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3/13/00

Who Owns Life? A History and Analysis of Genetic Patents

When Calvin Coolidge declared that "the business of America is business," he probably wasn't thinking of the modern health care industry. And yet, Coolidge's aphorism seems especially applicable to biotechnology, where, for better or worse, the interests of the public are inextricably linked to the companies responsible for discovering, designing, and distributing novel pharmaceuticals. In short, the basic welfare of all Americans depends on the biotech "business."

Increasingly, that business depends on patents for growth and survival. With research accelerating at a dizzying pace, companies need the protection of intellectual property law to make their discoveries worthwhile and profitable. Without patents, the development of drugs would be jeopardized as research slowed to accommodate industry secrecy. Undeniably, therefore, patent protection is essential to the biotech community. But just what are these companies patenting?

According to some, they are doing nothing less than patenting life itself. "Life," in this case, is genes, the building blocks of all organisms and, increasingly, the center of a major controversy regarding private rights and the public good. While patents are widely accepted as integral to innovation and growth, a number of people have challenged the legitimacy of patents on DNA and genes. Where one person sees genetic patents as proper safeguards of proprietary rights, another sees them as representative of the unethical privatization of the "human inheritance," and, at the same time, a concentration of massive power in the hands of a few

transnational corporations. The debate, like most in America, quickly turns toward polarization. An editorial in the *Ecologist*, for instance, declared, "So let us have the courage to say it: patents on life are wrong in principle and in practice. Private monopoly rights over life are morally repugnant. Life is a gift, not a human invention, and should not be privately owned or manipulated" (Paul 203). On the opposite side, an article in the Economist smugly observed, "The idea of patents being granted on genes…makes lots of people uneasy, especially when the genes concerned are human genes. Luckily, their discomfort has not prevailed; the world has listened politely, looked at its dividend payments, and carried on regardless" ("Mapping Mankind" 16).

This paper attempts to provide a balanced perspective, one that avoids both the sophistry of the *Ecologist* editorial and the profits-before-people stance of the *Economist*. To develop a critical understanding of the issues, the paper has been divided into two sections, the first dealing with the background of biotech patent law, the second with the current ethical issues surrounding gene patents. This paper is a survey, therefore, of an issue that has received relatively scant popular press attention but that, at its heart, affects the lives of everyone on the planet.

Gene Patents -- A History

Contemporary patent law dates back at least five centuries, when European countries first established the legitimacy of intellectual property (Baird 391). American patent law built on these foundations, with Article One of the US Constitution declaring, "Congress shall have the power…to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writing and Discoveries." The

purpose of original patent law was two-fold: first, to protect the property of the inventor; second, to ensure that such property disseminates into the public domain as quickly as possible (Grunwald 27). In effect, "the basic principles of patent law achieve a compromise between the broader social desirability of increasing technology developments, and the social undesirability of ongoing market monopolies for critical processes or products" (Baird 391). Patents, therefore, are a state-created entity designed to ensure the public good. Subsequent court cases and Congressional Patent Acts reaffirmed such basic principles (Ducor 14-21). But just as US law has historically reiterated the principles of intellectual property, the law has just as clearly forbade the patenting of any forms of life or naturally occurring substances. Despite lenient patent laws, the US has a history of hesitancy regarding the patentability of life.

In a court case only those with a sense of humor could love, General Electric in 1928 attempted to patent pure tungsten -- a naturally-occurring element. A US appeals court denied the claim, arguing that the company could only patent a method of purifying tungsten, not the element itself, because tungsten is a "product of nature" (Sagoff 37). Subsequent court cases reiterated this "product of nature" doctrine. In 1948, the Supreme Court rejected the patent claim of a seed company which had produced a unique strain of bacteria by mixing two different bacterial species. The court declared in their ruling, "Patents cannot be issued for the discovery of the phenomena of nature…they are part of the storehouse of knowledge of all men" (qtd. in Sagoff). With the unpatentability of naturally-occurring substances clearly established, Congress had to step in to ensure the protection of new forms of intellectual property. In the Plant Patent Act of 1930, and the Plant Variety Protection Act of 1970, Congress effectively sidestepped patent law and guaranteed the proprietary claims of companies creating new plant hybrids. While still largely hesitant about patenting life forms, the PTO in the 1970's began issuing patents on

products of nature in which "some human intervention had been necessary to make them available," such as purified hormones or vitamins (Ducor 16). Still, any hesitancy effectively disappeared with a landmark court decision in 1980.

That year, Ananda Chakrabarty, a scientist working for GE, succeeded in splicing together the genomes of two different bacteria in order to create a hybrid organism capable of degrading hydrocarbons. The PTO originally denied Chakrabarty's application for a patent, citing the traditional "product of nature" doctrine, but the Supreme Court overturned the PTO's ruling. In a sweeping decree, the court announced that products derived from life were "eligible" for patents, according to section 101 of the Patent Act, as long as they were the products of human innovation. In effect, the bacterium was "perceived [by the court] as a non-naturally occurring manufacture or as a composition of matter" (Graaf 117). Furthermore, the court determined Chakrabarty's bacterium, and any other products of biological material, were patentable, so long as they fit the traditional requirements of patentability: utility, novelty, and non-obviousness (United States Code, Article 25). In a now-famous statement, the court declared that patents could be issued for "anything under the sun that is made by man" (Diamond v. Chakrabarty).

Effectively, the Chakrabarty decision opened the floodgates to patents on proteins, naturally-made chemicals, and – most importantly – genes. Over the next decade, companies and government agencies rushed to patent full-length genes, in effect combining the "purification" doctrine that had always allowed proteins, for example, to be patented, with the Supreme Court's decree of the eligibility of all living substances. The PTO "began routinely issuing patents on products of nature (or functional equivalents), including genes, gene fragments and sequences, cell lines, human proteins, and other naturally occurring compounds" (Sagoff 37). This caused little uproar through most of the 1980's. In fact, the decision to allow gene patents of all kinds,

impossible before the Chakrabarty decision, slowly became codified in the public and scientific communities through PTO decisions following 1980. Between 1980 and 1997, for instance, the PTO granted patent applications on almost 1500 full-length genes (Marshall, "Companies" 780). In effect, if a scientist identified the location and function of a particular gene, he would be almost assured of a patent. By the early 1990's, however, the PTO was confronted with a new problem: patent applications for gene sequences that had *no* location or function.

In 1992, Craig Venter at the NIH applied for patents on more than 2,000 ESTs, or "expressed sequence tags." An EST is a fragment of DNA whose sequence is determined by working backwards from expressed messenger RNA. The DNA therefore, is the bit of the gene that is actually translated into a protein. Though Venter had established the sequences of his 2,000 ESTs, he had not discovered anything about the larger genes' function or location, nor had he specified the specific functional uses of the ESTs he had discovered. In effect, Venter was "trying to patent a bunch of genes, without knowing their functions or where on the chromosome they occur" (Hubbard 123). When James Watson, then director of the NIH's genome project, heard of Venter's plan, he declared that it was ridiculous to patent ESTs because "any monkey" could perform Venter's work (qtd. in Hubbard). Venter's actions caused a similar outcry in the larger scientific community, which was outraged that the mere elucidation of a sequence could garner intellectual property protection (Baird 391). The PTO rejected Venter's patents, largely out of issues of utility, and the newly-instated head of the NIH, Harold Varmus, declined to pursue an appeal.

Today, the major controversy in gene patenting continues to center on ESTs. (Another issue, the patentability of SNPs, or single nucleotide polymorphisms, has becomes more contentious in the last few years, though it is beyond the scope of this paper.) By 1997, over

500,000 ESTs had patents pending with the PTO. Writing in May of 1998, John Doll, director of the Biotechnology Examination Office of the PTO, declared that, "Although some ESTs may not directly identify genes, they may still be extremely useful and thus satisfy the utility requirement" (689). Doll also indicated that the subsequent discovery of the function and location of full-length genes would merit its own patent -- regardless of any previous EST claims. The patent holder for the full-length gene would simply be required to pay licensing fees to the patent holder of the EST that is a part of the larger gene.

Doll's comments aptly describe the actions of the PTO in the last few years. The office has begun issuing a number of patents for ESTs, so long as they have some functional importance. This practice should, in principle, negate objections by some critics that ESTs have no novelty associated with them. One critic for instance, Mark Hoffer of Genzyme Corporation, argues that patents on ESTs "are like filing a claim on miscellaneous bolts and claiming they could be used to make a car" (qtd. in Marshall). Even the PTO Commissioner, Bruce Lehman, has pointed out that "a lot of this stuff is just data" (qtd. in Marshall).

In order to reduce the backlog of EST patent applications, Lehman instituted a policy allowing no more than ten gene sequences per application, forcing companies to spend a good deal of money on the filing and legal fees associated with each patent application. However, Lehman's actions have not slowed the flood, with companies such as Hyseq continuing to file massive numbers of applications (Abate B1). Currently, the PTO has not made any definitive rulings on the validity of EST patents. While the current trend seems to be limiting patents to those ESTs which have well-elucidated uses, no one knows how the PTO will eventually settle the issue. Most likely, the next few years will bring a major ruling (either by the PTO or through a court order) that will set a new precedent for gene patents. But while the legal questions may

soon be resolved, the ethical questions swirling about gene patents are far from finding resolution.

The Current Debate

Nothing emboldens the public like hyperbole. And it is hyperbole that the public gets when newspapers throw around terms such as "patenting life itself." Still, the debate over gene patents raises honest questions; the public and scientific communities alike have a right to be critical over anything that commodifies the basic phenomenon of life. In the last few years, the debate has centered on three different issues. First, some critics question whether gene patents will limit the free distribution of knowledge crucial to scientific progress at academic institutions. Second, others express fears about the moral and religious implications of being able to "own" pieces of life. Finally, some people worry whether the current practices of the PTO really advance the public interests as well as they could. Perhaps gene patents give corporations too much control over basic research, thus slowing the development of new drugs and treatments the patents are supposed to encourage.

Science has always been predicated on the wide distribution of information. Many feel that gene patents will endanger this distribution. One scientist, for instance, has suggested that "any political development that jeopardizes the freedom of science and scientific progress will be a danger to future generations" (Vogel 8). By making discoveries of the functions of genes "property," the dissemination of that knowledge into the public domain will be slowed. As researchers delay publication of their knowledge in order to secure patent rights, scientific progress will be stifled. Furthermore, other critics charge that the construction of proprietary

databases of gene information is antithetical to the ideas of science, where basic knowledge such as the function of genes should be freely available to all, rather than available to only a few for a price. ESTs, specifically, also warrant fears, as "some in the biotechnology community are concerned that patents on ESTs may impeded cooperation among laboratories and limit the ready availability of data and materials to researchers" (Doll 689).

Many people in the biotech industry as well as the scientific community respond that gene patents, far from limiting the distribution of the knowledge, actually ensure it. Patents, after all, enable a discovery or invention to be disseminated to the public as quickly as possible – it is that dissemination which is preserved in giving the patent-holder an exclusive right to his invention. The alternative to gene patents, trade secrecy, would "be even worse" (Elizalde-Perez 97). John Doll explains: "Without the incentive of patents, there would be less investment in DNA research, and scientists might not disclose their new DNA products to the public. Issuance of patents to such products…results in the dissemination of technological information to the scientific community" (689). Finally, the issue of slower publication of data is not a large problem in this country, because patent holders can legally receive a patent even if an application is filed after such knowledge enters the public domain. However, the United States is the only major country with this protection; in other countries, delaying publication is essential to securing proper patents. On the whole, though, patent laws ensure the dissemination of knowledge much better than any other system or the lack of one.

Perhaps the most general area of criticism of gene patents arises from the religious and moral objections to patenting life. According to Patricia Baird, "patenting genes is seen as transforming them into a commodity, and this is viewed as being disrespectful of life." Religious leaders, such as Ted Peters of the Center for Theology and Natural Sciences, argue that "patent

policy should maintain the distinction between discovery and invention, between what already exists in nature and what human ingenuity creates. The intricacies of nature…ought not to be patentable" (qtd. in Sagoff). Other leaders suggest such patent rights involve a kind of blasphemous arrogance, where people can claim as their own something invented by God. Mark Hanson observes, "Among certain Christian critics, DNA is thought to provide the biological blueprint for human beings in the image of God. It thus possesses a special kind of intrinsic value that makes patenting of it inappropriate" (S1). Other moral critics distance themselves from the religious perspective, instead suggesting genetic knowledge should be open to all. To attach proprietary rights to a natural phenomenon is by itself amoral – knowledge so essential to the human condition is necessarily collective property because it is the foundation of life. In short, most of this criticism springs from a general discomfort with the idea of patenting natural phenomena; such patenting is considered a challenge to the sanctity of life. In other words, genetic information – whether arising from the hand of God or the hand of biology – should not be reduced to commercialism.

Industry supporters respond to this criticism in a general way, arguing that most moral objections to gene patenting have a logical fallacy at their root. "According to the industry view, patents create temporary legal monopolies to encourage useful advances in knowledge; they have no moral or theological implications" (Sagoff 37). Indeed, patents are not issued on natural genes -- no one can own the contents of a person's cells. Rather, gene patents cover only purified products that, as they have been constructed in the lab, do not exist in nature. ESTs, for instance, do not come from anybody per se but exist as "manufactured" DNA sequences constructed from strands of mRNA. According to Doll, "you can't turn over a rock and find a gene" (qtd. in Marshall). Therefore, the assertion that companies and scientists are "patenting life" has no

grounding. Rather, the companies are being granted commercial licenses on gene sequences they have discovered or materials they have purified. The essential "knowledge" of DNA remains a human collective property, available free to anyone to study or develop. Patenting simply confers proprietary rights to commercial applications of such genes. Biotechnology Industry Organization president Carl Feldbaum notes, "A patent on a gene does not confer ownership of that gene to the patent holder. It only provides temporary legal protections against attempts by other parties to commercializes the patent holder's invention" (qtd. in Marshall).

While the purely legal aspects of patents satisfy most moral objections to gene patenting, the overall effect on the public good of such patents is far from clear. Many critics argue that contemporary gene patents fail to serve their purpose of ensuring innovation and instead retard the development of new drugs and treatments. Patricia Baird explains: "Keeping new information secret to protect future patent rights or to prevent competitors obtaining it may be seen as necessary and justified in order to protect stockholders in the biotechnology company. However, this secrecy is directly opposed to the goal of medical research, which is to prevent suffering from disease" (391). The very idea of gene patents, therefore, introduces a commercial element to science that can only reduce innovation and scientific freedom.

Furthermore, even with the publicly-disseminated information of patents, some critics wonder whether companies will shy away from developing certain drugs given the prohibitive costs associated with licensing a plethora of different patents in order to conduct research and development. Higher costs associated with drug development reduce the profit potential of a theoretical drug, necessarily slowing or stopping certain forms of innovation. Might it not be wiser, critics argues, to limit patents to the drugs developed from genetic knowledge, rather than patent that genetic knowledge itself? After all, the public does not need companies to map and

explain the human genome. The NIH and other public institutions will determine the function of genes on their own through the Human Genome Project, negating the need for companies such as Celera. Effectively, giving patents to Celera's ESTs, for instance, would do nothing to advance the public good; it would only privatize information that would otherwise move into the public domain free of charge.

The biotechnology industry responds largely by pointing out that patents are essential to ensuring the profitability of research, and that profitability is what motivates the creation of new drugs. According to E.S. van de Graaf, patent protection is essential to the biotechnology field because:

a) High research and development costs prohibit the investments of small biotech firms if they cannot recoup the costs.
b) The fast development of modern biotechnology has blurred the distinction between basic and applied research, making patents necessary to conduct almost any research.
c) Biotechnology innovations are strongly interrelated…patents ensure access to competitor's inventions that are necessary for new developments.
d) Patents...assure the acquisition of venture capital. (38)

Effectively, gene patents may, in some ways, slow down medical and drug research, but that research would not be occurring *in the first place* were it not for the intellectual property protections that make such research valuable. Patents, far from being antithetical to public welfare, "encourage investments that are beneficial to society as a whole" (Sagoff 37).

Balancing the Public and the Private

Resolving the controversy of gene patents depends largely on identifying the ultimate social costs of current patent law. At the present, the question of whether extensive EST patents, for instance, encourage or discourage drug development remains unanswered. And while intellectual property rights necessitate at least some patent protection, the extent of that protection should depend largely on which policies most advance the public good. Furthermore, because discovery, invention, and research "a monkey could do" have such ambiguous distinctions in modern genetics, the notion of rights to "property" becomes even more muddled. After all, throughout their dealings with gene patents, the PTO has maintained that both discoveries and raw data are not patentable, and the elucidation of simple gene sequences is really just a discovery.

In developing a policy to deal with genetic patents, therefore, the PTO should strive to consider what is in the best interests of the public. For all their fervor and consternation, religious leaders argue something undeniable in their objection to gene patents: DNA is part of the universal heritage of mankind. That heritage does not invalidate patents; it does, however, necessitate that any patent laws serve the interests of those people from which that heritage springs.

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