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Keywords: DNA, genes, patenting, ethics, bioethics, rights, consensus, common good

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The ethics of patenting DNA

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Date received (in revised form): 18th January, 2003

Abstract

Should DNA be patented? This paper argues that the patenting of DNA (whether of human or other origin) is in general acceptable and should be regulated by the same rules and practices as govern other patenting. However, patents on DNA sequences have been and are being granted too liberally.

INTRODUCTION

Is it right to patent DNA? The question continues to be an important one partly because DNA is being patented and partly because countries differ in the extent to which they allow such patenting. The position for which I shall argue in this paper, and have argued previously, 1 is easily stated: the patenting of DNA (whether of human or other origin) is in general acceptable and should be regulated by the same rules and practices as govern other patenting. However, I agree with the argument that patents on DNA sequences have been and are being granted too liberally. My argument will fall into four stages. First, I consider whether or not patenting in general is acceptable; secondly, whether the patenting of non-human DNA is acceptable; thirdly, whether the patenting of human DNA is acceptable; fourthly, whether having a religious faith makes any difference to the conclusions reached.

IS PATENTING ACCEPTABLE?

As is well known, there are slight, though significant, differences among countries in their legal definitions of patents. However, the essence of a patent is that it is awarded to allow those responsible for the invention of something (whether a product or a process that can result in products) to benefit financially from their invention by prohibiting others for limited periods of time (typically 20 years) from profiting, without the consent of those who hold the patent, from the sale of that product or process. In effect, if I

am granted a patent for something, I have a temporary monopoly on it. I alone am entitled to make money from its sale, unless, of course, I choose to let others profit from it.

From an ethical standpoint, patents (along with design rights, trademarks, copyrights and further mechanisms that protect designers, writers, musicians, academics and others) are a sub-class of intellectual property rights. They enable the person responsible for something that is novel and desired by others to profit from it. In the case of patents, a number of safeguards exist (the precise nature and extent of which vary among countries). In particular, it is not permitted to patent something, such as an instrument of torture, that is considered contrary to morality or ordre public. Nor can someone be prevented from carrying out research on that which another has patented. Indeed, such research is made easier by the patenting process which requires full disclosure. Further, a patent lasts only a limited period; indeed, considerably less that the 50 or 70 years permitted under copyright laws and the virtually unlimited period of protection afforded to a registered trademark which continues in use. In addition, legislation exists to prevent, in certain circumstances, a person from sitting on a patent without exploiting it or from charging too much for what is patented. Greater deployment of such compulsory licensing and limits to fees might do much to reduce inequality and related injustices in the use of patents.

It is possible to object to patents in themselves. For example, it might be

argued that people should not profit from their greater expertise or inventiveness, but should share the fruits of their labour among others gratis, from each according to their ability, as it were. Marie and Pierre Curie, for instance, refused to take advantage of the lucrative industry that grew up around their discovery and isolation of radium, believing that investigators should not profit from the results of their research. Before them, Michael Faraday could have made a fortune from his scientific discoveries but declined on ethical grounds. Something of this attitude persists in the non-Celera publication of the human genome sequence in the Human Genome Project. Against the argument that people should not be allowed to profit from their greater expertise or inventiveness - no one says that they should be prohibited from voluntarily relinquishing such profits there is the argument that it is wrong to prevent individuals from being allowed to benefit financially from their inventions. As the United Nations Universal Declaration of Human Rights puts it:

'Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.'²

The argument becomes one concerned with the balances between liberty and distributive justice.

A different approach is to adopt a utilitarian perspective. The fundamental utilitarian argument in favour of patenting (ie with regard to its consequences) is that in the absence of patenting, individuals and companies would invest far less in research because the existence of patents gives patent holders an increased chance of getting their investment back. The research costs in industry are often significant, so that in the absence of patent protection far less research, it is maintained, would be carried out and fewer products would reach the market. (In certain industries, for example the food, tobacco, automobile and other

transport equipment sectors, patents play a smaller role than in other industries, such as the pharmaceutical industry. The reasons for these inter-industry differences are complicated but are more to do with different ways of protecting innovation³ than with any different conceptions about the appropriateness or worth of protecting innovation.)

Several arguments have been put forward against patenting in science in terms of its consequences. It has been argued that patents hinder the publication of scientific findings because of the time lag needed for patent applications to be made. It has also been argued that patenting encourages researchers to target their efforts where money is to be made, rather than where work is most needed. On the other hand, it has been argued that any delay caused by patenting to the publication of scientific findings is typically only a matter of a few months and that, in the absence of patenting, a significant proportion of commercially funded research would simply not be published because the best way to maximise financial return would be to keep secret the details of the product or process for as long as possible. Similarly, the argument that patenting encourages researchers to target their efforts where money is to be made has been countered by the assertion that this would be equally true in the absence of patents.

As is often the case in attempting to decide an ethical question on utilitarian grounds, there exists genuine factual uncertainty about the precise consequences of abandoning the whole approach of patents. I have still to read any rigorous, detailed analysis of this issue. All one generally gets is one side arguing that the ending of the patenting system would be a great loss (much research would not take place, medical and other advances would be held back, etc.) while the other responds that it would not be. There is still a lack of systematic and convincing evidence either way. However, hardly anyone seriously suggests that all patents should be

There is a range of arguments for and against patenting but still a shortage of empirical data

outlawed. Arguments against patenting in general usually occur when someone wants to object to the issuing of a specific patent or set of patents and is trying to find every available argument to bolster their case.⁴

IS THE PATENTING OF NON-HUMAN DNA ACCEPTABLE?

In many people's minds there is a significant difference between patenting per se and the patenting of DNA. Many of the arguments against the patenting of non-human DNA reappear with even greater force when the question of the patenting of human DNA is considered, so I shall leave them for the next section. The question here is, is there something special about DNA that means that this should prevent if being patented? We need to decide whether this question is to be answered using the customary 'rules' of the patenting 'game' (novelty, inventiveness, practical utility, disclosure) or whether DNA sits on another field of play altogether. An analogy may be helpful: we can ask whether there is such a thing as a distinctive sexual ethics – ie right set of ways to behave sexually - or not.5

At first the answer to this analogical question may seem obvious. Surely sexual behaviour has its own ethics! People, at different times and in different cultures, argue about the acceptability of polygamy and homosexuality and the age of consent and whether rape can exist within marriage and so on. However, it can be argued that sex has no particular (ie distinctive) moral significance. Igor Primoratz, for example, holds that sex is morally neutral, so that moral guidance regarding sexual behaviour is provided by the same general moral rules and values that apply in other areas:

'Thus adultery is not wrong as extramarital *sex*, but only when it involves breach of promise, or seriously hurts the feelings of the non-adulterous spouse, etc. Prostitution is

not wrong as commercial sex, but if and when the prostitute is forced into this line of work by the lack of any real alternative. Pedophila is not wrong as adult—child sex but because even when the child is willingly participating, its willingness is extremely suspect in view of the radical asymmetries of maturity, knowledge, understanding, and power of children and adults. Sexual harassment is not wrong because it is sexual, but because it is harassment. Rape is not wrong as sexual battery, but as sexual battery.

For me, Primoratz's argument is convincing. Extended, it means that there is nothing distinctive not only about sexual ethics but about business ethics, about the ethics of war, or any other question – including the ethics of patenting DNA. Here, though, it is worth mentioning one particular objection to the patenting of non-human DNA and that is that such a practice works only to the advantages of countries such as the USA, Japan and those in the European Union with a strong and well-established patenting system. Other countries are disadvantaged.

Consider, for instance, the case of the neem tree (*Azadirachta indica*):⁷

'The Neem is a beautiful tree. It looks really regal. It grows best in arid zones. The poorest of homes will have a Neem in the backyard. The Neem has terrific anti-malarial properties – it doesn't allow mosquitoes to come near; it doesn't kill mosquitoes, it numbs them and keeps them away. It has been used by our mothers and grandmothers; they used the dry leaves in clothing, so that silk and wool did not get eaten by worms. Neem leaves have been used in storing grain, so that, again, bugs don't get to the grain. Neem is a reliable skin treatment for all kinds of infection. My own little boy used to pick up infections all the time. The only thing that would work was the Neem oil massage I gave him. It is

Is there something special about DNA to prevent it being patented?

now being found to be very effective as a contraceptive. The Neem is a sacred tree in India. It is the olive of India. It's always been known that if you use the Neem twigs as a toothbrush, you never get any kind of tooth decay; but there's a US company that now has a patent on its dental care properties. There's a company that has a patent on its skin care properties; and, of course, you have about ten companies which have patents on its biopesticide properties. So every aspect of Neem that has been known in India is being treated as an innovation of a Western corporation.'⁷

The workings of the present patent system are not just

How does patenting relate to ownership, control and exploitation?

Faced with this sort of injustice, we can agree that the present workings of the patent system have major shortcomings when viewed from the perspective of global justice. (This is the case irrespective of the fact that the neem example does not concern the patenting of DNA itself.) Indeed, a well-known report commissioned by the UN concluded in 1994 that 'biopiracy' was cheating developing countries and their indigenous peoples out of some US\$5.3bn a year.8 But this does not mean that the best way forward is necessarily to abandon the patenting of non-human DNA or other biological extracts. One option would be to strengthen the ability of non-Western countries to take out their own patents. Another would be to ensure that such countries entered into more bilateral arrangements with Western countries or multinationals to enable them to benefit financially from patents taken out on 'their' species.

IS THE PATENTING OF HUMAN DNA ACCEPTABLE?

The arguments in favour of patenting human genes are broadly the same as those in favour of patenting in general – namely that such patenting fairly rewards those who do the work (ie the patents are ethically defensible in themselves) and that the consequences of such patenting

are of widespread benefit (eg treatments for many human disease are likely to result). These arguments of natural justice and the reduction of human suffering need to be kept in mind when objections to the patenting of human genes are considered.

The arguments against the patenting of human genes are more numerous than those against patenting in general or of the patenting of non-human DNA. For a start, it is often assumed that patenting of human genes can be equated with the ownership of human genes. We no longer condone slavery – ie the ownership of one human by another – so why should we allow patenting? A possible response is that patenting and ownership are not the same thing. After all, I own many things in my home, including books, kitchen gadgets and even two domestic cats, but I do not hold patents on any of them. Equally, the person who holds the patents on the various gadgets in your kitchen does not own them - you do.

Then there is the equation of patenting with control and exploitation. The person who has a patent on something has control over the commercial exploitation of that thing. Against this it can be pointed out that things can be commercially exploited and controlled in the absence of patents. It has been argued by those in favour of the granting of patents on human genes that the question of whether this should be permitted needs to be kept separate from the question of whether particular uses of human genes in medicine or for any purpose should be allowed. Whether or not one finds this argument convincing, it may be that the existence of patents can make it easier for a judiciary to check whether certain moral boundaries are being transgressed by virtue of the fact that the granting of a patent brings that which is patented more clearly into the public arena.

A different objection to the patenting of human genes is that this may be perceived as the thin end of a wedge. As is widely acknowledged, though, thin edge of the wedge arguments on their own are unconvincing. For one thing, practically every desirable thin end leads eventually to an undesirable thick end. Are we to ban all speech on the grounds that people often say hurtful things to one another?

A further objection to the patenting of human genes stems from many people's unhappiness with the idea that this implies that someone has invented the gene in question. This objection has considerable force. After all, patents are given in most countries – though not all – for inventions, not discoveries. One may accept that a scientist can discover a human gene, but in what sense can a naturally occurring gene be invented? One answer to the objection that naturally occurring genes are not invented is to maintain that this is a semantic argument based on the specific historic formulation of what a patent is. We could easily envisage a situation in which all countries allowed patents for discoveries as well as for inventions. We would still then have to decide whether or not the patenting, in this broader sense, of DNA was acceptable.

A different answer is to accept that to some extent the question of the extent to which a gene can be invented revolves around the amount of ingenuity required to determine the precise sequence of bases that is the genetic code for that gene.

The recent discussion paper produced by the Nuffield Council on Bioethics⁹ is particularly helpful in this regard. In essence, the Council accepted the standard criteria that something should only be patented if it is novel, inventive, useful and disclosed. In common with a number of other writers they hold that 'the application of these criteria to DNA sequences has not been sufficiently stringent' (p. xi). In particular, they consider that:

- the granting of product patents which assert rights over DNA sequences for use in diagnosis should become the rare exception, rather than the norm;
- protection by use patents of specific

diagnostic tests based on DNA sequences could provide an effective means of rewarding the inventor while providing an incentive for others to develop other tests;

- the granting of patents which assert rights over DNA sequences as research tools should be discouraged;
- in the case of gene therapy, patent protection should be concentrated on developing safe and effective methods of appropriate gene delivery rather than on the DNA sequences themselves;
- rights asserted over DNA sequences which are used to make new therapeutic proteins are generally acceptable but should be narrowly defined, extending only to the protein described.

In essence, the Nuffield Council on Bioethics holds that downstream patents (on actual tests and gene delivery approaches) are more acceptable than upstream patents on DNA sequences. Again, as I argued above when considering sexual ethics as a model to examine whether there are distinctive issues raised by the patenting of genes, there are useful analogies. One is Internet patents. It is probably the case that early patents in this area were, as with patents on DNA sequences, too broad ranging. In both cases what is meant by 'too broad ranging' is (albeit somewhat imprecisely) clarified by appeals to 'the common good'.

THEOLOGICAL CONSIDERATIONS

A variety of theological positions exist about the acceptability of genetic engineering in general and the patenting of DNA in particular. A particularly powerful theological critique of the patenting of living organisms and of the patenting of human genes was provided by a September 1996 submission to the

Early patents on DNA sequences were too broad ranging

European Parliament and the European Commission from the European Ecumenical Commission for Church and Society. ¹⁴ This document makes a number of points which can be illustrated by three quotations. First it argues that:

'Patenting makes an implied statement about the fundamental relationship between humans and nature. Simply extending the rules for inorganic materials to the biological sphere can encourage inappropriate attitudes to nature. We suggest that consideration should be given to developing an alternative form of intellectual property for biological material, free from the assumptions and associations of a system designed originally for mechanical inventions, and which explicitly recognises that 'inventions' affecting living things are in a different category from all other activities and products of industry and commerce. (p. 1)'

Three points can be made. First, whether or not the patenting of biological material actually results in inappropriate attitudes to nature is debatable. In part such an assertion is open to empirical testing, though I am unaware of any evidence, other than anecdotal, either to support or refute it. Secondly, I too feel there is much to be said for the development of an alternative form of intellectual property for biological material. However, as I predicted in 1997, global agreement on this front is highly unlikely in the foreseeable (say, five years) future, yet the next few years are likely to be the critical ones. Thirdly, while I can understand why some biologists might argue that inventions affecting living things are in a fundamentally different category from all other activities and products of industry and commerce, it is perhaps less obvious why theologians and religious believers would. After all, every religion that believes in God(s) holds that everything is created and sustained by God(s), not just living things.

Secondly, the European Ecumenical

Commission for Church and Society argued that:¹⁴

'We deplore the implications of the various US court decisions regarding patenting of living organisms that have led to the notion that animals, plants and living organisms generally are now thought of as nothing more than 'products of industry', having no more status than a mechanical part of a machine. This represents an unacceptable paradigm shift in how life forms are regarded, with respect to patenting. This view sees nature entirely in anthropocentric terms of its utility to humans, as tools and products, and has lost the sense of respect for animal or plant as of value in itself. This perception runs contrary to Christian understanding that all of creation owes its existence to God, and its significance is first of all what it is before God, irrespective of any use to which human beings might think of putting it. This seriously limits what human beings may legitimately do to other living creatures, because they are God's first, and not ours to do exactly what we like with. (p. 5)'

Again, there are several problems with this argument. First, the passage, and in particular the sentence 'This perception runs contrary to Christian understanding that all of creation owes its existence to God, and its significance is first of all what it is before God, irrespective of any use to which human beings might think of putting it', makes sense only if it uses 'creation' to refer solely to living organisms. This, of course, is unacceptable theologically. The Earth is the Lord's and all that therein is. Secondly, while I accept that patenting presumes an anthropocentric view of nature, so do vaccines against human diseases, animal ownership and much else besides. I would argue that the anthropocentric view is a partial view, one that can be built on rather than rejected out of hand. Thirdly, the assertion that patenting of living

Many of the theological arguments against patenting lack coherence

organisms involves a loss of the sense of respect for animals or plants is, I would argue, no more necessarily the case than the fact that I own my cats means that I do not respect them.

Thirdly, the European Ecumenical Commission for Church and Society argues that:¹⁴

'Patenting of any part of the human genome is ethically abhorrent, in principle (p. 5)'

I believe in taking arguments about abhorrence extremely seriously. However, we cannot allow abhorrence, on its own, to be the final arbiter in matters of legislation. I would find it abhorrent to eat dog flesh but I would not approve of a law forbidding such a practice. Returning to the issue of the patenting of human genes, I find myself asking why such a practice is considered abhorrent, realising that my question belongs more to the domain of psychology than moral philosophy. I know I find it awful that anyone born with cystic fibrosis dies a premature death. I know that I find it hopeful that it now seems as though genetic engineering may help prevent this from always being the case. I am informed by those in industry that the patenting of human genes is likely to lead more rapidly to such treatments and cures. I admit that I am not certain that this argument is correct but I would like to be very confident that it is false before agreeing to the prohibition of the patenting of human DNA.

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