

Life Patents: The Reason, the Ramifications, the Proposed Reversal

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6.901 Term Paper
December 9, 2004

Background on Patents

The purpose of granting patents to inventors is to “promote the progress of science and the useful arts” (Article 1, Section 8, Clause 8, US Constitution). The constitution gives Congress the duty of bestowing exclusive rights to inventors for their creations. To meet this end, Congress created the United States Patent and Trademark Office (USPTO). The USPTO’s philosophy was in line with Thomas Jefferson’s hope that “ingenuity should receive a liberal encouragement” (USPTO, 2105). In 1952, during a revision of patent code, committee reports allude to Congress’ intention to “include any thing under the sun that is made by man” for patent consideration (447 U.S. 303, 309). There are, however, exceptions to this broad generalization: natural discoveries, such as waterfalls, physical laws, such as Newton’s $F = ma$, and abstract ideas are not patentable material. Moreover, Thomas Jefferson, who helped create some of the first patent laws, wrote that “whenever the monopoly granted by a patent was contrary to public interest, the public interest should take precedence” (Charnas). There are some technologies, such as materials used for atomic weapons, that are not patentable because of their inherent potential for destruction. Natural creations, such as genes, cell-lines, microorganisms, embryos, animals, and humans--all life forms--should join the elite ranks of non-patentable objects, because they are essentially products of nature, which may have been slightly altered by humans, and a monopoly over such creations is detrimental to the public.

Diamond VS. Chakrabarty: First case to legitimize life patents

The first life-patent was filed on June 7, 1972 by Ananda Chakrabarty, a G.E. employee. He sought to patent genetically engineered *Pseudomonas* with at least two energy-generating plasmids that follow different degradative pathways, both of which can be used to digest hydrocarbons. In other words, a hybrid microorganism that can eat away oil spills—US patent #4,259,444. The patent was initially rejected by the USPTO, specifically because of the claim on the organism itself. According to the patent examiner, “(1) micro-organisms are "products of nature," and (2) that as living things they are not patentable subject matter under 35 U.S.C. 101. However, the decision was appealed and the patent was narrowly legitimized by the United States Supreme Court. The majority opinion centered around the fact that Chakrabarty had created something. The role of the supreme court is to interpret Congress’ laws. As a result, the majority and minority opinions focused on the Plant Acts of 1930 and 1970 as guidance for their decisions. The majority opinion stated, “Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions”[in response to a patent issued on the cultivation of novel plants]. Here, respondent’s microorganism is the result of human ingenuity and research” (USPTO, 2100-4). The new microorganism was considered a manufacture, or composition of matter. However, the minority opinion revealed the court’s uncertainty about the decision. According to Justice Brennan, author of the minority report, Congress had originally excluded animate objects from being patented and therefore had to pass two subsequent laws in 1930 and 1970 allowing certain plants to be patented. He continues, “The fact is that Congress, assuming that animate objects as to which it had not specifically legislated could not be patented, excluded

bacteria from the set of patentable organisms” (Diamond Vs. Chakrabarty). Thus, it is clear that the only issue the Supreme Court could debate upon was whether Congress had previously confirmed

the patentability of living objects. According to author of Biotech Century, Jeremy Rifkin, “The court’s action laid the all-important legal groundwork for the privatization and commodification of the genetic commons” (Rifkin, 43).

Questioning the Patentability of DNA sequences

Current USPTO guidelines on Patentable Living Subject Matter heavily quote the Chakrabarty case. The bottom line, “ ‘The production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery’ is a manufacture under 35 U.S.C. 101.” Simply typing in the word “gene” in the USPTO website search engine results in over 47,000 hits. Most of these “inventions” constitute finding a DNA sequence from the genome (human, mouse, whatever), isolating it, pasting it into a plasmid (bacterial DNA) behind a promoter, and allowing the bacteria to produce the protein that is dictated by the gene. In the sample “invention” described above, the DNA sequence, protein, and purification process are most often patented. In some cases, the bacteria itself is patented. I have multiple objections to granting a patent for the events described above. To begin with, nothing novel was created by isolating the DNA sequence. It has been purported that pure DNA outside of the genome gives the sequence new properties. Yet, the information encoded by the DNA in the form of nucleotides is the same inside or outside the genome it was purified from; it is merely the environment surrounding the DNA sequence that has changed. The process of isolating a specific DNA sequence is similar to looking into

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someone’s private handwritten journal and typing out one paragraph. The information is the same, even though the medium the words are written in is different. In the case of DNA, the encoded information was created by nature. The building blocks of the code are nucleotides, just as letters

are the building blocks of writing. Thus, nucleotides are the raw material needed to create sequences. So, if an inventor creates a novel sequence of nucleotides, not already specified in nature, then a real invention has taken place, and a patent should be issued. Otherwise, simply copying information from nature is piracy, and should not be patentable.

Questioning the Patentability of Proteins

Furthermore, proteins resulting from natural sequences are not novel objects. If the sequence is naturally derived, then surely the protein already exists in the body of the organism whose genome was copied. Thus, the protein resulting from a natural sequence is already in existence – nature’s prior art. For example, the patent on VEGF-like factor filed by Japanese inventors Hirata et al, excludes everyone from isolating the human Vascular Endothelial Growth Factor (VEGF) gene and using it to create the VEGF protein (patent #6,828,426). The implications of such patents are huge. First, all humans inherently have the VEGF DNA sequence and protein, unless the human has VEGF deficiency. In the latter case, therapies that can supply the body with external VEGF are needed. However, the patent on VEGF effectively gives the inventor the right to exclude others from research that involves VEGF. VEGF is involved in countless processes in the human body that result from its primary role in angiogenesis, the formation of new blood vessels. These processes include wound healing, feeding tumors, and leukocyte trafficking to name a few. Moreover, VEGF has been implicated

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in the treatment of cancer, psoriasis, rheumatoid arthritis, and endometriosis. This one patent alone can give the “inventor” a total monopoly over research of all diseases having to do with angiogenesis. Because a single protein can and usually does carry out a variety of tasks in the body, a patent on just a single protein can carve out a substantial market for researchers. In addition,

many of the roles of proteins like VEGF may not have yet been determined. Thus, granting patents on proteins without stating the specific functions that the protein carries out is issuing too broad a patent on an object that is not novel in the first place.

Patents on Animate Objects

Genes and proteins, both units of life, should not be patentable if they already exist in the human body. But, what about new forms of life that are created as a result of genetic engineering? The Chakrabarty case set the precedent for patenting animate objects, particularly bacteria and microorganisms. Shortly after, in 1988, Harvard researcher Philip Leder filed a US patent application for the oncomouse—a mouse carrying an oncogene (patent #4,736,866). This was the first transgenic animal to be patented in the United States. Aside from the ethical concerns surrounding the patenting of animals and the slippery slope leading to the patenting of humans, this form of creation should not have been patented according to patent law. Again, mice are creations of nature, as are oncogene sequences. Neither could be called raw materials. The oncomouse is simply two things put together—an external DNA sequence and a mouse. Moreover, this mouse has properties already found in nature: increased susceptibility to cancer! Although the mouse provides an excellent model for cancer researchers, it should not be a patentable invention.

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The United States Stands Alone

Interestingly, as of 2002, the oncomouse enjoys three patents in the United States, 1 patent in Europe, 1 patent in Japan and 0 patents in Canada (CBC News). Only the United States has issued a patent on the mouse itself. Elsewhere, only the method used to produce transgenic animals is patented. This is not unusual. The United States leads the rest of the world in rigorous intellectual property rights. At times it is difficult to distinguish how much of the US's

commitment to intellectual property rights is due to valuing the inventor, and how much is due to corporate pressure. Pharmaceutical companies invest a lot of money into making drugs. According to a study done at Tufts University, it costs upwards \$800 million dollars on average to bring one drug to market (2001 numbers). So, it is only natural for pharmaceutical companies to lobby Congress heavily in favor of intellectual property rights that protect their research investments. In fact, the oncomouse was developed by an academic researcher who was funded by corporate money. DuPont has licensing rights for the oncomouse.

The United States is trying to push other countries to accept its patent standards, which includes almost anything under the sky that is manmade. Under pressure from pharmaceutical companies, the US is even trying to minimize the effects of the Doha Agreement (an addendum to TRIPS), which excludes essential medicines from fully conforming to US patent laws.

Ramifications of Patents

In the biological research field, which is tightly coupled to medicine and public health, the effect of patents on fundamental units of life, such as genes and proteins, and animate research models, such as the oncomouse, have possibly caused more harm than good for the

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public. Oftentimes, patents have been associated with a culture of secrecy in science. Coworkers can not freely discuss their findings, or give poster presentations for fear of losing the option to patent findings. Furthermore, publication is often delayed for the same reason. In biological research, more than any other field, this has a direct impact on public health. Many of the biological science breakthroughs that have surfaced in the past few decades are a result of active sharing of results. There is more progress in science when there is collaboration between researchers. In a way, patents on fundamental units of life negate collaboration, and in the long run

may hamper scientific advances. Moreover, delayed publications lead to delayed treatments for suffering patients. Time is always of the essence for the sick. Instead of hastening the speed of discovery, it seems as though patents are slowing down the pace of biological research. Perhaps patents on certain biological units should be banned because the public interest must precede the inventor's interest.

Suggestions for Congress

It is clear that only Congress can rectify the problems we face with life patents. Congress needs to give the current patent laws a thorough review and revise them in light of the direction of biological research. The laws created in the 1800's or even the 1950's will no longer suffice. There is no point in having the Supreme Court interpret what Congress had in mind when creating past laws, because at the time no one could possibly foresee the research potential we have today. In revising the laws, Congress should place public interest before corporate interest. As was done in Canada, perhaps a Biotechnology Committee needs to ponder these questions and make specific suggestions to Congress on which types of patents to issue. Or perhaps, as was

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done by the Atomic Energy Act of 1954 with atomic weapon's material, life patents should be excluded from patentability. Overall, it is up to Congress to ponder these questions and encourage a public discussion of the issues at hand. The choices made by Congress about life patents have the potential to affect millions. Dollars or people, they will decide.

Diamond VS. Chakrabarty: Supreme Court Decision

<http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=us&vol=447&invol=303>

CBC News: http://www.cbc.ca/news/features/harvard_mouse.html

Tufts University Study: <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6>

The Atomic Energy Act of 1954 excludes the patenting of inventions useful solely in the utilization of special nuclear material or atomic energy for atomic weapons.