent monopolies can restrict access of biological material for research. In the OncoMouse patent case, researchers cannot use the OncoMouse without payment or legal agreement from the patent holder. Since Harvard owns the cancer-causing gene (oncogene), it owns all the mammals with its recombinant cancer-causing gene. The patenting of the oncogene has some troubling ramifications. Owning this cancer-causing gene legally means that "biotechnicians can patent organism types that they have never actually produced"[134]. Since Harvard owns any mammal or

[134] Ned Hettinger. "Patenting life: Biotechnology, intellectual property, and environmental ethics." *BC Envtl. Aff. L. Rev.* 22 (1994), 268.

ancestor that contains Harvard's cancer-causing gene, this shows the scope that patent property rights can have on a broad class of organisms.

Patents can be seen as monopoly rights. Patent monopoly rights are granted by governments to patent holders to promote science and technology. But in actuality intellectual property (IP) patents can leads to a reduction in research and product development in "new medicine"[135]. The purpose of these grants is to encourage patent holders to disclose their inventions, as opposed to keeping the invention secret. Ultimately, as I have shown, the USPTO, the standard by which patent law is measured is contingent on public benefit. As is well known, there is more to public benefit than the above arguments suggest. The shift from academic research to private biotech monopoly is clear.

The Commission on Intellectual Property Rights remind us that purpose of the patent system was to stimulate invention. Moreover, it was to provide for an incentive to technical progress. "The emphasis has shifted toward viewing the patent system as a means of generating resources required to finance R&D and to protect investments..."[136] I also what to show that there is a private public harmony found is some courts which both sides need to pursue; as monopolies copyright and patents:

> are neither unlimited nor primarily designed to provide a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved. It is intended to motivate the creative activity of

[135] Rebecca S. Eisenberg. "Genes, patents, and product development." *Science* 257, no. 5072 (1992): 903-908.
[136] Barton, John H. *Integrating intellectual property rights and development policy: Report of the commission on intellectual property rights*. Commission on Intellectual Property Rights, 2002

> authors and inventors by the provision of a special reward, and to allow the public access to the products of their genius after the limited period of exclusive control has expired.[137]

What is glaringly missing so far, regarding principles that address public benefits or public good, is whether genetic material patents can be justified by way of biomedical ethical principles. This is so, because biomedical ethical principles, such as Beneficence, Autonomy and social justice, which we will address later, are used to examine the ethical issues regarding health care, health science, and public/private health policy at the very least.

Given what we know about the justification for the patenting process and arguments for and against the patenting genetic material, we can see that biomedical ethical principles such as human Beneficence and Autonomy[138] are some of the moral underpinnings that must be addressed.

[137] *Twentieth Century Music Corp v Aiken* 422 US 151, 156 (1975)
[138] Tom L. Beauchamp, and James F. Childress. *Principles of biomedical ethics*. Oxford University Press, USA, 2001.

5.0 On Moral Grounds: Beneficence and Autonomy, Court and Patents

In this chapter we have two concerns: Should patent laws be concerned with moral outcomes and can patents be justified via bioethical principles? We address some ways in which laws can influence moral issues. In particular, how can patenting genetic material and testing effect moral outcomes. We also look at whether the patenting of genetic material can be justified via the bioethical principles beneficence and autonomy. But first, we look at the connection between law, morality and some moral access issues in current genetic information by technology companies like 23andMe.

Why consider the value of gene patenting and morality, when the legal system and USPTO does not consider morality to be part of its mandate? "Under current law, there is no moral determination made at the USPTO and a patent

examiner *may not* reject a patent application on moral grounds"[139]. The USPTO Patent Code of 1952 has separated law and morality.

> It is interesting that although the Supreme Court decision concerns human genes, humanness had no bearing on the decision. Nor does the law allow courts to consider whether patenting human genes—or anything else—should be disallowed on grounds of morality[140].

This passage clearly shows the immense disconnect between the Supreme Court decision and moral public policy concerns. In this chapter I take the judiciary and USPTO's lack of moral mandate to be mistaken. Given that there are no moral guidelines established by the USPTO, why consider the value of gene patenting on morality grounds? It is not enough to simply base genetic monopolies and genetic information on legal grounds. Some take an opposing view with regard to excluding morality from the patent process. Ronald Dworkin expresses this view well as "a one system picture: law is a part or aspect of morality"[141] since both require justice and/or fairness.

A central moral concern for gene patenting is that it enables patent holders to deprive persons (humans and other creatures) of the very fundamental genetic material from which they are made, sustained and flourish. The current patent system advances technology at the cost of depriving persons of their genetic information.

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[139] Jennifer McCallum. "The Reality of Restricting Patent Rights on Morally Controversial Subject Matter"." *New En. L. Rev.* 39 (2005) 517-518.
[140] Aaron S. Kesselheim , Robert M. Cook-Deegan, David E. Winickoff, and Michelle M. Mello. "Gene patenting—the Supreme Court finally speaks." *The New England journal of medicine* 369, no. 9 (2013): 869
[141] See Dworkin Justice for Hedgehogs.

Patents take the basic natural genetic material (for example DNA) of life out of the realm of natural personal freedoms, control of public life, and nature. Control over genetic material and information is subsequently given to the advancement of profit, not just for promoting the progress of "Science and useful Arts" as mandated by the USPTO via Congress. The current patent, bioresearch and product development systems need not address individual's moral needs (to deliberate about present and future actions) to access their personal genetic information. As we showed above, in order to obtain a genetic patent, a new genetic product, and earn the right to exclude genetic information to persons, one can artificially manipulation natural DNA. That is, nature's genetic information and the power to exclude others from their genetic information is acquired via patented synthesized DNA. There are, however, those who would counter the above critics of gene patents and attempt to do what is right for their patrons.

Given 23andMe the biotechnology company, with the largest genealogical database of DNA in the world, counters the genetic patent critic's claim to genetic (information) exclusion. 23andMe provide personal genomic information and ancestry directly to consumers for a low fee (as low as $59). 23andMe claim to empower persons and patients by providing genetic BRCA risk information, for example. 23andMe expresses its core values stating that it is good to give persons the means to access their genetic information. Moreover, that "everyone should have...the opportunity to contribute to improving human understanding"[142].

[142] 23andMe, Inc. 2013b. "About Us: CoreValues – 23andMe." www.23andme.com/about/values (downloaded May 12, 2013).

Reply: It is not the case, however, that 23andMe necessarily empowers others to improve their genetic understanding and life. Shobita Parthasarathy challenges the claim that 23andMe necessarily empowers patients and improve their genetic understanding to support life decisions. Giving BRCA risk information to persons without genetic expertise, or access to genetic specialists can undermine a patient's power to make informed medical and life decisions. On the other hand, 23andMe, to assist patrons, does offers by way of 23andWe, a community of users benefiting by a variety of collective experienced users.

Again, as stated succinctly by Parthasarathy a genetic community of varied and collective experiences can decrease empowerment:

> In this [23andWe] system, there is even more potential for disempowerment because users could make health and life decisions based on test results that have not been validated by replicated scientific study[143].

Efforts like 23andMe (and Myriad) who collect user data purporting to improve future services may not be in their user's best interests.

First, what is morally missing from this discussing is that individuals must pay for personal genetic information with little scientific direction as research subjects, undermining their autonomy in seemingly beneficent acts. Finally, patent holders and researchers may continue to have the power to restrict individuals form their personal genetic information.

[143] Parthasarathy, Shobita. "Producing the consumer of genetic testing: The double-edged sword of empowerment," in *Routledge Handbook of Science, Technology, and Society* Routledge (2014) 104.

Genetic searchers are under no obligation to share their research finding with research subjects. This is the current situation, notwithstanding the fact that the deemed "new gene" or gene to phenotype connection, for example, was synthesized from the, now, restricted person's original (natural) ancestor gene. The stance a legal system takes on genetic material has moral consequences. Moral consequences exist irrespective of whether DNA is invented (artificial) or natural (discovered). Genetic information affects the autonomy of persons and can becomes beneficial or detrimental to their health with regard to medical decisions, for example.

To offset possible detrimental health restrictions on personal freedom, the biomedical moral principle of "*Autonomy*" must be considered. "*Autonomy*" is defined "as self-governance or self-determination"[144]. Persons have the right to make their personal decisions with or without the collaboration of a physician or others based on their own values.

Take a hypothetical person, say, Gina and the BRCA1 and BRCA2 mutation gene. Prior to the US Supreme Court's 2013 decision, in order for Gina to become knowledgeable about her possible cancerous BRCA genes she must pay the biotech company Myriad up to $3,120, [145] since Myriad had the exclusive rights to the genes.

Moreover, Myriad did not allow second opinions. Myriad's patents limited Gina's ability to make an informed decision regarding the possibility of having breast and/or ovarian cancer. Myriad, by holding the BRCA1 and BRCA2 patents

[144] Thomas A. Mappes and David Degrazia. "Biomedical Ethics." (1996), 25.
[145] Texas Medical Association: http://www.texmed.org/template.aspx?id=6997 last visited April 22, 2013.

may prohibit (for 20 years) the use, production or sale of their patent for any future health care needs.[146] Although the BRCA1 and BRCA2 mutation gene information has enormous potential for supporting the health and wellbeing of those who may develop cancer, Myriad could act solely on utilizing their BRCA1 and BRCA2 patents for profit. Persons/patients, doctors or the scientific community may not get information on their DNA for personal health care or to make informed decisions about the possibility of having breast and/or ovarian cancer.

The biotechnology industry has replied to these personal health care concerns by stating that gene patents do not grant ownership to the patent holder. Patent holders only have *negative rights*: gene patents only temporarily protect the patent holder against others from commercializing their patent[147]. In spite of a patent holder's negative rights, moral authority and discretion of one's wellbeing is given to the patent holder, again notwithstanding the fact that BRCA1 and BRCA2 are found in all human DNA.

BRCA1 and BRCA2 genes are part of Gina's natural DNA, she is denied access to information and ultimate control of her genes. This violates the biomedical moral principle "*Autonomy*" for self-governance or self-determination.

BRCA1 and BRCA2 patents reduces Gina's health care and future wellbeing to that of "Paternalism."[148] Gina and her physician become children, and companies like Myriad the parents. In the classic case of paternalism, "physicians [considered parents] are expected to promote their [children's] patient's well-being, but nothing

[146] Myriad has allowed for some BRCA research.
[147] Mark Sagoff."Patented genes: an ethical appraisal." *Issues in Science and Technology* 14, no. 3 (1998): 37-41.
[148] Thomas. Biomedical Ethics. (1996), 51-54.

is said about a patient's right to define his or her own well-being or to participate in decisions affecting it."[149] Gene patenting promotes a paternalism that lacks respect and dignity for person and patients.

Although patent holders can restrict patient information form bio-researchers and physicians, physicians can no longer ethically withhold information from patients. They must "make relevant information available to patients, colleagues, and the public, [and] obtain consultation..."[150]

Furthermore, the principles of medical ethics state that the physician shall provide "competent medical care, with compassion and respect for human dignity and rights."[151] Unlike the USPTO patent system, medical ethics is not based on promoting the progress of "Science and useful Arts" via patenting. As argued above, patenting genetic material has violated the biomedical ethical principle of autonomy. It must be said, biotech information companies continue to evolve and that 23andMe, to it its credit, was one of the first to provide valuable genetic information to the general public. More to the point, often, it is not just the actions that one performs, but how one fulfils the actions that one brings to completion that makes an empowering difference. Making relevant genetic information available to patients with validated scientific information, competent medical care, compassion and respect for human dignity and rights promote furthers public empowerment as well as public good.

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[149] Ibid. My brackets.
[150] Frank A. Riddick Jr. "The code of medical ethics of the American Medical Association." *The Ochsner Journal* 5, no. 2 (2003), 9.
[151] American Medical Association (AMA), Principles of Medical Ethics: http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.page. Accessed April 29, 2013.

Beneficence and Autonomy

Biomedical ethics is concerned with ethical principles such as human dignity and beneficence. Historically and culturally, David Hume informs us, morality resides in human sensibilities and nature:

> The quick sensibility, which, on this head, is so universal among mankind, gives a philosopher sufficient assurance, that he can never be considerably mistaken in framing the catalogue, or incur any danger of misplacing the object of his contemplation: he need only enter into his own breast for a moment, and consider whether or not he should desire to have this or that quality ascribed to him…[152]

We cannot ignore our desire to act morally. As Hume argues, beneficence is based on humanity's obligation to reciprocity. Our responsibility to act morally comes from the benefits given to us via experienced reciprocity through social interaction.

The USPTO patent system is part of our social reciprocity. Social reciprocity is experienced as "sentiment or reason," and is central to Hume's argument for our obligation to act morally and cannot be separated from human interaction.

> A MAN who retires from life does no harm to society: He only ceases to do good; which, if it is an injury, is of the lowest kind. – All our obligations to do good to society seem to imply something reciprocal. I receive the benefits of society, and therefore ought to promote its interests… [153]

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[152] David Hume. "An Enquiry Concerning Human Understanding, ed. By PH Nidditch." *Enquiries Concerning Human Understanding and Concerning the Principles of Morals* (1975), 174.

[153] David Hume. "Of Suicide," in Essays Moral, Political, and Literary, ed. Eugene Miller (Indianapolis, IN: Liberty Classics, 577-89.

We return generous conduct toward us, for example, with appreciation. The reciprocity of beneficent acts is an essential part of social life. Persons are the product of benefits received from others. Persons are not independent of medical health givers. Biotech researchers are not independent of patients. Biotech and biomedical research are dependent on the needs and market economy of medical patients. The USPTO patent system's claim to act (solely for Science and useful Arts) independently of biomedical ethics, based on an independence that should not consider the possible negative or positive ramification of other persons, is de facto improbable subject to legal rights or not . USPTO decisions are encapsulated in moral outcomes.

In addition to the USPTO patent system's lack of concern for morality, regarding the patent criteria and the moral ramifications of gene patenting, the USPTO does not consider the respect of human dignity or beneficence for persons and patients. For example, the USPTO can, in principle, patent a useful or non-useable medical genetic product etc. Its control over patents is agnostic as to whether the product will ever be used to save lives – just as long as it follows USPTO guidelines. The USPTO allows for the patenting of a car speed radar detector with no regard to the fact that it is unlawful to use the speed detector, or whether restriction and uses of a patent will be accessible to enhance file.

In reply to, what seems, complete patent control by USPO, and patent holders one can appeal 1980 Bayh-Dole Act:

> The Bayh-Dole Act...provides federal agencies with "march-in rights," codified at 35 U.S.C. §203. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the

patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself[154].

The conditions for Bayh-Dole March-in rights span from cases in which a "contractor or assignee has not taken or is not expected to take within a reasonable time... [actions] necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees...to domestic manufacture [that are] not commercially feasible"[155]. Bayh-Dole March-in rights can put a limit on the control given to USPO and patent holders. Notwithstanding the Bayh-Dole March-in rights, currently its use is in question. According to Parthasarathy "...the 1980 Bayh–Dole Act gives the US government 'march-in' rights in the case of taxpayer-funded research, although it has never been used in this way"[156]. Although, some have addressed ways to attract private companies and the

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[154] John, R. Thomas. *March-In Rights Under the Bayh-Dole Act*. Congressional Research Service, (2016) Summary.

[155] Codified at 35 U.S.C. §203, the Bayh-Dole Act specifies four circumstances under which march-in rights may be exercised must reach are:

> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
> (2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
> (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
> 4) action is necessary because the agreement required by section 204 [generally requiring that patented products be manufactured substantially in the United States unless domestic manufacture is not commercially feasible] has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

[156] Parthasarathy, Shobita. "Use the patent system to regulate gene editing." (2018): 486. https://www.nature.com/articles/d41586-018-07108-3?fbclid=IwAR16fIHBUr9TxVYuv6u7FlSMhvjhrgZ0597j8ov-_g71SrfN3rAzon4_snw
And Eberle, M. *Marquette Intel. Prop. Rev.* **3**, 155 (1999).

government to do biodefense research,[157] it is not clear how march in rights work for other kinds of access to genetic information.

Some have argued (President's Council on Bioethics) that gene patents violate the moral principle of human dignity.[158] Chuang and Lau summarize many of the main points against human gene patents and human dignity as follows;

> Ethical and moral arguments against human gene patents are based on the premise that the human genome is qualitatively different from other naturally occurring things, and even distinct from the DNA of other plants and animals. Therefore, human dignity should prevent anyone from owning patents over human genes. After all, if the human genome is part of human's common heritage, and if each person has an inalienable right to ownership of one's body, including one's genes, what right does any one person have to own part of the genome? [159]

Let us consider the human genome qualitative similarities. Is the human genome qualitatively different from other naturally occurring things? In one sense humans and other natural living things are not different. Living organisms store genetic information. These organisms use the same molecules DNA and RNA. We all have much of the same nucleotides of DNA: adenine (A), thymine (T), cytosine (C) and guanine (G). These nucleotides are the structural components of DNA and RNA in

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[157] Pertruzzi, Heather. "The Missing Link: The Need for Patent Protection in the Development of Biodefense Vaccines." *Pub. Cont. LJ* 37 (2007): 71.
[158] Leon, E. H. Kass, Blackburn, R. S. Dresser, D. Foster, and F. Fukuyama. "President's Council on Bioethics." *Beyond Therapy. Biotechnology and the Pursuit of Happiness, Washington* (2003). Timothy Caulfield. "Human cloning laws, human dignity and the poverty of the policy making dialogue." *BMC Medical Ethics* 4, no. 1 (2003), 3. Michael Walzer. *Spheres of justice: A defense of pluralism and equality*. Basic books, 2008.
[159] Chuang, Chester S., and Denys T. Lau. "The pros and cons of gene patents." *The Recorder, December* (2010), 3.

all living organisms. Nevertheless, there are differences. Although all humans have the same genes (99.9%), the difference found in humans is due to each person's (personal) sequence of DNA. Chimpanzee genes are about a 98% match to human DNA or genes; a mouse around 92% and yeast 26%. When considering human dignity and bodily rights, there are good reasons for looking beyond the close percentages in the DNA structure of different living organisms. In the next section we consider important issues that go beyond the close percentages in the DNA structure of different living organisms and consider rights to ownership claims.

Dignity, Universal Human Rights and Bodily Rights

The obvious issue is not the genetic similarities and differences found in animals and other naturally occurring things. Different organisms do share the same kind of DNA. The ethical and moral dimension of this argument is predicated on what kind of outcomes are formed from the DNA or genes present in each kind of naturally occurring organism.

One standard philosophical view is that persons have qualities that other kinds of things do not, for example, reason. This view when applied to the human genome is the view, given the appropriate attributes or genetic structure of an organism, the appropriate attributes produce intelligence; intelligence gives humans dignity. Intelligent individuals are autonomous agents. Autonomous agents govern themselves in accordance with universal valid moral principles (Kant, 1785). This does not discount the possibility for considering the dignity of other organisms. The important point here, given we assume the importance of intelligence with regard to DNA/genes, is that unlike other organisms the structure of the human

genome produces dignity for autonomous agents who require access to their genetic information.

Genetic information assists agents with regard to human axiology and in the deliberation of future moral actions. Dignity and diversity of choice are internationally recognized as inherent in the Human Genome and the fundamental unity of all members of humanity. In addition to Chuang, & Lau's assessment of human dignity, there are two international declarations for human dignity. These declarations are the Universal Declaration on the Human Genome and Human Rights UNESCO and the 2000 Helsinki Declaration article 5. The 1997 article 1. The Universal Declaration on the Human Genome and Human Rights UNESCO, regards the human genome as:

> ...the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity...In a symbolic sense, it is the heritage of humanity. [160]

Moreover, there is the 2000 Helsinki Declaration article 5 addressing human subjects engaged in medical research. The declaration states that:

> In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.[161]

It should be noted that the 2013 Helsinki Declaration of International Code of Medical Ethics has dropped its 2000 declaration "human subject precedence"

[160] Noelle Lenoir. "Universal declaration on the human genome and human rights: the first legal and ethical framework at the global level." *Colum. Hum. Rts. L. Rev.* 30 (1998): 537.
[161] World Medical Association - 2001 https://www.who.int/bulletin/archives/79(4)373.pdf

language. Although the 2013 Helsinki Declaration now states… "It is the duty of the physician to promote and safeguard the health, well-being and rights of patients," those who oppose gene patenting can hold to both 2013 and 2000 Helsinki Declarations.

The Helsinki Declarations make human dignity a basic criterion for ethical conduct regarding medical and life sciences, especially regarding research in human genetics. The 2013 Universal Declaration on the Human Genome and Human Rights UNESCO make it clear that human dignity acknowledges that human genes are the heritage of humanity, and that human "health and well-being should take precedence over the interests of science and society" respectively. These acknowledgements of dignity, at the very least, imply a respect for the rights of human ownership of their body. That is to say, one's body can be seen as central to one's health and well-being, not excluding psychological factors as part of possible phenotypes.

With regard to persons having rights of ownership of their body, US policy on the commodification of genetic property is inconsistent. The National Organ Transplant Act (NOTA), title III bans the sale of whole persons, body parts and organs:

> It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.[162]

[162] National Organ Transplant Act, 42 U.S.C. § 274e (a) (2000).

This passage can be seen as reflecting the dignity of persons and their body parts. In contrast to human organs, bone marrow, ova and sperm are legally commodified.

With regard to human rights and dignity, Caulfield et al, set a working definition for human dignity as:

> ...human dignity is an engine of individual empowerment, reinforcing individual autonomy and the right to self-determination."[163]

For some (Mapow and Rao) the rights of ownership and autonomy one has over one's body is better thought of as privacy rights.[164] For example, a woman is free from undue state interference in cases dealing with the termination of a pregnancy. Also, feminists have been critical of "the mining of women's bodies as the recourse" for human embryo stem cell research.[165]

But as we know these rights are not always clear and have limits. In the often-cited case of *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990), the California Supreme Court considered whether John Moore had property rights over his cells or products of his body. The court denied John Moore's claim for property rights over his cells or products of his body. The court ruled that individuals have no rights to share in commercial profits produced from research conducted on individual's biospecimens.

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[163] Timothy Caulfield, and Roger Brownsword. "Human dignity: a guide to policy making in the biotechnology era?" *Nature Reviews Genetics* 7, no. 1 (2006), 72.
[164] David A. Mapow. "Do people have ownership over their body parts and if so, can the state control their ultimate disposition in the interest of public health and safety." *Rutgers JL & Religion* 16 (2014), 118. Radhika Rao. "Property, privacy, and the human body." *BUL rev.* 80 (2000): 359.
[165] Rose and Rose. *Genes*, 236.

In light of the lack of guidance and consistency in US policy on the commodification of genetic property and rights, we turn to David Resnik's[166] specific argument regarding the violation human dignity and DNA patents. Resnik argues that DNA patents do not violate human dignity. According to Resnick, for DNA patents to violate human dignity they would have to treat people as complete commodities, analogous to human servitude, which they do not. Patent rights are rights of exclusion, not complete rights to suit the patent holder's desires. DNA patents do not violate human dignity, inasmuch as patent holders do not have full ownership rights over persons. As we now know, patent rights do not grant positive rights:

> ...to use, make, or commercialize human beings, because all of these activities are currently illegal."[167]

Gene patents do not confer complete ownership of genes to the patent holder. Patents only provide temporary legal protections against attempts by other parties to commercialize the patent holder's discovery or invention.

Resnik concedes that since the human genome has "strong causal and axiological connections" to persons, holding patents on a whole genome enabling the patent holder to generate a human embryo, potentially developing into a person, would violate human dignity. One way to look at Resnik's argument, which is to say that patenting DNA (i.e. human person parts) is not the same as patenting and controlling a person. DNA patents do not violate human dignity, since they only have control over parts of a person. Patents do not have power over persons.

[166] Resnik, "The morality," 43-61.
[167] *Ibid*, 113.

I will address this part in relation to the whole argument later and will argue that there are additional ways to violate human dignity via parts. Here I consider the artificial genes and/or body parts argument, since Resnik uses this argument to support his claim that DNA patenting does not violate human dignity.

Based on the USPTO's pre 2013 Supreme Court's decision, *artificial* invented genetic material is patentable. Genomic DNA (gDNA) can be patented as isolated complementary DNA (cDNA), removed from the encircled genome. According to Resnik, the patenting of DNA sequences, fragments or sets of genes does not violate human dignity. Gene patent does not violate human dignity because DNA sequences, fragments or sets of genes do not have the same moral and cultural status as does the whole genome and the human being. In 2013 the Supreme Court upheld Resnik's claim that artificial cDNA is patentable. But the court also held that natural isolated genomic DNA (gDNA) is not patentable. DNA in the nature/body cannot be patented.

Resnik argues that the control one has over gDNA and cDNA, by way of patent ownership, is analogous to one having control over purified or isolated DNA. Embodied DNA is not artificial DNA. Embodied DNA is in its natural form, whereas purified and isolated DNA are artificial forms created from natural DNA. Patents on DNA apply to purified and isolated DNA; hence DNA patents do not apply or have any control over living or natural DNA. Again, what constitutes artificial DNA as patentable is that artificial DNA has been created, made or formed as something new when purified or isolated. This artificial DNA does not apply to the whole genome, and as Resnik makes clear:

> …the intimate connection between the person and their DNA only holds between the whole genome and the person; it does not hold between parts of the genome and the person.[168]

The argument goes: at the very least, if not for the biotechnical purification and isolation, this artificial DNA and its qualities would not have existed. But what is central to Resnik's argument is whether patenting DNA, i.e. human (person) parts, results in one having control over or commodifying whole persons.

The moral principle Resnik appeals to is DNA patents violate human dignity only when one controls the whole person. Patents on DNA only control parts of persons and "would not violate human dignity because these small parts of the genome do not bear a special causal or axiological relationship to the person" (ibid).

For Resnik, there is no special causal or axiological relationship to persons and DNA and human parts. We do not attribute the same degree of "moral or cultural" importance to single or fragments of genes as we give to the whole human genomes. Nor can the patent holder use individual or fragment genes to produce an embryo with the potential to control and produce a person.

Is it the case that small parts of the genome do not bear a special causal or axiological relationship to the person? In one sense, Resnik quite rightly points out that owning the patent on a whole genome, or owning each cell of any multicellular organism, does not give the patent holder the control of the whole of that multicellular organism. For example, Resnik can claim that one can hold patents on the whole of the human genome, yet not control a whole person's right to choose

[168] Resnik, "Owning," 120.

basic everyday issues. This is analogous to a car company owning all the parts of some car model and not controlling the use of the car as a whole. How a car or organism performs or used is independent of who can buy or sell their parts.

Let's consider another possible principled case. Given this part to whole argument, we can consider a case in which one may own a part of some whole and consider whether that part may control the whole. Say a company Gbrain has mapped the human brain and found the location and specific DNA segment that gives persons their ability to make reasonable decisions. Since Gbrain artificially synthesized this DNA, call it the *reason gene*, Gbrain can patent and restrict information on the *reason gene*. One may be prohibited from one's *reason gene* information. For example, say, a person Ms. X has the *reason gene*. The patent holder can control information on Ms. X's *reason gene*, with respect to determining whether she has diminished capacity. That is, if Gbrain so deems, persons can be restricted from any information about their *reason gene*; they can be tried in a court of law with incomplete knowledge. For one to be restricted from knowing whether one has diminished capacity as a defense places one's life in the uncertain position of whether they may be executed or live.

One may challenge the Gbrain case as follows: given the present state of brain neurology it is unlikely that we will find a single gene that accounts for a person's capacity to reason. Gene neurons work together as a connected system with other neurons in that "circuits *working together* form specialized *brain*

systems" (National Institute of Mental Health) and not, as once was thought, as exclusive compartments of function.

This connectionist challenge, however, does not exclude cases in which one may hold most of or the significant parts of the *reason gene system* that enables human reasoning. In this case one does not possess patents on all parts of a person's complete genome, but only on parts of the *reason gene system*.

The patent holders of the additional gene parts can restrict access to others for completing the reason gene system and rational function. Patents on one gene or many genes restricts patient information from bio-researchers, doctors or on patients that impacts their live. The principal point here is that parts of persons can affect persons as a whole.

The above Gbrain hypothetical case is of particular interest in light of the current research on the g factor or general intelligence, also known as general cognitive ability (GCA). GCA is viewed to effect mathematical and vocabulary abilities as well as the complex abilities needed to navigate everyday life. These abilities affect "various social pathologies (such as criminal convictions), and even health and mortality" (McGue, & Gottesman, 2015; Gottfredson, 1997). One of the most widely research issues by behavioral geneticists has been on CGA and its correlation to low IQ.

CGA research shows a relationship between intellectual disabilities, and multiple "genetic and environmental factors" McGue, & Gottesman, 2015). It is clear that knowledge of the role that genetics and environments play in CGA can assist in understanding its origin and possible therapies. GCA is human capital that

drives societies and is important, not only for neuroscience and behavioral geneticists but for government policy makers.

In contrast to possible therapies, policy makers, employers and educational institutions may choose to consider GCA as a significant predictor of person's dispositions and individual differences. Difficulties that presuppose unwanted caricature in persons and their future opportunities. GCA studies may influence governments, legal criminal systems and public or private institutional policies. The above arguments for gene patents fail the autonomy principle because these arguments do not address the possible abuses due to gene patents.

Persons and Moral Dimension Revisited

Some may challenge gene patents with the following argument: if one believes in copyrights, say, a novel or some form of nonfiction, then they should allow the patenting of genes. Owning a copyright on a text or book is noncontroversial. Book information may also be expressed in the form of entertainment. Nevertheless, this copyright argument is dis-analogous to the patenting of genes. Both fictional and nonfictional texts contain information.

In the case of nonfictional books or texts, information may be expressed to produce the transfer of knowledge or treasured principles. The holder of a book copyright cannot restrict the uses or commodification of the actual product after sale (used book) or principle she has described.

As with the case of genetic information as nature and patents, it is clear that one cannot own or patent products or principles of nature. As in the case of copyrights, one can only copyright the description or expression of a product of

nature: abstract ideas or physical phenomena. But products or concepts of nature cannot be patented.

The genes in the human genome patent dispute is not just concerned with genes related to healthcare. When one patents a gene, one patents the natural intrinsic self-generating information code ISIC. That is, one does not patent the artistic expression of a gene, but instead has a monopoly on the genetic information itself - the type and not the token gene. Genes are not just chemical compounds or bluebooks for the creation of life. They are molecules necessary for carrying information of themselves: embodying information about their own molecular structure, and how to string together its double-stranded backbone of DNA.

Gene or DNA instructions or information is not a blueprint of information per say. It is not a scaled-down version translated into a lower set of dimensions of something. "There is [no] one-to-one correspondence between features of the blueprint and features of what it is a blueprint of."[169] Gene or DNA instruction information is more like a 'recipe' in that the "*differences* in instructions correspond to *differences* in the product." But there is more to Gene (DNA) information than just a recipe. It seems to me that the correct configuration of DNA, and the presence of that DNA, implies that the DNA is a necessary ingredient. That is, it is an ingredient for a particular outcome, given the appropriate environment.

These genes (DNA) are necessary as an intrinsic self-generator for persons and phenotypes. As a possible generator for a person's genes and their use, genes

[169] Mathieu Queloz. "The double nature of DNA: Reevaluating the common heritage idea." *Journal of Political Philosophy* 24, no. 1 (2016).

have a moral dimension. David Koepsell reminds us of our moral responsibility with regard to gene and our continuous personhood:

> If we can locate not just the qualities of personhood philosophically, but the sources of personhood genetically, then we can exercise better ethical judgement where tricky decisions might be made about potential persons.[170]

Although we have not reached a scientific understanding of the "genetic roots" of personhood, it is not reasonable or wise to permit the restrictions of patent law on potential personhood genes.

The differences in humans/persons and other species is not just in the percentage of similar genes found in relation to each other or copyrights on information. One important difference in gene species is the outcomes that the genes produce. We must be morally concerned with genes that have the potential to produce persons and their qualities. We are not concerned here only with parts of a person that Kant may allow, for example "amputating one's own leg in order to save one's life."[171] We are also concerned here with the effects these gene patents will have on the quality of a person's life over time.

Patenting genes from the human genome as we know pertains to the wellbeing of persons and means that persons have lost *autonomy.* For Kant the loss over *autonomy* results in losing that which gives persons value and responsibility,

[170] David Koepsell, "*Who,"* 69.
[171] Resnik. "Owning," 99.

via their will and practical reason. Morality is an aspect of rationality by which we are conscious of rules or laws of behavior:

> Rational beings...are called persons because their nature already marks them out as ends in them self—that is, as something which ought not to be merely as a means—and consequently impose...a limit on all arbitrary treatment of them...for unless this is so, nothing at all of absolute value would be found anywhere.[172]

Without practical reason there would be no law as we know it. It is a person's ability to reason that enables individuals to understand and create biotechnology patent law and moral principles. Reason is a necessary condition for the creation of biotech and patents, since without it we would not be able to understand or implement science, laws or morality. The mere promotion and progress of "Science and useful Arts" via patenting, void of moral principles, negates the value of personhood and human dignity. Furthermore, reason via a person's actions is the foundation by which persons are deserving of approval and admiration.

Aristotle instructs us, reason is the foundation by which persons are blameworthy and praiseworthy:

> ...virtue is concerned with passions and action, and on voluntary passions and actions praise and blame are bestowed...then, what has been decided on by previous deliberation? At any rate choice involves a rational principle and

[172] Immanuel Kant, and Herbert James Paton. *Groundwork of the metaphysic of morals. Translated and analysed by HJ Paton*. Harper & Row, 1964, 428.

thought[173].

Persons are responsible (can be blamed or praised) for their actions precisely because they are rational agents who can act voluntarily and reason about possible outcomes and consequences that follow from their actions.[174]

Additionally, our laws assume persons are rational and free to choose their own actions. For example, it is well known in the legal system that if a defendant can show she has diminished capacity, she is eligible to be convicted for a lesser crime. In the case in which a defendant can show that they are legally insane they would not be guilty by reason of insanity. So, if it were lawful to patent genes relating to rationality, there must be moral restraints on these gene patents. The moral restraint on rational genetic patents is the moral principle "*Autonomy*" and respect of persons.

Proponents for gene patenting may argue that if not for their patent technology, important gene information would not be available. However, they must concede that if it were not for the existence of natural genes in humans, appropriate biology and rational *Autonomy,* the genomic industry would not exist.

It is important to remember that currently the only way anyone can attain information on their natural genes, say, for healthcare or to enhance one's

[173] McKeon, Richard. "Nicomachean ethics." *The basic works of Aristotle* (1941), 964-969.
[174] See also Charles, 1984.

wellbeing, is through access to their biological information. And currently this information can be patented and restricted via the patent holder or researcher.

There is no moral issue for patenting a new Art-DNA process or invention in general. What is at issue is the patenting of Art-DNA products which have the same ISIC as natural DNA. In principle, if *Autonomy* of persons is lost via gene patenting, one can be deprived of control, information and DNA testing concerning their personal capacity to reason and be responsible. A person's reason and responsibility, i.e. blameworthiness and praiseworthiness can be given to the discretion of the patent holder.

Let's look at the specific case in which pharmaceutical companies restrict access to patented drugs. For example, billions of people are denied access to essential lifesaving medication. "The World Health Organization (WHO) estimates that 15 percent of the world's population consumes over 90 percent of the world's production of pharmaceuticals." The global poor are excluded from essential medicines and vaccines due to the high price of patent drugs.

Global companies such as Bristol-Meyer-Squibb, Johnson and Johnson, Merck, and Pfizer crafted the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The explicit goal of the agreement was to prohibit "free trade of low-price generics from the emerging pharmaceutical industries in developing countries,"[175] TRIPS is a global bilateral intellectual property trade agreement crafted on the US model. The above small number of global companies do not simply find themselves confronted with the problem of global access to medicines,

[175] Kevin Outterson & Light, D. W. (2010). Global Pharmaceutical Markets. In Kuhse, Helga, and Peter Singer, eds. *A Companion to Bioethics*. John Wiley & Sons, (2013), 424.

they assisted in the creation of a system to block poor developing countries from generic production activities.

The patent-based drug companies achieve their goal by way of applying for patents in the markets of developing countries and blocking generic drugs. The actions of these patent-based drug companies are particularly egregious, since there has been a long standing "tradition around the world of exempting medicines from patent laws"[176] (ibid). No drought, pharmaceutical companies have created many important benefits for individual persons and human healthcare. The patent-based drug companies bear more than a casual responsibility. They are beneficiaries of the global system they have fashioned. As active participants and beneficiaries of the global system to exclude the poor from low-priced generic drugs, these companies are the creators of the problem not "innocent bystanders."[177]

Moreover, Donald Light underscores the fact that the biotech industry holds some responsibility, not only to its shareholders, but to the pubic based on governmental and public financial contributions to biotech R&D:

> …the global estimate for basic research to discover important new pharmaceutical products is US$ 52.7 billion for 2001. This equals 54% of the total US$ 105.9 billion global estimate on all health research. Governments and the public contribute 84.2% of the world's basic research budget for health, industry contributes 12%, and private non-profit sources contribute 3.8%...In conclusion, while it is true as *Monitoring Financial Flows* states that

[176] *Ibid*.
[177] *Ibid*.

> "The private for-profit sector is the largest investor globally", the public sector is by far the largest investor globally in basic research to discover important new drugs and vaccines178 (Light, 2010, p.34).

The above taxpayers' subsidies to the biotech R&D industry may actually be higher (ibid). The biotech R&D industry, the private for-profit sector, and the patent-based drug companies hold some responsibility to insure more public access to bio information and to make free trade low-price generics available. This is the case, since pubic funds account for half of the global R&D medicines. With regard to the discovery of new medicines, 84% of all global funding comes directly or indirectly from public funds[179] (Outterson & Light, 2010; Light, 2006; Outterson, 2008).

In this chapter we found that genetic patents could not be justified on logical or moral grounds. Although, biotech companies do bring about human benefits and proponents argue that their industry is in the public interest, they do not necessarily promote the moral principle "*Autonomy*" and respect of persons. We now move on to the question of justice and the distribution of genetic technology.

[178] *Ibid*, 34.
[179] *Ibid*.

6.0 Justice

Just distribution of genetic technology is not merely a matter of what constitutes a just ownership of genetic material; it is an issue of distributive justice, one's self interest and social issues with regard to genetic health care access, for example as the benefit or well-being of the pubic (public good). In is chapter we began with Locke and Nozick's libertarian justification for genetic ownership. We reexamine Locke and Nozick's libertarianism here, since it is the standard torchbearer for property rights (Locke is one of the three general forms supporting moral justification for intellectual property). If the justification for the appropriation of property is inconsistent with its foundational principles, the justification for the appropriation of property is inconsistent. Locke and Nozick's libertarian justification for the appropriation of genetic material is based on the "Lockean proviso" that

others are not made worse off. We find the appropriation of genetic material worsens genetic access to others. Locke and Nozick's libertarian justification for the appropriation of genetic material is unsatisfying, since it is inconsistent with its "Lockean proviso".

Subsequently, we move on to examine the distribution of genetic technology as genetic justice in light of Rawls's more robust theory of justice. We consider possible alterations to Rawls and the distribution of genetic technology, not just to combat genetic diseases, but to have access to genetic enhancement.

Here we also examine additional Lockean libertarian views such as Moore's appropriation argument and move on to attempts by Farrelly to shore up some Rawlsian problems. We examine principle rights granted to inventors based on a Lockean labor theory of property. Finding these libertarians faulty, we settle on a capability theory of justice as a future way to support genetic distributive justice.

Appeal to Libertarianism

Libertarian arguments and their implications for gene patenting such as the USPTO Guidelines principles, "rights that are granted to the inventor," can also be seen as a Lockean labor theory of property, or natural rights argument that spurred libertarianism[180]. Locke's arguments provide support for the view that one can appropriate the fruits of their labor and share information when no one is robbed or disadvantaged. For example: "Locke's classic property theory provides a useful

[180] Buckle. *Natural.*

mechanism for adjudicating between claims about how best to ensure that individuals will be able to continue to access information..." [181]

Tavani is concerned with access to information, the commons and intellectual property rights (IPRs). According to Tavani, by applying Locke's theory to the current IPR debate we can avoid "overly-strong copy right laws" that diminish access to information once open to the public domain.[182] Copyright laws are justified to the extent that they do not unfairly diminish ordinary individual access to information commons.

These contemporary issues are good reasons to begin with Locke's view that no one should be disadvantaged or worse off (Proviso), via the appropriation or patents on worked nature. That is, whether we are dealing with natural physical objects, information, or genetic information commons we have a standard for appropriation—the taking of something for one's own use. The standard is: the taking of something for one's own use should be beneficial for humanity, and other individuals should not be worse off in the course of a property right appropriation.

For John Locke, as argued above, property rights are given by God as a common belonging to mankind to be shared for his preservation.[183] Hence, society has an obligation to honor man's property rights. Humanity has rights over their person, labor and the works of their hands. So, as early as Locke we can see the beginnings of a distinction between inventions and discovery for property rights.

[181] Herman Tavani T. "Locke, intellectual property rights, and the information commons." *Ethics and Information Technology* 7, no. 2 (2005), 87.
[182] *Ibid*., 96.
[183] Locke: *Two treatises*, 26.

First, property can be seen as a common to be shared, discovered, non-patentable or appropriated. Again, given certain conditions, when property is altered property can be seen as an invention and appropriated, or as in our time patentable. According to Locke's CRVP, the origin of property rights (the possession of something) comes about when man mixes his labor with objects commonly found in nature. By mixing one's labor, one adds something, creates something new and excludes the rights of appropriation by others. For Locke, since others lose their rights to their share, one must justify the appropriation of a divine given common. To ensure that no one is robbed or disadvantaged, one's share cannot be more than one can use or waste. Above we see Locke addressing possible disadvantaged to other individuals, and the start of a standard for genetic justice. That is, genetic justice is to be seen as: in the appropriation of genetic material no individuals are to be worse off.

For Locke and Nozick property ownership is justified by what Nozick coined a "Lockean proviso" (Nozick, 1974), that others are not made worse off by the appropriation of some object:

> … I venture to assert boldly that if it weren't for just one thing the same rule of ownership—namely that every man is to own as much as he could make use of—would still hold in the world, without inconveniencing anybody….[184]

One's obligation is to ensure that one used their new appropriated fruits. The fruits of their labor were not allowed to be spoiled, for otherwise they took more than their share and in essence robbed others.[185] Let us now look to a particular

[184] Locke: *Two treatises*, 36.
[185] *Ibid*., 46.

Lockean argument given by Adam Moore and Moore's justification for the appropriation of genetic property and information.

Moore's Lockean Argument for Genetic Appropriation

Moore's[186] appropriation argument can be reduced down to Lock's NWOP principles (Not Worse Off Proviso) and overrides genetic property rights, genetic privacy rights, and genetic personal information. The Lockean aspect of Moore's argument asserts that genes and genetic information are a type of property and as such are subject to the principles of property rights. If the appropriation of "intangible work" makes the well-being of others no worse-off after the appropriation, then the appropriation is permitted.[187]

Moore's argument for the appropriation of genetic material begins by asserting that almost all advancements in medicine were first available to the rich. Investors and companies devote countless hours and resources to create or discover new medical procedures for profit. Medical procedures and advancements that were cost prohibitive in the past altimetry become available for everyone. "If this system yields everyone better prospects in the end, the resulting initial inequality of distribution is hardly objectionable."[188] Furthermore, regarding the system of initial inequality and genetic appropriation Moore contends:

[186] Moore. "Owning genetic."
[187] Moore, "Owning," 103.
[188] *Ibid*., 117.

> There is no reason to think that Genetic enhancement procedures won't follow this same course. In fact, our entire market system seems to necessitate this kind of inequality.[189]

Moore's argument *necessitates* an initial inequality and genetic appropriation in order to bring about genetic benefits for ever one. Moore ultimate concludes, based on past genetic benefits following from initial genetic access inequality, that the appropriation of genetic property rights, genetic privacy rights, and genetic personal information is justified.

There are, however, good reasons to reject Moore's appropriation argument, since his system of initial inequality does not consider alternate cases. It is reasonable to "reject Moore's proposal because the baseline comparison does not consider all the viable alternative scenarios."[190] The appropriation argument focuses on cases in which individuals are better off after the appropriation of genetic property. Moore does not consider possible cases in which one is not better off after the appropriation or possible outcomes in which there is no genetic appropriation.

Moore can reply to his appropriation argument critics that he is using standard economics and market arguments. Nonetheless, Moore's appropriation argument moves much too swiftly:

> ...that market regulation...will, eventually, bring benefits to everyone ...does not substantiate the Libertarian Efficiency Argument, which requires it to be the case that *no viable alternative* regulatory framework would have brought

[189] *Ibid*.
[190] Farrelly, "Genes," 75.

these technologies into existence as effective and affordable technologies *sooner*...[191]

If Moore is to persuade us with the appropriation argument, we need to be given reasonable grounds other than the claim that inequality and genetic appropriation has work in the past, therefore it most likely will work in the future. We needn't evoke Hume's problem of induction regarding purported claims of future cases becoming the same as past cases, past futures do not necessarily predict futures,[192] to find Moore's argument untenable.

The principle of charity can be extent to Moore's position, seen as reasonable, yet inadequate. That is, Moore's appropriation argument can be read with the best interpretation, consistency, but found inadequate. One can appeal to the history of economics and markets as reasonable evidence. Given the principle of charity however, Moore must additionally give reasons why there are no feasible possibilities other than his inequality and genetic appropriation system; or why we should not consider alternative possibilities. It is commonly said, in the vernacular, if it ain't broke don't fix it. Nonetheless, somethings and situations can work adequately, yet be greatly enhanced or improved by changes. The history of economics and markets can show, in some cases, that inequality and genetic appropriation have produced benefits. However, Moore has not shown that a change from genetic patents to open access for genetic research will not enhance human genetic benefits to the same degree as the past, or greater.

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[191] Ibid., 176.
[192] David Hume. "Enquiries Concerning Human Understanding and Concerning the Principles of Morals." (1975). (E, IV, II)

Let us look to Nozick[193] to consider a more fundamental requirement and see if the genetic appropriation argument can be defended on its basic claim that genetic appropriation does not render individuals worse off in its limiting use, whether now or in the future.

Nozick's Argument for Genetic Appropriation

For Nozick,[194] the possession and restriction of patent use does not in fact worsen benefits to others. Nozick acknowledges that a worse-off objection may be applied to him. The objection, applied to Nozick is that full ownership of an improved object (of say a patent) cannot be given, since the appropriation of objects limits their use to others. Nozick does not find limiting the use of an improved object to others as a problem. As Nozick explains, "If I appropriate a grain of sand from Coney Island"[195] I do limit that grain of sand to others. Despite limiting the use of that grain of sand to others, Nozick replies that there are many more grains of sand for others to use.

Although, Nozick's reply seems to have merit for patents in general, it has limits with regard to genetic material. Contrary to Nozick's view the grains of sand argument does not address the worse-off objection, because it does not apply to genetic material. Gene patents by definition monopolize and limit access of the human genome to other humans. For Nozick's grains of sand argument to address the worse-off objection it must show that a monopoly on genes and their use does not harm others. Gene patents and information protect the patent holder against

[193] Nozick. *Anarchy.*
[194] *Ibid*.
[195] *Ibid*., 175.

other individuals from biomedical research and use of their patents, there by excluding genetic enhancement to others.

Say we accept Nozick's libertarianism grains of sand argument, and that there are additional genes (DNA) for others to patent and use. Note that in accepting Nozick's grains of sand argument we still have a problem of scope. The influence one patent may have on useful gene information, products, cures and enhancement on human health can be immense. Gene patents affect a great number of health and social outcomes. The scope of gene patents monopolizes and limits access to genic material use and products such as: agriculture, biomedical research, human health, and the future of human enhancement through genetic engineering.

With regard to the use and monopoly of a limited number of gene patents available and their scope, Sigrid Sterckx addresses a problem with Nozick's grains of sand argument. Sterckx says that once a patent is issued:

> A patent includes one or more claims containing a description of the product or process… in question. Every other product or process that fits the description is *also* covered by the patent.[196]

Here we see, in the case of DNA or genetic material patents, one patent or process can limit the use of many other DNA segments or products. This is particularly the case when a patent is drafted with a broad description. A case in point is the Harvard OncoMouse cancer-causing gene (oncogene as argued in chapter 4) patent. The oncogene patent is written to include all mammals with its recombinant

[196] Sigrid Sterckx. "The moral justifiability of patents." *Ethical Perspectives: Journal of the European Ethics Network* 13, no. 2 (2006), 254.

cancer-causing gene. Owning this OncoMouse gene legally means that biotechnicians can patent organism types that they have never actually produced.

Nozick is unconvincing. Given that there were or are many more gene patents available for use, a small number of patents can and do affect an enormous number of outcomes. Take another case, the Microsoft operating system. There are many more algorithms available now and in the future to run on Microsoft's operating system. A change on Microsoft's current operating system and patents could affect millions if not billions of future algorithms, software and users.

The number of patentable genes is quite limited in stark contrast to the number of Coney Island grains of sand. In addition to grains of sand and gene patent limitations, gene patents affect and monopolize many more possible genetic uses. As in the case of the OncoMouse, Nozick's grains of sand argument does not cover the magnitude of ways DNA patents can affect the health of persons and future use.

The above arguments for gene patents assume the disclosure of new medical cures, health therapies, and human gene enhancement scientific knowledge and imply there will be additional difficulties that result from gene patents. Without clear and fair distribution of genetic information guidelines, public and private patent partnerships will be free to pick and choose investments for profit-driven technologies. These investments will result in negative outcomes at the cost of truly beneficial medical, pharmaceutical, and agriculture advancements.

In addition to the lack of clarity concerning scientific research and genetic health, supporters of gene patents do not address the distribution and use of genetic information to nonscientific communities. The above Libertarian gene

appropriation arguments are unsuccessful, since they do not address how and when genetic knowledge will be used and distributed.

Patents limit genetic access and make others "worse off." Those in need of pharmaceutical, healthcare, and human enhancement can and will be excluded from genetic products and cures, if patents are allowed to monopolies genetic material. We now take up Rawlsian issues of distributive justice.

Rawlsian Distributive Justice

In this section we will see, given the genetic revolution, human genetic intervention, and its contribution to future biogenetic healthcare and enhancement we must turn to genetic justice (public access) as it relates to (distributive justice) the fair distribution of burdens and benefits of a political society. Biogenetic information, biotechnology and genetic appropriation affect future healthcare and their just distribution must ultimately be addressed. The ultimate question regulating genetic patents and genetic justice is how are we to distribute general welfare? General welfare and public good refers to individual freedom and basic interests, health, happiness, and fortune. In light of general welfare, individual freedom and basic interests are central to John Rawls' *A Theory of Justice* and an individual's rational plan of life.

This section examines how a Rawlsian theory of justice might ensure a more just distribution of biogenetic information and healthcare with or without genetic ownership. First, we present an overview of Rawls' justification and importance for general welfare as individual freedom and basic interests. Genetic ownership and genetic justice are central to general welfare.

Genetic ownership and genetic justice are ultimately a question of general welfare - that is, individual freedom and basic interests, but entangled in political society. Why start with the Rawlsian concept of "general welfare"? Our starting point is with Rawls since he is concerned with political society, freedom and personal basic interests. Herbert Hart presents Rawls' view as follows:

> Thus Rawls has argued in *A Theory of Justice* that though any rational person must know that in order to live even a minimally tolerable life he must live within a political society with an ordered government, no rational person bargaining with others on a footing of equality could agree to regard himself as bound to obey the laws of any government if his freedom and basic interests, what Mill called 'the groundwork of human existence', were not given protection and treated as having priority over mere increases in aggregate welfare, even if the protection cannot be absolute.[197]

This passage makes it clear that for a rational person to obey the laws of any government, it is necessary that their freedom and basic interests are protected. In Rawls' theory of justice as fairness, an individual person's freedom and basic interests are played out in the basic structures of society. Basic structures of society are the ways in which major social institutions function when distributing fundamental rights and duties as they choose "among the various social arrangements which determine this division of advantages...for...the basic institution of social cooperation"...[198]

[197] Herbert Lionel Adolphus Hart. *Essays in jurisprudence and philosophy*. (OUP Oxford, 1983), 195.
[198] Rawls, *Theory*, 4.

Rawlsian justice appeals to a conception of justice that is reasonable or justifiable to free and equal moral agents. Under this conception of justice, the state should reduce the harmful effects of morally random natural and economic factors imposed on persons by nature and the "lottery of life." This is the case, since these random natural and economic (lotteries) factors create severe disadvantages and stifle a person's rational plan of life. For Rawls, the general principle that enables one to pursue their rational plan of life is "a more general conception of justice"[199] that can be expressed as follows:

> All social values—liberty and opportunity, income and wealth, and the social bases of self-respect—are to be distributed equally unless an unequal distribution of any, or all, of these values is to everyone's advantage.[200]

For persons to pursue their rational plan of life, it is necessary for them to have basic rights and duties (see footnote 26) that regulate the distribution of social and economic advantages. Basic rights and duties are social values that cannot be bargained by political institutions. As we will see, social values and Natural Primary Goods, including gene, are also in need of just distribution

Social values reflect some social primary goods that Rawls defined as "things that every rational man" wants and are said to normally have and use in the pursuit of their rational plan of life. The chief primary goods are divided by Rawls' as Social Primary Goods "at the disposition of society are rights, liberties, and opportunities,

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[199] When Rawls refers to a more general principle of justice he is referring to the two principles below. A discussion of these two principles would take us too far afield of our discussion. The first statement of the two principles reads as follows. First: each person is to have an equal right to the most extensive scheme of equal basic liberties compatible with a similar scheme of liberties for others. Second: social and economic inequalities are to be arranged so that they are both (a reasonably expected to be to everyone's advantage, and (b) attached to positions and offices open to all. (*Ibid*., 60)

[200] *Ibid*., 62.

and income and wealth... and self-respect" (Ibid). These social primary goods are to be equally distributed. All are to evenly share similar rights, duties, income, and wealth in pursuit of their rational plan of life.

Next are the Natural Primary Goods "such as health and vigor, intelligence and imagination...,"[201] Rawls claims only the Social Primary Goods, not the Natural Primary Goods, are to be distributed equally. Although the Natural Primary Goods are somewhat influenced by the basic structure, Natural Primary Goods are "not so" influenced by the basic structure and directly under its control. The point here for us is that via the Social Primary Goods, we have a benchmark for judging improvements regarding Rawls general conception of justice.

For Rawls distributive justice begins when image a state of affairs in which all the social primary goods are equally distributed. All "rights and duties, and income and wealth" are similarly obtained and shared. Moreover, given a case in which some inequalities of wealth and differences in authority made everyone better off, they would still be in "accord with the general conception" of justice. The benchmark for judging improvements in Rawls' general conception of justice "only requires that everyone's position be improved."[202]

Rawlsian distributive justice only addresses the fair distribution of burdens and benefits of Social Primary Goods in a political society. Can we adapt the Natural Primary Goods to addresses the fair distribution of burdens and benefits of genetic information? To address this question, we now look to the Natural Primary Goods and Genetic Justice.

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[201] *Ibid*.
[202] *Ibid*., 62.

Natural Primary Goods and Genetic Justice

Although Rawls' theory of justice does not include Natural Primary Goods, Natural Primary Goods and gene patents can aid and address human well-being by way of improving health. Unlike the past in which we had little control over our genetic wellbeing individuals have and will continue to have additional control over their medical and genetic needs. Human genetic research and healthcare are central to just biomedical advancements. Francis Collins expresses some examples like high-throughput biochemistry, a method providing efficient measurements of the effects of agents or conditions in biological or chemical essays—the presence of a substance and the amount of that substance, are:

> Interwoven advances in genetics, comparative genomics, high-throughput biochemistry and bioinformatics are providing biologists with a markedly improved repertoire of research tools that will allow the functioning of organisms in health and disease to be analyzed and comprehended at an unprecedented level of molecular detail.[203]

Biogenetic technology has dramatically changed since Rawls first wrote *A Theory of Justice*. Biomedical research is in our control altering or enhancing humanity, relieving human ailments via healthcare, and making genetic testing inclusive of the Natural Primary Goods. Because biogenetic technology has given persons the power to influence their future health, Rawls' benchmark for judging improvements of justice can now be based on Natural Primary Goods. Given they do more good than harm, and that social and natural primary goods are in our control to be equally

[203] Francis S. Collins, Eric D. Green, Alan E. Guttmacher, and Mark S. Guyer. "A vision for the future of genomics research." *Nature* 422, no. 6934 (2003): 835.

distributed, it seems to follow that in extending Rawlsian justice as a fairness distribution of NPGs Rawlsian principles should override genetic property rights, genetic privacy rights and genetic personal information.

Rawls' Theory of Justice and Genetic Appropriation

Based on including a fair distribution of NPGs, we must address whether the Rawlsian theory of justice supports the appropriation of genetic property and privacy rights? That is, how might Rawlsian principles override genetic property rights, genetic privacy rights and genetic personal information? Rawls' theory of justice as fairness, requires major social institutions to "distribute fundamental rights and duties and determine the division of advantages from social cooperation." [204] Rawlsian theory of justice includes mitigating the social lotteries that may stifle our rational plan of life. A Rawlsian theory of justice must mitigate the social lotteries of life, since persons are randomly born into poor or wealthy families, born healthy or with disabilities.

Rawls' theory of justice intends to alleviate the social lotteries that stifle our rational plan of life. One's health and one's environment can stifle or improve one's rational plan of life. An application of the Natural Primary Goods must address biomedical, social and political institutions to fairly distribute burdens and benefits of genetic information that effect individual's health needs as a benchmark for genetic justice or fairness.

[204] Rawls, *Theory*, 7.

Distributive Justice, Biogenetics Technology and Healthcare

Given the pre-genetic revolution, Rawls' decision to exclude Natural Primary Goods based on a lack or limited control via the "basic structure" of institutions may have some merit. The current genetic revolution, for example, genetic testing and intervention, make it possible for individuals to have access and control over their health and future biogenetic healthcare. The Natural Primary Goods now have control over future genetics in the same manner that individuals had control over the Social Primary Goods for liberties, opportunities, income and wealth and self-respect.[205] Natural Primary Goods (NPG) will be controlled by current and future biotechnology as well as the positions taken by genetic patents holders and legal policy makers.

NPG are increasingly important for the continued application of biomedical technologies as people acquire more genetic control and genetic justice. Is control adequate to support the distribution of Natural Primary Goods? Yvonne Denier thinks not:

> ...control, understood as directing capacity and capability to change the situation, is indeed a necessary condition for justice. Conversely ... not everything we can control is a matter of justice or injustice. As such, control is a necessary but not a sufficient condition for justice. We need further refinement of our conception of control as related to distributive justice and to the primary goal of just institutions.[206]

[205] Farrelly. "Genes."
[206] Yvonne Denier. "From brute luck to option luck? On genetics, justice, and moral responsibility in reproduction." *Journal of Medicine and Philosophy* 35, no. 2 (2010): 101-129.

It is indeed the case that there are many things we control that do not belong to the domain of justice. More to the point, Rawlsian supporters like Farrelly need to flesh out which goods we can control that are so important that they belong to the realm of distributive justice.

Farrelly supports a Rawlsian application of Natural Primary Goods and genetic justice, given our newfound control over our genetic future. Farrelly proposes the genetic difference principle which stipulates that genetic:

> ...inequalities in the distribution of genes important to the NPG are to be arranged so that they are to the greatest benefit of the least advantaged.[207]

The genetic difference principle (GDP) is intended to assist with cases in which individuals are born with poor natural endowments. That is, GDP is designed to redress further inequalities exacerbated by a lack of access to life altering biological sciences, for example. Because GDP is a Rawlsian principle supporting a just life, it must also address genetic justice as person's rational plan of life.

Farrelly must determine which genes are to be distributed and to what extent one must advance genetic distributive justice. That is to say, he must state how one is to distribute a genetic theory of justice as fairness? Farrelly is quite aware of the critics who oppose the distribution of genes. Now that NPG are in our control we need not strive "for equal distribution of poor genetic profiles..."[208] GDP only addresses the genetic information important to NPG. Genetic appropriation is justified (as a Rawlsian distributive justice) only to the extent that patent holders and policy makers take into account the outcomes of genetic information and

[207] Farrelly. "Genes," 81.
[208] *Ibid*.

greatest benefit of the least advantaged. If common ownership achieves the greatest genetic benefit of the least advantaged over genetic patents, then the private appropriation of genetic information negates a genetic theory of justice as fairness.

Some Rawlsian critics of luck based distributive justice (those worse off partly because of their bad luck), and the lottery of life with regard to SPG and NPG, claim that it fails and we must move on to a capability approach to justice which we develop below.[209] To see how the lottery of life works as luck, we are reminded that we do not personally choose our social and health endowments. Our social and health endowments are a matter of luck. Rawlsian justice as fairness must redress the inequalities, of NPGs or SNGs, given to us by chance. Moreover, since we now have control over our genetic information, in competition with genetic patents holders and legal policy makers, we need to be mindful of the distribution and use of our genetic future i.e., NPG.

Farrelly, for example, presents a lax version of his GDP to guide us in a just distribution of our genetic information that inequalities should be arranged so that they are to the "greatest *reasonable* benefit of the least advantaged."[210]
Farrelly's lax GDP for a just distribution of genes presents a case in which one has control of genetic information or NPGs; however, the lax GDP is too general for our purposes.

[209] Papaioannou, "New." Denier, "Brute."
[210] Colin Farrelly. "The genetic difference principle." *American Journal of Bioethics* 4, no. 2 (2004): 21-28.

The lax GDP fails to be informative when having competing NPGs. The lax GDP is unclear on which person shall we consider genetically worst-off.[211] There can be many disadvantage groups and why should one be considered worst-off over another. Consider the case of the cognitively impaired.[212] The cognitively impaired are a disadvantage group and as such could be given priority over the genetically impaired groups.

Farrelly can prioritize and reply that cognitively impaired groups fall within the domain of genetically impaired groups, since cognitively impairment may be the result of a genetic mutation. Furthermore, to alleviate the future endowment of bad luck, we could distribute the needed genes to alter the cognitive impaired by genetic enhancement.

What prioritarians like Farrelly fail to address are environmental influences and freedom of choice to acquire life functions or capabilities. These functions or capabilities as well as genetic interactions that affect phenotypes, our personal rational plan of life and influence our genetic and personal wellbeing. Given these capability objections we need to address functions or capabilities that enable persons to achieve a valued rational plan of life. I what to be quite clear here. Farrelly can be quite helpful in his approach when he states:

> I...urge moral and political philosophers to invoke a pluralistic and provisional moral analysis: an analysis that takes seriously a variety of nonideal empirical considerations, such as the severity and prevalence of different

[211] Papaioannou, "New." Denier, "Brute.
212 Ronald A. Lindsay. "Enhancements and justice: problems in determining the requirements of justice in a genetically transformed society." *Kennedy Institute of Ethics Journal* 15, no. 1 (2005): 3-38.

> types of disadvantage, as well as the costs and likelihood of success of different types of interventions (e.g., genetic and nongenetic).[213]

Farrelly currently emphasizing that philosophers need to "think sagely about social justice in the 'here and now.'" However, his approach will take us too far afield from the intent of this chapter. We move on to a capability theory of justice.

Distributive Justice as Capability theory and Genomic Enhancement

What is additionally needed to advance the current and future genetic control advancements made possible by the human genome? Freedom must be part of placing humanity in a position to create a genomic distribution of justice for both SPG (income, wealth, etc.) and NPG (rationality, intelligence, etc.). As capabilities of freedom of choice, Theo Papaioannou[214] argues that Capability theory (Sen, 2013; Sen, & Quiggin, 1994; Nussbaum, 2001) can bring about a new genomic distribution of justice. Capability theory focuses upon capability that achieve a person's value of life:

> the capability theory allows not only for the identification of injustices linked to natural lottery but also for their elimination through the use of new genomic technologies, including gene-based diagnostics, gene therapy, somatic cell engineering (SCE) and germ-line engineering (GLE).[215]

[213] Colin Farrelly. "Gene Patents and the Social Justice Lens". *The American Journal of Bioethics*, *18*(12), (2018): 49-51.
[214] Papaioannou, "New."
[215] Papaioannou, Theo. "New," 1.

The genomic technologies, for Papaioannou have the potential, "to reduce variability in natural goods" and enable individuals to convert natural goods and social goods into well-being or welfare.

Capability theory, for our purposes, began with Amartya Sen in the 1980s and his concerns with current issues and approaches to evaluate individual's well-being. Individuals differ greatly in their abilities, like physical disabilities or abilities to achieve good health. Moreover, individuals differ greatly in abilities to convert identical resources into what Sen calls valuable "functionings", or beings and doings. For Sen focusing merely on means without evaluating and considering that which a particular individual can do with the options they have is insufficient. To consider what a particular individual can do with their options to achieve a valued rational plan of life, we need to look at basic informative human capabilities.

Papaioannou informs us that capabilities approach is a general approach. Sen's capabilities approach centered on information relating to individual advantages. These advantages are judged in terms of opportunity not on specific social normative 'design' (Sen, 1980). Since for Sen Capabilities are a quite general bases of information to identify and choose a life of value, we need to look elsewhere to find more specific capabilities.

Nussbaum's[216] Senian perspective (Nussbaum and Sen), has created an interpersonal index of basic capabilities that we can use to secure genetic justice. For example, the basic capability of "Life:" being able to live a life worth living and living life to the end of a human normal lifespan is a capability one can choose to achieve, a valued rational plan of life. Moreover, we have the "Bodily Health"

[216] Nussbaum, "*Sex.*"

capability: one being able to have good health, adequately nourished, adequately sheltered, with sanitary and safe living and working conditions; having access to preventative, curative, and rehabilitative medical services.[217]

According to Papaioannou the good health aspect of Bodily Health is compatible with genetic justice and germ-line engineering (GLE). By way of GLE, the transmission of genetic information is passed on to offspring as well as to future generations. The Senian approach allows enhancement when it can bring people above a minimum decent accepted standards of basic capability deprivation:

> By preventing people from arriving at a state of basic capability ...deprivation through both social and genetic interventions, Senians are likely to succeed eliminating oppressive social and political relations. Redistribution of income, gene therapy or GLE might be crucial for enabling some people to function as equal citizens.[218]

Does this basic capability deprivation prevent genetic equality above the basic capability deprivation? There is no reason not to have a principle that addresses NPGs distribution of heredity base on human capabilities for the greatest benefit of the least advantaged[219] enhancements. Papaioannou suggests that the Senian's capabilities proposal of freedoms, not primary goods, permits the elimination of natural lottery injustices. Senian capabilities are a model for the elimination of natural lottery injustices and can be achieved by way of biogenetic innovation, including GLE and or genetic enhancement when applied to good health, adequately

[217] Ibid.
[218] Papaioannou, Theo. "New," 12.
[219] Dov Fox. "Luck, genes, and equality." *The Journal of Law, Medicine & Ethics* 35, no. 4 (2007): 712-726.

nourished, adequately sheltered, sanitary and safe living and working conditions; access to preventative, curative, and rehabilitative medical services.

Moreover, the appropriation of genetic material must be sensitive to Senian capabilities if genetic appropriation is to be justified. That is, genetic appropriation can be justified when biomedical technology enables Nussbaum's Senian capabilities such as "Life and "Bodily Heath." One can challenge the application of Nussbaum's Senian capabilities approach to genetic justice in that the capabilities approach is too general in that it is a broad bases approach to inform genetic justice.

This lack of a more specific index of capabilities challenge miss represents Nussbaum's Senian capacity approach and the state of biotech. Apart from using Nussbaum's index of basic capabilities as a start, it is clear that current and future of genetic biotechnology is a work in progress. Any hard and fast rules, at this time are premature.

It is unclear which Biotech and genetic research is achievable and valuable, for individuals, society, global humanity and the planet. Biotech and genetic research are in their embryonic stage. Genetic justice capabilities must be assessed, constructed and evolve as biotech and society evolves. Given the new evolving biotech landscape, a Nussbaum Senian (Sen) capability approach currently is our best starting point to address achievable and valuable genetic justice. We address the Nussbaum Senian capability approach to genetic justice and the US Supreme Court's dubious opinion on genetic patents in the final chapter.

7.0 Conclusion Arguments and Possible Future

In this chapter, I challenge the Supreme Court's position on the patenting of genetic material based on its view of invention, lack of moral principles, and I address possible ways to remedy some of the current moral genetic justice patent problems via a foundational Nussbaum and Sen approach. The court fails to show that cDNA (invention) is different from DNA (nature). Because this work is of Axiological concern encompassing bioethics, social and political philosophy, it is important to restate the US Supreme Court's failure to uphold the original intent and justification for the Human Genome Project. President Clinton and Prime Minister Tony Blair initially addressed these moral principles. The moral justification for the Human Genome Project includes human values such as ethics, open access and human flourishing as public good (see chapter 4 above).

But first I revisit and present a general account of the current standing of gene patenting via the US Supreme Court's 2013 decision on gene patenting. The

US Supreme Court failed to show that DNA - a product of nature - and cDNA are different. Due to the US Supreme Court failure, regarding the difference between DNA and cDNA, the Court incorrectly concluded cDNA to be patentable. We begin with the US Supreme Court summary.

The US Supreme Court's 2013 decision Summary

On November 30, 2012, the U.S. Supreme Court took up the case of Association for Molecular Pathology v. Myriad Genetics.[220] The plaintiffs in this case were: Public Patent Foundation (PUBPAT), the American Civil Liberties Union (ACLU) and Breast Cancer Action—referred to as Molecular Pathology. The plaintiffs, Molecular Pathology, challenged Myriad Genetics' claim that Myriad's BRCA genes, associated with ovarian and breast cancer, is patentable. Moreover, this case underscores the US Supreme Court's lack of concern for the principles of biometrical ethics and justice by focusing on the question regarding whether genetic material was discovered or invented. Although this case was fraught with ethical, public policy, and healthcare issues, the Court's exclusive concern was with whether DNA/genes are patentable inventions or products of nature. It is worth noting that the court is only concerned with USPTO procedural criteria. The court is not concerned with moral or social goods, we will address this issue later. It should further be noted that the Court's decision corresponds with the administrations brief written by the United States in support of petitioners in AMP v. Myriad Genetics (Supreme Court

[220] "The US Constitution, 35 U.S.C. § 101 and the Association for Molecular Pathology v. Myriad." Ingram, Tup. "Association for Molecular Pathology v. Myriad Genetics, Inc.: the product of nature doctrine revisited." *Berkeley Tech. LJ* 29 (2014): 385.

Case Docket No. 12-398).[221] The court is only concerned with whether human genes, DNA and/or cDNA, are patentable material as a non-natural product?

First, we must be clear on what the court considers the difference between DNA and cDNA (complementary DNA). The sequencing of cDNA occurs outside the living human body. It is claimed by the proponents for gene patenting that artificially synthesized cDNA, used for protein production, for example, unlike natural DNA found in the body, are not a product of nature. That is, cDNA undergoes an unnatural process.

The processed DNA is cDNA without the intron sequence. An illustration of these artificially synthesized (non-protein-coding information) and natural genes is given in Fig. 2.1 and Fig. 2.2., as DNA and cDNA sequences:

exon exon exon exon = protein coding information

_____......_____....._____....._____

intron intron intron = non-coding

Fig. 2.1. A natural strand of DNA with both coding exons and non-coding introns.

Natural DNA (found in the body, see Appendix B) consists of exon and intron before they are isolated. Fig. 2.2 below is cDNA without coding introns, seen by the Court, as a manmade product. The noncoding regions of introns are sometimes called

[221] The Amicus brief reads:
The judgment of the court of appeals should be affirmed insofar as it holds that cDNA is patent-eligible and reversed insofar as it holds that isolated but otherwise unmodified DNA is patent-eligible.
The open question is to what extent did the Amicus influenced the Courts decision.

‘junk” DNA, since it was thought, at that time, they had little to no function in coding for proteins.

exon exon exon exon = cDNA

Fig. 2.2. Above cDNA coding for phenotypes and protein, without introns.

The court concluded that lab isolated DNA/genes, what the court called separating a gene from its surrounding environment, is patentable as cDNA.

Before we move on to my critique of the U.S. Supreme court’s decision, we need to understand that the concepts DNA and Art-DNA (artificial DNA), with regard to invention and nature, continue to be problematic.

DNA vs. Art-DNA

In an effort to gain a deeper understanding of the U.S. Supreme court’s decision on invention vs. nature, and problems with DNA and Art-DNA we must look to their differences. As we will see, one difference between DNA and Art-DNA is that they are not structurally the same. These artificial genetic copies, I will call Art-DNA. Resnik[222] gives a good account of some of the differences between DNA and Art-DNA. In the process of isolating and purifying DNA, natural DNA is no longer structurally and functionally the same. As in the case of cDNA, “junk” DNA is deleted from the remaining DNA.

Although the noncoding regions of introns are called ‘junk” DNA (and non-protein coding), “junk” DNA can be helpful. These noncoding regions can be used in

[222] Resnik, “Owning.”

studying genetic diversity. This is done by identifying and analyzing shorter DNA fragments and comparing their similarities and differences to see if they come from the same individual.[223] When DNA is taken from a natural source and isolated in the lab, scientists may add, remove, or change DNA sequences. For example, in the process of modifying DNA for protein production, scientists add nucleotide sequences. In discovering differences in DNA one can identify mutations. Typically, a microbiologist can categorize mutations[224] as follows:

M1. Deletions, a section of DNA (base pair see Appendix B) is lost or deleted.

M2. Insertions, in which one or more base pairs are inserted into a new place in the DNA.

M3. Substitutions, in which a base pair is exchanged for another base pair.

M4. Transposition, "which is a change in the order of one or more base pairs."

Most mutations are benign, but others can express some diseases. By identifying, analyzing, and comparing mutations to known normal DNA sequences, scientists can identify diseases such as cystic fibrosis (CF) or sickle cell anemia (SCA).

When DNA sequences are altered from their natural state, scientists can create something new and non-natural. For example, scientists invent new non-natural DNA (Art-DNA) when they separate DNA sequences from nonhuman or human biological organisms in the lab. This is done by deleting, inserting, substituting or transposing DNA in the manner explained with mutations M1-M4.

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[223] Ibid. Kitcher also discusses these issues in, Philip Kitcher. *The lives to come*. Simon and Schuster, 1997.

[224] Resnik, "Owning."

Structural modification of natural DNA to create cDNA is central to the US Supreme Court's decision – genetic modification transforms DNA into novel cDNA. Scientists also make modifications such as adding nucleotide sequences to DNA "in protein products" or to purify DNA.

Resnik[225] argues, even in cases when no changes are made to isolated and purified DNA, the isolated and purified DNA is not the same as natural DNA. Isolated and purified DNA is not the same as natural DNA, because natural DNA "always exists in an impure form." The very fact that scientists in the lab separate DNA segments from the human body alters the natural DNA configuration or structure. That is, scientists in the lab separate these segments from the DNA of human chromosomes. The separated natural DNA is purified from its nonessential biological matter. A specific example is artificial vitamin $B_{12,}$ which is used for the treatment of megaloblastic anemia.

In the case of artificial vitamin B_{12}, B_{12} has a specific and substantial invented use as a treatment for anemia. In order for vitamin B_{12}'s use to be realized, human ingenuity was required and applied to transform natural vitamin B_{12} to a tangible application. Since artificial vitamin B_{12} is isolated and purified it is considered different from natural B_{12} and is patented (by Merck & Co. V. Olin Mathieson Chemical Corporation 1958). Hence, just as isolated and purified vitamin B_{12} is considered different from natural B_{12}, the isolated and purified DNA (Art-DNA) segments from a human body should also be seen as different from natural DNA. According to the USPTO, it is human ingenuity and inventiveness that transformed natural B_{12} to the patentable artificial substance (isolated and purified) vitamin B_{12}.

[225] Resnik, "Owning."

Even if we accepted the product of nature vs. the product of human ingenuity with regard to vitamin B_{12}, Resnik is unable to give an objective standard for the product of nature vs. product of human ingenuity distinction. Some counterexamples to an objective standard for human ingenuity are cases in which, say, one finds a tree blocking one's path and moves it out of the way. These examples may constitute human ingenuity or inventiveness. Or, a case in which one makes a house or shed out of fallen trees. Trees are not found in nature as readymade objects for human habitation. Is the creation of habitable structures for humans or the creation of a safe pathway by moving rocks a patentable creation?

These tree counterexamples satisfy the unnatural use standard, but it is not clear that objective human ingenuity was performed. Is there an objective criterion for when something becomes a work of human ingenuity? As we know, the USPTO has its patent standards based on historical, social/political and personal interests. But we are endeavoring to find an "objective" standard for human ingenuity; and not to accept standards by political power, commercial concerns or what satisfies the USPTO based on what has been accepted via historical interests.

Conceptual Pragmatism

Resnik[226] is aware of the difficulties with articulating a clear objective demarcation between products of nature and products of human ingenuity. Since there are no objective criteria for distinguishing a product of nature form a product of human

[226] Resnik, "Owning," 86-87.

ingenuity, Resnik's solution is to "appeal to normative concerns, such as our goals, purposes and value."[227] Resnik relies on what I call Conceptual Pragmatism.

Conceptual Pragmatism is aptly fleshed out in two parts by Peter Carruthers as follows:

> C1. [T]here are always more concepts available to us in a given area of discourse than we need.
>
> C2. [O]ur selection of concepts from the range of alternatives should be governed by the purposes for which we wish to employ them.[228]

Let us apply the above conditions for Conceptual Pragmatism to the products of the nature vs. human ingenuity question. Here we take the term conceptual to mean a way of classification or dividing up products of nature from products of human ingenuity. Statement C1 says that there are more ways to classify products of human ingenuity than we can use or need. Consider the many ways we can divide up human ingenuity. Humans can be clever, as in being skillful in using their hands, body, or mind. Humans can be creative, as in having or showing an ability to make new things. Alternatively, humans can be innovative in unusual ways introducing or using new ideas or methods.

What is the objective or correct characterization for ingenious or inventiveness vs. nature and patent law? Again, in the words of Resnik, "there are no such criteria." This is reasonable in that products of ingenuity and product of nature do not already exist divided up for us to discover. C1 justifies our challenge

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[227] "Ibid."

[228] Peter Carruthers. *Introducing Persons*. SUNY Press, 1986, 215. Caruthers elaborates on conceptual pragmatism in Peter Carruthers. "Conceptual pragmatism." *Synthese* [73] no. 2 (1987): 205-224.

to patent law based on the products of ingenuity (invention) vs. the product of nature criteria.

Statement C2 claims that the concepts or classifications we are to use, from our many possibilities, should be based on our purposes. As Resnik puts it, such choices should be based on "normative concerns, such as our goals, purposes, and value." This is the case, inasmuch as we cannot always assume that there are objectively clear scientific and causal laws that exist (or that we understand).

We cannot always use causal laws to define and classify products of nature from products of human ingenuity. Nor do we always find clear and objective legal standards to appeal to. That is not to say that sometimes we may not want our choices to conform to, what is taken to be, a natural classification of science or law in a state of uncertain objectivity.

In the case of our desire to conform to natural classification of science an argument or rational justification is needed. Notwithstanding our desire to conform to natural classifications, in some certain and uncertain cases we need to defend our personal and social purposes. Not to do so would be, for us, to give into what Carruthers calls "scientific imperialism," [229] and I add "legal imperialism" which I take to be the courts and legislature deciding what is important regarding genetic patents – void of direct public (membership) input.

Diamond vs. Chakrabarty

Given that we leave open the validity of legal imperialism, how do the courts reach their decision on the patenting of biological living organisms independent from an

[229] Carruthers. "*Introducing,"* 215-7.

objective nature vs. invention standard? Since Diamond vs. Chakrabarty[230] is the standard supporting case for gene patenting, we review the general workings of Diamond vs. Chakrabarty and the courts grappling with the questions of patenting life. How does Diamond vs. Chakrabarty relate to or not relate to a product of nature vs. a product of human ingenuity as Legal imperialism.

Legal imperialism can be seen at work in Diamond vs. Chakrabarty. This amounts to, some say, the first genetic life form patent case. The substantive point here, supporting my claim that Legal imperialism is at work in genetic patents, is that the courts are the only avenue for setting genetic patent standards. As pointed out earlier, Ananda Chakrabarty had applied, in 1972, for a patent on the bacterium (from the genus) Pseudomonas. This microorganism degrades crude oil (hydrocarbon). Chakrabarty's patent claim was based on the 1930 Plant Protection Act (PPA) that allowed the patenting of unique or invented plants contingent on the fact that the new plant could be reproduced asexually. In 1976, Chakrabarty's patent application was denied by both USPTO and the U.S Patent Office Board of Appeals (POBA). The patent examiner denied Chakrabarty's patent on the grounds that the bacterium was not a plant and alive. Prior to the 1930 PPA, life was not patentable. Life was seen as a product of nature.

The U.S Patent Office Board of Appeals affirmed the USPTO's decision to deny Chakrabarty's patent. Wilson gives an account of the POBA's decision. The U.S Patent Office Board of Appeals decision was solely based on the question, is a manmade invention that was "alive" patentable? The POBA states that living organisms:

[230] "Diamond."

> …even if they were sufficiently modified so as not to be products of nature, were not patentable subject matter under U.S. Code Title 35 sec. 101231 (Wilson, 2002, p.28).

This passage makes two significant points:

> D1. In rejecting Chakrabarty's patent the Patent Office Board of Appeals' interpretation was that The 1930 Plant Protection Act did not include non-plant life.
>
> D2. That in rejecting Chakrabarty's patent, the POBA also negated the patent examiner's claim that the bacterium Pseudomonas was a product of nature.

In statement D1 it is clear that the POBA assumes The 1930 Plant Protection Act to exclude non-plants and in this case the bacterium.

In statement D2 we see that the POBA accepted that the bacterium was not a product of nature. In D1 and D2 we see the beginning of the courts negating their prior view that life is not patentable. The first step in accepting or considering that life is not patentable, is to acknowledge that the passage considers that some manipulated multicellular life can be manmade. The POBA's reasoning was an extension of the 1930 Plant Protection Act, at the time of its drafting, which was taken to be an extension to plant breeders and not to be extended to invention in general.[232]

Chakrabarty appealed the Patent Office Board of Appeals' (bacterium Pseudomonas) patent rejection to the Court of Customs and Patent Appeals (CCPA).

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[231] Jack Wilson. "Patenting organisms: intellectual property law meets biology." 2002). In David Magnus, and Arthur L. Caplan. *Who owns life?* 2002, 28.

[232] Wilson. "Patenting organisms" intellectual property law meets biology, 34-5.

The Court of Customs and Patent Appeals (1979) reversed the patent office and the POBA's rejection, based in part on the In re Bergy case, that there is: "no sound reason to refuse patent protection to the microorganisms themselves-a kind of tool used by chemists and chemical manufacturers in much the same way as they use chemical elements, compounds, and compositions which are not considered to be alive"[233]

Above we see the courts altering their view of a microorganism from a living nonchemical to a chemical tool used for manufacturing. The Court of Customs and Patent Appeals reversed the USPTO and POBA's decision to deny patents on life. The CCPA's decision was that living organisms should have patent protection as "composition of matter" or "manufacture." [234]

The CCPA's decision ignored prior legal precedent deeming life a product of nature and un-patentable. The CCPA incorporated the view of the POBA in its decision and both assumed that:

> If it be accepted that all things in our world are either product of nature or things produced by man [and the Board of Appeals (POBA) has agreed that this organism is not a "product of nature"], then by the process of elimination the Board of Appeals has agreed… that his new bacterium is a thing produced by man, i.e. a manufacture.[235]

Above, and as follows, we see the courts struggling to classify microorganisms. Are they a product of nature, a tool for manufacture or something else?

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[233] The Court of Customs and Patent Appeals reversal was based on its prior decision *In re Bergy,* 563 F.2d 1031, 1038 (1977).
[234] In the Matter of the Application of Malcolm E. Bergy et al, 563 F. 2d, 1034-1035 (1977).
[235] "Court of Customs.'

In an interesting dissenting argument Judge Phillip Baldwin argued that the Supreme Court had three alternatives, not two as stated by the CCPA. There are products of nature and statutory subjects of matter or "manufactures;" but, also, an "intermediate category." This third category consists "of things sufficiently modified so as not to be product of nature, but not sufficiently modified so as to be statutory 'manufactures.'" Judge Baldwin's example was a boraxed orange cited from American Fruit Growers v. Brogdex Co., presented in 1931, before the US Supreme Court. The human modified boraxed orange does not occur in nature and fell ambiguously in between "manufacture and product of nature." Baldwin makes his point clear by stating that he can find no one accepting Chakrabarty's "invention as a statutory "manufacture." According to Baldwin, for the purposes of patent law, "Manufacture" and "manmade" are not synonymous.

Judge Baldwin again in citing the American Fruit Growers v. Brogdex Co. states that "a modified natural product does not become statutory subject matter unless its essential nature has been substantially altered…"[236]

What then is the essential nature of a microorganism for the purposes of patent law? Baldwin's answer was that the essence of bacterium is "its animateness or life." Baldwin argued that Chakrabarty has modified the bacteria so as not to make it a product of nature, yet not modified enough to make it a statutory manufacture.

Baldwin's move is interesting, but more to the point, it is important. First, Judge Baldwin's position is important, since it seems that he returns to prohibition

[236] Wilson. "Patenting organisms." These comments were part of The Court of Customs and Patent Appeals 1979.

on patenting life. His position was that in order for organisms not to be products of nature, their "animateness" must be substantially altered. One way to understand Baldwin's position is for the organism to be changed such that it is less than alive. Secondly, Judge Baldwin's position is quite interesting because Baldwin could have consistently argued that an organism's, or in this case bacterium, animateness is its self-replicating nature making it distinct from the nature of a chemical compound. DNA as self-replicating is an argument I take up later, showing DNA is more than a chemical compound. It turns out that Baldwin was not committed to the prohibition of live microorganism as patentable.

Baldwin reconsiders supporting the prohibition on the patenting of life to conforming to the legal statue of the time. Baldwin in a later consideration of the case, reversed his opinion to concur with the CCPA's majority opinion in favor of patent protection for Chakrabarty's modified bacteria. As we know, in 1980 the U.S. Supreme Court concluded that genetically modified organisms are patentable.

The courts from (at least) the 1800s to today have been grappling with addressing the issue of nature vs human ingenuity. We can see the courts ambiguous views from the early years on the prohibition of patenting life, as a product of nature, to interpreting living organisms as chemical tools used for manufacturing, (i.e. a human ingenuity or manufacture). All these views are based on particular judges, at particular times, and the majority rule of that particular committee of judges. The above legal history supports the use of Conceptual Pragmatism in the past and our use of it in the future. But we must not lose sight of our goal, genetic justice that furthers human flourishing as public good.

Resnik[237] on the issue of Conceptual Pragmatism as a way to address the nature vs. human ingenuity "objective" criteria problem, and DNA access for scientific research is valid. However, Resnik's argument on products of nature vs. products of human ingenuity and gene patentability is questionable. What are the values and normative concerns Resnik appeals to? Resnik[238] used and presented his normative concerns when he argued for gene patenting on utilitarian grounds to support genetic patents. This examination is based on his view that Art-DNA (created or manufactured-DNA) is different from natural DNA.

According to Resnik, artificial B_{12} should be patentable, but he concedes that those who study natural occurring DNA should have free access to natural DNA[239]. Resnik concludes researchers should have access to natural DNA, for utilitarian purposes. That is, "inventor exclusive rights" should not be extended in general; as for product of nature and scientific research, they should be available for scientific research.

Given the Art-DNA process as a general archetype, we can restate the argument as:

i. The methods used by microbiologists to create Art-DNA, sufficiently manipulated, changes original DNA.

ii. Art-DNA is unnaturally produced.

iii. The Art-DNA product is an unnatural product.

iv. Unnatural products are patentable.

[237] Resnik. "Owning."
[238] Resnik. "The morality."
[239] Resnik. "Owning," 89.

v. As an unnatural product (given all PTO criteria), cDNA is a token of Art-DNA.

vi. cDNA is not the same as natural DNA and patentable.

As with Resnik's view, the transformation from DNA (Fig. 2.1) to cDNA (Fig. 2.2), the US Supreme Court agreed that cDNA is manmade. Therefore, the US Supreme Court concluded that since cDNA is artificially synthesized/manipulated and is not found in nature, cDNA can be patented.

On the other hand, Lab-generated DNA/genes are not patentable if they have the same segment sequence as natural DNA and are identical. The Court found that Myriad in discovering the location of the BRCA genes is helpful, but usefulness of location does not render genes eligible for patent protection. Since products of nature are not patentable, if isolated (BRCA) genes contain the same sequence of nucleotides with coding nucleotides, human genomic DNA is not patentable.

Is it the case that non-patentable DNA is not the same as patentable cDNA? There is more to the view that DNA is not patentable, in contrast to cDNA based on its manmade condition. The argument that in the production of cDNA laboratories or technicians removing the noncoding introns containing only exons create new non-natural cDNA, presupposes nature does not make cDNA. The substantive question is what remains in this process? In the next section, I take up these questions regarding the Supreme Court's conclusion that cDNA, excluding introns, is manmade. Subsequently, I challenge the Supreme Court concluded that cDNA is not a natural occurring molecule and is patentable.

My opposition to human gene patenting and US Supreme Court

Ultimately in 2013 the US Supreme Court ruled against Myriad Genetics. Although the court also concluded that natural DNA was not patentable, it also ruled that cDNA was patentable. The court argued, what I call, Art-DNA methods used to purify, synthesize or isolate cDNA is a new "composition of matter," since it is not found in nature. The US Supreme Court's claim is questionable. Notwithstanding the court's conclusion cDNA is found in nature. Moreover, I argue that original DNA and cDNA (Art-DNA) copies are identical at their most basic structural level i.e., genetic information. Next, I challenge the claim that cDNA is not found in nature.

Natural retroviruses such as HIV, for example, use reverse transcription to synthesis their RNA into DNA, and cDNA can naturally occur. Scientists learned this technique from viruses. These viruses copy the coding DNA for, say, the production of proteins or cDNA, and eliminate the unneeded introns. That is, the cDNA (Art-DNA) process track methods found in natural viruses.

Naturally existing retroviruses such as HIV convert their RNA-based genomes into cDNA before they integrate into a host genome. They do this using the same naturally occurring enzyme that scientists and technicians use to convert an mRNA template into a cDNA.[240]

The Supreme conceded the point that, in some cases, cDNA can be found in nature. In note 8 of the Supreme Court's discussion, it did acknowledge what it called a pseudogene, the existence of natural cDNA. The court, however, considered natural cDNA of little importance, a "rare instances, a side effect of a

[240] Susan Y. Rojahn. *U.S. Supreme Court Says "Natural" Human Genes May Not Be.* MIT Technology Review. (2013): *http://www.technologyreview.com/news/516101/us-supreme-court-says-natural-human-genes-may-not-be-patented/*

viral infection of a cell can be the random incorporation of fragments of the resulting cDNA." The court concluding that:

> The possibility that an unusual and rare phenomenon might randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter non-patentable.[241]

The main problem with the Court's reply is that the Court does not elaborate on its claims that cDNA is a rare phenomenon or a randomly created molecule. For example, how does the Court differentiate between rare phenomenon, a randomly created molecule, and a maturely created molecule by evolution? The only substantial argument the Court gives for natural cDNA is that it is different in structure from DNA.

Again, the court's main argument is that the structure of introns (non-coding DNA) in c-DNA is eliminated by a "lab technician" and by way of eliminating introns cDNA is distinctly different from natural DNA. The Court's argument is flawed. To see the weakness in the Court's argument, consider the following thought experiment. Say, we discovered a rule book for the construction of some machine. We will call this the new gene generator (NGG) machine. Furthermore, say one eliminated all the non-essential words, for example, adjective, adverbs, etc., to create another rulebook for the construct a NGG machine. Next we compare the two machines. In this case, the necessary instructions for creating the proper function of both the NGG machine and the original machine is unchanged. The important point about these cases is that the essential information is consistently

[241] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013).

assumed in the above court's opinion as introns, and the NGG machine case as essential instruction.

In the NGG machine case, as with the US Supreme Court's opinion, one cannot reasonably claim to have created new information, or a rule book to create a new machine. Given that the artificial process, methods and significant sense of "genetic information" were different in creating cDNA, it would satisfy the significant sense for different genetic material; and it would be incumbent on us to reconsider the Court opinion.

The significant sense for identical gene replication, or copy is its informational biological microstructure or replicated genetic code and function. That is, its intrinsic self-generating information code (ISIC) is identical. The central intent for which geneticists copy or synthesize genetic material is for future manipulation of human biological systems, genetic cures for a variety of diseases and prevention. None of these future outcomes would be possible if not for DNA's and cDNA's intrinsic self-generating information code.

Future genetic medical remedies and prevention occur by experimentation on gene copies that have identical genetic informational: the ISIC of genes found in nature's human bodies. This is the sense that matters. Because DNA is "self-replicating," it creates the identical microstructure: intrinsic self-generating information code (ISIC) segment of DNA. That is why the ISIC produces the desired results.

The ISIC in copying and synthesis manipulation is transferred from genetic material to genetic material. DNA's ISIC regenerates itself in a natural or unnatural lab setting, irrespective of natural or unnatural lab catalysts. The enzyme or

catalysts used to create the appropriate pre-RNA, mRNA, proteins and cDNA duplicate sequences in an artificial lab are all-natural enzymes. The hope is that through the understanding of these mechanisms and microstructures we can discover gene function and produce future desired results.

It was ISIC that the US Supreme Court was after in its decision not to patent genomic or natural DNA. They just missed this important bit, that ISIC was the same in both natural DNA and cDNA. The logical step that the US Supreme Court failed to see is that one can isolate or perform some new biological technique in the lab with DNA, yet not change the ISIC nature of DNA. This is also the point the US Supreme Court fails to address.

The necessary component in DNA and cDNA is ISIC. In order to patent a gene, it is not sufficient that geneticists merely isolate cDNA segments of a gene. They must know the phenotype relationship or possible cDNA segment use. Hence, ISIC is necessary for cDNA to retain its informational phenotype relationship. DNA has a causal factor in that the biological function supervenes on the genetic ISIC information.

It is the ISIC microstructure that is duplicated by Art-DNA (cDNA and other duplicating process) used in genetic research, genetic treatments and diagnostics for diseases etc. If the identical microstructure code/information was not duplicated, the biological function would not occur. In the event that an identical biological copy of gene information mechanism and microstructure did not reveal future genetic function (e.g., remedies and prevention, genetic copying, synthesis) the patenting of genetic material would be a moot issue. Again, this assumes no pragmatic or pure scientific pursuits. Were gene information not self-regenerating,

artificial copies would not be produced by way of original self-regeneration (ISIC) and biological function did not supervene on microstructure, producing the desired results, we might have some novel product—we would have to reexamine microstructure and patentability.

Based on this genetic self-regenerating-information supervenient sense of identity, Art-DNA copies are identical to human genes. Hence, because DNA, cDNA, and Art-DNA are all identical and natural at the ISIC level, they are not patentable. To do so would violate the criteria of Utility (new "composition of matter") and patent nature.

The patenting of gene processes is not controversial. Patenting nature's intrinsic self-generating information code (ISIC) is more than controversial, it contradicts its own patent standards. As argued above, given ISIC, the USPTO should not grant human gene patents on moral or legal grounds. The US Supreme Court did make some positives strides in its 2013 decision in prohibiting the patenting of natural DNA.

Although the court made some positive finding, its error is in allowing the patenting of cDNA. The error the courts make is based on the move geneticists make in order to produce cDNA, transfers ISIC (the essence of heredity and information) from DNA to cDNA.

The essence of DNA and cDNA are the same. This fact has not been addressed by proponents of DNA patenting or the US Supreme Court. The problem with the USPTO and the US Supreme Court's decision allowing cDNA patenting ignores ISIC - the sense of identity that matters, giving gene patenting its cache and that which contributes to flourishing personhood. Consequently, I do not

advocate or support The Supreme Court's decision for the patenting of DNA or cDNA as invention.

The nature vs invention ambiguity persists. The Supreme Court holds that naturally occurring DNA are not patentable. Via the Court, non-naturally occurring synthetic strands (cDNA) are patentable. But what of organisms created using both cDNA and naturally occurring DNA? Advances and success in cloning and genetic engineering may mean passenger pigeons, dodos, gastric-brooding frogs, thylacines, woolly mammoths, and other extinct species will once again inhabit this planet. As de-extinction becomes a reality, it becomes unclear whether these animals are patentable.[242]

Currently the Court has not considered organisms created from both naturally occurring and synthetic DNA. This is the case of de-extinction cloning. The Federal Circuit upheld the prior decision to deny a patent for the cloned sheep Dolly. Moreover, the court left room for future patents of other cloned animals. The upshot is that the court's decision to patent of DNA is unjustifiable. Again, the court's additional failure is based on its lack of guidance on future de-extinction cloning. Subsequently, the US Supreme Court's decision and claim that cDNA is not a "product of nature" is incorrect. Furthermore, any of Myriad's cDNA patents violate both the USPTO and US Supreme Court's patent standards for Utility as new "composition of matter," as well as the non-patenting of nature principle.

[242] Swedlow, Miriam Ricanne. "The Woolly-Mammoth in the Room: The Patentability of Animals Brought Back from Extinction Through Cloning and Genetic Engineering." *Wash. JL Tech. & Arts* 11 (2015), 183.

What I argued above is that the Supreme Court's opinion on patenting cDNA is logically inconsistent with its own patent criteria patenting nature, but more importantly, what the above discussion reveals is that the US patent system is a system preoccupied with what it sees as objective procedural and technical expertise. In addition, the Court's inconsistency with regard to patenting nature is also absent in any contribution to human flourishing.

Given the current state of the Patent and Trademark system and that cDNA is patentable, the court shows little interest in biomedical ethics or genomic distribution of justice. Proponents of gene patents and supporters justify using public money by claiming that advanced research in genetic engineering would greatly contribute to a genetically based health care system, public health benefits that would free us from our hitherto biological limits and the creation of personal genetically based medicine. We find this not to be the case.[243]

As shown below, there are things that governments can do to support a moral stance, promote genetic justice that furthers human flourishing as public good through "Science and useful Arts. Governments can implement policies that make public DNA/genes information, drugs, and vaccines affordable and accessible.

A Foundational Start

The central issue of this philosophical work has been achieved—to examine whether genetic patents are justified on moral and legal grounds—which it has been argued here that genetic patents are not justified on moral or legal grounds.

[243] Rose. "*Genes."* Benatar. "Responsibilities," 194-197.

Although a full account of genetic justice is outside the scope of this work, I want to show there are possible ways to move forward. As we have shown above, and history has shown that the US patent system:

> ...has largely dismissed ethical, socioeconomic, health, and environmental concerns, characterizing them as distractions in a domain focused on technical questions of novelty, utility, and inventiveness. The only relevant question, US decision makers suggest, is whether an innovation is a novel technology or simply a natural discovery.[244]

Moreover, the US Intellectual Patent system is used as an alternative "to a legislative approach" to support industry by way of subsidies or other market advantages.[245] Given the current state of genetic patents, I first address health research and healthcare access for low and middle-income individual. I will flesh out biotech funding and reconcile the Constitution's desire to promote the progress of "Science and useful Arts" via patenting.

Genetic justice with regard to any appropriation of genetic information (inclusive of genetic material and healthcare) in a growing genetic world view must begin by taking into account the lack of benefits to vulnerable populations. This includes a "proactive research ethics" in health research and healthcare for low and middle-income individual worldwide.

Genetic research is a global phenomenon, so, one basic start to achieving genetic justice is to implement the Nussbaum Senian capability of human "health," at the very least, to reach a decent level of health. A decent basic level of health

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[244] Shobita, Parthasarathy. *Patent politics: Life forms, markets, and the public interest in the United States and Europe*. University of Chicago Press, 2017
[245] Davis, Michael H. "Patent Politics." *SCL Rev.* 56 (2004): 33

care access must be prioritized for those who are worst-off or disadvantaged. That is, genetic health justice requires a provision for public health, healthcare goods and services. These capabilities services will establish institutions for health, with broader social mandates: political, legal, economic and cultural structures promoting and sustaining individual global health. The development of orphan drugs, commercially undeveloped pharmaceuticals due to limited potential for profitability, remain crucial to this mission.

We need to pursue funding by multiple sources such as: public non-profit, private commercial for-profit and philanthropic funding for example. Funding sources must have distinct accountability, oversight and direction. Direction funding for genetic justice research must avoid for-profit type genetic cosmetics enhancements. Such cosmetics appearance enhancements should be left to the market since this research is not intended as maintenance for normal health care human function.

Public funding should support global genetic research that the market does not. Normal human health care maintenance that minimizes disease and disability should be funded by public and private funds. This does not exclude private funders or philanthropic funders wanting to support genetic research in disease and disability. For-profit biogenetic tech companies should fund these research goals, as the cost of doing business, since pubic funding was the foundational funding for the genome project. An example of a commercially appealing incentive, for-profit research, is found in European legislation. European legislation provides commercial

companies the ability to hold patents on orphan drugs that might not have been developed without the patents[246].

Genetic and biomedical technologies do hold some responsibility to give back to the public interest. Genetic and biomedical for-profit companies often claim that if not for private companies the genetic biomedical industry would not have been created. These genetic and biomedical companies, as shown above, have it the wrong way around. For the most part, first came the public genetic egg, then the proverbial biogenetic chicken industry funding. Which came first were genes, mutations, and then those willing to fund their development. That is, governments as R&D with universities come first, then tech-companies.

Again, since funding will always be an issue to consider, we may ultimately want human genetic enhancement to be funded by a combination of public non-profit, private commercial for-profit and philanthropic funders. These genetic enhancements will focus on mind/body and social issues, since genetic enhancement will be developed as technology moves forward. A combination of funding is needed to ensure development and access to public genetic research such as human enhanced cognition and wellbeing.

Scientific Funds and Useful Arts, Public Genetic Access and Gene Justice

Moreover, let me flesh out tech funding with the following critical dilemma. How is one to reconcile my argument with the Constitution's desire to promote the

[246] https://www.ema.europa.eu/en/human-regulatory/overview/orphan-designation/legal-framework-orphan-designation *Legal framework: orphan designation***.** This page summarizes the legal background to the procedure for orphan designation in the European Union (EU). It includes the key milestones in EU legislation adopted since the Orphan Regulation was first adopted in 1999.

progress of "Science and useful Arts" via patenting. [247] There is a need for changes in the gene patent system. We need to ensure that the R&D genetic and biomedical industries support access: freedom, ability to obtain and make use of DNA/genes information. Genetic and biomedical genetic information access includes affordable drugs and vaccines.

As argued above, given taxpayers' subsidies to the biomedical R&D industry, there is an obligation for the bio-industry to support public access to bio information and free trade low-priced generics drugs. With regard to additional ways to fund public access to bio information and new innovations, governments or world organizations can purchase and support biotech discoveries.

One way to support innovation while assisting in bio information and public health access is through voluntary patent buyouts for developing countries and persons of low income. For example, rights for generic pharmaceutical patents would be given to low-and medium-income countries for antiretroviral drugs used, such as, in AIDS treatments. Innovation and profits would continue via royalties (for buyouts) and ongoing higher income priced markets will also add to profits.

There can also be involuntary compulsory license patent buyouts. In cases of compulsory licensing, patent holders would have to make generic pharmaceuticals available for low-income persons, countries, and public health needs as above. The same gains from higher income priced markets would continue to support innovation and profit.[248]

[247] Us Constitution's (Article 1, section 8, clause 8)
[248] For an additional discussion on compulsory intervention in cases of public health see Singer 1972: Oxfam, 2007; Hunt, 2007.

An additional method for innovation and public access is the prize fund. New drug and gene discoveries (if need be patents) are purchased by governments or world organizations prize funds: rather than give drug developers the exclusive rights to sell products, the government would award innovators money, large monetary "prizes" tied to the actual impact of the invention on improvements in health care outcomes that successful products actually deliver.[249]

With prize funds we can purchase new innovative drugs. Also, we can apply prize funds to purchase new genes discoveries that go into patent pools. These patent pools will be available to all researcher and public organizations in need of healthcare information. This method will stimulate innovation and public access to biotech information.

It does not follow that the prohibition of exclusive DNA & Art-DNA patenting will stifle or cease progress in biotechnology, historical evidence suggests otherwise[250] "Gene pools" can advance the progress of biotechnology. Although a full-blown argument on gene pools is also beyond the scope of this paper, I will give a quick sketch of the gene pool process. A gene pool, as I envision it, is like a patent pool: an agreement between patent owners to grant licenses to pool

[249] Live, James, and Tim Hubbard. "The Bid Idea: Prizes to Stimulate R& (and) D for New Medicines." *Chi.-Kent L. Rev.* 82 (2007): 1519.

[250] Historical evidence suggests that in countries with patent laws, the majority of innovations occur outside of the patent system. Countries without patent laws have produced as many innovations as countries with patent laws during some time periods, and their innovations have been of comparable quality. Even in countries with relatively modern patent laws, such as the mid-nineteenth-century United States, most inventors avoided patents and relied on alternative mechanisms when these were feasible. Secrecy emerged as a key mechanism to protect intellectual property... Overall, the weight of the existing historical evidence suggests that patent policies, which grant strong intellectual property rights to early generations of inventors may discourage innovation. On the contrary, policies that encourage the diffusion of ideas and modify patent laws to facilitate entry and encourage competition may be an effective mechanism to encourage innovation (Moser, P., 2013, 40).

members or non-pool members. The gene/drug pool is only a clearinghouse that administers the collection of human genes and newly discovered drugs. Gene and drug pools will be funded by private, governmental, or international administrators. These pools do not grant patents. Contributors to the pool will be paid for their contribution to encourage additional R & D. Users of the pool technology may also be required to contribute a monetary percentage of any profits gained.

Via open low-cost access to new biotech information and revenue streams, gene biotechnology pools will advance existing and new biotech startups. The gene/drug pool can also be seen as a bio/drug bank administering open access as needed by interested biotechnology and public health agencies. As I explain above, the kind of biobank I propose is one in which all have access to genetic material for research, development etc. Compulsory licensing and prize funds can be incorporated in this biobank as needed.

Apart from the conditions I present above, this will be a common heritage (commons) biobank. Having open access to gene mutations is important because for some mutations, known as genetic variants, it is unclear which mutations confer cancer, for example. Having access to all these mutations helps guide decision making for patients and cancer research. The U.S. lags in using genetic testing as a prevention mechanism and allowing DNA mutation availability. A case in point with regard to open access to cancer mutation is the Consortium of Investigators of Modifiers of BRCA1/2, who make BRCA mutation available:

[T]he Europe-based CIMBA (Consortium of Investigators of Modifiers of BRCA1/2) has pooled mutation data from more than 40,000 BRCA mutation carriers, but 'in the U.S., valuable information is locked away in databases.[251] As a commons biobank its intent is to ensure competition and that many biotech companies work on developing solutions for genomic technologies such as pharmaceuticals directly targeting genetic ailments, gene therapies, new proteins and drugs.

Research has shown that intellectual property (IP) leads to a reduction in "scientific research and product development on the order of 20–30 percent" [252] "compared with diagnostic products arising from freely available sequences."[253] In principle, if biotech and biomedical companies have the ability to exclusively pursue, monopolize and research a particular gene that affects human health, human wellbeing and research, the future of innovation is held in the dubious position of only one entity responsible for innovation. Genetic patens allow future innovation to be controlled by the restricted patent holder decisions, controlling future genetic use, entity void of competition.

One may argue that it is not always the case that IP patents lead to reductions in scientific research and access to needed pharmaceuticals. It is important to address this a prior question. Nonetheless, as Aristotle taught us, one need not always argue via a priori arguments, which must account for every

[251] Ann Azvolinsky. "Supreme Court ruling broadens BRCA testing options." (2013): 1671-1672.
[252] Heidi Williams. "Intellectual property rights and innovation: Evidence from the human genome." (2010).
[253] Kesselheim, Aaron S., Robert M. Cook-Deegan, David E. Winickoff, and Michelle M. Mello. "Gene patenting—the Supreme Court finally speaks." *The New England journal of medicine* 369, no. 9 (2013): 869.

possible case.[254] In some cases, *a posteriori* arguments will do. As argued above, scores of people in the developing world needlessly die due to the lack of pharmaceutical research and access to existing medicine. One of the most egregious moral catastrophes of our time is that a few cases of patent control in the biotech field can and do adversely affect billions of people—now and in the future.

As we have seen above, there is no shortage in ways to fund biomedical genomic research and extend access. It goes beyond gene ownership and patent law. Ultimately, biomedical genomic technology affects the future of human health, enhancement and humanity as created by future genetic manipulation; moreover, the issue regarding a just distribution of genetic technology and success is a matter of our will to achieve what we value.

A Nussbaum Sen Model for Genetic Distributive Justice

We must now address the inevitable. Genetic appropriation exists and will continue to dominate the future. How do we move forward with the basic Nussbaum Sen capability approach to genetic distribution of justice? First, any attempt at hard and fast rules, is currently premature. Genetic biomedical and genetic research is fluid and a work in progress. We currently do not know which aspects of biotech and genetic research is achievable and valuable for individuals, society, global humanity and the planet. That is, these technologies are in their embryonic stage:

[254] Jonathan Lear. *Aristotle: the desire to understand*. Cambridge University Press, 1988, 193-194.

> ...Consider the failure of IBM's oncology-support software, which attempts to use machine learning to identify cancerous tumours, but which was rejected by medical practitioners "on the ground" (Ross and Swetlitz 2017). The system was trained using synthetic data and was not refined enough to interpret ambiguous, nuanced, or otherwise "messy" patient health records (Strickland 2019). It also relied on US medical protocols, which are not applicable worldwide. The heedless deployment and the poor design of the software led to misdiagnoses and erroneous treatment suggestions, breaching the trust of doctors and hospitals.[255]

Given the Nussbaum-Senian capability approach we can consider "context-specific design," moral capabilities, and flexible deployment to foster a future for genetic justice.

With regard to capabilities addressing genetic justice, it must be constructed and evolve as biotech evolves. Given the new evolving biotech landscape a Nussbaum Sen capability approach is our best starting point. But we must have a strategy that is as fluid as the technology. I propose to reverse engineer a genetic distribution of justice. We can consider the following chemists retrosynthesis method as a thought experiment applied to genetic justice.

Chemists use retrosynthesis to create chemical compounds or recipes. Chemists work backwards starting from the desired product to construct new ways to produce that desired end. For example, take a cancer medicine one can use:

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[255] Josh Cowls, Thomas C. King*, Mariarosaria Taddeo, and Luciano Floridi. "Designing AI for Social Good: Seven Essential Factors." (2019), 2.*

given "Knowledge of possible chemical reactions, you work out which bonds in the compound could be cut until you are left with a list of simple ingredients."[256] One can now take those simple ingredients and create a new way to make the cancer medicine. Pharmaceuticals use artificial intelligence to find these simple ingredients and steps to create a new way to create a new drug and bypass old patents. However, in our case we do not want to avoid patents and make the same drug, we want to create new ways to construct a genetic distribution of justice.

We begin with a goal, say one of Nussbaum's index[257] of basic capabilities, "Bodily Health" capability: one being able to have good health, adequately nourished, adequately sheltered, with sanitary and safe living and working conditions; having access to preventative, curative, and rehabilitative medical services. We next work backward to find the best-known ways to achieve Bodily Health. But we do not stop there. Once we find some steps to achieve our goal, we test it, look for new ways to reach our goal given new technologies and old proven methods. Moreover, we implement these methods and rework methods that do not work. I call this process a proto-capabilities method, because the method is intended to be as fluid as Biotech, but more importantly as fluid as persons and life.

We know that this view will not go unchallenged. Some may say that genetic justice is intractable. Another example will be helpful here. Let's take another intractable problem, say, racism or sexism and use the proto-capabilities method to see how one may start to alleviate these intractable problems.

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[256] *New Science, (January 2019) AI knows how to bust drug patents, Volume 241, Issue 3214, 26, Page 15.*

[257] Nussbaum, Martha C. *Women and human development: The capabilities approach*. Vol. 3. Cambridge University Press, 2001.

I take these cases because it is commonly argued that racism has and will always be with us. This is easy to refute. First think of a time when we were, for the most part, free from racism. Is there a time when we were free from racism or sexism? That time is infancy to early childhood. This is a time of innocence when we were willing to play or interact with others and were blind to racism or sexism. We work backwards, revering through that time of innocence and recapture those moments of freedom from societal and cultural bias. In this way we can work our way back to that time and reconstruct it. The point there is that when there seems to be no way to start addressing an intractable problem; there may be ways to begin reconstructing and reverse engineer capabilities for our justice needs. The proto-capabilities method for genetic justice is intended to be self-generating and developing as genetic material and technology.

So, can genetic appropriation be morally justified or improved in the future? At first sight, given the historical state of biomedical ethics and the USPO, genetic appropriation seems resistant to moral justification. A more constructive way to ask the genetic justification appropriation question, given that courts are determined to patent genetic material is: how might one improve genetic appropriation? The genetic justification appropriation question, posed in this way, exposes a crack for a method to exploit.

The method I propose, ex hypothesi, which supports our axiological genetic concerns is a proto-capabilities capabilities using Nussbaum’s index in cooperation with the legal system. To reverse engineer our axiological genetic concerns we need to start with targets to reach. Nussbaum’s capabilities index approach tells us what we should look at to enable and “plan a life in accordance with one's own evaluation

of ends."[258] Nussbaum's capabilities index approach can also guide the direction genetic patents should be sensitive to. In order to balance the US Intellectual Patent system's market driven policies toward more public access, genetic patents must support and not stifle Nussbaum's capabilities, for example:

> 1. Life**.** Being able to live to the end of a human life of normal length; not dying prematurely, or before one's life is so reduced as to be not worth living.
>
> 2. Bodily Health. Being able to have good health, including reproductive health; to be adequately nourished; to have adequate shelter[259] (See appendix F).

It is clear that market driven policies are entrenched in current US Intellectual Patent and legal systems. On the other hand, there are ways to implement Nussbaum's dignity capabilities into the legal system.

Ideally, these dignity capabilities should be used in an Intellectual Patent system with open access to human genetic information.[260] One ideal method would be the implementation of the Common Heritage of Mankind approach to access genes and genetic information. Applying the Common Heritage of Mankind approach means genetic resources are not subject to appropriation and will be managed with universal interests. The economics of the Common Heritage of

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[258] Nussbaum, *"Sex,"* 57.
[259] For the full list see APPENDIX F THE CENTRAL HUMAN CAPABILITIES. Martha Nussbaum C. "Symposium on Amartya Sen's philosophy: 5 Adaptive preferences and women's options." *Economics & Philosophy* 17, no. 1 (2001): 67-88.
[260] For an overview of potential international approaches to ownership and control of human genetic resources see Catherine Rhodes. "Potential international approaches to ownership/control of human genetic resources." *Health Care Analysis* 24, no. 3 (2016): 260-277.

Mankind approach requires that any benefits from genetic use or exploitation is to be shared internationally; and their use is limited to peaceful purposes. Moreover, all biotechnologies and (genetic resource) scientific research benefits will be accessible to all. An example of a genetic common heritage of mankind principle is express by Christopher C. Joyner as:

> 1. not… subject to appropriation of any kind, either public or private, national or corporate… owned by no one, though hypothetically managed by everyone. Sovereignty would be absent, as would all its legal attributes and ramifications… legally the entire area would be administered by the international community.[261]

To apply the Common Heritage of Mankind approach would take a monumental shift in world politics and must come from a universal agreement of all governments. It is my hope that one day we reach this agreement.

We could consider using Nussbaum's dignity capabilities at the Intellectual Patent system level similar to the European Union (EU). The Trade Related Intellectual Property rights (TRIPs) allow member countries to exclude patents or inventions that may offend public order or morality of society. The TRIP's Article 27.2 states that:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such

[261] Christopher C. Joyner. "Legal implications of the concept of the common heritage of mankind." *International & Comparative Law Quarterly* 35, no. 1 (1986): 190-191.

> exclusion is not made merely because the exploitation is prohibited by their law.

The terms "ordre public" and morality, and exclusion in Article 27.2 needs clarity and will development over time. For example, Ordre can mean "matters that threaten the structure of civil society as such... and morality can mean...degree of conformity of an idea to moral principles."[262] This approach is one I hope will continue to move forward, and it will also need major governmental changes. Is there an approach that can be used more direct in the genetic industry?

We do have a more direct genetic industry approach. We can implement Nussbaum dignity capabilities with what Sherkow calls "ethical licensing" for foundational tools like CRISPR-Cass9."[263] Just as patents can exclude others from using the claimed invention, patent holders can dictate to the world how one is to use the inventors' technology:

> The license that Editas Medicine, Inc. (Editas), the surrogate licensee to which the Broad Institute has outsourced its licensing and commercialization rights, granted to Monsanto (recently acquired by Bayer) is an example of such ethical licensing. In this license, specific applications were expressly prohibited, such as the creation of sterile "terminator" seeds or the conduct of research aimed at commercializing tobacco products...[264]

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[262] UNCTAD – ICTSD, Resource Book on TRIPs and Development, (Cambridge University Press, New York 20 05), 375.
[263] Jacob S. Sherkow "Patent protection for CRISPR: An ELSI review." *Journal of Law and the Biosciences* 4, no. 3 (2017): 571-572
[264] Nienke de Graeff, Léon E. Dijkman, Karin R. Jongsma, and Annelien L. Bredenoord. "Fair governance of biotechnology: Patents, private governance, and procedural justice." *The American Journal of Bioethics* 18, no. 12 (2018): 57-59. See also Oliver Feeney, Julian Cockbain, Michael Morrison, Lisa Diependaele, Kristof Van Assche, and Sigrid Sterckx. "Patenting foundational technologies: Lessons from CRISPR and other core biotechnologies." *The American Journal of Bioethics* 18, no. 12 (2018): 36-48.

Other "ethical licensing" inventers prevent uses of their invention or technology, unless the user discloses the research plans, safety, and ethical issues.[265] The "ethical licenses" can be used to endorse Nussbaum's capabilities index approach. Biotech companies can put some time and R&D work to enhancing capabilities. Biotech companies can work on Nussbaum's dignity capabilities on the side in addition to their normal work as the price to acquire patents. Capabilities to develop and consider would be, for example Life: developing and giving access to genic technology that support normal length of human life; and Bodily Health: being able to have good health, including reproductive health. Those who would challenge this approach as unlikely to work in the biotech world are reminded of the current uses of the "ethical licenses" Editas Medicine above.

What I bring new to this discussion is the proto-capabilities approach using Nussbaum's index in cooperation with the legal system, as a start, to further be developed. The proto-capabilities approach using Nussbaum's index, supports Lockean human flourishing and avoids Moore and Nozick's Lockean proviso problem. Additionally, the proto-capabilities method is compatible with Beneficence and Autonomy. Beneficence and Autonomy are implied in the Nussbaum-Sean proto-capabilities method. Additionally Nussbaum's index of capacities underscore her commitment to public good as:

> ...an account of the central capabilities provides a necessary basis for political principles, giving not a complete account of the good or of human flourishing, but a political account, specifying certain capacities, liberties, and

[265] Christi J. Guerrini, J., Margaret A. Curnutte, Jacob S. Sherkow, and Christopher T. Scott. "The rise of the ethical license." *Nature biotechnology* 35, no. 1 (2017): 22.

opportunities that have value in any plan of life citizens may otherwise choose.[266]

According to Nussbaum her approach is an account "that is worthy of the dignity of the human being." The basis of Nussbaum's account is to get on with life, which includes a prominently political life. Nussbaum's basic capacities as the political good are political "...constraints: citizens should be provided with these, whatever else politics also pursues." An example of Nussbaum's is

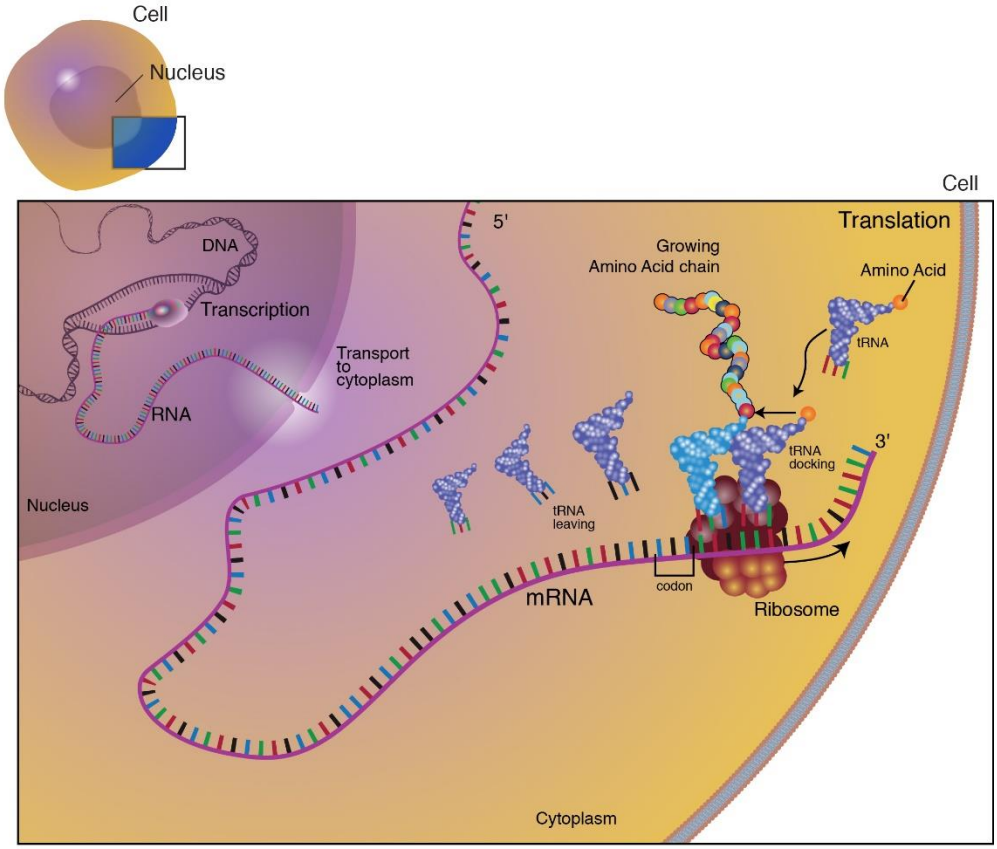
> Affiliation... Being able to live with and toward others, to recognize and show concern for other human beings, to engage in various forms of social interaction; to be able to imagine the situation of another. (Protecting this capability means protecting institutions that constitute and nourish such forms of affiliation, and also protecting the freedom of assembly and political speech.)...[267]

Subsequently, this work is a call to arms to develop and reverse engineer genetic justice - that is, to implement genetic justice via the proto-capabilities method in support of human flourishing as ethical research, and to support the public good in the legal system.

[266] Nussbaum C. "Symposium" 83.
[267] Ibid. 87. See APPENDIX F for complete quote.

Appendix A1

DNA Packed into Chromosomes and Molecule



SOURCE:

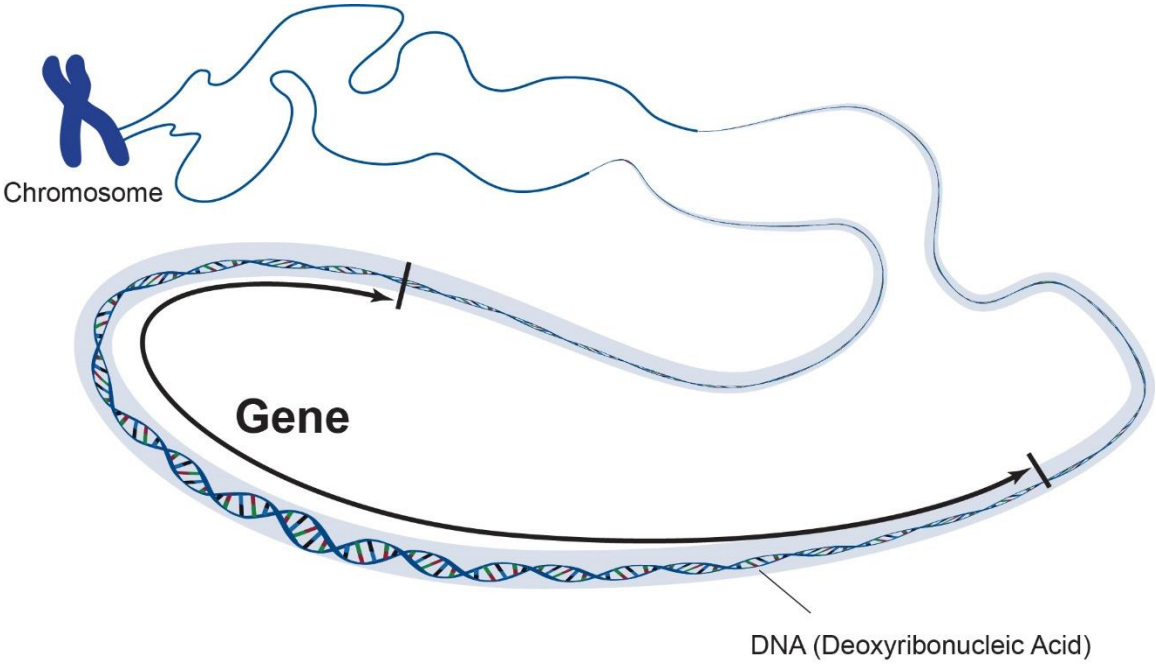
https://www.genome.gov/dmd/img.cfm?node=Photos/Graphics&id=85282

DNA is found in chromosomes, and chromosomes are found in cells.

A chromosome is an organized package of DNA found in the nucleus of the cell. Different organisms have different numbers of chromosomes. Humans have 23 pairs of chromosomes--22 pairs of numbered chromosomes, called autosomes, and one pair of sex chromosomes, X and Y. Each parent contributes one chromosome to each pair so that offspring get half of their chromosomes from their mother and half from their father.

Appendix A.2

X Chromosome that Contains DNA



SOURCE: genome.gov

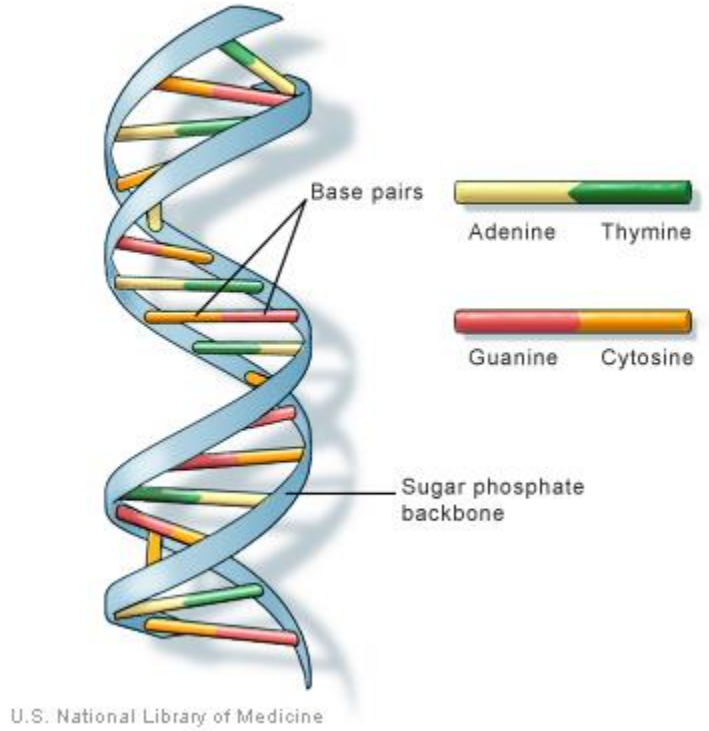
https://www.genome.gov/dmd/img.cfm?node=Photos/Graphics&id=85170

Above on the left we see an X chromosome that contains DNA.

The gene is the basic physical unit of inheritance. Genes are passed from parents to offspring and contain the information needed to specify traits. Genes are arranged, one after another, on structures called chromosomes. A chromosome contains a single, long DNA molecule, only a portion of which corresponds to a single gene. Humans have approximately 23,000 genes arranged on their chromosomes.

Appendix B

DNA Double Helix Formed Base Pairs Attached to Sugar Phosphate Backbone



Source: National Library of Medicine: https://ghr.nlm.nih.gov/handbook/basics/dna

Deoxyribonucleic acid (Nucleotides) are organic molecules consisting of four chemical bases. The four chemical bases are adenine (A), guanine (G), cytosine (C), also known as DNA. These DNA bases pair up as follows: A with T and C with G. DNA bases pairs together with to a sugar molecule and a phosphate molecule to form units called a nucleotide. DNA contains the material and information for

hereditary, natural growth and self-replicate for almost all other organisms. In this image we can also see the double helix form of DNA.

Appendix C

TruGenome Predisposition Screen (Whole Genome Sequencing)

The National Center for Biotechnology Information (NCBI) has a predisposition screening site for gene function: http://www.ncbi.nlm.nih.gov/gtr/tests/515046/ There are 1578 genes and variants one can test which include name of the gene, disease and symptoms some examples are:

ALXDRD (Gene) Alexander disease

Alexander disease is a progressive disorder of cerebral white matter that predominantly affects infants and children and has variable life expectancy.

ACLSD (Gene) Acid-labile subunit deficiency

Acid-labile subunit deficiency is characterized by severely reduced serum insulin-like growth factor…Pubertal delay in boys and insulin insensitivity are common findings.

BRCA1 (GENE) Inherited breast cancer

Mutations in this gene are responsible for approximately 40% of inherited breast cancers and more than 80% of inherited breast and ovarian cancers.

BRCA2 (GENE) Inherited breast cancer 2

BRCA2 is considered a tumor suppressor gene, as tumors with BRCA2 mutations. Both BRCA1 and BRCA2 are involved in maintenance of genome stability, specifically the homologous recombination pathway for double-strand DNA repair.

From Office of Science, U.S. Department of Energy. Biomedical Applications of Genomics and Human Genome Sequencing. http://web.ornl.gov/sci/techresources/Human_Genome/publicat/BattelleReport2011.pdf

Appendix D

The National Center for Biotechnology Information (NCBI) Genetics Home Reference: https://ghr.nlm.nih.gov/gene

This site is the U.S. National Library of Medicine. The reference site explores the normal functions of human genes and the health implications of genetic changes. Some examples are:

CFTR (Gene) Cystic fibrosis

The CFTR gene provides instructions for making a protein called the cystic fibrosis transmembrane conductance regulator. This protein functions as a channel across the membrane of cells that produce mucus, sweat, saliva, tears, and digestive enzymes. The channel transports negatively charged particles called chloride ions into and out of cells. The transport of chloride ions helps control the movement of water in tissues, which is necessary for the production of thin, freely flowing mucus. Mucus is a slippery substance that lubricates and protects the lining of the airways, digestive system, reproductive system, and other organs and tissues.

The CFTR protein also regulates the function of other channels, such as those that transport positively charged particles called sodium ions across cell membranes. These channels are necessary for the normal function of organs such as the lungs and pancreas.

HFE (Gene) Hemochromatosis

Normal Function

The HFE gene provides instructions for producing a protein that is located on the surface of cells, primarily liver and intestinal cells and is also found on some

immune system cells. The HFE protein interacts with other proteins on the cell surface to detect the amount of iron in the body. The HFE protein regulates the production of another protein called hepcidin, which is considered the "master" iron regulatory hormone. Hepcidin is produced by the liver, and it determines how much iron is absorbed from the diet and released from storage sites in the body. When the proteins involved in iron sensing and absorption are functioning properly, iron absorption is tightly regulated. On average, the body absorbs about 10 percent of the iron obtained from the diet. The HFE protein also interacts with two proteins called transferrin receptors; however, the role of these interactions in iron regulation is unclear.

SRY (Gene) sex determining region Y

Normal Function

The SRY gene provides instructions for making a protein called the sex-determining region Y protein. This protein is involved in male sexual development, which is usually determined by the chromosomes an individual has. People usually have 46 chromosomes in each cell. Two of the 46 chromosomes, known as X and Y, are called sex chromosomes because they help determine whether a person will develop male or female sex characteristics. Girls and women typically have two X chromosomes (46, XX karyotype), while boys and men usually have one X chromosome and one Y chromosome (46, XY karyotype).

The SRY gene is found on the Y chromosome. The sex-determining region Y protein produced from this gene acts as a transcription factor, which means it attaches (binds) to specific regions of DNA and helps control the activity of particular genes.

This protein starts processes that cause a fetus to develop male gonads (testes) and prevent the development of female reproductive structures (uterus and fallopian tubes).

From Office of Science, U.S. Department of Energy. Biomedical Applications of Genomics and Human Genome Sequencing. http://web.ornl.gov/sci/techresources/Human_Genome/publicat/BattelleReport2011.pdf

Appendix E

Table 14: Biomedical Applications of Genomics and Human Genome Sequencing

Potential Application	**Genomics Advances Today**	**Hope for the Future**
Diagnosis of single gene Mendelian diseases and Disorders	Specific genes for over 3,000 Mendelian monogenic diseases[268] discovered. Genomic tests are being used to accurately diagnose rare diseases and disorders, many of which were previously misdiagnosed with inappropriate courses of treatment prescribed. Prenatal genetic screening is being performed to inform potential parents of risks for catastrophic inheritable disorders.	Gene therapies will achieve success in repairing genetic abnormalities leading to diseases and disorders. Custom therapeutic products will block or change expressed activity of defective genes.
Knowledge of predisposition towards specific diseases	Multiple genes and biomarkers have been identified for predisposition to multiple diseases such as cancers, neurological diseases, psychiatric disease and cardiovascular disease.	Understanding of risk for disease based upon multi-gene tests will likely lead to appropriate therapeutic interventions and personal behavior/lifestyle modification. Environmental components of disease emergence and progression will be

268 Mendelian monogenic diseases, diseases caused by mutations in one gene, and they sometimes run in families.

		teased-out from genomic factors and addressed appropriately.
Genomics driven drug discovery, known as rational drug development	New drug targets have been identified. Cancer drugs based on the genomics of tumors are on the market, including Gleevec (for chronic myelogenous leukemia), Herceptin (breast cancer),Tarceva (lung cancer) and Avastin (colon, lung and other cancers).	Many new drugs and biologics will be developed to successfully exploit elucidated drug targets.
Therapeutic products custom prescribed based on patient genomics, to maximize effect and reduce or eliminate side effects	Already being applied in the treatment of some forms of cancer and cardiovascular disease. Genetic tests are used for dosage levels in prescription of some drugs such as Coumadin (warfarin).	Routine sequencing of a patient's entire genome will guide treatment selection and dose for the optimum response. Potential adverse reactions to drugs and treatment regimens, identified via genomic markers, will result in the avoidance of adverse events.
Repurposing or revitalization of some drugs shelved in development because of impact on a "genomic few"	Successful discovery of subpopulations for which previously unapproved drugs are efficacious. Iressa, for example, has been approved with patents testing positive for the EGFR mutation.	There will be a substantial volume of existing drugs found to be efficacious in selected sub-populations, and drug companies will have mined their previously "failed" R&D pipelines to bring forward previously nonmarketable drugs to work in selected sub-populations.

Identification of means to combat infectious organisms	Multiple infectious organisms have had their whole genomes sequenced. Public health professionals sequence emerging infectious disease organisms to monitor migrations and mutations. Genetic testing already being applied to direct therapy for HIV/AIDS patients.	Multiple infectious organisms have had their whole genomes sequenced. Public health professionals sequence emerging infectious disease organisms to monitor migrations and mutations. Genetic testing already being applied to direct therapy for HIV/AIDS patients.
Gene therapies for inherited genetic diseases and disorders	After publicized setbacks, gene therapies are now achieving success. For example, the fatal brain disorder adrenoleukodystrophy has been treated, with progression stopped, in a sample of children.	Gene therapy may be routinely provided to newborns with identified genomic profiles to correct defective genes, particularly in conditions associated with devastating monogenic disorders.

"Modern medicine arose when scientists learned to fight some of the worst infectious disease with vaccines and drugs. This strategy has not worked with AIDS, malaria, and a range of other diseases because of their complexity and the way they infiltrate processes in cells. Curing such infectious diseases, cancer, and the health problems that arise from defective genes will require a new type of medicine based on a thorough understanding of how cells work and the development of new methods to manipulate what happens inside them."

The HGP was and is one of the central projects leading to this "understanding of how cells work" and opening the way for new applications of molecular medicine.

Russ Hodge, "The Future of Genetics: Beyond the Human Genome," 2010

Source: Economic in Pack of the Human Genome Project May 2011, .p 23. http://web.ornl.gov/sci/techresources/Human_Genome/publicat/BattelleReport2011.pdf

APPENDIX F

THE CENTRAL HUMAN CAPABILITIES

1. Life. Being able to live to the end of a human life of normal length; not dying prematurely, or before one's life is so reduced as to be not worth living.

2. Bodily Health. Being able to have good health, including reproductive health; to be adequately nourished; to have adequate shelter.

3. Bodily Integrity. Being able to move freely from place to place; to be secure against violent assault, including sexual assault and domestic violence; having opportunities for sexual satisfaction and for choice in matters of reproduction.

4. Senses, Imagination, and Thought. Being able to use the senses, to imagine, think, and reason, and to do these things in a `truly human' way, a way informed and cultivated by an adequate education, including, but by no means limited to, literacy and basic mathematical and scientific training. Being able to use imagination and thought in connection with experiencing and producing works and events of one's own choice, religious, literary, musical, and so forth. Being able to use one's mind in ways protected by guarantees of freedom of expression with respect to both political and artistic speech, and freedom of religious exercise. Being able to have pleasurable experiences and to avoid non-beneficial pain.

5. Emotions. Being able to have attachments to things and people outside ourselves; to love those who love and care for us, to grieve at their absence; in

general, to love, to grieve, to experience longing, gratitude, and justified anger. Not having one's emotional development blighted by fear and anxiety. (Supporting this capability means supporting forms of human association that can be shown to be crucial in their development.)

6. Practical Reason. Being able to form a conception of the good and to engage in critical reflection about the planning of one's life. (This entails protection for the liberty of conscience and religious observance.)

7. Affiliation. A. Being able to live with and toward others, to recognize and show concern for other human beings, to engage in various forms of social interaction; to be able to imagine the situation of another. (Protecting this capability means protecting institutions that constitute and nourish such forms of affiliation, and also protecting the freedom of assembly and political speech.)B. Having the social bases of self-respect and non-humiliation; being able to be treated as a dignified being whose worth is equal to that of others. This entails provisions of non-discrimination on the basis of race, sex, sexual orientation, ethnicity, caste, religion, and national origin.

8. Other Species. Being able to live with concern for and in relation to animals, plants, and the world of nature.

9. Play. Being able to laugh, to play, to enjoy recreational activities.

10. Control Over One's Environment. A. Political. Being able to participate effectively in political choices that govern one's life; having the right of political participation, protection of free speech and association. B. Material. Being able to hold property (both land and movable goods) and having property rights on an equal basis with others; having the right to seek employment on an equal basis with others; having the freedom from un-warranted search and seizure. In work, being able to work as a human being, exercising practical reason and entering into meaningful relationships of mutual recognition with other workers.

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