1 INDIVIDUAL AND COLLECTIVE RIGHTS IN GENOMIC DATA: PRELIMINARY ISSUES

Life on earth is bound together by a common heritage, centered around a molecule that is present in almost every living cell of every living creature. Deoxyribonucleic acid (DNA), composed of four base pairs, the amino acids thymine, adenine, cytosine, and guanine, encodes the data that directs, in conjunction with the environment, the development and metabolism of all nondependent living creatures. (There are ribonucleic acid (RNA)-based viruses and phages, but these are dependent upon other living creatures for their development and propagation.) DNA is composed of genes, each of which is a segment of an organism's DNA (which for humans is 3 billion base pairs long). Each gene does something specific, encoding the instructions for a cell's creation of a protein or enzyme, which in turn is responsible for cell differentiation, development, and reproduction. The mechanisms are now well understood. We know what DNA does in a very basic sense. The task that science is now completing is developing a full understanding of the relation and role of each gene, and other information encoded in DNA, to the development, functioning, and reproduction of the whole organism. The human genome is of course the one that interests us most, and understanding the role of each gene in causing us to grow and function as we do will afford us greater prediction and control over human health.

The first stage of that degree of understanding was *mapping* the genome. Once we know where each individual gene falls on the 3 billion base pair chain, we can start to understand differences among individuals and how they relate to the health and particular characteristics of each organism. The Human Genome Project (HGP) began in the early 1990s as a publicly-funded, international project to develop that essential map. Along the way, something happened that was only vaguely anticipated, and that has resulted in private ownership claims to portions of the human genome.

Let's look carefully at the history of the HGP and the emergence of human gene patents before considering some of the ethical implications posed by this new trend.

The Current Conundrum

The human genome has been mapped, and daily more of its territory becomes known and understood. The current map of the human genome is general, giving us a high-level view of the landscape, but much of it remains virgin territory. We have yet to understand precisely how the expression of the data represented by the map helps make us who we are and function as we do. Even so, the outlines of the territories of the map are being claimed, with nearly a fifth 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 HGP, spurred on by market competitors, and funded by the future value of ownership of DNA sequences and the pharmaceutical promise they hold.[2] While Craig Venter's company, Celera Corp., was investing millions in developing new rapid sequencing technologies, part of its value statement and justification to its shareholders for the tremendous capital outlays was the proposition that genes discovered in the process could be patented and become part of Celera's general portfolio of patents. As the US Patent and Trademark Office (PTO) began granting gene patents, other companies, individuals and institutions got into the act. Only after the fact did philosophers, lawyers, and activists begin to consider the practical, legal, and ethical implications of gene patents.

Numerous authors have since 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. 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 blanche and insist that it ought not to be so. It assuredly is so, and a quick search of the PTO filings will reveal thousands of patents currently owned on portions of your genome and mine.[3] How can this be? Is it right? Don't you own your own genetic code or isn't it at least a commonly-owned human good? These questions have been posed, and various

ethicists, legislators, lawyers, and theologians have answered in differing 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. For instance, in 2000 the PTO, concerned about "patent stacking" by which companies were filing patents on genes with no yet-known utility, imposed more stringent requirements for utility claims in gene patent applications. As well, some lawmakers have attempted to stop the patenting of gene altogether, as with Congressmembers' Becerra and Weldon's H.R. 977, "The Genomic Research and Accessibility Act," which has not yet passed. Still, thousands of new patents continue to issue every year, and the public domain in the human genome continues to shrink.[4]

I have written in the past about the nature of intellectual property in general, arguing that there is no natural possessory right to *expressions* (man-made objects, intentionally produced),[5] 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 (our understanding of the nature of the objects themselves and their relations to each other) of intellectual property leaves us free to restructure our systems of 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 US 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.

My methodology rests on a few general assumptions which I believe are uncontroversial, and while much of what follows depends in part on those assumptions, other elements of my argument are merely pragmatic, resting on no particular methodology. The be fair, I assume the following: 1 that while genes do not fully determine who we are, they are largely responsible for our individual traits, 2 that while we can never know

anything with absolute certainty, science works because it accepts as true certain foundational beliefs, and 3 that *justice* is real, not merely invented by human preferences, but founded upon certain immutable, inherent natural kinds. For the philosophers reading this, this makes me more or less a genetic essentialist, a foundationalist, and a natural law theorist, if we must use labels. Nonetheless, while these assumptions work behind much of my argument, other less philosophical, and more clearly pragmatic arguments discussed later lead to many of the same conclusions about gene patenting. Moreover, the arguments made by others who have addressed this issue also hinge upon various philosophical assumptions, and they have ranged over a variety of common themes. Whatever their underlying assumptions, the literature and ongoing debate regarding the ethics of genome ownership has so far centered on discussing the following issues:

1 Is the generic human genome part of some collective human heritage?
2 Can individuals exert property rights over their individual genomes?
3 Do patents and other forms of intellectual property protection fairly produce economic efficiencies and innovation?
4 Can states or communities justly regulate economic exploitation of populations' genomes collected in databases?

All of these issues are important and worth considering, and viewpoints differ markedly. 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, our intuitions suggest that it is ill-conceived and worth reconsidering before we draw conclusions. For instance, the current legal and social framework for ownership rights presently being granted and recognized by patents 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 science in light of 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.

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 their environments. 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. In other words, when you split it in half down its length, two complete copies of the strand can form due to the natural pairing of the bases. 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 physical machine of an individual is built, and upon which it builds its offspring. All of the mechanical functioning of the organism is bound up with this molecule in conjunction with scores of other ongoing cellular and biological processes and the environment, 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 way amoebas reproduce, by splitting themselves in two – 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 which by working together constitute genes of various lengths. Codons are the syntax for the language of DNA.[6]

DNA directs protein production and metabolism indirectly by interacting with messenger RNA, ribosomes, and other organelles (see Chapter 3 for more discussion of these parts of cells) 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 of a species is a unique entity, distinct from each instance of that genome in the form of individual members of the species. 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 abstracted 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 30,000 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 codes 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.

So, 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, mind, and the 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 ownership of parts of the human genome, we ought to attempt to describe those relations in order to discern whether property relations among those entities are proper or even conceivable.

The Legal 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. There are a number of reasons for this, including two important legal decisions, *Chakrabarty* and *Moore*.[7]

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.[8] Between these two cases, and a massive land-grab for parts of the human genome initiated by Celera Corp.'s entry into the HGP race, the borders of the current situation were drawn by the PTO, courts, and corporations without much in the way of public involvement or ethical consideration, much less any sound ontological investigation. Despite the fiat boundaries set by these forces, there is no public consensus over the justice of the status quo.

Most ordinary people do not seem viscerally to 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 and practical objections.

The arguments are plentiful and strong in favor of exceptionalism, though some reasoned objections to the notion have been made.[9] 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.[10]

The stakes under the current framework are significant and should be cause for concern. Objections to patenting genes are not alarmist nor simply academic. Besides the obvious impact on justice, 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 and costly conflicts regarding unintentional infringements. The economic incentives of patent are also significant, and if the current framework can be sorted out in order 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. It is not yet too late to consider whether there is a sound theoretical basis for this.

We can challenge DNA patents on a number of grounds, including ethical objections to owning life or living tissues, or upon notions of human dignity. We might also challenge the economics and practicality of gene patents which arguably interfere with scientific research and innovation. All of this discussion ought to follow some more basic inquiry into the nature of DNA and genes themselves, and whether they properly fit into any existing paradigms of ownership or property. These categories inform our moral choices, and consist of a number of basic possibilities. DNA and genes might be property like other forms of property, like hammers, cars, or homes. Or possibly genes are properly considered to be intellectual property, sharing all essential qualities with other forms of intellectual property. Finally, genes and DNA might be a form of commons, immune to ordinary forms of possession or ownership. Let's briefly look at each of these paradigms.

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 include: real

property (land), moveables (hammers, cars, etc.), and chattels (cattle, goats, etc.). Each of these forms of property can arguably arise extra-legally, 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 brute facts of the world exist with or without human intentions. The legal and social status of *ownership* follows the brute facts of possession.[11]

The Intellectual Property Paradigm

As I have argued in *The Ontology of Cyberspace*, there is no "natural" or brute fact possession of the expressions (the "types" or universals at least) we have chosen to 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. This is because there is no *natural* way to possess the "type" of an expression – anyone may easily copy most expressions without depriving the original author or creator of anything. Intellectual property law 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 easily into this broad category. The subcategories of copyright and patent have covered the spectrum of those man-made, intentionally produced objects whose uses have been primarily aesthetic (copyrightable) to those whose uses are primarily utilitarian (and thus patentable), 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.[12]

Is the genome or are genes intellectual property? 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? Are genes or the genome even expressions of the sort

which can have intellectual property protection under the current legal scheme?

The Commons Paradigm

There is no world-wide consensus yet as to whether portions of the human genome should be granted intellectual property protection, as indeed they are in the US and a number of other nations.[13] Some international agreements, conventions, and experts have argued that genetic exceptionalism requires we treat human DNA not as property to be owned by individuals nor granted intellectual property status, 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 argues against individual ownership. Examples of parts of the world typically agreed to be a part of the commons include: air, fresh water, airwaves, outer space, and airspace. These sorts of things cannot be enclosed, and treating these things as part of the commons enables the efficient working of markets by the fact of their common availability. Common goods may also not be appropriated by one without diminishing their 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.[14]

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 enclosable 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 theoretically unique to the individual, and can be appropriated with no diminution of its immediately useful value to the individual. The same may be argued about the generic "human genome." Its appropriation by one individual does not deprive humanity in general, and in fact may arguably enrich 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. Still others have argued for creating a "contractual" commons for genetic information, purposely making policy decisions to share the resource, regardless of ontological claims about its status.[15]

We will consider these arguments in greater depth, after we explore first the proposed method for inquiry, and delve a bit more in-depth into the science which, I will argue, should first and foremost guide our decision-making.

Special Challenges of DNA

DNA is clearly unique. No other chemical or compound directs its own replication like DNA 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 portions of their DNA with all the others. For instance, fruit flies and humans share genes that conduct similar processes and in all likelihood share the same historical evolutionary origin. Yet, genetic exceptionalism has not been reflected in any exceptional legal or social treatment.[16] Why, if DNA is so different than other types of compounds or objects, is it treated in the law as though it were just another 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.[17]

Ordinarily, products and laws of nature are not granted patent or other property protection. Yet today more and more human genes are claimed under various patents held by corporations and universities. These patents embody 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. Patent protection has previously been limited only to inventions which are novel, useful, and new. Thus, if new naturally occurring compounds are discovered, no patent protection could ordinarily issue. There are a handful of exceptions to this general rule, the most notable being plant patents, but

these have traditionally required some mixture of human innovation with a natural product to create something *new* and *useful*. Patents could be granted for *applications* of a 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 PTO. It is being treated now as a blatant exception to the general rule against patenting discoveries. Moreover, this exceptional legal treatment is being urged on the rest of the world through various international agreements and trade practices.

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. Ultimately, 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.

Property and Parts

As argued briefly above and in more depth in chapters to come, certain types of legal ownership are reflections of brute facts regarding possession that make such legally recognized rights and duties *grounded*. From this natural law perspective, just laws derive their justice from natural states of affairs. Positive legal theorists reject this notion, and argue that law and justice are purely human constructions with no particular grounding. According to positive legal theorists, we could simply legislate, for instance, that private property is unjust and should be illegal, make it a crime to own anything, and thus dispossess people of their property without moral or ethical repercussion.

I will argue in more depth later that the term "justice" fails to have any meaning under such a view, and state simply now that my argument is founded upon a modified natural law theory, in which there are such things as right and wrong, and just laws must be grounded in natural facts. Under this view, *justice* reflects an accurate correlation of laws and natural states of affairs. Thus, legal codes that recognize theft as conferring property rights are unjust. Socially and historically speaking, 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 which cannot be owned by any one individual, but which must be shared by all. 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 for genes 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 perhaps 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 generally recognize traditional property rights in one's own body parts, at least not of the sort encompassed by ordinary property claims. 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 relations of DNA to individuals, we will need to discern the mereology (the study of parts and boundaries) and topologies of highly complex objects. We won't complete that task in these pages, but we will certainly begin the task, pointing out important boundaries and features where we can. 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 could have significant implications for how we ought to treat DNA legally and socially.

There are many things in the world that never receive protection under property or intellectual property regimes. Not everything may be possessed, and there are legal restrictions on ownership of certain things.[18] It may well be that DNA fits under no current legal, cultural, or social scheme of ownership, and that genes are not the sorts of things that can be owned. Moreover, we might wish to clarify whether and to what extent our possession of our own individual genes extends to some sort of *rights* over those genes (both tokens and types). Not every act of possession confers a right, after all. Fully answering questions over the patentability of genes, or other ownership or possessory rights over them, will also rely upon a sound understanding of the relations between genes and ourselves as autonomous individuals.

Autonomy, Individuality, and Personhood

Many of our instincts about patenting DNA, and suspicions about its similarities to other more onerous forms of ownership of persons, may derive from our misunderstandings about the relationship of DNA to individuals and species. In this age of genetic reductionism, and of popular movies and books depicting cloning and genetic engineering, there is a rather frequent tendency to conflate our genes with *ourselves*. If indeed we are nothing but the products of our genes, then surely allowing others to own those genes is a form of slavery or something akin to it. This same tendency may also cause us to mistake the use of a particular population's genetic homogeneity with either racism or some form of unwarranted exploitation. While we may wish to make arguments about the justice of rewarding individuals who donate their tissues to science with remuneration more fitting than we have in the past (for instance, linked to profits, or with more balanced tangible benefits) we ought not to mistake genes for ethnic destiny. Neither should we make the reverse mistake and link historical accident with desert.

None of us is fully the product of our genes, as we shall see in subsequent chapters. Nor is any population, despite its relative genetic homogeneity, the architect of its genetic makeup – its nature is not the result of the sort of intention ordinarily required for invention. Our genetic diversity is greater than scientists previously suspected, even while the genes we share are shared widely and rather fully. That is to say, while you and I share 99 percent of our genes, the important stuff is going on in that 1 percent of difference. The differences amount to much more than genes as well. Information is encoded in the gaps between genes, single-nucleotide polymorphisms(SNPs), and copy number variations (CNV), all of which will be explained in more detail later. Suffice it to say for now, however, that you are not your genes and your genes are not you.

Genetic determinism is being challenged not just for philosophical reasons and without reference to any troubling intellectual puzzles like "free will." Rather, we are learning that the environment interacts with genes in complex ways over time. Epigenetics is the study of the relations and interactions among genes and their environments, and it is showing that genetic determinism or reductionism does not even work at the cellular level. There is reason to suspect that at a higher level, at the level of consciousness and personhood, the extent to which your genes

determine who you are, or make you be you, has been exaggerated significantly.

We must account for all of this in deciding whether patenting genes violates more than mere legal norms, but also social or cultural traditions respecting notions of privacy and autonomy. We will thus delve into the relations of genes to autonomy, privacy, and some tricky concepts like *personhood* as we investigate the ethics of gene ownership in general. We'll have to look both at the science of individuality at the genetic level, and touch upon the nature of autonomy and personhood as they relate to our individual genetic make-ups.

All of these inquiries are nonetheless part of a recent context in which gene patents already abound. While justice demands we challenge the status quo, and perhaps even change it, we must also be mindful of the economic purposes of intellectual property law, and the likely impact of altering the present regime.

Economics and the Marketplace for Genes

Injustice alone may not be reason enough to significantly alter law or custom where the economic consequences of such a change would be too great. We should weigh the effects of the current situation against the likely effects of changing it. Clearly, there are numerous parties interested in maintaining the present system as they gain profits and are often motivated in part or wholly by the potential for economic reward. We should consider these motivations, the strength of other potential motivations, and other possible models that might accomplish the twin goals of scientific advance and profit within the confines of *justice*.

History is full of examples of the complex interactions among science, technology, and the marketplace. Scientific advance has long fueled technological progress and people have profited from both endeavors individually and collectively. The last century saw the development of new modes of scientific inquiry including so-called "big science" involving massive public investments in such things as the Manhattan Project, the space race, and particle physics. Scientific problems and technological solutions have benefited by the interaction of researchers, governments, and corporations in uncovering and exploiting natural phenomena. Some of those benefits have been economic. Science and technology now account for a large share

of the world's fastest growing economies, and the public benefits along with researchers and technologists.

Overhauling the present system, even were it unjust, may not be warranted if economic upheaval would be the only result. It is difficult to justify massive deprivations of property rights, although it has been done before where injustice outweighed all other considerations. That may be the case with gene patents, but if it is not, then we should consider alternatives. It may also be that the deprivation of rights to gene patents need not ultimately alter much at all. It could well be that other means of protecting innovation currently exist, and that the patent system can be used more properly to protect innovation, perhaps in partnership with corporations and governments, and that economies could benefit from more clearly defining those rights and relationships.

Have science and technology worked in synchrony before in ways that are being ignored or even undermined with the development of gene patents? Is the *status quo* a perversion of how the marketplace and scientific discoveries have typically benefited each other? If so, can we normalize this relationship without collapsing a burgeoning marketplace? Might we even provoke greater investment and encourage faster discovery and invention by subtle changes to the ways we interpret the existing patent laws? We will look at all of these possibilities and consider the practical effects both politically and economically.

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 (such as consequentialism or Kantianism) 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 *ontological* 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. 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, as a commons, or as something entirely new.

While I do not wish to argue from a particular ethical theory, neither consequentialism nor Kantianism, nor some other fixed ethical standpoint, my modified natural law standpoint assumes 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 consequentialists care about justice. Consequentialism 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 (duty-based) and pure consequentialist 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. That is, when values conflict, common sense dictates that breaking some rules are worthwhile to defend other rules, like lying to prevent a murder. This undermines pure deontological ethics which says that moral rules may never be broken ethically.

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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 ways of dealing with DNA and genes in the law. 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 particular definition of justice, the economic and practical utility of various schemes of treatment of human DNA.[19]

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.[20] 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* as an ideal is either instituted or fails. Observation of brute facts, and careful examination of necessary relations that exist pre-institutionally, should pave the

way for decisions about how or whether laws, customs, or social norms are supported by the natural conditions of the world.

An Outline for the Investigation

After some greater discussion of methodology, we will begin 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 extra-cellularly, 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 unique social continuants of, for instance, a Gandhi or a Hitler. 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. 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 degrees in 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. In what sense, if any, 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 relations between justice and groundedness under this particular version of moral realism and natural law theory.

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? 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 patents.

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 SNPs (which are unique changes in a single base pair), cannot be researched, manipulated, replicated, or innovated upon without infringing the ownership claims of the patent holders. There are real-world effects to this ownership, including undeni-

able 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 litigation inevitable.

If the current situation were ethically clear, then people would not react as they generally do when presented with the news that much 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 because they are grounded versus those that are ungrounded and unjust. 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.

AUTHOR QUERIES

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