Patenting and Transgenic Organisms: A Philosophical Exploration

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Transgenic organisms: how they differ from Mendelian hybrids[1]

The appearance and maturity of a new basic scientific discipline, that is, molecular biology, and in particular its sub-branch, molecular genetics, has engendered a technology, namely, biotechnology, which permits a quantum leap, so to speak, in the kind and degree of control of biotic nature, over its predecessor technology based on the classical gene-chromosome theory.[2] For the first time ever, we are able to cross the species barrier and, in principle, to dispense with natural evolution in the production of novel organisms and new species.[3] Biotechnology makes it possible for us to make over biotic nature to our will and design. To quote one writer:

> Many of the things that were discussed as science fiction five years ago have already happened. This is not just a change of technique, it is a new way of seeing. ... The limitations of species can be transcended by splicing organisms, combining functions, dovetailing abilities and linking together chains of properties. The living world can now be viewed as a vast organic Lego kit inviting combination, hybridization, and continual rebuilding. Life is manipulability. (Yoxen 1983, p. 15)

In the first half of the twentieth century, the technology of hybridization generated by the theoretical discoveries of Mendelian genetics produced with a greater degree of precision plants and animals possessing characteristics deemed to be desirable than the traditional methods of breeding. However, such Mendelian products, nevertheless, may be said, in comparison, to embody a lower level of artefacticity than those produced by rDNA technology induced by the fundamental discoveries of molecular genetics in the second half of the last century. In the case of the latter, their greater degree of artefacticity is due to the fact that their mode of production involves the manipulation of, and indeed, the exchange of genetic material at the molecular level across species, and even, kingdoms. This then locates them at the pole, which is directly opposite to that occupied by organisms regarded as naturally-occurring. In this respect, they are distinctly human artefacts in the same way as houses or paintings are paradigmatically human artefacts, which ex hypothesi could not be naturally-occurring entities. Transgenic organisms are biotic while houses and paintings are abiotic artefacts. However, unlike houses and paintings, many transgenic organisms are capable of biological reproduction or replication and could, under certain conditions, eventually escape from the human-controlled environment to lead an independent existence outside it. It is precisely because of this possibility, that so much angst and discussion have been generated about the environmental risks which could be involved in rDNA technology.[4]

The so-called quantum leap in the level of artefacticity between the hybrids produced by Mendelian whole-organism technology and those by molecular DNA technology lies in the fact that though the selection in the former is artificial, it is, nevertheless, more closely aligned with the processes of natural evolution. The hybrids are between varieties of the same species and though they are highly unlikely to occur in nature, that is, without deliberate human intervention,

nevertheless, they could be said in principle to be conceivable. But recombinant hybrids involve artificial selection (if one still cares to use that term) which radically defies the processes of natural evolution, as they cross the species barrier not merely within the respective contexts of animal and plant species, but also between animal and plant species themselves, and more significantly between the eukaryotes and the prokaryotes.[5] Transgenic organisms ex hypothesi cannot be naturallyoccurring entities in the sense that they cannot be the results of the processes of natural evolution. They are the paradigmatic biotic artefact.[6]

Patents and transgenic organisms

The status of transgenic organisms as biotic artefacts may be further elucidated via the issue about their patentability. Patents are about inventions and the legal rights over their financial exploitation (for a limited period). To obtain a patent, the item for which application has been filed must, first and foremost, constitute an invention; furthermore, at least three other conditions must obtain: the invention must be novel, it must not be something obvious to an expert in the field, and it should have industrial application. The discussion to follow will concentrate on the first requirement, that is, that transgenic organisms are indeed inventions within the meaning of the modern patent law. But it will also consider their novelty. However, the condition of non-obviousness will not be explicitly touched upon, and the discussion will simply assume that transgenic organisms have, on the whole, been fabricated with industrial application in mind.[7]

Up to 1980, no one could be sure in any country with a Western-type legal system whether patents could be granted to any living organism, which claimed to have been made by humans. Up to then, animal varieties and any biological processes which underpinned the production of animals and plants fell outside the ambit of patenting. However, there was legislation to protect plant varieties in several countries-for instance, in the USA, the 1930 Plant Patent Act (PPA) covers asexually reproducing plants, and the 1970 Plant Variety Protection Act (PVPA) covers sexually reproducing ones. The UK 1983 Plant Varieties Act comes under the aegis of the Ministry of Agriculture, Fisheries and Food, not the Patenting Office, and covers the reproductive materials of plants. There is also the 1968 International Union for the Protection of Plant Varieties. [8]

But in June 1980, the situation altered with the decision of the US Supreme Court in the case of Diamond v. Chakrabarty. Chakrabarty, a scientist, who worked for General Electric, submitted an application to the US Patent Office in 1972 for a new strain of the bacterium, Pseudomonas. The novel bacteria were intended to clean up oil spills in water by degrading the crude oil, then ingesting the degraded material, with the bacteria themselves, in turn, forming part of the normal food chain. Chakrabarty did not use rDNA techniques in producing the new strain. He relied on other techniques. Plasmids from separate organisms-each able to degrade one of the important hydrocarbons which constitute crude oil-were bred into a single bacterium, thus combining all their superior properties in a single strain of super bacteria. The Patents Office rejected the application for a patent on the organism itself on the grounds that the 1930 (PPA) and 1970 (PVPA) Acts showed that Congress had not meant living organisms in general to be patentable, and was simply making special arrangements in providing protection for plants. But the Court of Customs and Patent Appeals (CCPA) rejected this interpretation, arguing that 'the fact that micro-organisms, as distinguished from chemical compounds, are alive, is a distinction without legal significance.' The US government in 1979 itself lodged an appeal against the CCPA's decision. The crucial issue before the Supreme Court was whether 'a living organism which otherwise complies with legal requirements for patentability nevertheless [is] disqualified because it is

alive?' A five to four majority upheld the line argued by the CCPA, deciding in favour of patentability.

Two assumptions stood behind such recognition of patentability: that artefacts can be biotic or abiotic, and that the products of biogenetic technology qualify as biotic artefacts. Given these assumptions, it was expected that a favourable decision in the Chakarbarty case would clear the way for the numerous products of the biotechnology revolution which were rapidly coming on stream but which were held up until the Supreme Court had pronounced on the Chakrabarty case. After all, the rDNA organisms-be they animals, plants or microbes-compared with those produced by other forms of biogenetic technology, embody even a greater degree of artefacticity. It stood to reason then that rDNA organisms, their products and procedures are all patentable as they are paradigmatically human-designed, human-made, and are not the products of nature.

Following the work done by the research teams of Stanley Cohen at Stanford University and Herbert Boyer of the University of California in San Francisco in 1973 and 1974, Stanford University, in 1974, filed an application to patent rDNA techniques for transforming cells with recombinant plasmids, using antibiotic-resistance genes on plasmids as genetic markers, in vitro genetic recombination techniques for producing recombinant plasmids as well as for the recombinant plasmids themselves. But in 1978, the submission was divided into two applications, one for a process patent and the other for a product patent.[9] The process patent was granted in December 1980, following the Chakrabarty decision; the product patent was issued in 1984, covering as well products produced by bacterial plasmids in bacterial hosts.[10]

The first Cohen-Boyer patent is registered as No. 4,237,244 and issued for the 'Process for Producing Biologically Functional Molecular Chimeras.' The Patent Office spelt out the novelty of the procedure leading to the production of novel biotic artefacts very clearly indeed: 'The ability of genes derived from totally different biological classes to replicate and be expressed in a particular microorganism permits the attainment of interspecies genetic recombination. Thus, it becomes practical to introduce into a particular organism … functions which are indigenous to other classes of organism' (U.S. Patent Office 1980, 1). In other words, the patenting of transgenic organisms recognises that paradigmatically they are biotic artefacts.[11] Whether one disapproves of it or has reservations on other grounds is another matter, but the successful patenting is the logical conclusion from the fundamental premises that they are undoubtedly artefacts, and that they are novel artefacts.

Depth of manipulation versus extensiveness of manipulation

However, the situation may not be as simple as that portrayed so far, particularly when the biotic artefacts involved are not mere micro-organisms like bacteria, but animals and plants which are relatively much more complex organisms.[12] Here the counter arguments against patentability of transgenic animals and plants may lie not so much in refusing to accept that they are biotic artefacts, but on holding that in spite of the 'depth' at which they have been created, nevertheless, depth alone is not sufficient. Another dimension must be taken into account-extensiveness of change may be relevant and may, indeed, be said to override depth if depth is not accompanied by extensiveness.[13] A caveat may immediately be in order. As far as this author can ascertain, this argument against patentability has not played a role in current legal patent debate, but it is explored here for the sake of theoretical completeness, as it could in principle be articulated and enter such discourse. It could do so via the requirement of novelty. So far this paper has interpreted novelty to refer to 'depth' manipulation at the molecular level. However, according to

the line of reasoning under examination, novelty may also be understood to refer to extensiveness of phenotypical change (whether involving extensive or limited genotypical change). Judged by this alternative interpretation of novelty, extant transgenic organisms may be said not to be truly novel, thereby excluding themselves from qualification under current patent law. In other words, the argument points to a potential ambiguity in the concept of novelty in the context of transgenic organisms.

On one interpretation of novelty, the transgenic cow with the human DNA sequence which makes it manufacture a human protein in its milk, may be taken as a typical novel product of certain deep biotechnological techniques and procedures at work.[14] However, it could be argued that the alteration perpetrated by biotechnology is, according to the second interpretation, not very impressive as the phenotypical change is so minimal as to be hardly observable. This indeed is true today.

However, in 1985 when the first transgenic piglet was created, the situation was quite different. Scientists succeeded in inserting the piece of DNA encoding the production of human somatotropin into the nucleus of the fertilised pig eggs. These embryos were then transplanted into the sow's uterus. Nineteen-the Beltsville pigs-were born with the human gene in their genome. These pigs, unfortunately, suffered from 'deleterious pleiotropic effects', that is to say, they developed abnormally, with deformed bodies and skulls. Some had swollen legs; others ulcers, crossed eyes, suffered from renal disease or arthritis, as well as decreased immune functions, and were susceptible to pneumonia. And all were sterile.[15] These animals did suffer. However, genetic engineers have since refined their techniques, and transgenic animals fabricated today no longer display 'deleterious pleiotropic effects'; nor do they suffer from unintended sideeffects.[16] What this shows is that as biotechnological procedures advance and are refined, greater precision in manipulating genetic material becomes possible, and unwanted side-effects like those just mentioned could be eliminated, such that only phenotypical/behavioural changes of the limited intended kind manifest themselves. One could say that it was the early lack of sophistication in genetic manipulation, which produced a whole suite of unwanted phenotypical characteristics, rendering it obvious that DNA genetic manipulation could produce spectacular changes in the transgenic organism. Ironically, today, improvement in techniques and procedures seems to have robbed DNA engineering of this capability to induce a large suite of phenotypical changes to the organism.

So, from the point of view of patentability, one might then be tempted to argue that the transgenic organism is not a suitable candidate for patentability, as its extent of artefacticity is really quite minor or limited. Before rushing to this plausible conclusion, perhaps one should ponder other aspects, which may be relevant to the debate. First, does the point above involve nothing more than a purely empirical issue? True, the examples of transgenic organisms usually cited seem to involve only a specific limited change, like the ability to produce a human protein in their milk or whatever. But in principle, are biotechnological methods and procedures thus restricted? As far as one can ascertain, the answer seems to be no. One day, provided they can get away with it, genetic engineers in the agro-industries could well produce a non-sentient, wingless, featherless, beakless organism with avocado-coloured flesh tasting like strawberries. Such a transgenic organism, given the extensive range of its unique characteristics has a sui generis identity which, nevertheless, relies on the mechanisms possessed by the original bird to carry out its various biological functions, like that of digestion, respiration, defecation, etc. The degree of artefacticity of such a product of genetic engineering would then be both deep and extensive.

In other words, what should be a condition sine qua non for patentability in this context? Should one rely (a) solely on extensiveness of change to the organism in question? (b) solely on depth at which genetic material is manipulated? (c) or on both extensiveness and depth? In invoking extensiveness alone, then, on the whole, domesticated organisms produced by the less radical breeding technologies would be covered. (This scenario, however, has been included in this discussion solely for completeness and for the purpose of clarification, as it can have no policy implication-modern patent law, by and large, have left domesticated organisms of such kinds outside the domain of patentability.) But it would exclude those transgenic organisms with one alien DNA sequence inserted into its genome and displaying only a specific and limited change in its phenotype-let us call this type A transgenic organism. Vice versa, in invoking depth alone, domesticated organisms bred in relatively traditional ways would then be excluded. But if both depth and extensiveness were invoked, then transgenic organisms in principle would certainly qualify.

If organisms could, indeed, be manipulated at the deeper and more radical level of their genetic material, crossing both species and kingdoms barriers and in such a way as to display a suite of phenotypical changes attendant upon genotypical ones-let us call this type B transgenic organism-then it is merely academic to confine discussion only to the majority of extant transgenic organisms. In any case, as a matter of fact, some transgenic organisms have already been produced such as the 'liger' (or the 'tiglon') whose genome share the genetic components of both the lion and the tiger and which correspondingly exhibit extensive phenotypical changes from its respective parents.[17] The same holds true of the 'geep' or 'shoat' which incorporates the genetic material from the sheep and the goat. (The main technological procedure used in these examples of genetic manipulation is in vitro fertilisation, rather than the insertion of specific alien DNA sequences into the genome of either the lion or the tiger.)[18]

To date, type B transgenic organisms is not so common simply because, for the moment, the climate and the market are not quite ready for them. But agro-industries would not be averse to opting for this kind of manipulation should the circumstances turn out to be propitious. Furthermore, ponder what might be the response of such industries should type A transgenic organisms be denied patentability on the grounds that they are not sufficiently novel. This would immediately prompt these industries to change ploy; their genetic engineers would be instructed to design and manufacture type B transgenic organisms only.[19] Just to take one hypothetical example: the cow with the alien DNA sequence to produce a human protein in her milk could then be the recipient of other transgenic DNA sequences which might alter her skin pigmentation to blue, or render the animal luminescent in the dark, etc. so long as these other sequences do not interfere with the capability of the transgenic cow to produce the human protein in question or to cause it to suffer in the way the Beltsville pig did. The obstacle to patentability encountered by type A transgenic organisms could in practice be overcome by simply pursuing the strategy of manufacturing only type B transgenic organisms. The ability of biotechnology to confine itself to effecting only one limited specific change in type A transgenic organisms is testimony to its powers of precise control and not, necessarily, to an inability on its part to bring about more extensive changes, should those wielding the technology so wish to do.

Depth of manipulation is critical

However, although in principle there may be no incompatibility between depth and extensiveness, it remains the case that most extant transgenic organisms are type A, rather than type B. So the question remains whether the former ought to be considered patentable. The

inclination to answer it affirmatively remains strong in spite of the fact that, as they stand, they fail the test of extensiveness. The principal reason rests on the simple consideration that they are, indeed, transgenic organisms. Such organisms are, au fond, artefacts-ex hypothesi, without direct human manipulation at the molecular level of their genome, they could not, and would not, have come into existence. As already observed, non-transgenic organisms bred via the less radical technologies have, in their genomes, genetic material which come from related varieties; transgenic organisms have, in their genomes, genetic material which have crossed species and kingdoms barriers. No strawberry or tomato plant could have come to possess a gene from the flounder, a fish, either as a result of the processes of natural evolution, on the one hand, or from craft-based breeding technology or Mendelian hybridization technology, on the other. In other words, their very identity is defined in terms of their being transgenic in character and essence. This deep ontological dimension is of fundamental significance.

However, one must not allow this realisation to obscure the fact that a transgenic organism, though an artefact, nevertheless, remains, undoubtedly, an organism. As such, it functions as one with its various metabolic and other mechanisms intact. From the point of view of its biological functionings, it appears no different from a naturally-occurring organism or from domesticated animals and plants. The transgenic animal in which a DNA sequence encoding for a human protein has been inserted into its genome would eat, digest, defecate and mate in much the same way as its nontransgenic counterpart. However, one should not be over-impressed by such similarities, as these biological mechanisms simply define its identity as an organism of a certain kind. However, they do not define its identity as the transgenic organism it now is. That identity is given to it by the fact that its genome now contains DNA which is alien to the organism it was before it lost that identity. Some of its biological mechanisms, as an organism simpliciter, have been hijacked, as it were, by the foreign DNA, such that the transgenic animal, which it now is, expresses a human protein in its milk. In other words, direct human manipulation at the molecular genetic level has ensured that its naturally-evolved biological mechanisms are used to fulfil a human purpose, and not the end for which those naturally-evolved mechanisms normally serve, namely, the animal's own end, which is to produce milk containing proteins peculiar to the natural kind that it is.[20]

This constitutes the essential subversive character of biotechnology. To argue that depth of manipulation without extensiveness does not yield a sufficient degree of artefacticity to satisfy a condition sine qua non for patentability is precisely to fail to grasp this profoundly significant feature about the new technology. Earlier technologies of breeding can only eliminate undesirable (undesirable only, of course, from the human point of view) traits from an organism's genome, enhance existing or introduce new traits deemed desirable. But changes to the genetic constitution is done through mating, or of late, in the case of animals, via in vitro fertilisation, or in the case of plants, via hand pollination, a technique of long standing. But the traits chosen for reproductive manipulation are simply traits of different organisms belonging to the same variety, or species, that is to say, the same natural kind. But as biotechnology is able to by-pass such constraints, transgenic organisms, ex hypothesi, are beings whose genomes permit them to exhibit modes of behaviour or traits, which their naturally-occurring counterparts do not and cannot possess.

Identity of the transgenic organism

On the surface, it appears that the animal is carrying out its own telos as its biological mechanisms remain intact. But if the implications of being a transgenic organism are fully teased out, the appearance of normality vanishes. This can be brought out by posing the question, as

already observed, about its identity. There are two possible ways of answering the question: what is it? One way is simply to say that it is still a cow, a tomato plant or whatever, which happens to produce a human protein in her milk or which happens to be able to withstand frost. The other is to say that it differs so fundamentally from a normal non-transgenic cow or tomato plant that it would be misleading to say simpliciter that it is a common or garden variety cow or tomato plant. One could perhaps call it a Tgcow (short for 'transgenic) or a Tgtomato plant.

But to adopt the first approach is to go for appearances only while ignoring the underlying reality. It is to say that the animal looks every bit like a cow; it behaves like a cow as it still eats grass (or whatever substitutes modern cows eat), it moos, it lactates, etc. Its milk looks like ordinary cow's milk and probably tastes like ordinary cow's milk, too. It is only when you subject its milk to laboratory analysis that you would find human protein in its make-up. The presence of the human protein, therefore, seems to be the single 'odd' fact about the animal compared with the very long list of 'normal' facts, which one can draw up about it. However, such an approach fails to recognise the profound alteration to the genome of the ordinary 'normal' cow, which has enabled its transgenic counterpart to produce that so-called single 'odd' fact about its milk. But when that single 'odd' fact is properly placed and understood within the context of the kind of radical genetic manipulation, which biotechnology permits, then its singularity and its oddness should lead one to conclude that the degree of artefacticity, via depth of genetic manipulation, inherent in a transgenic organism is warrant enough to qualify as a condition sine qua non for patentability. The transgenic organism is the paradigm of a biotic artefact where the deep level at which genetic manipulation takes place and the ensuing degree of artefacticity are inextricably interwined. The manipulation of genetic material at the molecular level leads to a degree of artefacticity which is the antithesis of the processes of natural evolution and of the products of such evolutionary processes.

Technological procedures and their products

A related point, which should be borne in mind, is that the same technological procedure may yet yield two very different laboratory products from the standpoint of the depth of manipulation. Consider the technique of in vitro fertilisation in the following two contexts. The semen from a prize bull is used to fertilise the egg from a cow deemed in turn to possess a desirable trait, like being an abundant milk producer. In theory, and in many cases, even in practice, the farmer does not need to resort to in vitro fertilisation but does so primarily for reasons of economic efficiency- the semen of one prize bull can serve numerous cows without the bother of transporting any of the animals to meet for the purpose of mating. This shortcut to nature's way of producing calves is, however, still within the framework of possible mating in order to produce offspring. Both the resulting embryo and the calf, which eventually ensues from it, may be said to be laboratory products. However, this is not the 'deep' sense in which something is a laboratory product when in vitro fertilisation is used to produce the tiglon or the liger. Here, the procedure occurs, in principle, outside the framework of the processes of mating, or even of cloning (which is the mode of replication in the case of some plants). While the prize bull and the prize cow could have mated, while the prize plant could have been propagated by cloning, ex hypothesi, the cow and the human could not have mated; nor could the flounder impart its genetic material to the tomato plant. The use of in vitro fertilisation or other genetic engineering techniques in this second context is not a mere short-cut to the natural processes of reproduction; it is a full-frontal, 'in your face' by-passing of such processes.

End Notes

[1] Note that the term 'transgenic organism' (at least as used in this discussion) is not identical with the term 'genetically modified organism.' The latter is a much broader category, involving either the excision of genetic material from an individual organism, or the insertion of genetic material from other organisms, whether belonging to the same species or a different species. But 'transgenic organism' is used only in the context of inserting into an individual organism genetic material belonging to a different species-the inserted material may cross Species and/or Kingdom barriers. The term 'transgenomic' to characterise the insertion of genetic material from an organism belonging to the same species has been suggested by Richard Jefferson, a molecular biologist who heads a non-profit plant biotechnology research centre in Canberra-see Jefferson (2000).

[2] Classical genetics is Mendelian, based on Mendel's law of segregation. But it is a statistical theory while its partner, the chromosome theory (based on the work of Thomas Morgan and his fellow researchers) tells us where genes are found.

[3] To clarify the issues behind the controversy between those who hold and those who deny that there are species barriers in nature and whether rDNA technology has breached them, Krimsky distinguishes three forms of 'natural genetic barriers'-ecological, absolute and statistical:
Two organisms are separated by an ecological genetic barrier if the exchange of DNA between them is not observed under conditions resembling those considered as natural for the species in question. Two organisms are separated by an absolute genetic barrier if the exchange of DNA between them is not observed under natural or artificially engineered environments limited to non-rDNA techniques. Two organisms are separated by a statistical genetic barrier if the exchange of DNA is observed with low but not necessarily zero frequency under natural or artificially engineered environments limited to non-rDNA techniques (Krimsky 1982, p. 271).
Transgenic organisms via rDNA technology could be said to breach the first two barriers identified. (In spite of the fact that the second is labelled 'absolute genetic barrier, rDNA technology may, nevertheless, be said to breach it, given the way Krimsky has defined the term in the quotation cited above.) And even if they could not be said to breach the third kind of barrier, it remains true, as the plasmid biologist, Richard P Novick has said: 'Just because an organism can be coaxed to take up foreign DNA in the lab, one has no right to assume that it does so regularly, if at all, in the wild; and further, even if uptake occurs, experimental evidence now available suggests that incorporation of foreign DNA into the cell's genome is a very special and unusual event' (Krimsky 1982M, 276).

[4] See, for example, Cherfas (1982, pp. 126-41); Krimsky (1982); Wheale and McNally (1988); Ho (1998).

[5] Eukaryotes are organisms or cells whose DNA is contained in a well-defined nucleus surrounded by protein. Prokaryotes are organisms whose genetic material is not so contained, like bacteria, algae.

[6] The procedure for fabricating biotic artefacts based on DNA manipulation in the laboratory is immensely complex. Take as an illustration the result of the experiment published in Nature, May 1991 (by P. Koopman et al.) which reported success in turning a female mouse into a male one. Before giving a summary of such an account, one should remind the reader that in mammals, sex-determining genes reside in the XY sex chromosomes of the male and XX of the female. In particular, one region of the Y-chromosome is the sex-determining region; this, in mice, is abbreviated to the 'Sry' region. Below is an account of the experiment:
First, the researcher needs a sufficient amount of Sry DNA. DNA from mice is isolated and the Sry region is separated from the rest. This Sry region is then biochemically attached to bacterial DNA (plasmid-DNA), which in turn is put into a culture of growing bacteria. If conditions are suitable, it is then possible to isolate larger amounts of the Sry DNA. In what is called gene cloning through bacteria, the bacteria's metabolism produces many 'copies' of the mouse DNA by treating it as part of their own genome.
Now the second stage: injection of the DNA into fertilized eggs. This may sound simple, but it is a complicated and delicate procedure. Female mice are given hormones to induce the maturation of many eggs (superovulation). They are then mated. One day later fertilized eggs are removed from the oviducts. These egss are only 0.1 millimeter in diameter-the size of a needle tip. The compact head of the sperm has swollen and forms the male nucleus within the cytoplasm of the egg. Under a microscope the Sry DNA is injected into the male nucleus that is ready to fuse with the egg's nucleus. When the nuclei fuse, fertilization is complete and the new organism begins its embryonic development.
The fertilized eggs remain in cultures in the lab overnight. The next day the researcher selects those that have developed to the two-cell stage. These embryos are implanted into the oviducts of 'pseudopregnant recipients.' Then follow the threeweek gestation period (Holdrege 1996, p. 110).
The successful genetically altered mouse whose picture appeared on Nature's cover had XX chromosomes, and therefore, was female in her body cell, but male in anatomy and behaviour, presumably because of the Sry DNA-his testicles were very small, and although he was sterile, he displayed normal male mating behaviour. In the experiment, altogether ninety three mice were born, of which only five, however, were identified as having taken up the Sry DNA. Of the five, sex reversal only occurred in the one case, as just described.

[7] In general, research laboratories (both private and public funded) engage in producing transgenic organisms with

medical or agricultural/husbandry purposes in mind.

[8] One comment is called for here regarding the hybrids of whole-organism technology-clearly, these are recent biotic artefacts in which economic and intellectual resources have been invested in their production. However, as far as plants are concerned, the land races in Third World countries, which Western scientific researchers incorporate in the new varieties they develop, are often perceived by Western writers and commentators to be the simple products of nature. On such a view, as no capital or labour, economic or intellectual, has been invested in them and, therefore, strictly speaking, they belong to no-one (at least, according to the Lockean theory of property and possession). This, of course, is simply false. The land races are not raw germ-plasm. Collectively, over the millenia, these plants have been selected and improved upon during the entire history of their domestication by generations and generations of farmers.

[9] The standard legal term is 'process patent' but this author would prefer the term 'procedure patent' in spite of the concession to normal usage.

[10] The success caused a good deal of ill will within the scientific community as it credited Cohen and Boyer to be the inventors. Patent law after all assumes co-authors to be coinventors; yet co-authors were left out. The two patents together were estimated to be worth more than a 1,000 million dollars, but as the earnings in the end, in the main, went to the two universities for research purposes rather than the two individuals named as the inventors, the acrimony eventually subsided.

In 1984, Harvard University applied to the US Patent and Trademark Office to patent its 'oncomouse', a strain of laboratory mouse in which a gene, involved with the onset of breast cancer in humans, has been inserted. In 1988, the oncomouse was granted patent, the first bestowed on a transgenic vertebrate, whereas a year earlier, the US PTO had already granted patent on a transgenic oyster. In 1993, the European Patent Office granted patent on the oncomouse. However, 16 legal oppositions have been lodged with the EPO against it and hearings had been scheduled-see Wheale and McNally (1995, p. 152). By 1997, over 300 European patent applications on animals have been filed, but only three have been granted. The objections, on the whole, have come from animal welfare and animal rights groups. Their main argument appears to be based on the suffering and, therefore, its immorality, caused to such transgenic animals-see Stevenson (1995); Nott (1998); Schatz (1998, pp. 2-16); European Patent Office Database: http://ep.espacenet.com; Emmott (2001); Ben-Ami, et al. (1999) [cite as: 573 PLI/PAT 555]; Dastgheib-Vinarov (2000) [cite as: 4 Marq. Intell. Prop. L. Rev. 143]; Van de Graaf (1997).

[11] In 1989, Harvard Medical School presented the London Science Museum with the gift of two male oncomice, preserved by freeze-drying. This prompts one commentator to write:

The Science Museum collects artefacts, not organisms. This rule has applied in the Museum since its foundation. But in 1989 the rule was apparently broken when two mice were acquired for its permanent collection. … The interest in these mice reflects the revolution in the biological sciences that has accompanied the development of what is often termed genetic engineering. … The Harvard oncomice … represent an important phase in the development of molecular genetics. With the advent of biotechnology and transgenic animals, it seems that organisms can also be artefacts (Durant 1992, p. 214).

[12] Current biology, apart from the eukaryote/prokarycote distinction, recognises five kingdoms: Animals and Plants (multi-cellular eukaryotic organisms), Monera (prokaryotic organisms like bacteria), Protista (unicellular eukaryotic organisms like protozoa) and Fungi (multi-cellular eukaryotic organisms). But some biologists even talk of a sixth, Archaea.

[13] The author owes this point of view to the environmental philosopher, Ned Hettinger, especially through personal communication with him. See also Hettinger (1995).

[14] Another more recent example is a small herd of transgenic brown Nigerian goats whose milk is expected to contain a 'spider-fibre.' Their creator is a team of Canadian scientists at Nexia Biotechnologies of Quebec. These researchers first bred two male goats whose genome had been altered to include the silk-making genes of a spider. When the transgenic males reached sexual maturity, they mated with 50 female goats, thereby producing numerous 'spider-fibre' females amongst their offspring. Spider silk is exceptionally strong and light, but as it is difficult to farm spiders for their silk, which one could do in the case of silk worms, biotechnology has now stepped in to provide a solution through developing the new science of biomimicry which permits pharmaceutical and other materials to be harvested from genetically engineered domestic animals; in this case, the spider silk molecules from the goats' milk could be used to make anything from sutures to components of air/space craft. See Burke and McKie (2000).

[15] See Comstock (2000).

[16] See Comstock (2000, Chapter 3).

[17] The liger has a lion as father and tiger as mother; the tiglon is the other way round.

[18] But note that under the terminology used in this discussion, the term 'biotechnology' covers more than just DNA engineering and encompasses the techniques and procedures derived from a general understanding of molecular biology itself, including cell biology. In vitro fertilisation is a technique in biotechnology.

[19] For examples, which already exist of this move, see Bent, et al. (1991).

[20] Of course, one could point out that the mechanisms responsible for producing milk in the domesticated cow, too, have been hijacked by craft-based or Mendelian hybridization technologies and other techniques to serve a human end. This is to say that the milk produced is not destined for the cow's calves but for us, humans. However, there remains a crucial difference between the two situations. The dairy cow, nevertheless, produces cow's milk; the transgenic cow produces not cow's milk as such, with proteins in it peculiar to cows, but instead, milk which also contains a human protein. The (transgenic) cow's milk-producing capability has been captured and diverted by biotechnology in a fundamentally more radical fashion than in the case of the dairy cow. The dairy cow may have a DNA sequence inserted into her genome from another variety of cow noted for abundance in milk production; but such a genetically modified dairy cow still produces milk containing only proteins peculiar to cows.

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