INVENTIONS, PATENTS AND MORALITY

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Contents

Summary

This article reviews the criteria used for intellectual property protection, and how this has been applied to inventions and discoveries made in biology and biotechnology. The ethical arguments for and against patenting are reviewed, emphasizing whether beneficence is served by encouraging patents, and whether justice is served by the protection period for exclusive marketing given by patenting. Access to knowledge and discoveries is discussed in a global framework. The history of patenting is presented, with the use of exclusion clauses when a patent is against public order. European patent law has treated living organisms differently to inorganic matter, and despite recent directives that allowed patenting of transgenic organisms and genetic material, the matter does not appear to have been resolved. It is predicted that the global debate on the morality of patents will continue in the future, and it is argued that ethically it should continue so that deeper ethical goals of beneficence, justice and rights should be served beyond economic development itself.

1. Introduction

This theme of the morality of patents has been one of the more controversial aspects of biotechnology, often becoming political and heated. Despite the fact that many of the early patents on medical products of biotechnology, such as insulin and human growth hormone, and genetic engineering techniques will soon be terminated because the period of patent coverage is terminated, there is an expanding rate of new patent applications for novel gene discoveries and for inventions of new processes. The coverage of these patents and their enforcement has social implications of a global nature, between the private and public sector, and between many different countries.

Although the granting of patents has been demonized by many groups opposed to the idea that by genetic engineering we can modify any living organism to provide better goods or services to human society, it is a practice that has become a standard way for most academics to think. We have seen the growth of patent applications by academic and public sector researchers to a point where they may out- number those of industry applicants, especially in the case of biotechnology. The trend towards commercialized science is symbolized by the U.S. Congress which decided that publicly funded science should be commercialized, and during the 1980s intellectual property rights were decentralized from government to research institutions to create commercial incentives. This trend has become world-wide.

Ethically we can start by asking rather simple questions, is the principle of beneficence, or loving good, served more by having research than by not having research, and do we encourage more research into more beneficial areas of science by the incentive system of patents than we would by not having patents? We will also consider whether other ethical principles such as justice and doing no harm are served by systems of intellectual property protection. Ethically can anyone own a product of their mind, a product of nature, a product of a designed process, a discovery or even an invention? Does it make any difference whether the product or process involves living organisms or rocks? Should we expect the practical law to share the same goals as that of ethics, namely can we expect ideal ethical laws or some compromise?

This article will discuss the issues of inventions and morality with a specific focus on biotechnology. It will review intellectual property protection, and discuss the ethical arguments related to patenting in biotechnology research.

2. Intellectual Property Protection

There are several systems of intellectual property protection designed to reward inventors. To qualify for a patent an invention must be novel, non-obvious and useful. Industrial competitiveness leads to secrecy, and results may not be published at all if a company does not think they can keep the benefits to themselves from the research costs invested, or the money used to purchase the rights to the use of results of research from a university research team. A patent guaranties the publication of the results and the deposit of the product in a central repository, for use in the future development of research to create better inventions.

An alternative system to protect an invention against being used by a competitor is keeping it as a trade secret. The closing of results from other workers is against the principle of scientific openness, but is a common feature of certain forms of industrial research, especially when the process used to create a product may be expected to be kept a secret for some years. However, with biotechnology inventions, once the product is sold, the DNA can be sequenced and reproduced by another team of researchers. Specific techniques, such as nuclear transfer or cell manipulation techniques may be kept secret a little longer, but still tend to be made open through the patent system.

Patents can generally be sought either on products or processes used to manufacture the product. It is easier to obtain a process patent, but it has been harder to prove that a competitor is using your process, as access to their production facilities may be restricted. There were general patents awarded on the process for transfer of DNA into other organisms, and in the methods used to transfer, for example using *Agrobacterium* or projectiles (biolistics) in plants.

If the claimed invention is the next, most logical step which is clear to workers in that field, than it cannot be inventive in the patent sense. If a protein sequence is known, than the DNA sequences that code for it will not in general be patentable, unless there is a sequence which is particularly advantageous, and there is no obvious reason to have selected this sequence from the other sequences that code for the protein. In the case of natural products there are often difficulties because many groups may have published progressive details of a molecule or sequence, so it may have lost its novelty and non-obviousness. These are essentially short pieces of the human genome. However, recently, genomics companies have applied for patents on previously published sequences from databases, and the policy seems to be emerging in the United States that will favour reward of research investment and interpret novelty in a way so as to encourage industry.

There are also patents on protein molecules which have medical uses. In this case the protein structure is patentable if it, or the useful activity, was novel when the patent was applied for. The invention must also be commercially useful. A new use may be allowed a new patent, although an Australian judge in 1998 rejected such an application. There are patents on short oligonucleotide probes used in genetic screening. If someone can demonstrate a use for a larger piece of DNA than they can theoretically obtain a patent on it. An example of a larger patentable section of genetic material would be a series of genetic markers spread at convenient locations along a chromosome. Another set of genetic markers on the same chromosome can be separately patented if they also meet those criteria.

The question of patenting of genetic material continues to be a contentious issue, despite the global agreement with article 4 of the Universal Declaration on the Human Genome and Human Rights, passed by UNESCO General Assembly in 1997, and adopted by the UN General Assembly in 1998, which states "The human genome in its natural state shall not give rise to financial gain." This is because there are numerous interpretations of what natural state means, given that what is being patented is not a chemical substance but the information included in the sequence. The UNESCO International Bioethics Committee (IBC) issued a report to follow up an International Symposium on “Ethics, Intellectual Property and Genomics” recommending UNESCO to develop an international convention on intellectual property and living matter in 2002, however, it seems difficult for such a document to be agreed upon given world politics over this area. In 1998, Nelkin and Andrews asked, like many, what are the limits to commercialization of the human body, and wonder if we should change the species name to “Homo economicus”?

The trend to apply for patent protection on a large number of genes simultaneously could be considered to be a new use of the reward of invention principle, and has broad socio-economic impact because a few companies are dominating genomic sequencing.

One company, Celera (and former TIGR, both based in Maryland, USA) sequenced half of the first two dozen complete genomes to be sequenced. This is not restricted to USA, in 1999 the Helix Research Institute in Japan applied for a patent on 6000 human genes, in a similar way to how US genomics companies have applied for patents on many genes.

The direct use of products, such as therapeutic proteins, is well established. The information may also be used in the study of a particular disease, for example, by the introduction of a gene into an animal to make a model of a particular human disease, and it was for this reason "Oncomouse" was patented in 1988 in the USA. It was U.S. Patent number 4,736,866. The patent awarded was broad, applying to any non-human mammal containing an activated oncogene, although the animal itself was a mouse with one particular activated form of the myc oncogene. Precisely it read, "A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at the embryonic stage." The activated oncogene means that it is more easy to be mutated so that the animal is more susceptible to cancer-causing chemicals, so it can be useful for carcinogenicity testing. During 1987 the US Patent and Trademark Office made the following announcement: "The Patent and Trademark Office now considers non-naturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter ...". The conflict between economic advantage and moral objection is further highlighted in the granting of animal patents, as will be discussed below.

The first patent obtained for a living organism was obtained after the court case Diamond v. Chakrabarty in 1980, and the first patent on an animal was on an oyster in 1987 in the USA. The genetic information can also be used to cure a disease, for example using the technique of gene therapy with a specific gene vector, and this can also be patented. The ethical issues relevant to the debate on patenting life are discussed below.

3. Ethical and Moral Issues

Intellectual property protection is one of the social systems that have evolved in modern society. Like the technology that it is applied to protect, it is a system that needs to be subject to ethical analysis to examine whether it is suitable for a moral society.

The principle benefit claimed for patents is that rewarding an inventor creates a positive environment for progress of research that leads to the betterment of society. If this is true than this is consistent with the ethical principle of beneficence. History suggests that the financial interest in a free market creates more funding for research, and faster overall progress in research in important areas has been the result of the intense research efforts. This point has been used by industry to oppose moves to block patents on biotechnological inventions that arise from other ethical concerns.

The issue is, however, more complex than a simple examination of the benefits of intellectual property to one society, because there are always winners and losers in trade. We have to consider the ethical principles of justice, and non-maleficence. Even more complex is deciding just who the actors are involved in the equation. Some key ethical issues in patenting in scientific research include:

- Is the principle of beneficence, or loving good, served more by having research than by not having research?
- Do we encourage more research into more beneficial areas of science by the incentive system of patents than we would by not having patents?
- Is justice served by systems of intellectual property protection?
- How can we justly reward all the inventors in the often long process of developing a useful product? Should we only reward the final step, and how to value farmer's innovations in the development of plant and animal varieties?
- How to value indigenous knowledge, and to share the benefits with the communities whose ideas gave raise to pursuit of a new product, for example with medicinal plants?
- What are the tolerable limits of doing harm by research subject, e.g. animals including humans?
- What are the tolerable limits of doing harm by rigid enforcement of patents if price becomes a barrier to use of a product by persons in need?
- Ethically can anyone own a product of their mind, a product of nature, a product of a designed process, a discovery or even an invention?
- Does it make any difference whether the product or process involves living organisms or rocks?
- Should we expect the practical law to share the same goals as that of ethics, namely can we expect ideal ethical laws or some compromise?

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Biographical Sketch

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