

Patents on Human DNA Sequences: Patently Right or Wrong?

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My aim is to outline and briefly discuss the major ethical issues raised by the use of the patent system in biotechnology to protect intellectual property and reward innovation. I focus on patenting human DNA sequences, especially when patents are used for diagnostic purposes in human genetic tests. Similar ethical and policy issues are raised by the patenting of plant and animal DNA but the greatest public concern has been about patenting human DNA so I focus on it.

It is useful to distinguish two broad ethical concerns about DNA patenting. The first type of concerns are raised by those who object in principle to patenting human, plant or animal DNA. The second type consists of objections to the way that DNA patents have been used in practice (Hoedermackers, 2001). These two types of objections are often motivated by different approaches to ethical analysis: those who appeal to categorical ethical principles or deontological ethical theories often express the first type of objection. Those who favour utilitarian or consequentialist types of ethical reasoning tend to favour the second. The two types of objection also typically lead to very different remedies for perceived problems with the patenting of DNA. Those who object in principle to patents argue that we should abolish existing DNA patents and legislate to prevent new patents from being issued. Consequentialist critics of DNA patents tend to favour reforming patent law, or the ways in which the current patent system operates with respect to DNA, human or otherwise.

Why do ethical issues matter?

There are good non-ethical reasons why ethical disputes about DNA patents and biotechnologies more generally should be taken seriously. In a liberal democracy like Australia, public attitudes towards biotechnologies decide in part: what type of scientific research is permitted, what type of research is publicly funded; (e.g. research on human embryonic stem cells) and what biotechnologies the community will allow to be developed. They will also shape what biotechnological products will be sold in the marketplace and how they will be sold e.g. as in Australia with compulsory labelling in the case of food that is derived from GM organisms (Gold, 2000). Public attitudes towards all these issues in science and biotechnology often reflect ethical concerns about biotechnology and the uses to which it will be put (Barnes, 2002). Biotechnologists who wish to develop and market new technologies therefore need to be informed about public concerns, to understand the arguments of leading critics of biotechnology, and to participate effectively in ethical and policy debates about biotechnology (Gold, 2000).

Why does DNA patenting matter?

The rationale for a patent system is not always well understood by its advocates or its critics. In particular, advocates or critics often do not appreciate that the central justification of the patent system is that it is intended to provide a *public benefit*. This is not always appreciated by those who are interested in the benefits that the system confers on patent holders. The fact that patents are time limited is also not widely understood.

Objections to the application of the patent system to DNA sequences may affect public attitudes towards biotechnology for the worse, leading to calls for the imposition of severe regulations on new technologies (Gold and Caulfield, 2002). Some people in the community have strong reservations about patents being granted for human genes and whole organisms. They are concerned that patents, as a tool of globalisation, cede control of new technologies to multinational companies that use patents to their benefit by extracting high prices and restricting public access to their benefits. These concerns often prompt calls for greater government regulation of various biotechnologies (Gold and Caulfield, 2002).

The Rationale of Patent System

The granting of a patent on an invention represents government interference in the market to grant an inventor a monopoly on the use of his or her invention for 20 years. The monopoly is conferred on the inventor *in the public interest* with the aims of: providing incentives for future research and development by rewarding past innovation and making the details of the invention public. In both these ways, the patent system is intended to increase opportunities for further innovation (Caulfield et al, 2000; Nuffield Bioethics Council, 2002).

The following criteria have to be met if a patent is to be granted on an invention:

- the invention should be eligible for patenting (“patentable subject matter”);
- the invention should be novel;
- it should be truly inventive, that is, involve something that is not obvious to anyone “skilled in the art”;
- it should be useful or have an industrial application;
- it must be fully disclosed in the patent application;
- and in some jurisdictions it should not be contrary to public morality or order .

The public interest rationale for the patent system prompts the obvious question: How does the patent system work in practice to achieve these goals? As we will see, there has been surprisingly little evaluation of its operation in respect to DNA patents (Nuffield Bioethics Council, 2002). Public benefit has often been assumed by its advocates rather than demonstrated by an analysis of how the system has operated. The same may also be true for many of the putative failures of the DNA patent system identified by its critics.

The patent system has been most extensively developed and applied in the biomedical sciences to stimulate the development of new pharmaceutical drugs (Nuffield Bioethics Council, 2002). It rewards companies for the substantial investments they make in developing a new drug and bringing it to market by giving them a monopoly on sale of the drug for the period of the patent. The patent period is nominally 20 years but it is often considerably less in fact because the period of patent protection starts from the time that a patent application is lodged rather than from when a patented drug reaches market.

Contrary to common opinion, the granting of patents on living things is not a late 20th century invention. Such patents were first granted in the 19th century. Louis Pasteur, for example, took out a patent on yeast in 1876 in the US. The naturally occurring substance adrenaline was patented in 1912 and Vitamin B in 1958 (Nuffield Bioethics Council, 2002).

The modern legal case that is seen as setting the precedent for widespread patenting of genetically modified organisms (GMOs) is that of *Diamond vs Chakrabarty* (1980). In this US case a patent was awarded to Diamond for a genetically modified organism that processed oil. The court's judgment included that often quoted line that a patent could be awarded for "anything under the sun" made by man. Patents on organisms and biological processes are now routine and the income that patent holders obtain from licensing their patents is a major source of income for US biotechnology firms who often licence their IP to pharmaceutical companies and other biotechnology companies in return for funds to finance further research and development. Advocates for the biotechnology industry argue that without patent protection there would be no funding to develop a biotechnology industry.

In Principle Objections to DNA Patents

In principle objections to DNA patents are expressed in a variety of ways. The Council of Europe and UNESCO argue that genes are part of our "common human heritage" and so are not suitable subject matter for patenting (Nuffield Bioethics Council, 2002). Others argue that genes are "public property". Those who defend the patent system counter that these claims do not preclude commercialisation of DNA in principle because the public still has access to such a common heritage under a patent system.

Others object that DNA patents "commodify" human nature by treating people (or part thereof) as a market commodity. Such critics argue that genes are "inalienable". Defenders of patents argue that genes are not owned or alienated; inventors have only been given time-limited rights to the exclusive use of DNA sequences for technological purposes.

There are also theologically based objections to gene patents. Genes, it is claimed, belong to God, not to humanity. Because such theological beliefs are not widely shared these arguments only persuade the theologically committed. Such arguments therefore operate in much the same way as theologically based arguments that an embryo has the same moral status as a child or adult do in public policy debates about human embryo

experimentation. Undoubtedly though these theological sentiments resonate more widely in the community, receiving a sympathetic hearing from many who do not share the underlying rationale or justification.

In principle objections to gene patents have had no impact on the US patent system which eschews the use of any moral criteria in favour of using purely “technical criteria” when assessing applications for patents on DNA. In principle objections receive a more favourable reception in Europe where the European patent system includes a “morality” or “ordre public” provision. Similar language has also been incorporated into the World Trade Organisation agreement on intellectual property, TRIPS. As we will see, critics of DNA patents argue that these morality provisions should be used to prevent the patenting of human and animal DNA sequences.

Objections to Current DNA Patent Practice

These objections to DNA patents are shared by people who do not necessarily object to DNA patents in principle on moral or theological grounds. These criticisms are also made by some scientists, researchers and policy analysts who are concerned about the ease with which DNA patents have been granted and about the public policy consequences of existing gene patents, particularly, those on gene-based diagnostic tests. A variety of criticisms have been made of existing practice. Some critics argue that DNA patents do not satisfy the essential criteria that must be met to grant a patent (e.g. Nuffield Bioethics Council, 2002). Others argue more broadly that DNA patents are not justified because they do not serve the intended public interest of the patent system in that they stifle rather than stimulate research and innovation and they hinder public access to the benefits of biomedical research (e.g. Caulfield et al, 2000; Knoppers et al, 1999). Many critics of DNA patents would use combinations of these arguments.

1. Patentability: Inventiveness

A fundamental objection to patenting human, plant or animal DNA sequences is that such sequences have been discovered not invented. DNA sequences are “facts of nature” that have been discovered by researchers rather than novel inventions that have been fabricated by those who claim a monopoly on their use under the patent system (Nuffield Bioethics Council, 2002). The fact that genetic discoveries can now be patented has prompted calls to allow the patenting of clinical syndromes (such as AIDS) in order to provide incentives for clinical research and development like those currently enjoyed by the pharmaceutical and biotechnology industries (Rees, 2000).

Those who defend DNA patents have a rejoinder which I don’t find very convincing. This is: “genes” are not, in fact, patented; rather, patents have been awarded on a DNA sequences to those who identified, isolated and cloned it using inventive methods. This is a disingenuous claim that probably convinces very few. But even if we accept that it may once have been true of early research that isolated and identified genes, it is a defence that no longer has much force. The identification of sequences of DNA as genes is now a routine process (NCB, 2002). It is usually accomplished *in silico* using statistical methods

applied to publicly available genomic sequence data sets searching for correlations between the presence of a particular sequence and a specific human disease (NBC, 2002). This process looks much more like discovery than invention.

2. Patentability: Usefulness

A strong criticism of DNA patents, particularly as they have been awarded in the USA, is that the threshold for establishing the utility of a DNA sequence has been set too low (NCB, 2002). The theoretical possibility that a DNA sequence may have some future utility has often been sufficient for the US Patent Office to grant a patent on a DNA sequence or indeed on Expressed Sequence Tags, sequences of “junk DNA” and Single Nucleotide Polymorphisms (SNPs). This looks more like speculative prospecting than inventive developments of useful technologies.

The practice of granting patents too freely, critics argue, stifles rather than stimulates innovation. It allows patent holders to “free-ride” on the work of others who subsequently establish the utility of a DNA sequence by enabling the patent holder to claim rights to any of these uses. Thus, if a clinical researcher establishes that there is a diagnostic or therapeutic use for a specific DNA sequence that has already been patented, then the patent holder is entitled to the benefits of their discovery.

Critics argue that patent applicants should have to demonstrate a specific utility for a DNA sequence. Identifying a simple biological function for a DNA sequence (e.g. coding for a protein) should be insufficient to warrant the award of a patent because it only establishes a “fact of nature” rather than an invention with utility.

3. Patents and the public interest: DNA-based Diagnostic Tests

A number of related criticisms have been made about the way in which the DNA patent holders have exercised their monopoly on the use of DNA sequences. The use made by Myriad Genetics of patents on two “breast cancer genes” BRCA1 and BRCA2 has featured prominently in criticisms of the way that existing DNA patents work. The argument is that the use made by Myriad of these DNA patents has not served the public interest in the way that the patent system is intended to do (Caulfield et al, 2000; Rimmer, 2003; Williams-Jones, 2003; Willison and MacLeod, 2002).

The first criticism is that the patent system, in allowing DNA sequences to be patented, confers monopoly not just on the sequence but upon any and all uses that can be made of the sequence. The DNA sequence cannot be “invented around”, these critics argue, in the way that pharmaceutical companies can develop a related drug to get around a patent on a specific chemical compound (Nuffield Bioethics Council, 2002). This may mean (although this is still uncertain) that all other genetically based diagnostic tests, including tests based upon protein products of a DNA sequence, are also covered by the patent on a specific DNA sequence. This precludes the use of the sequence in DNA microarrays without a licensing agreement with the patent holder. In the absence of clear rules on what research uses can be legitimately made of a DNA sequence, it also arguably restricts

the research use of the sequence, e.g. in epidemiological research on correlations between genes and disease and in basic research to develop new drugs.

Second, as a consequence of the breadth of many DNA patents, the patenting of a specific DNA sequence, many critics argue, discourages innovation by removing any incentive that other researchers may have to develop or improve upon existing DNA based diagnostic tests (Caulfield et al, 2000). The benefits of any such innovations or improvements go to the person or company that holds the patent on the original DNA sequence rather than to the innovator.

Third, critics argue that giving a patent holder a monopoly on the diagnostic (and other uses of a DNA sequence) prevents independent quality control of new diagnostic technologies. The patent holder can, for example, prevent any independent checks on the performance of a diagnostic DNA-based test by insisting on their exclusive right to use the test (Caulfield et al, 2000). Myriad Genetics has done this with diagnostic tests for BRCA1 and BRCA2 by threatening to enforce its patent against public laboratories that perform the test and by entering into exclusive licensing arrangements in each country. These practices, critics argue, not only prevent independent checks upon the specificity and sensitivity of such tests; they may also have an adverse impact on the development of new diagnostic tests, such as, high-throughput DNA microarrays.

Fourth, the restrictive use of patents on BRCA1 and BRCA2 and other disease gene sequences has arguably reduced access to these diagnostic tests. Patent holders charge high fees for their tests that many patients are unable to afford and Governments and health insurers may be unwilling or unable to pay the fees charged by the patent holder. In one well publicised case, the relatives of patients who gave DNA samples that were used to identify the BRCA1 and BRCA2 sequences were subsequently unable to afford the tests.

Fifth, DNA patents have had other impacts on research that are less direct and a little more speculative. Among these putative adverse effects are: increased secrecy about research in the interests of securing patent protection for discoveries; delays in the publication of research results in order to secure patent applications, which undercuts the rationale of the patent system to provide increased access to innovations; and substantial licence fees for the research use of patent creating disincentives to undertake research on the subject of the patent (Caulfield et al, 2000).

Sixth, another potential cost of DNA patents (and the more general policy push in most developed countries to commercialise basic research) is that the perceived independence of scientists will be put at risk. If scientists are seen to be primarily motivated by commercial gain, their credibility and the integrity of scientific research may suffer. This has become a major issue with the pharmaceutical industry with increased participation of researchers in industry sponsored research on drug efficacy. It is likely to become a larger problem in future with researchers having patents on DNA sequences and a financial interest in specific diagnostic tests (Knoppers et al, 1999).

Seventh, the tradition of patients participating in research for altruistic reasons may be threatened if large profits are made from patents and high costs restrict patient access to the benefits of research. Under the patent system substantial profits may be derived from samples that have been freely given by patients - the only parties who are unable to profit from the transaction. Patenting genes discovered in medical research may lead to the patients who participated in the research being denied access to the new diagnostic technologies because of their high costs. This happened in the USA with patients suffering from Canavan's disease who participated in the research studies that identified the gene (Gold and Caulfield, 2002). Many people would regard this as an unjust outcome of current policies towards patenting DNA sequences.

4. Failures of the Marketplace

Those who defend the current system of granting DNA patents are reluctant to acknowledge that there have been problems in the use of these patents and argue that any such problems will be resolved with time if they are left to the market place. Legal challenges to specific patents will clarify matters; companies that charge licensing fees that are too high will not prosper (e.g. Resnik, 2001); and diagnostic products that are too expensive will fail in the marketplace so we should let the system regulate itself.

Critics respond that the market place and the courts have not resolved many of these problems to date (Polombi, 2003) The high costs of litigation to resolve patent disputes is a major disincentive to making legal challenges for all but the largest companies and governments. Legal challenges also take time, as have the European challenges to the BRCA1 and BRCA2 patents (Rimmer, 2003; Williams-Jones, 2003). The delays in resolving these issues mean that patents can continue to be used in ways that undermine the system until issues are resolved. The current situation in the USA has been called the tragedy of the "anticommons" (Heller and Eisenberg, 1998). They argue that: there are too many DNA patent holders, each with too little power to challenge other patent holders in order to enable research to proceed; and there are too few resources to negotiate agreements with large companies that hold patents.

Proposals for Reforming DNA Patents

A popular recommendation for reform by many critics of the patent system (e.g. Caulfield et al, 2000; Nuffield Bioethics Council, 2002) is that no new product patents should be awarded for DNA sequences. These proponents argue that the stricter application of the patent criteria for novelty and utility, especially for *in silico* DNA sequencing, would exclude patents from being granted on new DNA sequences (Nuffield Bioethics Council, 2002).

The Nuffield Bioethics Council (2002) has argued that only "use patents" should be allowed on DNA sequences. That is, a DNA patent would only apply to a specific use of a DNA sequence for a diagnostic test, with the use very narrowly defined for using in the diagnosis of a specific disease. The Council proposes that patents should instead only be given to the development of new genetic diagnostic technologies, such as DNA

microarrays. The Council also advocates that the experimental use of a DNA sequence should be more clearly defined to provide researchers with a defence against prosecution for the violation of a patent.

A second policy remedy has been suggested for dealing with the misuse of existing DNA patents. This is compulsory licensing of patents if patent owners abuse their patent by refusing to licence its use for a reasonable fee (Caulfield et al, 2000). This policy would compel the patent-holder to license the test for use by others for what the regulator decided was a reasonable fee. The argument is that such behaviour abuses the patent system by using it for anticompetitive purposes that are not in the public interest. Provisions for compulsory licensing exist within patent law in most developed societies but they have rarely been invoked.

The use of compulsory licensing provisions has been discussed in the pharmaceutical industry in recent years. The intention has been to use compulsory licensing to increase access to effective anti-retroviral drugs to treat HIV/AIDS in patients in the developing world where most AIDS cases are to be found (UNAIDS, 2002). The threat of compulsory licensing of anti-retroviral drugs has prompted the pharmaceutical industry to agree to sell anti-retroviral drugs to developed countries at a discounted rate. The US government has also recently announced plans to fund the donation of AIDS drugs to developing countries whose populations have high rates of HIV infection and whose governments and citizens are unable to pay for the treatment.

The use of compulsory licensing has recently been advocated as a way of compelling companies with DNA patents to license them for use as genetic diagnostic tests at a reasonable fee (Caulfield et al, 2000). This has been proposed as one way of dealing with the behaviour of Myriad Genetics which has offered only exclusive licenses for the use of BRCA1 and BRCA2 tests at a fee that is considerably higher than can be provided by publicly funded laboratories. Similar suggestions may soon be made about the patent held by Mercator Genetics on the C282Y and H63D alleles for hereditary haemochromatosis.

Ethical Remedies for DNA Patents

A number of critics of DNA patenting have proposed remedies for the perceived shortcomings of the patent system that include the specific consideration of ethical issues. One proposal is that patents should be regarded as a type of “moral toll booth” (Gold and Caulfield, 2002). Ethical criteria would be inserted into the criteria used in deciding whether or not to grant a DNA patent. In principle, this could be done in Europe by expanding upon “ordre public” and “morality” criteria that are already included in European patent law (e.g. Knoppers et al, 1999). According to these proposals, any ethical issues raised by a patent application (such as, patient access to a new technology) would be assessed by expert panels of ethicists in parallel with the more traditional assessment of inventiveness, novelty, and utility (Gold and Caulfield, 2002).

These proposals would impose ethical constraints on patent holders who would be legally and morally liable for all uses that were made of their invention (Caulfield et al, 2000). The claim is that this system would ensure that patent-holders had a personal interest in ensuring that their patent was not misused by anyone to whom they licensed it.

Another proposal has been to address the ethical issue of patient access by including provisions for “benefit sharing” with patient groups who participate in research (Gold and Caulfield, 2002). Investigators would also be required to ensure that patients who participated in research that may lead to a gene patent would give informed consent to their participation in the knowledge that the researchers intended to commercialise any discoveries arising from the research. Tissue donors would be explicitly made aware of the researchers’ intent to patent under this proposal.

Moving the Debate Forward

As one can see from this overview of the debates about DNA patenting, further analysis is needed to adequately evaluate the claims made by proponents and opponents of DNA sequence patents.

Much more empirical research is required on how the patent system performs in the area of biotechnology. An important question that needs to be addressed is: When does the public interest rationale of the patent system work? An answer to this question will require good empirical studies of both the putative successes and failures of the patent system in its applications to DNA sequences. We will need reforms that address public concerns about ethical issues, such as public access to benefits, while improving the efficiency of the patent system in stimulating innovation, without increasing costs of the patent system or reducing incentives for innovation.

Advocates of the patent system will need to provide a more considered defence of it. We cannot assume that the public benefits of DNA patents are self-evident to the public or its political representatives. The public interest rationale for the patent system would arguably be better served by the stricter application of criteria for novelty, inventiveness and utility when assessing applications for patents on DNA sequences. Benefit sharing with patient groups whose samples have been used to identify genes is one possibility. The use of compulsory licensing may become necessary to prompt some companies to make more responsible use of the monopoly conferred on them by the patent system.

Summary

A patent is a form of monopoly granted to inventors by the state in the public interest of encouraging innovation by rewarding inventors and ensuring that new inventions are made available to the public. Patents have been widely used in the pharmaceutical industry to protect the interests of companies in developing new drugs but their application to DNA sequences has been controversial.

Those who object to DNA patents in principle appeal to theological and categorical ethical principles which they claim preclude patenting of human DNA sequences. Their remedy would be to exclude DNA (whether human, animal or plant) from the patent system. This set of views has not so far been decisive in the debate about DNA patents.

A more popular set of views is shared by those who do not object in principle to DNA patents but who are critical of the ways in which DNA patents have been used in practice. Some critics argue that DNA sequences are not suitable subject matter for patents because they constitute discoveries about nature rather than inventions. Many DNA sequences, moreover, fail to meet another essential criterion for patenting, namely, they do not have any obvious utility or industrial application. More broadly, many critics of existing practice argue that DNA patents fail to meet the basic rationale of the patent system in that they do not serve the public interest. These critics argue that DNA patents discourage innovation, deny patients access to the benefits of the new technology at an affordable price, and are likely to have undesirable effects upon the perceived independence and integrity of science and altruistic reasons for research participation.

The remedies for the perceived shortcomings of DNA patents depend upon the nature of critics' reservations about them. For those critics who object in principle to DNA patents, the only remedy is a ban on patents being allowed on DNA sequences, whether these be human, plant or animal. Critics of DNA patents in practice propose a variety of reforms to the current system. Foremost among these would be: stricter application of criteria of inventiveness, novelty and utility which would radically reduce the number of DNA patents that were granted; the use of more restricted "use patents" instead of the existing "product patents" on DNA sequences; and the use of compulsory licensing in cases where patent holders misuse their patents. More adventurous proposals are to explicitly include ethical criteria in the patenting process, and to require informed consent procedures to ensure that patients who give samples are informed or researchers' intentions to patent DNA sequences that may be discovered in the course of the research.

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