



Individual and Collective Rights in Genomic Data: Preliminary Questions

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Abstract

Within the past decade, nearly 1/5 of the human genome has been patented by corporations, universities and research institutes. This happened with little in the way of philosophical debate nor ethical inquiry. There are a number of practical, ethical questions raised by this practice which should be explored, and which are introduced here, which should inform debate in the public policy arena regarding the patenting of human genes. Among these issues are: the ontological status of human genes and persons, the ethics of ownership of human parts and information, the practical consequences of undoing the present situation, and issues of justice regarding the practice of bio-prospecting.

1. The Current Conundrum

The human genome has been mapped, and daily more of its territory becomes known and understood. Scientists are discovering the complex web of relationships between the four-molecule alphabet and the 3 billion base pairs that comprise our genetic identities, and the ongoing dance of proteins and RNA that results in our individual existences. The map is general, giving us a high level view of the landscape, but it is virgin territory for the most part. We have yet to understand just how the expression of the data that makes us who we are actually occurs. Even so, the outlines of the territories of the map are being claimed, with nearly a quarter of the genome now staked out by various parties, patented against the claims of other newcomers.¹ In fact, the ability to stake those claims was largely responsible for the early completion of the Human Genome Project, spurred on by market competitors, and funded by the future value of ownership of DNA sequences and the pharmaceutical promise they hold.

Numerous authors have considered the practical and ethical issues involved in granting ownership over parts of the human genome. The range of considerations has spanned concerns over autonomy, dignity, economic efficiency, and other important ethical considerations. Certainly, most people, when confronted with the fact that their genetic

code is now partly owned by a plethora of universities, corporations and research institutes, visibly blanching and insisting that it ought not to be so. It assuredly is so, and a quick search of the Patent and Trademark Office filings will reveal thousands of patents currently owned on portions of your genome and mine. How can this be? Is it right? Don't I own my own genetic code, or isn't it a commonly-owned human good? These questions have been posed, and various ethicists, legislators, lawyers and theologians have answered in numerous ways. Some attempts have been made to reconcile these varied points of view into declarations, codes, and even laws meant to either settle the ownership question, to create means of remuneration, or to prevent ownership of the human genome or its parts. Yet thousands of new patents continue to issue every year, and the public domain in the human genome continues to shrink.

I have written in the past about the nature of intellectual property in general, arguing that there is no natural right to *expressions* (man-made objects, intentionally produced), and that we are free to create laws regarding the ownership of expressions as we see fit. I have argued that the dichotomy that pitches "utilitarian" versus "aesthetic" expressions, inherent in the distinct realms of copyright and patent, is confusing and ontologically unsound. In truth, expressions are all of a kind, falling along a spectrum, but in no sense are the natural categories of patent and copyright law mutually exclusive. I have argued that understanding the errors of the current ontology of intellectual property leaves us free to restructure our ownership of expressions in more sensible and efficient ways, to carry out better the goals of the authors of Article 1, Section 8 of the U.S. Constitution. Given that intellectual property law is the currently accepted and yet most troubling context for discussing whether one ought to be able to exert property rights over the human genome or its parts, it is natural for me to begin with the methodology I have used in the past, namely, exploring the underlying ontological issues and assumptions and considering whether these have a sound basis, or whether we need a fresh perspective.

The literature and ongoing debate regarding the ethics of genome ownership has so far centered on discussing the following issues:

- a) Is the generic human genome part of some collective human heritage?
- b) Can individuals exert property rights over their individual genomes?
- c) Do patents and other forms of intellectual property protection fairly expedite economic efficiencies and innovation?
- d) Can states or communities justly regulate economic exploitation of populations' genomes collected in databases?²

All of these issues are important and worth considering, and arguments from many viewpoints have been made on all potential sides of these issues. However, no one has adequately addressed a much more basic question which would frame each of these debates. Namely: what are the relations among the following entities: individuals, populations, species, the generic "human genome," and the specific genome of an individual?

In other words, we need to work out the ontology of the above-named entities to better frame the context for the ethical debates about rights, genes and property. Although there is clearly an inherent or assumed ontology underlying the present debate, it seems ill-conceived and worth reconsidering before we draw conclusions. For instance, the current legal and social framework for ownership rights presently being conferred and recognized seems at first glance to be unsound, and various attempts to clarify, restrain, or contain that framework have failed for one reason or another. Let's look at the current framework and those attempts to re-conceive it, and ask whether all of these efforts have jumped the gun, and made erroneous ontological assumptions.

2. The Objects of Our Study

Except for some viruses that rely only on RNA, all living things are built by the interaction

of DNA and RNA within cells and the environment. Deoxyribonucleic acid (DNA) was discovered well before its central function in reproduction, cell differentiation, development, and ongoing existence of organisms was fully realized. It consists of four bases, -- thymine, guanine, cytosine and adenine, -- held together by a phosphate "backbone" and famously revealed by Watson and Crick to twist in a double helix. Because thymine always pairs with adenine and cytosine always pairs with guanine, replicating the three billion base pair length of a full human genome requires only enzymatic splitting of that DNA. Although part of a highly complex process, the simplicity and necessity of the structure of DNA as revealed through the work of Watson, Crick, Wilkins and Franklin, is immediately apparent. DNA is the code upon which the machine of an individual is built, and upon which it builds its offspring. All of the functioning of the organism is bound up with this molecule, in conjunction with scores of other ongoing cellular and biological processes, all nonetheless wholly dependent for their inception and continuation on that code.

Reproduction of all organisms involves the reproduction of the code of an organism's DNA to produce a new organism. In the case of parthenogenesis, the organism's exact code is merely duplicated (although mutations inevitably occur over generations). In the case of sexual reproduction, the codes of two organisms are recombined into a new, unique individual. While biologists had noted that certain traits appear to be inherited by offspring with predictable frequencies, the mechanism of that inheritance was not fully understood until the role of DNA was revealed. The "genes" responsible for certain traits are instructions embedded within an entire DNA sequence to turn on and off the production of various proteins at various stages of development or function. The entire sequence, all three billion base pairs, for an individual, exists in each cell of an organism. As cells differentiate, however, certain parts of the genome necessary for the proper function of discrete organs remain switched "on" while others are switched "off" according to the organ or system in which that cell is situated. DNA is organized into triplets or "codons" each of which is responsible for the production of a known protein, and working together constitute genes of various lengths. Codons are the syntax for the language of DNA.

DNA directs protein production and metabolism indirectly by interaction with messenger RNA, ribosomes and other organelles in each cell. The nucleus, where the DNA is harbored, is essentially a central processing unit that mediates cellular and biological development and function for an entire organism, and it transmits the evolutionary adaptations of the species from one generation to the next. In the sense that an entire species shares much of the same genome, the generic genome is a unique entity, distinct from each instance of that genome in the form of individuals. The genome of the species defines the general characteristics of a species, and the unique genome of an individual defines the unique characteristics of an individual. Thus the "human genome" is an entity, characterizing in general the human species, consisting of certain necessary collections of genes.

The "code" analogy is helpful, as indeed we are learning to decipher the instructions that compose the nearly 24,000 human genes, and to understand how they relate to the development of individuals of a species, and to the evolution of a species itself. This code, however, is unlike most man-made code in that it underlies the formation of the second critical object of our study, namely – *persons*. We are only interested in the moral consequences of owning portions of the human genome because it impacts persons, and persons are the typical objects of moral consideration. Human beings and persons are distinct social entities. Human beings can be dead, or lack consciousness or the capacity for consciousness, but persons cannot. Persons are conscious or potentially conscious, rights-bearing, and duty-bound creatures.

Critical to our study will be uncovering the relationships among DNA, genes, the "human genome," human beings, and persons. At some level, the higher level social

objects we call *persons* consist of the interaction of the DNA molecule with a body and its environment. All of the higher-level functions that we associate with personhood depend ontologically on the chemical processes forming a person's day-to-day development and functioning. Before we make decisions about the justice of allowing for ownership of parts of the human genome, we ought to describe fully those relations in order to discern whether property relations among those entities are proper or even conceivable.

3. The Framework So Far

In the western world, the law of intellectual property has prescribed the legal bounds for ownership of genes and other portions of the genome. A number of reasons account for this, including two important Supreme Court decisions, *Chakrabarty* and *Moore*. *Chakrabarty* established the principle allowing for patents on genetically engineered organisms, and *Moore* established that individuals do not have ownership rights over the fruits of discoveries made by harvesting of their DNA.³ Between these two cases, and a massive land-grab for parts of the human genome justified by Celera Corp.'s entry into the Human Genome Project race, the borders of the current situation were drawn without much in the way of public involvement or ethical consideration, much less sound ontological investigation. Despite the fiat boundaries set by these forces, there is no public consensus over the justice of the current situation. Most ordinary people do not viscerally accept the fact that products of nature, tied up with all human DNA, could be declared to be private property. Moreover, no other analogous legal entity enjoys this status. Partly because DNA is "unique," as argued by those who promote "genetic exceptionalism," the current state of affairs goes largely unchallenged in the public sphere, despite considerable philosophical objections.

The arguments are plentiful and strong in favor of exceptionalism. DNA is indeed unique, but there is very little in-depth argument tying together DNA's clear uniqueness and its current legal and social status. In order to do that, work, more must be done than simply highlighting DNA's uniqueness. What are the relationships among DNA, identity, personhood, rights, duties and property? Are there any analogous objects that might inform these issues?

A number of conflicting statements from world leaders and international organizations have challenged the current framework, suggesting that DNA may be part of a "common human heritage" and thus not prone to private ownership, or suggesting that individuals themselves own the rights to their own DNA. These alternative frameworks have been proposed late in the game, and rarely adopted, to little net effect in the race to patent portions of the human genome.⁴

The stakes under the current framework are significant and should be cause for concern. They are not alarmist nor simply academic. The practical consequences of patenting segments of DNA without ethical clarity about the subject may include increased litigation, costlier research and therapies, and the potential for significant conflicts regarding unintentional infringements. The economic incentives of patent are also significant, and if the current framework can be sorted out to dampen controversies regarding the practice, then important research can flourish without unnecessary impediment. Currently, and without adequate reason, DNA is being treated like software, steam engines, man-made chemical compounds, and other more likely candidates for patent. And estimated 20% of the human genome is now claimed under patents held by corporations, research institutes and universities. It is not yet too late to consider whether there is a sound theoretical basis for this.

a) The Property Paradigm

Property is perhaps one of the oldest concepts in law, and it is not surprising that it has arisen as a dominant theme in arguments for control over DNA. The most common forms of property historically are real property, moveables, and chattels. Each of these can arguably arise extralegally, with the brute facts of ownership exerted by possessors and those who literally stake out the bounds of their possessory interests. Possession is extralegal in that it is a fact independent of any legal or social facts. It is a brute fact as described by Searle's account of social reality. The legal and social status of *ownership* follows the brute facts of possession.⁵

As I have argued in *The Ontology of Cyberspace* (Open Court 2000) there is no "natural" or brute fact possession of the expressions we protect via intellectual property law. If we can say that certain forms of natural possessory facts are legally valid or validated by the legal institutions of property and ownership, we cannot say anything similar about intellectual property law. We are free, essentially, to create intellectual property laws as we wish, unbounded by concerns of justice and validity with respect to brute facts of possession. Intellectual property is an expedient designed to improve economic efficiency. Certain types of objects fit neatly into the categories we have created for intellectual property law, although the broad category of such objects is, as I have argued, simply "man-made objects intentionally produced." All intellectual property has, until recently, fallen into this broad category. The subcategories of copyright and patent have covered the spectrum of those objects whose uses have been primarily aesthetic to those whose uses are primarily utilitarian, but there is no natural basis by which to draw clear lines between these two ends of the spectrum of expressions. Thus, I have proposed a unitary scheme of intellectual property protection based upon the ontology of the entities involved and arguments for efficiency.

Are we similarly free to define the bounds of ownership and property rights over the human genome, or are there brute facts grounding certain valid claims and not others?

b.) The Commons Paradigm

There is no consensus yet as to whether portions of the human genome should be granted intellectual property protection, as indeed they are in the U.S. and a number of states, however some international agreements, conventions and experts have argued that genetic exceptionalism requires we treat human DNA not as property to be owned by individuals, but rather as a common good. The notion of the commons involves goods which are difficult to contain, over which no natural, brute facts of ownership are easily exerted, and for which general public well-being argue against individual ownership. Examples of the world typically agreed to be a part of the commons include: air, fresh water, airwaves, outer space, airspace, etc. These sorts of things cannot be enclosed, and enable the efficient working of markets by the fact of their common availability. Common goods may also not be appropriated by one without diminishing its value or amount to the community in general. Many have argued that ideas too are a part of the commons, and that intellectual property law unjustly encloses that which ought not to be enclosed.

Various international and regional agreements as well as a handful of statutes have at one time or another described human DNA or the Human Genome as being part of a "common heritage" and thus unencloseable – in essence, a common good. Some notable features of common goods do seem to overlap with features of DNA, namely: it is not containable or encloseable to any natural exclusion of others, it is abundant and necessary for people in general to thrive, and it arguably benefits economic efficiency in some ways for it to not be circumscribed. On the other hand there are obvious differences between DNA and other common goods. For instance, each particular individual genome is unique to the individual, and can be appropriated with no diminution of its value to the individual. The same may be argued about the generic "human genome." Its appropriation does not deprive humanity in general, and in fact arguably enriches

everyone given the health benefits expected to be achieved by scientific research and technological development conducted with the help of profits garnered through intellectual property protection.⁶

Convincing arguments have been made regarding the strain on efficiency and drag on innovation that treating the human genome as a commons might pose. Indeed, with about a quarter of the territory already claimed, it seems clear that a reversal of the trend would be costly. But it should not be too late to inquire into whether a current practice is just, or philosophically warranted, and as to whether it ought to be adjusted or even abandoned in light of updated thinking or ethical considerations.

4. Special Challenges of DNA

DNA is clearly unique. No other chemical or compound directs its own replication as it does. It has evolved a remarkable range of strategies for replication, resulting in all of the millions of species here on Earth. Most of those species, in fact, share much of their DNA. We share with the fruit fly genes that conduct the same processes, and in all likelihood share the same historical evolutionary origin. Genetic exceptionalism has not been reflected in any exceptional legal or social treatment. Why, if DNA is so different than other types of compounds or objects, is it treated in the law as though it were a man-made object intentionally produced? Why are we shoving a double helix into a square hole? There may well be arguments to back this up, but they have not been well-expressed. The most frequent arguments have been purely utilitarian, and the theoretical underpinnings are lacking.⁷

Ordinarily, products of nature are not granted patent or other property protection. Yet today, nearly 4000 of the estimated 24,000 human genes are claimed under various patents held by corporations and universities. These patents exert claims in most instances over the specific genetic sequences of the genes – the strings of base pairs that form the genes themselves, as well as techniques and processes associated with finding those specific strings. The limits of patent protection have previously been to inventions which are novel, useful, and new. Thus, if new naturally occurring compounds are discovered, no patent protection could issue. Patents could be granted for *applications* of the new discovery to processes, or methods of synthesizing those compounds, but not for the structure of the compound itself. In the case of DNA, there is certainly a form of legal exceptionalism going on in the Patent and Trademark Office. Moreover, this exceptional legal treatment is being urged on the rest of the world through various international agreements and trade practices.⁸

DNA poses numerous challenges to the current legal framework for protection, and may suggest developing an entirely new social and legal category, recognizing its uniqueness. First, however, we should unravel the actual nature of the relations of DNA to individuals, and species. We must delve into the ontology of the genome and its relationship to persons.

5. Property and Parts

As discussed briefly above, certain types of legal ownership are reflections of brute facts regarding possession that make such legally recognized rights and duties *grounded*. Justice reflects an accurate correlation of law and natural states of affairs. For instance, legal codes that recognize theft as conferring property rights are unjust. The sorts of things that can be owned legally are those whose possession can be asserted openly, publicly and maintained through various social acts. Those sorts of things that cannot be stolen or adversely occupied are generally treated as commons. An in-depth analysis of property

and property relations ought to precede determining that DNA can be property. Along the way, we will have to consider whether DNA is more like intellectual property, under which protection is currently granted, or more like other forms of property. We may in fact discover that DNA is a unique type of object fit for unique property protection, or none at all.

We may also determine that DNA is not a distinct entity, but rather a part of another entity. This is an important distinction because the law does not recognize property rights in one's own body parts. We might inquire into the justice of this prohibition, but it seems to be a rather universally accepted norm that one cannot alienate one's own body parts at whim. Is there a sound ontological basis for treating body parts this way? If so, is DNA to be treated like a body part?

In determining the relation of DNA to individuals, we will need to discern the mereology (the study of parts and boundaries) and topologies of highly complex objects. In so doing, we will need to elaborate the nature not just of the DNA that instructs the formation of a person, but of a person itself. One reasonable conclusion of our investigation may be that DNA and persons are holistic objects, incapable of reductionism. Such a conclusion would have significant implications for how we ought to treat DNA legally and socially.

6. Ethics and Method

So far, those who have considered the issues raised above have done so by analogy, or by applying ethical theories of various sorts (utilitarianism, Kantianism, etc.) to the present legal and social status of human DNA. This has been putting the cart before the horse. It assumes too much about the nature of DNA to accept its current classification while arguing either for or against the ethics of its ownership. The best literature on the subject has argued for genetic exceptionalism, pointing out DNA's unique nature.¹⁰ Neither those who have done this good work, nor those who have prematurely argued either for or against the ethics of DNA ownership, have done the foundational work of describing the objective relations among genomes, genes, individuals, persons and species. Only by first describing these relations can we begin to consider the justice of treating DNA as property or as a commons, or as something entirely new.

While I do not wish to argue from a particular ethical theory, neither utilitarianism nor Kantianism, nor some other fixed ethical standpoint, I do assume that there is such a thing as *Justice*. Part of my argument will involve defending the claim that certain laws are *grounded* and others are not. If in fact there is no *justice*, and laws bear no relation to it, then there is no sense in evaluating the justice of any particular system or institution as against any other. I also assume that even those who call themselves Utilitarians care about justice. Utilitarianism concerns itself also with the "good" and is thus an ethical theory by which *justice* is often measured. There are many flaws more able philosophers have noted with both pure deontological and pure utilitarian theory. For instance, utility is itself based upon an arbitrary yet absolute value: happiness. Deontological theories of the good are flawed because they must admit of defeasible values, and evils must be weighed one against another. These objections and arguments are well-known. While the first stage of our investigation will seek to uncover the ontology of the genome in relation to persons, etc., we will at some point wish to make decisions about the *justice* of the present state of affairs as measured against other possible states of affairs. In so doing we will look to bolster arguments I have mentioned so far in passing, regarding the groundedness of certain legal institutions and objects, allowing for us to call certain of them "valid" and others not. We will also consider, for those not swayed by this definition of Justice, the economic utility of various schemes of treatment of human DNA.

Ultimately, I will argue that our normative ethical decisions about property as an institution precede theory, and that pure ethical theories fail because they are not

themselves scientific. They start from first principles, rather than observation. Institutions, laws, rules and customs are based, at some point, on brute facts. It is at that nexus, between pre-institutional or extralegal facts, and the institutions we devise, that *Justice* is instituted or fails. Observation of brute facts, and careful examination of necessary relations that exist pre-institutionally, pave the way for decisions about how or whether laws, customs or social norms are supported by the brute facts of the world.

7. An Outline for The Investigation

Our first step will be to look carefully at the science of the relations among the smallest constituent parts of our study, namely, the biochemistry of the genome. How are genes formed from their organic components, how do they interact with the environment, both at the cellular level and extracellularly, to produce proteins, and how do those proteins interact with the environment and each other to create a functioning unique organism? This inquiry will lead us to our first big philosophical puzzle: how does the mechanism described by these processes correlate to the social object we call a "person?" We will consider some problems of genetic determinism, including the role of genes in forming behaviors, and the role of the environment in interacting with genes and behaviors to shape the social continuants of, for instance, George Bush or Osama Bin Laden. The link between personhood and the genome is crucial to discerning whether DNA ought to be treated as property, part, or as some other object given that the social and legal institutions of property and ownership only apply to *persons*.

Next we will look into the relationships among individuals and species. DNA is not like any other known compound in that each individual's genome is unique, but all DNA shares certain general features.¹¹ How are the general features of DNA reflected in the "human genome" as opposed to individual genomes? How are these similarities and differences reflected in individuals of a species versus the species itself? Uncovering these relations should help us discern the nature of individual or collective rights, if any, over the human genome or individual, unique genomes or their parts.

We will examine the dimensions of gene ownership under current regulatory and legal regimes internationally. We will look also at cultural norms regarding ownership in general, and consider the application of various property and ownership norms to the special characteristics of the human genome and individuals' genomes. We will also look at the current dominant scheme of intellectual property protection for genes, consider to what degree genes are like other forms of intellectual property, and the degree to which they differ. We will then compare this with objects that are generally considered to be part of the "commons" and analyze the ontology of common goods versus property in general before applying this to the special problem of the human genome. To what degree is the notion of a commons supported by the world of brute facts, and can an argument be made that the human genome is a part of that world?

In the process of considering the above, we will examine arguments in favor of moral realism based upon the "groundedness" of legal and social institutions. Examples from the relatively uncontroversial world of real property, moveables, and chattels will be compared with the human genome and individual genomes. We will also continue to discuss the relation between justice and groundedness under this version of moral realism.

Because we are concerned not just with pure theory, we will delve into practical considerations of both the current scheme of DNA protection and potential alternatives. What are the economic consequences of patent and other forms of protection?¹² What results could we anticipate from treating DNA as a commons, and are there other possible means of achieving the goals of justice and spurring innovation by economic reward?

Finally, we will synthesize the results of the investigation to determine whether there is reason to accept the current situation, to modify it, or to revise it entirely. This holistic approach to the problem has not yet been conducted, and only by considering first the

underlying ontological assumptions and applying them to existing and accepted norms of ownership and ethics may we reach considered opinions as to justice, which is our ultimate concern regarding DNA, the human genome, and ownership rights.

8. The Challenge Ahead

Like it or not, we have plunged headlong into a world where large portions of the organic code that is responsible for the development and functioning of every living human being, and generations to come, is claimed as owned by various individuals, corporations, and institutions. These bits of code, in the forms of whole genes, Expressed Sequence Tags (ESTs which indicate where certain genes are located) and even Single Nucleotide Polymorphisms (SNPs, which are unique changes in a single base pair), cannot be manipulated, replicated, or innovated upon without infringing the ownership of the patent holders. There are real-world effects to this ownership, including undeniable effects on further development and research of the function and structure of the human genome. Groundbreaking pharmaceuticals, and greater understanding of the interactions between genes and health are coming to light every day as a result. Meanwhile, we are also experiencing increased litigation, and costs associated with it. The complexity of the patent system, combined with the complexity of the genome, make inadvertent infringements and thus litigation inevitable.

If the current situation were ethically clear, then people would not react as they generally do when presented with the news that 20% of their genome is owned by someone. It is viscerally uncomfortable, and I suggest it is so because it conflicts with something we sense or know about the brute facts of our world and property relations that we tend to accept versus those we do not. Before we move further in the direction we are headed, we ought to sort out the relations among DNA, genes, human beings and persons, and consider how the present situation may or may not accommodate our sense of justice in according others rights over something upon which we all depend and to which we all owe the same debt for our existence.

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