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The human genome: common resource but not common heritage

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Introduction

Since the 1980s, biotechnology and pharmaceutical companies have aggressively pursued intellectual property rights in biological materials in order to protect their proprietary interests and secure a reasonable return on their research and development costs. Although the biotechnology industry is still only in its infancy, it has generated billions of dollars in private investment, hundreds of thousands of jobs, as well as the promise of new treatments for various diseases and substantial improvements in agricultural production. It has also created a storm of ethical and political controversy. Many new applications of bioscience, ranging from gene therapy and pharmacogenomics to genetically modified foods and animals, require the ability to isolate, purify, analyse, clone and modify DNA. It should come as no surprise, then, that the various stakeholders in biotechnology, including private companies, universities and government agencies, have sought to acquire intellectual property rights in DNA. It should also come as no surprise that ethical and political controversies have erupted from the intellectual property race in biotechnology.

Those who oppose proprietary control of DNA have voiced a variety of objections to the patenting of DNA sequences, including the claim that patenting DNA violates human dignity, the assertion that patenting DNA violates the sacredness of nature, and the hypothesis that patenting DNA will have adverse effects on the progress of science, medicine and agriculture (for further discussion, see Resnik 2003). This essay will not attempt to explore all of these different objections to DNA patenting but will focus on one particular objection that has had considerable international influence, the idea that the human genome is the common heritage of mankind (referred to hereinafter as the ‘common heritage’ idea).

The common-heritage idea has influenced ethical and policy debates concerning the commercialization of the human genome. Many different organizations have championed this idea, including the Human Genome Organization (HUGO) Ethics Committee (2000), the Council on Responsible Genetics (CRG 2000), the International Federation of Gynaecology and Obstetrics (1997), The Parliamentary Assembly of the International Council of Europe (Council of Europe 2001) and the United Nations Educational, Scientific and Cultural Organization (UNESCO 1997). A UNESCO declaration states that, “The human genome underlies that fundamental unity of all members of the human family...in a symbolic sense, it (the human genome) is the heritage of humanity...The human genome in its natural state shall not give rise to financial gains” (UNESCO 1997). Additionally, some scholars, such as

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Looney (1994) and Sturges (1997) have argued that the human genome should be viewed as our common heritage, while others, such as Juengst (1998), Ossario (1998), Spectar (2001) and the Nuffield Council on Bioethics (2002) have critiqued this idea.

The claim that the human genome is our common heritage coincides with the debate about patenting of DNA sequences that began in the 1990s. People opposed to DNA patenting argued the common-heritage idea has important policy implications for the commercialization of human DNA. Some writers argued that viewing the human genome as our common heritage implies that there should be no patents on human DNA sequences (CRG 2000). This paper will examine and critique the idea that the human genome is the common heritage of mankind. It will argue that the human genome is not literally our common heritage; it is best viewed as a common resource, but not as our common heritage. Since the genome is a common resource, the patenting of DNA is morally acceptable, provided that we honour our moral duties to the genome, which include duties of stewardship and justice. This essay will give a brief overview of treating DNA as intellectual property before proceeding to the main arguments.

Patent Law and DNA

To understand how one can patent a DNA sequence, it will be useful to review quickly U.S. patent law. European patent law is similar to U.S. law in many respects (Nuffield Council on Bioethics 2002). A patent is a right granted by the government to exclude others from using, making or commercializing an invention for a limited period of time. In the U.S., the life of a patent is 20 years from the date of the application (Miller and Davis 2000). The legal basis for patents has its roots in the U.S. Constitution, which states that Congress shall have the power “To promote Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive right to their respective Writing and Discoveries” (*United States Constitution*). In 1790 the U.S. enacted a federal law, the Patent Act (*Patent Act 35 USC 101* 1952, 1995), to implement this constitutional mandate. The Patent Act has been amended several times (Miller and Davis 2000).

The main ethical and policy rationale for granting patents is utilitarian: patents promote scientific and technological progress by giving financial incentives to inventors, investors and entrepreneurs (Resnik 2001b). Scientific and technological progress are valuable for their own sake and because they contribute to economic growth and to advancements in medicine, engineering and agriculture. One reason why people invest time and money in developing inventions is that they expect to be able to make money from those inventions. Prior to the development of the patent system, inventors and craftsmen would use trade secrecy to protect their intellectual property. The patent system encourages inventors to forego trade secrecy and make their inventions available to the public. Under a theory known as the patent ‘bargain’, the government grants an inventor a private right in exchange for public disclosure of information in the patent application (Miller and Davis 2000).

Before an invention can be patented, it must qualify as a patentable subject matter. Under U.S. law and European law, one may obtain a patent on any new and useful process, product or improvement on a process or product (Miller and Davis 2000). For example, a light bulb would qualify as a product; a method for manufacturing light bulbs would qualify as a process, and an energy-saving light bulb might qualify as an improvement on a product. In biotechnology, one can patent various biochemical products, such as DNA sequences, as well as biochemical processes, such as methods

for isolating, purifying, cloning, modifying, analysing and manufacturing DNA (Eisenberg 1990).

In applying patent law to particular items, the courts have drawn distinctions between products of nature, which are not patentable, and products of human ingenuity, which are patentable (Miller and Davis 2000). For example, the courts have held that laws of nature, natural phenomena and naturally occurring species are not patentable, because they are products of nature. However, a genetically engineered plant or animal can be patented because it is a product of human ingenuity (Diamond vs. Chakrabarty 1980).

Although these distinctions relating to subject matter have a philosophical tone, they are best understood as pragmatic exercises in line-drawing: these distinctions are based on political and public-policy concerns rather than on any objective, metaphysical theory that divides the world into 'products of nature' and 'products of human ingenuity' (Resnik 2002).

The patenting of DNA sequences has posed a conceptual challenge for patenting agencies because DNA occurs in a natural state in organisms. How can DNA be a product of human ingenuity? To deal with this problem, patenting agencies have held that DNA is similar to other chemicals found in nature that can be patented under the doctrine of isolation and purification, such as vitamin B12 or human growth hormone (Doll 1998). By isolating DNA from its natural state and reproducing the compound in a highly purified form, scientists have used a sufficient modicum of human ingenuity to transform DNA into a patentable invention. Someone who has patented human DNA does not own a human being or even have patent rights over a living human being; he only has patent rights over some of their DNA produced under laboratory conditions (Resnik 2001a).

In order to obtain a patent an inventor must submit an application to the patent agency that describes the invention in sufficient detail to allow a person trained in the relevant practical art to make and use the invention. Once the patent is awarded, the application becomes a public record. To receive a patent, the invention must be novel (it has not been previously invented or disclosed in the prior art), non-obvious (it is not obvious to someone trained in the relevant practical art), and useful (the invention serves some practical use) (Miller and Davis 2000). Once an inventor obtains a patent, he (or she) may assign the patent to a university or corporation, or he may license others to make, use or commercialize the invention. Under U.S. law, the inventor is also free to do nothing with the invention and keep it off the market. Unlike Europe, the U.S. has no compulsory licensing provision in its patent law (Miller and Davis 2000).

If someone makes, uses or commercializes his invention without the patent holder's permission, the holder may sue that person for patent infringement. The U.S. courts have recognized (but rarely used) an exemption to patent infringement known as the research exemption. The research exemption allows a person to use or make an invention for purely 'philosophical' research that has no prospect of any commercial application (Karp 1991). Since almost all research in biotechnology has potential commercial applications, the research exemption may not be available to most university-based researchers (Resnik 2001b). Some writers have suggested that the research exemption should be clarified and legislatively reinforced in order to promote progress in biotechnology and biomedicine (Nuffield Council on Bioethics 2002).

During the term of the patent, patent holders have exclusive rights pertaining to their inventions. They derive economic benefits from their patent during its lifetime,

such as sales of the product or service and licensing. Patents are generally far more lucrative than copyrights in biotechnology, although copyrights on databases could hold considerable financial promise (Resnik 2003). Trade secrecy is not a very attractive form of intellectual property protection because it is very difficult to keep secrets in biotechnology. Unless a researcher invents an entirely new product or process, i.e. one with no simulacrum in the natural world, then other people will be able to discover his product or process simply by reproducing it from available natural materials and phenomena (Resnik 2003).

The common-heritage idea

Having set the legal and ethical context for the common-heritage idea, we can explore the argument in more detail and critique it. As noted earlier, the common-heritage idea asserts that the human genome is the common heritage of humanity. How should we interpret this idea? What does it mean to say that the human genome is the common heritage of humankind? A heritage is usually defined as a property that can be inherited or passed down from one generation to the next (*The American Heritage® dictionary of the English language* 2000). To say that something is a common heritage, there must be a) an identifiable thing (or set of things) that is (are) inherited; and b) an identifiable person (or set of persons) that inherit(s) the heritage; c) an identifiable person (or group of people) who bequeath(s) the inheritance. For example, suppose a man dies and leaves some land to his four children. Each child has 25 acres of land and access to a river that runs through each child's land. Under these conditions, each child has a personal heritage, i.e. his or her land, as well as a common heritage, the river. The man bequeaths the river and the land.

If the human genome were literally mankind's common heritage, then DNA patenting would be, for all practical purposes, illegal, because one would need to obtain consent from every human being to commercialize the human genome, since every human being would have a property interest in the genome. In the river example, no child should be able to commercialize the river without obtaining consent from the other children, because they all have a property interest in the river. The Law of the Sea Convention, adopted by the United Nations, makes explicit use of the common-heritage idea (Sturges 1997). Under this doctrine, no country can appropriate for itself the territories held in common, such as the moon, Antarctica or the deep sea beds.

Some scholars and organizations have argued against any DNA patenting on the grounds that the human genome is literally mankind's common heritage. There are at least two reasons why one might regard the human genome as our common heritage. First, we all share a common ancestry through the genome. Although different human populations have evolved somewhat since the origins of *Homo sapiens* over 1 million years ago, every human being can trace his or her ancestry back to the founding members of our species. Second, human beings have almost all of their genes in common: we share over 99% of our genes.

A moment's reflection on the nature of DNA is sufficient to show that there are some significant problems with regarding the human genome as mankind's common heritage. The first problem is that there is not a single, identifiable thing (or set of things) that constitute(s) the human genome. There is a significant amount of genetic variation among members of the species *Homo sapiens*. Although human beings share most of their DNA, there are thousands of single-nucleotide polymorphisms (SNPs), which vary from person to person (Venter et al. 2001). Human beings also exhibit a

great deal of variation in haplotypes (or patterns of sequence variation). The second problem is that there is not a single, identifiable set of people who inherit the human genome. Human beings share 98.5% of the DNA with chimpanzees, 95% with other primates, a great percentage of their DNA with other species, including fruit flies and yeast (Venter et al. 2001). So, only 1.5% of the human genome is actually ‘our’ common heritage; the other 98.5% of the genome is the heritage of other species. Should we say that the human genome is also the common heritage of the chimpanzees, the primates, all mammals, or even yeast? Does it make sense to say that non-human species can have property interests? The third problem is that we cannot identify the persons or set of persons who have bequeathed our DNA to us. Did our ancestors ever intend to bequeath their DNA to all of humanity? These three problems show that it does not make much sense to regard the human genome as literally our common heritage. The common heritage idea may have symbolic importance, but it is an empirical fiction (Juengst 1998).

If we do not regard the human genome literally as humankind’s common heritage, we could still view it as symbolically humankind’s common heritage. The UNESCO declaration speaks of the human genome as our common heritage in a symbolic sense (UNESCO 1997). Rejecting the literal interpretation of ‘common heritage’ in favour of the symbolic interpretation has important implications for ethics, law and public policy. Since the human genome is not literally our common heritage, patenting human DNA is not *ipso facto* immoral or illegal. The morality and legality of patenting depends on the facts relating to the type of patenting in question as well as the values at stake. Some types of patenting may be immoral, some may be illegal, and some may be both immoral and illegal. We have to examine each type of patenting on its own merits to determine its morality and legality.

The human genome as a common resource

Suppose that we think of the human genome not as humankind’s common heritage but as a common resource. What follows from this postulate? First, the common-resource idea does not imply that every person has an ownership interest in the genome; it does not create a common property right in the genome (Ossario 1998). Individuals, corporations or countries may commercialize the genome without obtaining permission from every human being. Second, the common-resource idea does not imply an ‘anything goes’ approach to our duties toward the human genome, since we have moral duties relating to common resources. It is morally acceptable to commercialize the Earth’s resources, provided that we honour our moral obligations vis-à-vis those resources. We have duties to take care of these resources and use them wisely and fairly. Likewise, we have moral duties relating to the human genome as a common resource, even though we may commercialize this resource.

If we think of the human genome as a common resource, we can apply some insights from environment ethics to genome policy. Duties to the environment include duties of stewardship and justice, which are based on duties to current and future generations (Rolston 1994). We should take care of the oceans, for example, so that people will be able to use and enjoy the oceans both now and in the future. Similar duties also apply to our treatment of the human genome. If we think of the genome in this way, then the duties of stewardship and justice arise from the fact that current and future generations have a common interest in the human genome, even if that interest is not a property interest.

Duties of stewardship

If something is a common resource, we have duties of stewardship toward that resource. A steward is someone who is in charge of taking care of something for someone else. Like a trustee, a steward has duties to preserve and develop the thing he or she is entrusted with. In a sense, we are entrusted with the human genome in the same way that we are entrusted with the earth, or an investment banker is entrusted with an investment portfolio. Our duties of stewardship toward the human genome should include protecting the genome from harm, such as loss of genetic diversity or the propagation of harmful (human-induced) mutations.

Some writers, such as Juengst (1998), have expressed some concern about the eugenics implications of the stewardship idea: if we have an obligation to avoid harming the genome, don't we also have an obligation to benefit the genome by eliminating 'undesirable' mutations? The trouble with the idea of 'benefiting' the genome is that it could be used to justify the horrors associated with the eugenics movements in the 20th century, including Nazism. There is a slippery slope from attempting to improve the genome to attempting to purify the human race, as well as a slippery slope from attempting to prevent genetic harms to seeking genetic perfection.

Clearly, one needs to describe carefully the duties of stewardship of the genome to avoid eugenics implications. Certainly, we should not engage in forced sterilization, restricted procreation, ethnic cleansing, genocide, genetic discrimination or other immoral activities under the mistaken idea that we should purify the genome. On the other hand, most people would agree that we have obligations not to engage in activities such as cloning and germ-line manipulation, if we determine that these activities pose a significant risk to future generations as well as a threat to the human gene pool. We must find some way of drawing a distinction between the obligation to avoid harming the human genome and the obligation to benefit the human genome. Although stewards normally have positive duties to benefit those things that they are entrusted with, there are sound moral reasons that these positive duties of stewardship should not extend to the human genome until we have a better understanding of the difference between therapy and enhancement in human genetics (for further discussion, see Buchanan et al. 2000).

Duties of justice

If something is a common resource, we also have duties to use the resource justly and fairly. We have duties relating to the sharing of benefits derived from the resource. Current generations should share the resource with each other and with future generations. While most people will agree that we have some duties relating to the sharing of the benefits from resources, few people will agree on the precise way in which benefits should be shared, because benefit sharing raises fundamental problems concerning distributive justice. Distributive justice addresses questions of how we should distribute benefits and burdens in society (Rawls 1971). Problems relating to distributive justice are some of the most contentious issues in contemporary moral and political philosophy. There currently is no consensus among scholars, commentators, politicians or the public concerning the substantive principles of distributive justice, even though there is a widespread agreement that considerations relating to justice are important in public policy debates. In response to these disagreements about substantive principles of justice, many writers have urged that we should develop theories of justice that focus on procedural notions of justice and fair procedures (Rawls 1993; Gutmann and Thompson 1996). Since distributive justice is a very complex and controversial topic, there is not adequate space in this essay to discuss

the strengths and weaknesses of all the various theories, concepts and principles of justice. I will therefore limit my discussion to theories, concepts and principles of justice that have special relevance to benefit-sharing issues in human DNA patenting.

To begin the discussion of benefit sharing in genetic research, let's consider the infamous case of John Moore. Even though this case does not involve a DNA patent, it merits discussion because it illustrates some potential local benefit-sharing problems that can arise in DNA patenting. Moore contracted hairy-cell leukaemia, a rare form of cancer, in 1976. Dr. David Golde, Moore's physician at the University of California, Los Angeles (UCLA) Medical Center, recommended that Moore undergo a splenectomy. After Moore's spleen was removed, Golde asked Moore to make several visits to the Medical Center, so that Golde could take some additional samples of Moore's blood, skin, bone marrow and sperm. Golde lied to Moore and told him that these samples were needed to monitor his health. In reality, he used these extra samples to develop a cell line from Moore's tissue. Moore's tissue had a great deal of potential commercial value because it was overproducing lymphokines, which are proteins that play a key role in the immune system. The market for these compounds was estimated to be \$1 to \$4 billion. Golde and his research assistant signed agreements with the University of California and several pharmaceutical companies to develop the cell line. They also applied for and obtained patents on the cell line, which they assigned to the University of California. Moore eventually found out that he had been deceived, and he sued Gold, his assistant, the private companies and the University for medical malpractice and for conversion, i.e. substantial interference with personal property. The case eventually reached the Californian Supreme Court, which ruled that Moore did not have property interests in the cell line and could therefore not prove the tort of conversion. The researchers had property interests in the cell line because they had gone to the trouble of isolating, purifying and culturing the cell line. The cell line was their invention, and they had property interests in the cell line as patent holders. In the end, a divided court acknowledged that the defendants were negligent because they failed to obtain adequate informed consent, but it did not grant any property rights to Moore (*Moore vs. Regents of the University of California* 1990).

Although the Moore case involved a patent on a cell line, it could just as easily have involved a patent on a human gene. Indeed, a patent on a gene that codes for lymphokines might be even more valuable than the special cell line. There are many ethical problems with the Moore case, including deception, manipulation, fraud and inadequate informed consent. Although the court did not find that Moore had a property interest in his own cells, one does not need to make this assumption in order to assert that the researchers, the company and the university had a moral duty to share benefits with Moore and that they violated that duty. Moore provided the cells that became their gold mine. Although he did not deserve to be listed as a co-inventor on the invention, he made an important contribution to the invention. Without him, there would have been no invention. Thus, a principle of sharing benefits based on contribution would support sharing benefits with Moore, depending on the significance of his contribution. Of course, many different parties contributed to the invention. The inventors contributed labour, effort, skill and knowledge. The company contributed money. The university contributed its facilities, laboratories, technical support and supplies. Depending on how one measures these other contributions, Moore's contribution may have amounted to only 1% of the total. However, even if the invention netted \$100 million in profit, a 1% share would still be

worth \$1 million. The bottom line in this case is that Moore got nothing, which is unconscionable.

For a different benefit-sharing case, consider the patent on the Canavan gene. Mr. and Mrs. Daniel Greenberg had two children who were born with Canavan disease, a rare neurological disorder that occurs almost exclusively in Ashkenazi Jews. The Greenberg's first child died when he was 11 years old. Their second child also developed the disease. The Greenbergs led an effort to identify the mutation that causes Canavan disease, and they enlisted the assistance of Dr. Reuben Matalon, a physician who was working at the University of Illinois Hospital in Chicago. The Greenbergs helped Matalon acquire skin, blood and urine samples from diseased children and their parents. They also raised about \$100,000 in money to support the project. Miami Children's Hospital (MCH) soon hired Matalon to establish a centre for research on genetic diseases, and spent \$1 million per year in support of his research. Matalon isolated the gene that causes Canavan disease in 1993. MCH applied for a patent on the gene, which the Patent and Trademark Office awarded on October 21, 1997. Matalon assigned all of his patent rights to MCH (Kolata 2000).

After MCH had obtained rights to the patent, it decided to charge royalties of \$12.50 per test to laboratories that perform the test. The hospital planned to use the money from these fees to help offset the costs of research and development and publicity. MCH considered \$12.50 to be a nominal and very reasonable royalty fee for the test. By comparison, Myriad Genetics has charged up to \$1200 in licensing fees for its BRCA1 and BRCA2 tests (Foubister 2000). People from the Canavan community objected to the \$12.50 licensing fee, however. They argued that MCH should make the test available to the public and that laboratories should be able to perform the test without paying any licensing fees. The Greenbergs and several other parties filed a lawsuit against MCH and Matalon in a Chicago federal court, alleging breach of informed consent, fraud, unjust enrichment, conversion and misappropriation of trade secrets. Recently, a federal court in Miami dismissed all of these claims except the unjust enrichment claim. The court found that the plaintiffs had invested enough money in the Canavan research that they could go forward with a claim of unjust enrichment against MHC (Greenberg v. Miami Children's Hospital Research Institute 2003).

The defendants in the Canavan case do not appear to be as unethical as the defendants in the Moore case. First, it does not appear that MHC and Matalon deceived people who contributed DNA samples to the research project. They did not take these samples in secrecy or under manipulative conditions. Second, the profit motive was probably not a major factor in the decision to charge licensing fees for the test, since \$12.50 for a license is a very nominal fee. By comparison, a license for Microsoft Windows[®] software costs about \$200. Unlike the Moore case, it does not appear that MHC will gain billions of dollars from its patent.

On the other hand, MHC, like the defendants in Moore, failed to establish a plan to share benefits with the Canavan community. It did not develop a plan to give members of the community money, healthcare, education or some other benefit as compensation for their contributions to the research. It also did not consult with members of the community or patients about how benefits would be shared. If one accepts the principle that benefits should be shared based on contributions, then one might argue that the MHC failed to share benefits with the Canavan community, who deserved some form of compensation. Although other parties contributed time, efforts, skills, knowledge, facilities, technical support, supplies and money, members of the Canavan community contributed essential resources. Without their tissue

donations, there would be no genetic test. MHC might reply, however, that it has already compensated the community for its contribution by developing the test. The test will benefit couples that carry the disease and allow them to prevent the birth of children with this crippling and painful illness. It has shared benefits from the community.

This reply raises an important point: what is just (fair or equitable) benefit sharing in genomics research? How much of a benefit should subjects and communities receive for their participation? Should researchers and companies provide them with financial compensation for their participation or with some other type of benefit, such as education or healthcare? Many organizations and scholars agree that there should be some type of benefit sharing in the commercialization of the human genome (Knoppers 2000; Human Genome Organization Ethics Committee 2000). The really hard questions have to do with the precise details concerning the structure of benefit sharing in any particular case.

Although developing a test or treatment is often a legitimate form of compensation for one's contributions to biomedical research, sometimes it may not be adequate. In this case, since the Canavan test is likely to be not very profitable, due to the small patient population, all that MHC needs to do to share benefits is to make the test available to members of the population at a nominal fee. Thus, in many cases the best form of compensation to a community or population will be to make the test, treatment or other application reasonably available to members of the population or community. In other cases, however, companies may need to offer individual subjects additional compensation. How much compensation is owed would be a function of the total benefits created from the research and development and the contributions of the various parties. Individual subjects have the best case for demanding financial compensation when 1) the profits are high, 2) individual subjects have made substantial contributions to the research. The Moore case would meet these two criteria. The Canavan case, on the other hand, might not, since the profits will probably not be very high and no individual subject made a substantial contribution to the research; the community as a whole made the contribution.

To summarize these two cases, researchers and research sponsors have substantive duties as well as procedural duties relating to benefit sharing in genomics. Principles of substantive justice require that researchers share benefits according to the contribution of a person or population: the greater the contribution they make to the research, the greater share of benefits they deserve. Principles of procedural justice support the idea that researchers should develop specific plans for benefit sharing and they should discuss those plans with the subjects and populations.

Let's move beyond these local cases and consider a global benefit sharing related to the commercialization of the human genome. From a utilitarian (or cost-benefit) perspective, the commercialization of the genome is reasonable and justifiable, since the probable benefits of commercialization for science, technology and society outweigh the probable harms (Resnik 2003). Nevertheless, one should still ask questions about the overall pattern of the distribution of the benefits and burdens resulting from the commercialization of the genome. What is a fair or just way to share the benefits of commercialization among people within a nation and among the people of the world? How should we address the concern that the commercialization of the genome will increase the socio-economic gap among developed nations and developing nations as well as the gap between rich and poor people within nations? What should we do to ensure access to genetic information and technology?

These are highly complex questions that touch on a variety of practical issues, such as insurance, discrimination, privacy and testing, and involve in-depth inquiries into different theories of justice, such as egalitarianism, libertarianism and utilitarianism (Mehlman and Botkin 1998; Buchanan et al. 2000). I cannot hope to answer all of these difficult questions here. However, I would like to address an issue relating to the commercialization of the human genome: will commercialization increase the gap between rich and poor? A number of different commentators have expressed the concern that the commercialization of the human genome will increase the gap between the rich and the poor (Andrews and Nelkin 2001; Cahil 2001). They are concerned that the benefits of commercialization are flowing directly toward private companies and researchers in the developed world but not to the developing world. This critique of the commercialization of genetic research is not entirely new and expresses the same kinds of concerns that people have had about a variety of new technologies, including personal computers, television and automobiles. In each of these cases people worried that only the rich people would be able to afford the new technologies and, therefore, the benefits would not be shared fairly because they would accrue to the rich and not the poor.

To gain some insight into the fairness (or unfairness) of the gap between rich and poor let us consider a theory of justice developed by the late John Rawls. Rawls' theory has had a huge influence on social and political philosophy in the last three decades, and many people have applied his insights to the distribution of health and healthcare (see, for instance, Daniels 1985). Rawls' theory is known as a social-contract theory, because it holds that principles of justice are the rules for governing society that hypothetical parties would accept, provided that they are placed behind a veil of ignorance that prevents them from knowing who they are in the society they are forming. The rules adopted by these hypothetical parties would be like a contract for forming a just society. According to Rawls, the contractors would adopt two basic rules: 1) fundamental moral and legal rights should be distributed equally, and 2) socioeconomic goods may be distributed unequally provided that (a) the unequal distribution makes everyone in society better-off, especially the worst-off members, and (b) there is fair equality of opportunity in society (Rawls 1971). The first principle is known as the equality principle; the second is known as the difference principle. If we apply Rawls' principles to the commercialization of the genome, we should ask the following question: will the commercialization of the human genome make everyone in society better-off without violating moral or legal rights? If the answer is 'yes' to this question, then commercialization is just.

Critics of DNA patenting argue that commercialization is unjust because patenting increases the price of genetically based tests and treatments by giving the patent holder a limited monopoly on his product or process (Andrews and Nelkin 2001). Unless competitors can develop inventions that 'work around' the patent, they will not be able to enter the market until the patent expires, and the cost of product or process will remain high until the patent expires. Most of these profits will benefit the large corporations that own DNA patents. Critics of DNA patenting point to the high costs of genetic tests, such as Myriad's BRCA1 test, and the high cost of genetic medicines, such as clotting factors or erythropoietin, as evidence of the injustice of patenting. Some critics argue that the best way to increase access to the genome and promote justice is to ban patents on all DNA (Rifkin 1998).

This argument makes several mistakes and oversights, however. The argument ignores the fact that the patent period lasts only 20 years, half of which usually occur when a product or service is undergoing clinical testing. For example, in the

pharmaceutical industry it usually takes about 10 years and \$500 million to develop and test a new drug and bring it to the market (Goldhammer 2001). This means that a company has about 10 years to earn back its investment. During this time, a company will charge what the market will bear, because it knows that its profits will diminish greatly once the patent expires. Once the patent on a drug expires, other companies can make generic versions of the drug, at a great savings to consumers. Costs will continue to fall as a result of improvements in manufacturing and economies of scale. If the company did not expect that it would have patent protection, it would not have invested its money in developing the drug, and the drug may have never entered the market. In the short run, patenting interferes with access to medications, but in the long run it increases access to medications by providing inventors and investors with incentives to conduct and sponsor research. Since the patent system grants inventors a temporary monopoly, it tends to produce short-term problems with access to technology, but its long-term effects promote access by stimulating investment in research and development.

The history of science and technology contains examples of many products and services that were initially very expensive – and therefore available only to the rich – that soon fell in price. Automobiles, refrigerators, microwave ovens and personal computers at one time were so expensive that they were available only to rich people in developed countries. Today, almost everyone in a developed country has access to these products, and many people in developed nations have access to the products. The point here is that new technologies can create a temporary gap between rich and poor, but that gap narrows over time. If the history of science and technology offers us any useful lessons for the DNA-patenting debate it is that the commercialization of the human genome will probably promote global benefit sharing in the long run, because it will encourage investment in genetic technologies that will eventually be widely available.

Opponents of DNA patenting may argue that the success of the patent system is overrated. Patents do not always lead to long-term benefits for society and may do more harm than good. Researchers and companies can abuse the patent system by using patents to block downstream research, by refusing to grant license, and by attempting to extend the life of their patents by ‘double patenting’ or other illegal activities. This is an empirical debate that cannot be resolved here. Economists and legal scholars continue to debate the social utility of the patent system; however, there is a general consensus that it plays a key role in promoting the development of science and technology, which benefits society. Thus, the patent protections that create problems with access to technology can be justified on the basis that they produce good consequence in the long run.

However, there are some exceptions to this patent-protection policy. In some cases the short-term inequities may be so unjust that countries are justified in restricting patent rights in order to make products or services readily available. For example, the HIV/AIDS epidemic in sub-Saharan Africa is a public-health crisis of such grave proportions that countries are morally justified in restricting or overriding patents on essential HIV/AIDS medications in order to increase access to these medications by lowering their cost (Resnik and De Ville 2002). In some rare instances the need to address inequities is so great that governments can set aside the laws that normally govern patenting. However, governments should use great discretion and care in applying this emergency exception to patents to avoid treating every problem as a crisis.

Conclusion

This essay has argued that the human genome is not literally our common heritage. If the human genome were literally our common heritage, the patenting of human DNA would be morally unacceptable because it would require the consent of every human being, a practical impossibility. Even though the human genome is not literally our common heritage, it is still a very important common resource, and we have moral duties of stewardship and justice vis-à-vis the human genome. Our duties of stewardship include duties to refrain from harming the human genome but not duties to benefit the genome actively, because the idea of ‘benefiting’ or ‘improving’ the genome has clear eugenics implications. Our duties of justice imply obligations to share benefits fairly in genetics research and development. Benefit sharing can take place at a local level when researchers develop treatments or tests that become reasonably available to the populations or communities that participate in research. Local benefit-sharing obligations require researchers to provide financial compensation to participants only in rare instances where researchers and companies stand to profit a great deal from the tissues collected from a single person or small group of people. Local benefit-sharing obligations also require researchers to develop plans for sharing benefits and for discussing these plans with study populations. Finally, global benefit sharing may occur as products and services developed by companies become less expensive and more widely available. Short-term problems with access to genetic technology can be justified on the grounds that the system that allows such inequities, i.e. the patent system, promotes the interests of all members of society, especially the worst-off members, in the long run.

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Chapter 13

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