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BIOTECHNOLOGY INVENTIONS AND THE MORALITY EXCLUSION IN PATENT LAW

LLM RESEARCH PAPER
INTELLECTUAL PROPERTY (LAWS 546)

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CONTENTS

ABSTRACT

This paper analyses the role moral arguments have played, and continue to play, in patent law. The historical development and basis of this exclusion is investigated. International developments in the area, such as the proposed European draft Directive on Biotechnology, are discussed. In particular attention is focused on the areas of DNA, gene and transgenic animal patents, and methods of medical treatment, including the emerging area of gene therapy. The divergent responses of the United States and the European Union to biotechnology inventions are explored.

In the light of this analysis proposed reforms to New Zealand's patent laws are discussed. It is argued that moral arguments have a valuable role to play in patent law. With the emergence of the biotechnology industry this role is perhaps now more important than ever before.

The text of this paper (excluding contents page, footnotes, bibliography and annexures) comprises approximately 19,000 words.

I INTRODUCTION

Do moral arguments have a legitimate role to play in patent law? This paper attempts to answer this question with a view to extracting principles which can be used to guide patent law reform in New Zealand. Included within the phrase "moral arguments" are arguments which refer to morality, ethics[1] and human dignity. The emergence of new technologies, such as biotechnology, has brought this question to the fore.

It will be argued that moral considerations do have a legitimate role to play in patent law. It is a mistake to argue, as opponents of morality provisions sometimes do, that the patent system is designed to encourage innovation *per se*, as a good in its own right. The patent system is meant to encourage innovation in the short term with a view to serving the long term public good.

A morality clause in patent law can be used to advance the public good in a number of ways. It can be used to encourage behaviour considered to be socially desirable (for example the autonomy of physicians); to discourage outcomes considered to be socially undesirable (for example the suffering of animals); and to make a statement about society's values (for example that it is contrary to human dignity for somebody to hold a commercial[2]

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1 Ethics has been defined as the "science of morals in human conduct": *The Concise Oxford Dictionary of Current English* (8 ed, Clarendon Press, Oxford, 1990).

2 The common law has been reluctant to recognise a property right in a dead human body, however it has recognised a right to possession of a dead body: P Skegg "The Interpretation of the Human Tissue Act 1961" (1976) 16 Med Sci Law 193; *R* v *Fox* (1841) 2 QB 246; *Williams* v *Williams* (1881) 20 Ch D 659.

property right in parts of the human body).[3] It can be argued that these diverse aims are all in the public good, and each is a legitimate aim of patent law. Equally it can be argued that some of these social goals are best achieved by laws directed specifically at the harm contemplated, such as laws to protect animal welfare, and that the patent system is not the appropriate place to address moral and social concerns.

If it is accepted that moral arguments do have a place in patent law, then the question has to be asked how much weight do they carry? For example few people deny the validity of the ethical arguments against the patenting of methods of medical treatment. However, proponents of such patents argue that their value in encouraging the development of new methods of medical treatment outweighs their detrimental ethical impact.

For centuries morality clauses have been a common feature of patent laws. These provisions have been used infrequently, and have attracted little interest from law reformers. However, in the latter half of the twentieth century, the advent of new technologies has put the focus on the morality ground for patent refusal. Some countries, such as the US, have responded by excluding moral considerations from the decision whether or not to grant a patent, while others, such as those of the European Union, have retained a morality exclusion. It will be argued here that the European approach, despite its difficulties, is to be preferred. The patent

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[3] Determining what society's values are in the latter half of the twentieth century is a difficult task. In New Zealand this will involve taking account of diverse cultures, including the 'Western' culture and the framework of Judaeo-Christian beliefs, and Maori culture. The 'ethic of care' propounded by the Canadian Royal Commission (see Part VI B below) may provide some guidance, in particular they say that "moral reasoning involves trying to find creative solutions that can remove conflict, rather than simply subordinating one person's interests to another."

system must not be allowed to operate as if it existed in a vacuum, isolated from other human values.

II THE BIOTECHNOLOGY INDUSTRY

Biotechnology has been broadly defined as "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific use".[4] Recent developments in biotechnology have focused on the understanding and manipulation of the hereditary units of life. World-wide there are over 1,300 biotechnology companies with a combined annual turnover of US$8.1 billion,[5] and sales of biotechnology-derived products may exceed US$100 billion by the year 2000.[6] Patent protection is critical for biotechnology inventions which often involve high development costs but are easily copied.

Biotechnology patents may encompass living organisms, components of living organisms, including components of human beings, and methods for the medical treatment of human beings. Biotechnology patents raise ethical and moral issues. This paper will focus on three areas of biotechnology inventions, namely inventions relating to human DNA/genes, transgenic animals and methods of medical treatment of human beings.

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4 Biotechnology for the 21st Century (FCCSETT Committee on Life Sciences and Health (Government Printing Office, Washington DC, 1993) 3.

5 C Roberts "The Prospects of Success of the National Institute of Health's Human Genome Application" [1994] 1 EIPR 30.

6 M S Greenfield "Recombinant DNA Technology: A Science Struggling with Patent Law" (1992) 44 Stanford Law Review 1051.

III SCIENTIFIC BACKGROUND

A Introduction

In the 1950s Watson and Crick worked out the structure of deoxyribonucleic acid (DNA), the basic hereditary material of human beings.[7] DNA and Ribonucleic acid (RNA) have since been found to be responsible for carrying the hereditary material of all life on Earth. In the 40 years since Watson and Crick described the structure of DNA advances in genetic technology have spawned the development of the biotechnology industry. The biotechnology industry is applying DNA technology to produce new products and processes, including medicines and methods of medical treatment.

B Genes and DNA

DNA is made up of constituent "nucleotide bases" which form a specific sequence, coding for[8] specific proteins. The DNA molecules are long and occur as a part of chromosomes. In humans there are 23 pairs of chromosomes, containing in total approximately 100,000 genes which are collectively referred to as the human genome. A gene is the length of DNA which codes for a particular protein. As a part of the Human Genome Project, scientists from around the world are currently attempting to sequence and identify the function of all human genes.[9] This project should be completed within the next decade.

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7 J D Watson *The Double Helix- a personal account of the discovery of the structure of DNA* (Harmondsworth-Penguin, London, 1970).

8 That is, containing the information necessary to instruct the cellular machinery how to construct a protein.

9 R Eisenberg "Patenting the Human Genome" (1990) 39 Emory Law Journal 721.

The cells of the body can be divided into two categories, somatic cells and germ cells. The germ cells give rise to the sperm and ovum (egg), and are located in the testes and ovaries respectively. The remaining cells of the body are the somatic cells, and do not contribute DNA to the next generation.

C Transgenic Animals

It is now possible to take a gene from one animal (for example a human being) and to insert that gene into another animal (a sheep for example). The resulting animal is a so-called "transgenic" animal.[10] Transgenic animals have many potential uses including the production of medicines,[11] as research tools,[12] or as farm animals.

D Methods of Medical Treatment

Biotechnology will result in the development of new methods of medical treatment,[13] such as gene therapy. Possibly as many as 1 in 3 people are affected by a genetic or part-genetic disease during their lifetime.[14] There

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10 For example the transgenic mouse protected by US Patent Number 4,736,866.

11 The transgenic sheep "Tracey" produced by Bayer/Pharmaceutical Proteins produces alpha-I-anti-trypsin in its milk: M Paver "A tale of two rodents, or a rodent with two tails: Europe grapples with patenting animals" Patent World, June 1993.

12 The transgenic animal of US Patent Number 4,736,866 is intended for use as a research tool.

13 By the phrase "methods of medical treatment" is meant the use in practice by physicians, or otherwise, of procedures to prevent, cure or alleviate human suffering or illness. This procedure may involve the administration of a drug, the use of a device or the performance of a sequence of steps. The drug or device *per se* does not constitute a method of medical treatment.

14 *Our Genetic Future-The Science and Ethics of Genetic Technology* British Medical Association (Oxford University Press, Oxford, 1992) 1.

are approximately 4,000 recognised monogenic (ie caused by a single defective gene) genetic diseases in humans. Cystic fibrosis is an example of a monogenic disorder in which the responsible gene has been identified. Many other diseases are multifactorial,[15] that is they are caused by the interaction of more than one gene (polygenic) and/or environmental factors.

Human gene therapy has been defined as "the deliberate administration of genetic material into a human patient with the intent of correcting a specific defect".[16] Gene therapy is a form of genetic engineering. Clinical trials of somatic cell gene therapy in humans are currently underway.[17]

Techniques for germ cell gene therapy in humans have already been developed.[18] Gene therapy offers the potential to treat genetic diseases such as cystic fibrosis. If offers the potential to help future generations, as well as to harm them. It enables the present generation to impose our idea of genetic perfection on future generations, raising the spectre of eugenics.[19] The issues raised by gene therapy are wider than the law, and include moral, bioethical, religious and social issues. In somatic cell gene therapy only the genes of somatic cells are modified. The changes made are not incorporated into the individuals sperm or ova, and are therefore not passed on to their children. In germ cell gene therapy the genes in the

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15 For example some types of cancer and cardiovascular disease.

16 United States Congress, Office of Technology Assessment, Human Gene Therapy (Washington, D.C.: Office of Technology Assessment, 1984).

17 L Prior *Somatic and Germ Line Gene Therapy: Current Status and Prospects* (Royal Commission on New Reproductive Technologies, Canada, 1992) vii.

18 For example see: A Coghlan "Outrage greets patent on designer sperm" 9 April 1994 New Scientist 4.

19 J Harding "Beyond Abortion: Human Genetics and the New Eugenics" (1991) 18 Pepperdine Law Review 471.

germ cells are modified. Consequently this modification will be passed on to future generations.

IV PATENT LAW

In New Zealand patent law is governed by the Patents Act 1953. The purpose of obtaining a patent is to protect a product or a process that is the result of inventive thought. The patent holder is granted an exclusive right to make, use, exercise and vend a manner of new manufacture within New Zealand.[20] The patent will usually last for 16 years.[21] The preparation of a patent application and the process of obtaining a patent is known as "patent prosecution". The applicant for the patent must submit a specification with the application which explains precisely how the invention works. Patents are available on "inventions" which are industrially applicable, novel, and involve an inventive step.[22]

Inventions are defined in section 2(1) of the Patents Act 1953 as "any manner of new manufacture the subject of letters patent and grant of privilege within s.6 of the Statute of Monopolies and any new method or process of testing applicable to the improvement or control of manufacture; and includes an alleged invention". The Statute of Monopolies 1623 declared that monopolies generally would be void and unlawful. Section 6 defined which monopolies would be lawful:[23]

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20 The Patents Regulations 1954, Third Schedule, Letters Patent.

21 This is to be increased to 20 years by the GATT (Uruguay Round) Bill 1994.

22 *Reform of the Patents Act 1953 Proposed Recommendations* (Ministry of Commerce, Wellington, 1992) 8.

23 "The Statute of Monopolies" means the Act of the 21st year of the reign of King James the First, chapter 3 intituled "An Act concerning monopolies and dispensations with penal laws and the forfeiture thereof".

> Provided also and be it declared and enacted, that any declaration beforementioned shall not extend to any Letters Patent and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm, to the true and first inventor and inventors of such manufactures, which others at the time of making such Letters Patent and grants shall not use, so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home, or hurt of trade, or generally inconvenient...

Mere discoveries cannot be patented. There must be some inventive ingenuity in the subject of the patent application, although "a mere scintilla of inventive faculty may be sufficient to support a patent".[24]

The acceptance of an application for a patent can be objected to on several grounds including: anticipation (or prior publication); obviousness (the invention is obvious and involves no inventive step); and the complete specification does not sufficiently and fairly describe the invention.

The owner of a plant variety may seek protection under the Plant Variety Rights Act 1987 or the Patents Act 1953, or both.[25]

The New Zealand Patents Act 1953 was drafted well before the emergence of the biotechnology industry. Reform of the Act is underway and further reforms are anticipated. How should these reforms respond to the moral and ethical issues raised by biotechnology inventions?

V THE ISSUES RAISED

Should patents be available on the products of biotechnology research once the requirements of novelty, inventive step and industrial applicability

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[24] *Maunder* v *Wanganui Sash & Door Factory & Timber Co. Ltd* [1928] NZLR 566, 581.

[25] C Brown "Protecting plant varieties: Developments in New Zealand" (1988) 18 VUWLR 83.

have been met? Is it acceptable to grant property rights in human genes, DNA sequences, transgenic animals and new methods of medical treatment? Do moral and ethical considerations have a legitimate place in the making of these decisions?

One problem in this area is to separate out issues which inherently relate to the patent system from those of a more general nature which would be best regulated elsewhere. For example if society is opposed to the unnecessary infliction of pain and suffering on animals then this can be reflected in specific laws aimed at protecting animal welfare. However, taking a wider view, if a society is concerned for animal welfare, should it allow its patent system to provide an incentive to innovation in areas likely to threaten animal welfare? Further, should it grant property rights in the means to inflict that suffering? The wider view involves incorporating concepts of ethics, morality and human dignity into patent law. If this wider view is adopted, then there is the practical problem of trying to define rules and tests for patentability which will deny the incentive of patent protection from those areas deemed to be undesirable, while continuing to provide an incentive in other, often closely related, areas which are considered to be acceptable. Some degree of certainty is required, so researchers will know what is and what is not patentable.

The practical problem posed by the wider view appears to be more easily solved in some areas than in others. It is relatively easy to render all methods of medical treatment of human beings unpatentable on ethical grounds.[26] A blanket exclusion on ethical grounds is workable. However, in the area of transgenic animals it is harder to decide when suffering to an animal is outweighed by the benefits of an invention. Likewise, it is difficult to decide how much human genetic material can be incorporated

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[26] The problem of distinguishing cosmetic from therapeutic or prophylactic treatments still remains.

into a non-human animal, before human dignity is compromised.[27]

Advocates of granting patents on biotechnology inventions take a fairly uniform position. They argue that once the traditional criteria of patentability have been met then patents should be available for biotechnology inventions. Morality does not properly belong as a consideration in patent law. The patent office is not equipped to make moral judgements. Technology is neutral, it is neither moral or immoral, it is what people do with technology that is sometimes immoral, and a patent does not require a person to use an invention in an immoral way.[28] Further, the concept of morality it too subjective and changes over time. The contraceptive pill might once have been regarded as immoral but it is no longer so regarded in many countries. The role of the patent office is to promote technology and not to regulate it. Regulation should be achieved by other laws directed to specific areas of concern. The patent system is to exist in a moral vacuum, hermetically sealed to exclude moral considerations and "other ways of knowing".[29]

Patents on DNA and genes will encourage research and innovation leading to great benefits for society. People have selectively bred and owned animals for centuries, so patents on transgenic animals are not really so new, and do not raise new moral issues. Likewise, the patenting of methods of medical treatment will encourage medical research and lead to

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27 Some people may even take the view that the utilitarian approach of balancing the competing considerations is not acceptable, and will argue that no amount of animal suffering can be outweighed by the benefits, and introducing even a single human gene into a non-human animal is contrary to human dignity.

28 E J Sease "From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms" (1989) 38 Drake Law Review 551.

29 A Wells "Patenting New Life Forms: An Ecological Perspective" [1994] 3 EIPR 111.

the discovery of new methods of treatment. Any cost to the physician-patient relationship will be outweighed by these benefits. Denying patents on biotechnology inventions will not stop biotechnology research.[30]

Those who argue for the removal of moral considerations from patent law are frequently those involved in the biotechnology and pharmaceutical industries,[31] or patent attorneys.[32] These groups have a vested interest in broadening the sphere of patentable subject matter. However, patent attorneys may also benefit from the disputes which could result from the application of morality provisions.

Opponents of patents on biotechnology inventions include animal welfare groups, patient's organisations, professional healthcare groups and watchdog groups.[33] Groups opposed to patents on human genes argue that such patents are unethical and will slow down the progress of research.

Groups opposed to patents on transgenic animals are concerned about experimentation on animals, because of the pain caused to such animals, and uncertainty as to where these experiments might lead.[34] They object to the concept of "owning life" and fear the consequences of the erosion of

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30 J Kim "Patent Law: Patenting Animal Life: Another Scapegoat for Small Interest Groups" (1989) 42 Oklahoma Law Review 131.

31 For example A W White : A W White "Patentability of Medical Treatment, Wellcome Foundation's (Hitching's) Application" [1980] EIPR November, 364.

32 For example M Bennett: M Bennett "The transgenic animal debate" NZ Biotechnology Association Newsletter No.18, August 1993.

33 An example of a vociferous watchdog group in the US is the Foundation on Economic Trends, headed by Jeremy Rifkin.

34 Some animal rights groups see a future full of sad mutant animals twisted into unnatural forms by greedy and inconsiderate genetic engineers: R Dresser "Ethical and Legal Issues in Patenting New Animal Life" (Summer 1988) 28 Jurimetrics Journal 399.

"species integrity". Animals are viewed as possessing the right not to have their species integrity destroyed by the widespread manipulation and interchanging of their genetic material. As species integrity is eroded the natural order will gradually be broken down into an assortment of artificial organisms manufactured by people.

A society that allows the patenting of life forms is institutionalising a devaluation of respect for life. To these groups patenting animals signals that society is regressing to an extreme Cartesian view of animals as "soulless, unfeeling creatures that may be treated like machine parts".[35]

Farm groups are not opposed to the application of biotechnology, rather they are eager to benefit from more productive genetically engineered livestock. They have no moral objection to genetically modified livestock and crops. However, they are opposed to patents on the products of biotechnology because they will have to pay to benefit from them.[36] The most significant difference here is the self-reproducing nature of the invention and the theoretical and practical issues that this raises for patent law. There is also concern that allowing patents on animals will lead to a reduction in the diversity of farm animals. Greater dependence will be placed on fewer genetically superior breeds. Maintaining the genetic diversity of species is an important issue but it is not usually viewed as being a moral issue.

Arguments against the patenting of methods of medical treatment are largely ethical. The fear is that such patents will interfere with the physician-patient relationship, either by intruding upon physician autonomy and/or physician-patient confidentiality. Physician autonomy

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35 S Krimsky *Biotechnics and Society The Rise of Industrial Genetics* (Praeger, New York, 1991).

36 M Paver "All Animals Are Patentable, But Some Are More Patentable Than Others" (1992) March, Patent World 9.

will be impaired if a physician has to obtain a licence for a fee from a patentee before they can use a method of treatment. Physician-patient autonomy is potentially compromised by the prying of patentees trying to detect unauthorised use of their patented method.

Patents on methods of medical treatment might impede the progress of medical research by introducing a commercial interest which will interfere with the timing and content of the publication of research results. A physician who invents a new method of treatment will face a potential conflict between personal commercial gain and the patients interests. They will want to describe the new method in the best possible light (in order to encourage others to licence the method), possibly neglecting to describe the negative aspects of the treatment fully. Subsequently, physicians who take out a licence will want to recoup the cost (the "opportunity cost") of the licence by using it. If a patient is on the borderline of requiring a patented treatment or not, then the decision whether to treat or not may be influenced by the physicians investment in the licence fee.

The challenge these issues raise is to design a patent system which encourages innovation while not swamping human dignity or values.

VI SOME RELEVANT REPORTS

Some recent reports on the issues surrounding new technologies may provide some guidance on how moral considerations might be incorporated into patent law, and in identifying some guiding principles.

A The Warnock Report

In 1984 the Warnock Inquiry in the United Kingdom looked at the issues of surrogacy and research on human embryos, and led to the passing of the Human Fertilisation and Embryology Act 1990 (UK). The Warnock Committee recognised the wide diversity in moral feelings between

different groups in society and the need to identify principles to govern the use of new technology.[37]

B Canadian Royal Commission on New Reproductive Technologies

In Canada the Royal Commission on New Reproductive Technologies chose to adopt an "ethic of care" as a guiding principle. The ethic of care holds that:[38]

> moral reasoning is not solely, or even primarily, a matter of finding rules to arbitrate between conflicting interests. Rather, moral wisdom and sensitivity consist, in the first instance, in focusing on how our interests are often interdependent. And moral reasoning involves trying to find creative solutions that can remove or reduce conflict, rather than simply subordinating one person's interests to another. The priority, therefore, is on helping relationships to flourish by seeking to foster the dignity of the individual and the welfare of the community.

The Commission set out the following guiding principles to assist in implementing the ethic of care: individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, non-commercialization of reproduction, appropriate use of resources, accountability, balancing of individual and collective interests.[39]

The Commission considered that the ethic of care was relevant to patent law, and observed that the basic principles of patent law which were

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37 Department of Health and Social Security *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (1984, "the Warnock Report").

38 Royal Commission on New Reproductive Technologies *Proceed With Care: Final Report of the Royal Commission on New Reproductive Technologies* (Canada Communications Group Publishing, Ottawa, 1993), 52.

39 Above n 38, 53.

developed 200 years ago were not designed to deal with some of the issues raised by modern technology.[40] The Commission felt that further study was required into the implications of granting patents in the area of new reproductive technologies. However, the Commission did not hesitate to conclude that medical treatments should not be patentable. The Commission noted that the reasons for the existing non-patentability of medical treatments in Canada included the public policy interest in the "unimpeded access to medical treatments, the need for impartial evaluation of their success, and the avoidance of conflict of interest for physicians."[41]

C Otago Bioethics Research Centre

The prevailing view among those who have considered the issue is that somatic cell gene therapy is acceptable,[42] while at present germ cell gene therapy is not.[43] In New Zealand the Bioethics Research Centre (BRC)[44] has recommended that germ cell gene therapy should be banned by legislation, while somatic cell gene therapy should be allowed. With the latter being restricted to the treatment of serious medical conditions. The BRC also recommended that the issue of patenting in connection with biotechnology be investigated.

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40 Above n 38, 720.

41 Above n 38, 721.

42 See "Report by the Committee on the Ethics of Gene Therapy (U.K.)" *The Dominion*, Wellington, New Zealand, 18 January 1992.

43 Above n 14, 185.

44 *Biotechnology Revisited, Ethical and Legal Issues in the Application of Biotechnology to Medical Practice*, A Report for the Medical Council of New Zealand by the Bioethics Research Centre, University of Otago, November 1991.

D The Health Research Council Report on Gene Therapy

The Health Research Council (HRC) commissioned a report on gene therapy for the Ministry of Health and the Ministry for the Environment.[45] The HRC Working Party preparing the report were given a broad brief to look at the issues surrounding gene therapy. The HRC report is due to be released for public comment late in 1994. This report may offer some guidance which could inform the approach patent law takes towards gene therapy.

E Assisted Human Reproduction, Navigating Our Future

In New Zealand the Department of Justice recently issued a report on new reproductive technologies.[46] This report avoided specifically discussing gene therapy due to the forthcoming release of the HRC report on gene therapy. However, the report supports the adoption of an "ethic of care" (as propounded by the Canadian Royal Commission on New Reproductive Technologies) as a guiding principle in policy formation, which includes respect for human life and dignity. The Committee considered the commercialisation of the use of human tissue to be contrary to the dignity of human tissue:[47]

> we nevertheless see great value in acknowledging that all human tissue has mana. This means that not only the embryo but also gametes should be accorded dignity. From this, it follows that there should be no commercialisation of the use of tissue, ie the sale of human parts, including

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45 The New Zealand Medical Association has not taken a position on gene therapy yet. However, it is currently on the agenda of their Public Issues Advisory Committee which is awaiting the HRC report before proceeding: personal communication K.Gibb, Chairman Public Issues Advisory Committee, 3 May 1994.

46 W R Atkin, P Reid *Assisted Human Reproduction, Navigating Our Future* (Department of Justice, Wellington, 1994).

47 Above n 46, 29.

> gametes and embryos, shows disrespect for the mana of human tissue. Another specific example that follows is that there should be no development of animal/human hybrids.

Whether the Committee intended the words "human parts" to include genes and DNA is not absolutely clear, but this would seem to follow since it expressly referred to the single celled and microscopic gametes (sperm and ovum), which are little more than genes packaged in a delivery system. The granting of patents over human genes and DNA is undoubtedly a form of commercialisation, and is therefore, according to the Committee, contrary to human dignity.

The Committee believed that animal/human hybrids should not be developed at all. This raises the question of what percentage of human genetic material has to be inserted into an animal for it to be considered to be an animal/hybrid? Is the insertion of a single human gene into a mouse enough to render the mouse an animal/human hybrid? Many animals have already had single human genes inserted into their genome. One suspects that more than a single gene is required, but exactly how much more is difficult to define. It would also depend upon the quality and nature of what was transferred, and not just on how much.

However, once the line is crossed and a transgenic animal is considered to be an animal/human hybrid, the Committee believe this to be contrary to human dignity. Logically it follows that the Committee would also consider the granting of patents on such animals to be contrary to human dignity. Such patents would involve the commercialisation of human parts and would act as an incentive to the development of animal/human hybrids.

F The reports support a role for morality in patent law

The lesson from the reports discussed above is that the application of new technologies should be done within a moral framework, guided by agreed moral principles. Patent law cannot be used as a complete system for the regulation of new technologies. However, considering the close association of these new technologies and the patent system it is inappropriate to try to exclude moral considerations from the patent system, where they can form a useful part of society's overall response to these technologies. This is particularly so when society regards the holding of certain property rights to be contrary to human dignity or otherwise inappropriate.

VII MORALITY IN THE LAW

Section 17(1)(b) of the Patents Act 1953 provides that the Commissioner of Patents may decline an application for a patent on an invention the use of which might be contrary to law or morality.

Opponents of the consideration of moral issues in patent law assert that morality is too subjective a concept to be a legitimate requirement of patent law. Morality changes over time and people have different views about what is immoral. Further, it is said that the patent office does not have the necessary expertise to assess what is immoral. Therefore they conclude that morality has no place in patent law. If something is immoral it would be illegal under some other law. They ignore the fact that the law frequently calls upon decision makers to make moral judgements, and that morality provisions are not unusual in the general law or in intellectual property law. They also ignore the possibility that there may be some inventions which society does not wish to render illegal, but does not wish to positively encourage by the granting of patents.

A Morality in the general law

Morality has long been, and remains, a feature of the general law. There is nothing unusual about the law addressing moral issues and applying moral tests. Underlying the criminal law are moral values. One example of this is the notion of dishonesty. Before a person will be convicted of fraud in New Zealand it is necessary to prove that they had an "intent to defraud". This test includes the moral test of dishonesty. In *R* v *Coombridge* the Court of Appeal said:[48]

> We think that in order to act fraudulently an accused person must ... act deliberately and with knowledge that he is acting in breach of his legal obligation. But we are of the opinion that if an accused person sets up a claim that in all the circumstances he honestly believed that he was justified in departing from his strict obligation, albeit for some purpose of his own, then his defence should be left to the jury for consideration provided at least that there is evidence that in all the circumstances his conduct, although legally wrong, might nevertheless be regarded as honest. In other words the jury should be told that the accused cannot be convicted unless he has been shown to have acted dishonestly.

In *R* v *Speakman*[49] the Court of Appeal confirmed that the test for dishonesty in *Coombridge* was a subjective one based on the accused's own beliefs.

In *R* v *Feely*[50] the English Court of Appeal said that for there to be a conviction for theft there had to be "moral obloquy". The English Court of Appeal in *R* v *Ghosh*[51] adopted a mixed subjective and objective test for dishonesty. The objective limb involved asking whether the accused

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48 [1985] 2 NZLR 381, 387.
49 (1989) 5 CRNZ 250.
50 [1973] QB 530, 541 (CA).
51 [1982] 2 All ER 689; [1982] QB 1053.

acted dishonestly "according to the ordinary standards of reasonable and honest people".[52] The adoption of a subjective standard has been criticised in England.[53]

Part VII of the Crimes Act 1961 is headed "CRIMES AGAINST RELIGION, ***MORALITY***, AND PUBLIC WELFARE" (emphasis added). Crimes included in this part include the distribution or exhibition of indecent matter, the performance of an indecent act in a public place and performing an indecent act with intent to insult or offend.

B Morality in intellectual property law

1 Morality in copyright law

In New Zealand copyright subsists in original works as a result of the Copyright Act 1962. The Act does not deny copyright in works which are immoral, illegal or irreligious. However the courts have developed a common law doctrine of non-protection of works the sale and publication of which would be contrary to the public interest.

In the nineteenth century Lord Eldon refused to grant injunctions to prevent the infringement of the copyright in what he considered to be immoral works.[54] This doctrine was firmly established in *Stockdale* v *Onwhyn*[55] in which copyright protection was denied to a book[56] detailing the adventures of a courtesan.[57]

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52 Above n 51.

53 Glanville Williams *Textbook of Criminal Law* (2 ed, Stevens, London, 1983) 722.

54 *Walcot* v *Walker* (1802) 7 Ves 1; *Southey* v *Sherwood* (1817) 2 Mer 435.

55 (1826) 5 B & C 173.

56 *The Memoirs of Harriet Wilson.*

57 The House of Lords referred to the non-protection of immoral works in *A-G* v *Guardian Newspapers Ltd* [1988] 3 All ER 545.

2 *Morality and passing off*

In the *Advocaat* case[58] Lord Diplock set out the five elements necessary to establish passing off. However, he made the point that these five elements were merely what is necessary to establish passing off, not what is sufficient:[59]

> The presence of those characteristics is enough unless there is also present some exceptional feature which justifies, ***on grounds of public policy***, withholding from a person who has suffered injury in consequence of the deception practised on prospective customers or consumers of his product a remedy in law against the deceiver. (emphasis added)

There may be individual cases in which the courts withhold a remedy in passing off on public policy grounds. Lord Diplock did not elaborate on what matters of public policy he had in mind. Drysdale and Silverleaf have speculated on what might fall within this category:[60]

> some matters in this category are not difficult to recognise. Thus the courts would not for example protect the reputation of a trader whose trade was immoral or illegal or whose goods could only be used for immoral or illegal purposes

This would be logical considering the prohibition on the registration of immoral trade marks under the Trade Marks Act 1953.[61] It would be strange if the common law of passing off protected an immoral trade mark which was prohibited from being registered on moral grounds.

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58 *Erven Warnink B.V.* v *J. Townend & Sons (Hull) Ltd* [1979] AC 731:[1979] 2 All ER 927 *(the Advocaat* case).

59 Above n 58, 938.

60 J Drysdale and M Silverleaf *Passing Off Law and Practice* (Butterworths, London, 1986) 16.

61 Section 16Trade Marks Act 1953.

3 *Morality and the Trade Marks Act 1953*

Section 16 of the Trade Marks Act 1953 provides that:

> It shall not be lawful to register as a trade mark or part of a trade mark any scandalous matter or any matter the use of which would be likely to deceive or cause confusion or would be contrary to law or morality or would otherwise be disentitled to protection in a Court of justice.

The purpose of this section is to protect the public interest.[62]

Section 11 of the Trade Marks Act 1938 (UK) provides that it "shall not be lawful to register as a trade mark any matter the use of which ... would be contrary to law or morality...". In addition to section 11 the Registrar has a discretion under section 17(2) to refuse applications "as he may think right".

Article 3 of the EC Directive on Trade Marks provides that a trade mark may be refused registration or invalidated on the ground that "the trade mark is contrary to public policy or accepted principles of morality."

The Trade Marks Act 1953 is currently being reviewed. The Ministry of Commerce have expressed doubts about the continued existence of a public policy/morality exclusion. According to the Ministry:[63]

> Assessments of this nature will inevitably involve subjective judgements by the Commissioner. It could be argued that these matters are more appropriately dealt with by other policy instruments.

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62 *Pioneer Hi-Bred Corn Company* v *Hy-line Chicks Pty Ltd* [1978] 2 NZLR 50, 63, per Richardson J.

63 *Reform of the Trade Marks Act 1953, Proposed Recommendations* (Ministry of Commerce, Wellington, 1991).

The Ministry do not actually make the argument why a change from the current position is indicated.

4 Morality and designs

Section 43(1) of the Registered Designs Act 1949 (UK) provides that:

> Nothing in this Act shall be construed as authorising or requiring the registrar to register a design the use of which would, in his opinion, be contrary to law or morality.

The Registrar also has a general discretion under section 3(5) to refuse applications "as he thinks fit".

In *Masterman's Design*[64] the applicant had applied to register a design for a doll which included a depiction of male genitalia. The Superintending Examiner held that the application was not contrary to law or morality under section 43(1). However, the application was refused under section 3(5) on the ground that registration would be likely to offend the susceptibilities of a not insubstantial number of persons. The applicant appealed against this decision to the Registered Designs Appeal Tribunal.

In the Appeal Tribunal Aldous J held that the test could not be solely whether a section of the public would be offended. However, some designs depicting nudity which would give offence, which might be pornographic, and which people would not regard as suitable for public display, should be refused registration. These designs "should not have the protection of property rights provided by Parliament."[65] Designs with racialist connotations might also be refused.

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64 [1991] RPC 89.

65 Above n 64, 103.

Aldous J considered "whether the design is of the kind that should be given the protection of the law including whether the design is of such a nature that its use would offend moral principles of right-thinking members of the public, such that it would be wrong to protect it." Aldous J believed that no reasonable person would object to the doll in question being sold, and allowed the appeal.[66]

In New Zealand designs can be registered under the Designs Act 1953. Section 7(3) of this Act is equivalent to section 3(5) of the Registered Designs Act 1949 (UK).

It is clear from the above discussion that the concept of morality is not alien to intellectual property law. Parliament and the courts have long felt that it was appropriate to deny protection to intellectual property that might be immoral or have immoral uses. This belief has been reflected in specific statutory provisions, and in common law and equitable doctrines.

VIII MORALITY AND PATENT LAW

Many biotechnology inventions may potentially be objected to on moral grounds. Like other areas of intellectual property law, patent laws have for many years included provisions which provided for the exclusion from protection of inventions which were "contrary to morality".[67] However, such provisions appear to have been infrequently invoked.[68] There are

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66 Aldous J also commented (above n 64, 104) that "Courts of Equity have in the past refused to grant injunctions to protect copyright in scandalous and pornographic works, but I cannot envisage that a Court of Equity would refuse to grant an injunction to protect the design in question". This apparent reference to the cases discussed above in Part VII B 1 suggested that Aldous J appeared to believe that there was a possible equitable jurisdiction to refuse the design in question.`

67 For example the Patents and Design Act 1907 sec 75.

68 R Nott "Plants and animals: Why they should be protected by patents and variety rights" (1993) July/August, Patent World 45.

morality provisions in the European Patent Convention,[69] and in the patent law of the United Kingdom,[70] Japan[71] and New Zealand.[72] Many other nations have similar provisions in their patent law.[73]

Section 10(1)(b) of the Patents Act 1949 (UK) provided that the Comptroller of Patents could refuse an application if it appeared that the use of the invention would be contrary to law or morality.

The UK Patent Office Manual of Office Practice gives little guidance on what will be regarded to be contrary to morality. However, it does state that inventions relating to contraception and the control of fertility are not to be objected to on this ground, while applications for "sexual appliances of an improper character are always refused under section 10".[74] Instruments of torture are also regarded as being immoral. In practice the "immoral invention" exclusion is virtually never used in the UK.

From the early nineteenth century to the mid-twentieth century the courts in the US denied patents on immoral inventions, such as gambling machines and inventions intended to defraud buyers.[75]

IX PATENTS ON INVENTIONS CONTRARY TO LAW

Section 6 of the Statute of Monopolies 1623 provides that inventions which are "contrary to the law" are not the proper subject for the grant of

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69 Article 53(a) European Patent Convention.

70 Section 1(3)(a) Patents Act 1977 (UK).

71 Article 32 of the Japanese Patent Law.

72 Section 17(1)(b) Patents Act 1953.

73 A Reverdin and F Schlaepfer *Katzarov's Manual on Industrial Property All Over the World* (9 ed, Katzarov S.A., Geneva, 1993).

74 *Patent Office Manual of Office Practice (Patents)* UK, First Edition (including revised pages) para 10,13.

75 R P Merges "Intellectual Property in Life Forms: The Patent System and Controversial Technologies" (1988) 47 Maryland L Rev 1051, 1058.

Letters Patent. This provision is still in force in New Zealand as a part of the definition of an invention.[76] Something which is contrary to the law is not an invention and is therefore not patentable.[77] Section 17(1)(c) of the Patents Act 1953 is of similar effect and provides that the Commissioner may refuse an application if the use of the invention would be contrary to law. The focus of this provision is on the use of the invention. These exclusions on the grounds of illegality can be used to implement moral judgements, for example by involving predictions about how an invention will be used.

There are at least three distinct areas within the concept of inventions being contrary to law. First, there are those inventions which are not illegal to own or use *per se*, but which may be used to facilitate the breaking of a law. Some inventions in this category may have some entirely legitimate uses, as well as a less legitimate one. This group is potentially enormous since virtually any invention could be used in an illegal manner. However, for some inventions the primary intended use is clearly not legitimate. Secondly, there are inventions which it is not illegal to own but which it is illegal to use. Thirdly, there are inventions which it would be illegal to own and/or use at all.

The purpose and value of the illegality exclusion is different for these three groups of inventions. For the first and second groups it can serve the useful function of denying patent protection to inventions which have the socially undesirable purpose of facilitating the breaking of the law, while perhaps not being illegal in themselves. This exclusion appears to have a

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76 Section 2 Patents Act 1953.

77 In copyright law the Courts have developed a doctrine of denying copyright protection for illegal works: *Wright* v *Tallis* (1845) 1 CB 893; *Slingsby* v *Bradford Patent Truck and Trolley Co* [1905] WN 122; *British Oxygen Co* v *Liquid Air Ltd* [1925] Ch 383.

moral element to it. It does not serve the public interest to allow the patent system to encourage innovation in these areas.

However, for the third group of inventions, the illegality exclusion serves no purpose other than perhaps to save the patent office from wasting time processing patent applications which if granted could never be exercised. Inventors may still wish to patent such inventions in some situations, such as if a change in the law is anticipated which would render a presently illegal invention legal. The Ministry of Commerce have argued for the removal of the "contrary to law" exclusion, apparently with only the third group of inventions in mind.[78] They appear to adopt the position taken by the EPO in the course of the Harvard/Onco-mouse application where the EPO noted that a patent was a right of exclusion and not an obligation to use[79] and that as a consequence the illegality exclusion was unnecessary, because illegal inventions will be prohibited by other laws. This ignores the socially valuable function the illegality exclusion can perform by sometimes excluding inventions in the first two groups outlined above.

In *The Wellcome Foundation Ltd (Hitching's) Application*[80] Davison CJ said that the words "contrary to law", in section 6 of the Statute of Monopolies, meant that anything designed to be used for an illegal purpose cannot be the proper subject matter for a patent. Implements for housebreaking, picking pockets and picking locks are given as examples. He observed that "[i]t would be absurd if by one law patents might be granted to reward persons for providing the means of violating any other law".[81] But what about the lock-pick invented to facilitate the work of reputable lock-smiths? Is it to be denied patent protection? This is one of

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78 Above n 22, 9.

79 See Part XII E below.

80 [1979] 2 NZLR 591;[1980] RPC 314, 332.

81 Above n 80, 322.

the problems with the illegality exclusion. Clearly is must be used with caution.

The UK Patent Office Manual of Office Practice[82] states that applications which might, or would be, contrary to the common law or statute law may be refused absolutely, or accepted if a disclaimer to the use contrary to law is inserted into the specification. Applications which have been refused on this ground include: an explosive safe or other device designed to maim or kill a trespasser or burglar; bombs intended for surreptitious use; devices which contravene Acts against cruelty to animals; and inventions which might be used to evade Inland Revenue and Customs duties. An application for a spiked device for stopping motor vehicles was allowed subject to the insertion of a disclaimer of use contrary to law. No objection is raised against applications for gambling appliances and apparatus. Special restrictions have been applied to applications for patents on nuclear devices and weapons technology. [83]

The Ministry of Commerce proposal to remove the exclusion from patentability of inventions which are contrary to law, can perhaps be viewed as one aspect of the attempt to remove moral values from patent law, as a part of the wider attempt to isolate patent law from the values of society as a whole.

X PATENTS ON LIVING MATTER

There has long been doubt about the patentability of living matter. This doubt has existed in many jurisdictions and been founded on several

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82 Above n 74, Volume II, paras 10,4 to 10,12.

83 For example sections 25 and 26 Patents Act 1953, 42 USC section 2181(a) (1982).

grounds.[84] The patentability of higher organisms has been particularly controversial.[85] Such patents undoubtedly raise moral issues.

The application of DNA technology to produce new, or modified, life forms has led to a flood of patent applications for transgenic animals. These applications have caused debate on the ethical and public policy issues such patents raise. Before 1970 it was widely accepted that only primitive forms of life, such as yeasts[86] and bacteria, could be patented.[87]

In 1980 the New Zealand Assistant Commissioner of Patents issued a Ruling,[88] as a guideline to patent examiners, which stated that:

> The distinction between living and inanimate matter no longer is appropriate, if it ever was, as a distinction between non patentable and patentable matter.

The development of transgenic animals has raised the issue of whether a patent on such an animal could ever amount to a form of slavery. And if so, whether such patents should be refused as being either contrary to law, morality or human dignity. To grant a property right in a transgenic mouse containing one human gene may appear innocuous, however granting a property right in a transgenic human containing one mouse gene may be a form of slavery. If transgenic animals containing human genes are to be patentable then one day a decision will have to be made at what point such

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84 R Nott "Patent Protection for Plants and Animals" [1992] 3 EIPR 79: J H Barton "Patenting Life" (1991) 264 Scientific American 18.

85 M Lawrence "The Patentability of Higher Life Forms in Europe: An Update" (1993) 12 Biotechnology Law Report 539.

86 In the United States Louis Pasteur was granted US Patent No. 141,072 for a purified strain of yeast in 1873.

87 J Curry *The Patentability of Genetically Engineered Plants and Animals in the US and Europe, A Comparative Study* (Intellectual Publishing Ltd, London, 1987), 1.

88 H Burton, *Ruling Patentability of Micro-organisms*, New Zealand Patent Office, 6 October, 1980.

patents cease to be acceptable. The option to refuse such applications should be available.

XI MEDICAL TREATMENT PATENTS IN NEW ZEALAND AND THE UK

It has long been considered that methods of medical treatment are not patentable.[89] In the UK between 1623 and 1977 the definition of an invention incorporated the phrase "any manner of new manufactures" and it was considered that a method of treatment was not a manner of new manufacture.

One of the first attempts to obtain a patent for a method of treatment in the UK was *C & W's Application.*[90] The Solicitor-General (acting as the Appeal Authority) decided that "new manufactures" within section 6 of the Statute of Monopolies must mean something associated with the manufacture or sale of products in commerce and trade. He held that "it cannot be suggested that the extraction of lead ... [from human bodies] ... is a process employed in any form of manufacture or of trade". The application was declined because it was not considered to come within the words "manner of new manufactures". As to ethical considerations involving "humanity" and the practice of the medical profession he added "I have altogether excluded such considerations from my mind". Thus the

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89 In 1795 in *Boulton* v *Bull* there are comments by Buller J which suggest that even then it was thought that the discovery of a new medical use (the use of arsenic to treat agues for example) for a known compound would not be patentable: (1795) Dav. P.C. 199. In Cunynghame's English Patent Practice (1884) it is said that "[t]he art of curing an illness cannot be said to be an art of manufacture": cited by Davison CJ in the *Wellcome* case, above n 80, 334.

90 (1914) 31 RPC 235: this case involved an application for a patent for a process for extracting metals from living bodies.

exclusion of medical treatment patents in the UK was not founded on ethical considerations. At least not explicitly.

In *GEC's Application*[91] Morton J said that for something to be a manner of manufacture it must result in the production of a vendible product, improve or restore a vendible product, or preserve a vendible product from deterioration. In *Maeder* v *"Ronda" Ladies' Hairdressing Salon*[92] the New Zealand Court of Appeal declined an application for the grant of a patent for a process for permanent waving of human hair on the basis that it did not produce a vendible article.

In *National Research Development Corporation* v *Commissioner of Patents*[93] (the *NRDC* case) the High Court of Australia expanded the concept of "manner of new manufacture". The Court said that the right question to ask when deciding whether an invention came within the words "manner of new manufacture" was "[i]s this a proper subject of letters patent according to the principles which have been developed for the application of s.6 of the Statute of Monopolies?". This was a relaxing of the "vendible product" test. It was said that "vendible" means a requirement for a practical commercial utility, while "product" means any end produced, such as the eradication of weeds. The High Court observed that "*apparently* ... processes for treating diseases of the human body" (emphasis added) were not to be regarded as a manner of manufacture. The Court did not have to decide this issue but appeared to have some doubt about it.

In *Swift & Company* v *Commissioner of Patents*[94] Barrowclough CJ broke new ground when he held that biological processes were a manner

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91 *In the Matter of an Application for a Patent by GEC* (1943) 60 RPC 1 (*GEC's Application*).

92 [1943] NZLR 122.

93 [1961] RPC 135;(1959) 102 CLR 252 .

of manufacture. In reaching his decision Barrowclough CJ was influenced by the *NRDC* case, while the earlier decision of the New Zealand Court of Appeal in *Maeder,* which if followed might have suggested a different result, was not discussed.

After the *NRDC* and *Swift* cases the ground given for the exclusion of methods of medical treatment in *C & W's Application* no longer adequately explained the continued exclusion of such methods. If the exclusion was to be maintained a different justification had to be found. The courts subsequently began to expressly refer to ethical arguments to maintain the exclusion. At the same time the exclusion was narrowed so as no longer to include the treatment of animals,[95] cosmetic treatments[96] and methods of contraception.[97]

Although in a subsequent case Davison CJ complained that these courts were making "distinctions without a difference"[98] this criticism is not entirely valid. The ethical issues surrounding cosmetic methods are different from those surrounding therapeutic methods. The concerns that surround maintaining the freedom of physicians to use potentially life-saving medical treatments do not extend to purely elective cosmetic treatments.[99] Difficult problems surround drawing the line between what is

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94 [1960] NZLR 775: This case involved a method for tenderising meat by injecting enzymes into the living animal.

95 In *U.S. Rubber Company's Application* [1964] RPC 104 in England a patent was allowed for a method of medical treatment, as long as it was restricted to non-human animals.

96 *Joos* v *Commissioner of Patents* [1973] RPC 59.

97 *Schering A-G's Application* [1971] RPC 337: Whitford J noted that it seemed that patents for medical treatment "in the strict sense" (ie for the cure or prevention of disease) were excluded. However, this did not include treatment which would produce a result in the human body, other than the cure or treatment of disease, for which people would pay.

98 Above n 80, 341.

99 Particularly cosmetic treatments sought by the vain and/or wealthy.

cosmetic and what is therapeutic or prophylactic. However, this practical problem aside, there is a genuine distinction between the two with regard to ethical issues.

In *Eli Lilly & Company's Application*[100] the Court observed that the exclusion of methods of medical treatment seemed to be based in ethics rather than logic.

In *The Upjohn Company (Robert's) Application*[101] the English Court of Appeal upheld the exclusion of methods of medical treatment from patentability. The Court felt that it was significant that section 41 of the Patents Act 1949 (UK)[102] did not cover methods of treatment. Section 41 included provisions for the compulsory licensing of substances capable of being used as a food or medicine. The purpose of this section was to ensure that where a patent for one of these inventions had been issued the Comptroller-General could make an order for a compulsory licence to ensure that the public would not be "held to ransom"[103] and that the inventions could immediately be made available, while providing that the patentee was reasonably rewarded.

Processes for medical treatment did not fall within section 41. If a patent could be obtained for such a process the Comptroller-General would not be able to safeguard the public by issuing compulsory licences. This omission was interpreted by the Court as suggesting that at the time the Act was passed Parliament believed methods of medical treatment to be unpatentable. Otherwise "here indeed would be a strange outcome".[104]

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100 [1975] RPC 438.

101 [1977] RPC 94.

102 Equivalent to sec 51 Patents Act 1953, which has now been repealed. A similar provision was also present in the 1919 and 1907 UK patent legislation.

103 Above n 97, 343.

104 Above n 101.

In *The Wellcome Foundation Ltd (Hitching's) Application*[105] the New Zealand Supreme Court held that methods of medical treatment were patentable. According to White the judgment of Davison CJ exposed the non-patentability of methods of treatment as a myth.[106]

The case involved an application for a patent for the use of known compounds for the treatment of meningeal leukaemia or neoplasm's in the brain. These compounds had previously been used to treat malaria. As these were known compounds the applicants did not seek, and could not have obtained, a patent for the compounds *per se*. The Assistant Commissioner of Patents refused to proceed with the application because it did not relate to a "manner of new manufacture" as required by the section 2 definition of an "invention". The applicant appealed to the Supreme Court.

Davison CJ noted that the *NRDC* case expanded the definition of a "manner of new manufacture" and had been subsequently followed.[107] Davison CJ considered the distinction between cosmetic and other forms of medical treatment which had been drawn in some of the cases[108] to be artificial, as was the distinction between a contraceptive and medical treatment. Why should a patent be allowed for suppressing conception (*Schering*) but not for suppressing ulceration (*The Upjohn Company (Robert's) Application*)? The courts had drawn "distinctions without a difference". Davison CJ ignored the different ethical considerations these categories raise which might justify different treatment under patent law.

He observed that the ground on which *C & W's Application* was refused had been overtaken by an expansion by the courts of the concept of a

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105 Above n 80.
106 Above n 31.
107 Above n 80, 330.
108 Such as *Joos*, above n 96.

manner of new manufacture, as illustrated in the *NRDC* and *Schering* cases, and could no longer be relied upon.

The argument based on section 41 of the Patents Act 1949 (UK)[109] could be simply overcome. When the legislation was enacted the law was based on *C & W's Application.* At that time it was not thought that a process of medical treatment was patentable. However, following the decisions in the *NRDC*, *Schering* and *Joos* cases the law had changed. Methods of treatment were now within the definition of an invention and were patentable. Parliament could amend the Patents Act to allow for the compulsory licensing of methods of medical treatment if it desired.[110]

Davison CJ could "find no warrant in law for grounding such refusal on ethical considerations".[111] If a drug could be the subject of a patent, and compulsory licences granted, then why not a method of treatment. Section 51 of the New Zealand Act could easily be amended to allow for the granting of compulsory licences for methods of treatment. Davison CJ ignores the fact that a patent on a drug primarily restricts the activity of drug manufacturers while a patent on a method of treatment primarily restricts the activity of physicians. If one is prepared to restrict the activity of manufacturers, it does not follow that restricting the practice of physicians is also acceptable. This latter restriction raises different issues relating to the physician-patient relationship which are not raised by the placing of restrictions on drug manufacturers. Also, the use of compulsory licensing may raise different issues when applied to physicians rather than manufacturers. Briefly, it is not sufficient to say, as Davison CJ does, that

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109 Section 51 of the Patents Act 1953.

110 Since Davison CJ's judgment section 51 of the Patents Act 1953 has been repealed. The wording of section 51 no longer provides an argument for the exclusion of methods of medical treatment claims from patentability.

111 Above n 80, 339.

if patents are allowed on drugs then it follows that they should also be allowed on methods of medical treatment. This is a gross over-simplification. A more detailed analysis of the benefits and costs of such a step must be carefully considered.

The Commissioner of Patents appealed to the Court of Appeal.[112] Cooke J (as he then was) observed that until Davison CJ's decision no court in the Commonwealth had treated the words "manner of new manufacture" as extending to a method of treatment of human illness or disease.

Somers J held that the opinion of the High Court of Australia in *NRDC* was also a correct statement of the law in New Zealand.[113] However, that case did not involve a method of medical treatment of human beings and could therefore be distinguished from the case before the Court. The Court accepted that the correct approach to determining whether a process or product was within the definition of an invention was not to ask whether it was a "manner of new manufacture", but rather to adopt the approach taken in *NRDC* and ask whether it is a proper subject of letters patent according to the principles which have been developed for the application of section 6 of the Statute of Monopolies.

On the issue of the patentability of methods of medical treatment of human beings Cooke J said that "there remains ... a deep-seated sense that the art of the physician or the surgeon in alleviating human suffering does not belong to the area of economic endeavour or trade and commerce".[114] He cited with apparent approval the words of Kahn J in *Wellcome Foundation* v *Plantex Ltd* :[115]

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112 *The Wellcome Foundation Ltd* v *Commissioner of Patents* [1983] NZLR 385.

113 Above n 112, 400.

114 Above n 112, 388.

115 Above n 112, 388, and [1974] RPC 514, 539.

> There exist grave reasons against the creation of a monopoly by a patent in respect of medical treatment. We are confronted here with saving human life or alleviating human suffering and one should take great care lest a restriction on the freedom of action of those who treat, caused by patents, should affect human life or health.

Somers J noted that the treatment of human ailment was "of a special character"[116] and that the policy content in the Courts decision was great. Cooke J said that it was necessary to balance the need to encourage the interests of those engaged in research in connection with the discovery and manufacture of new drugs, while not unduly restricting the work of those who engage in the therapy of humans. The temptation to break new ground and allow the patenting of methods of treating human illness or disease should be resisted, and the decision of whether to allow such patents should be left to Parliament. The issue required a wider range of review than the Court could accomplish. It would be necessary to consider the views of professional medical bodies. The economic implications also needed to be considered. The possibility that allowing patents in this area might result in "raising prices of commodities at home" or be "generally inconvenient" within the limitations contained within section 6 of the Statute of Monopolies, could not be discounted. The Court unanimously allowed the appeal and found that methods for the medical treatment of human beings were not patentable. This is the present state of the law in New Zealand.

The *Wellcome* case demonstrates that the New Zealand Court of Appeal accept that ethical considerations do have a place in patent law with regard to methods of medical treatment of human beings. Ethical concerns are thus to be permitted to restrict the area of patentable subject matter in New Zealand. There is no reason why, in an appropriate case, involving a

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116 Above n 112, 404.

transgenic animal for example, that moral concerns might not be successfully raised. These concerns could be raised when answering the question whether the invention in question is a proper subject of letters patent according to the principles which have been developed for the application of section 6 of the Statute of Monopolies. In the *Wellcome* case the Court of Appeal considered ethical concerns to be relevant to answering this question. They could also be raised under the specific morality provision.[117]

XII MORALITY IN EUROPEAN PATENT LAW

The US and the European Union have taken widely divergent approaches to dealing with the moral issues raised by patents on methods of medical treatment and biotechnology inventions. The European Union has attempted to incorporate moral values into its patent system, while the US has refused to do so.

A The European Patent Convention

In Europe patents can be obtained through the national patent offices of individual countries or through the centralised European Patent Office (EPO). The EPO was founded in 1977 under the European Patent Convention (EPC). European patents issued by the EPO are valid in up to 17 nations and are granted according to uniform standards. Filing applications through the EPO is becoming increasingly popular. It has been estimated that about half of US applicants file for protection in Europe through the EPO.[118]

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117 Section 17(1)(b) Patents Act 1953.

118 Report of the United States General Accounting Office (GAO) *Intellectual Property Rights: US Companies' Patent Experiences in Japan* (GAO/GGD-93-126, July 1993) 13. Reproduced in (1993) 12 Biotechnology Law Report 717.

The European laws in this area are derived from the Strasbourg[119] and UPOV Conventions.[120] These Conventions were drawn up at a time before the emergence of modern biotechnology. The criteria for patentability drawn up at that time no longer provide a clear demarcation line between the patentable and the unpatentable. The EPC adopted these inadequate criteria when it was drawn up in 1973.

The EPO Guidelines for examination interpret the EPC and the Rules made under the EPC. The EPO Guidelines are only advisory general instructions to cover normal occurrences and may be departed from by the EPO in an individual case.[121] The European Commission have emphasised that the normal criteria of patentability apply to biotechnology inventions.[122]

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119 The Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions.

120 The International Convention for the Protection of New Varieties of Plants.

121 The Chartered Institute of Patent Agents *C.I.P.A. Guide to the Patents Acts* (3 ed, Sweet & Maxwell, 1990) 3.

122 Above n 11.

B Criteria for Patentability Under the EPC

To be patentable under the EPC an invention must be new, involve an inventive step,[123] be capable of industrial application,[124] be sufficiently described in the disclosure, not relate to a discovery or a plant or animal variety and not be an essentially biological process.

EPC Article 53(a) excludes from patentability inventions which would be contrary to "*ordre public* or morality". The Guidelines[125] state that the purpose of these exclusions is to prevent the patenting of inventions likely to induce public disorder or riot, or to lead to generally offensive or criminal behaviour. The Guidelines state that a fair test to apply is to consider "whether it is probable that the general public would regard the invention as so abhorrent that the grant of patent rights would be inconceivable". A letter bomb is given as a possible example.

C Patents on Genes and DNA

Although a discovery *per se* is not patentable,[126] the practical application of it is. Therefore the discovery of a new gene will not be patentable *per se*, but if that gene is purified and/or isolated and a practical application

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123 An invention will lack an inventive step if a person skilled in the art would have thought the idea worth trying, and would have a reasonable chance of success. In the UK the test for obviousness/lack of an inventive step is that a skilled person would have thought that the idea was well worth trying in order to see whether it would have beneficial results: *Johns-Manville Corporation's Patent* [1967] RPC 479, cited with approval by the English Court of Appeal in *Genentech,* below n 172.

124 EPC art 52(1) provides that European patents shall be granted for inventions which are susceptible of industrial application, which are new and which involve an inventive step. EPO Guideline C-II, 4.12 indicates that susceptible of industrial application is synonymous with "capable of industrial application".

125 EPO Guidelines C-IV, 3.1-3.3.

126 Article 53(2) of the EPC excludes discoveries from patentability.

for it is disclosed, then it may be patentable. The NIH and MRC patent applications led to much debate about the morality of patents on human genes,[127] but at present such applications have been allowed under the EPC as long as they meet the standard criteria for patentability.

D Transgenic Animals

Patents on transgenic animals have led to a heated debate on the morality of such patents, and some applications have been refused on this ground. Under EPC Article 53(b)[128] plant and animal varieties, and essentially biological processes[129] for the production of plants and animals, are excluded from patentability.[130] Plant varieties are excluded from protection because many EPC states are members of the Union for the Protection of New Varieties of Plants (UPOV)[131] which provides for the protection of plant breeders' rights over plant varieties. The Convention also provides that the same plant variety or genus should not be afforded both patent and plant breeders' rights protection. A transgenic animal will not be patentable if it relates to an animal variety, or is produced by an essentially biological process. UPOV does not cover animal varieties and so cannot be used to explain the reference to animal varieties in Article 53(b).

A transgenic animal is likely to satisfy the novelty requirements of the EPC because while mice are found in nature, mice carrying human genes are

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127 See Part XV C below.

128 EPO Guidelines C-VI, 3.4-3.5.

129 Traditional breeding methods would be classed as essentially biological processes and would not be patentable. For something to fall outside this exception there must be significant technical intervention: see above n 11.

130 This provision is equivalent to section 3(b)Patents Act 1977 (UK).

131 UPOV was established by the International Convention for the Protection of New Varieties of Plants as revised in 1972 and 1978.

not. Likewise this will ensure that the transgenic animal is not a discovery. Transgenic animals could potentially fall down at the inventive step hurdle. It will quickly become obvious to transfer useful genes between species. The sufficiency of the disclosure is potentially a problem for a transgenic animal patent. Rule 28 of the EPC requires a deposit of a sample of a relevant micro-organism which is not publicly available. Such deposits are recognised under the Budapest Treaty.[132]

Transgenic animals may be rejected under Article 53(a) as being contrary to morality. The precise shape of this morality objection can take a number of forms as demonstrated by the debate surrounding the Harvard Onco-mouse patent application.

E The Harvard/Onco-mouse application in Europe

The Harvard Onco-mouse is a transgenic animal which has a cancer causing gene (an "oncogene") inserted into its genome which causes it to develop cancers within a few months of birth. The animal is useful as a tool for the investigation of the causes and treatment of human cancer. The inventors applied to the EPO for a European patent on this animal. The Examining Division of the EPO rejected the Harvard Onco-mouse application.[133] On appeal the Technical Board of Appeal set aside this decision and remitted the application to the Examining Division for further examination.[134]

The Examining Division applied the test of morality described above.[135] That is was it probable that the general public would regard the

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132 Budapest Treaty on the International Recognition of the Deposit of Micro-organisms (1977).

133 OJ EPO 1989, 451.

134 T19/90, *Harvard/Onco-mouse*, OJ EPO 1990, 476.

135 *Harvard/Onco-mouse* OJ EPO 10/1992, 588; [1991] EPOR 525.

Onco-mouse as so abhorrent that the grant of patent rights would be inconceivable. They weighed the competing public interest considerations and held that overall the invention would reduce the amount of animal suffering and was not contrary to EPC Article 53(a). Animal suffering would be reduced because it was predicted that fewer animals would be used in conventional testing as a result of the Onco-mouse. The public benefit outweighed the risk to the environment and the harm to the animal. Mice are a higher taxonomic group than a variety and are hence not excluded from patentability by Article 53(b). The patent was granted in October 1992, four years after the equivalent patent was granted in the US. It was the first granted for a transgenic animal by the EPO.

Oppositions have been lodged against this patent by 16 parties.[136] The arguments of the opponents which follow illustrate a number of different moral positions:

the Technical Board of Appeal (the Board) failed to sufficiently consider the suffering of the animal (especially the suffering of an Onco-chimpanzee which was also included in the patent);

the Board overrated the benefit of the invention;

the Board underrated the environmental risks (if an Onco-dog were to escape and breed with other normal dogs the results would be unpleasant);

the balancing test is not suitable to determine whether the invention was patentable under EPC Article 53(a) (the argument is that something inherently immoral cannot be made moral just because it benefits humanity in some way, a moral balancing act is not appropriate for

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136 H Jaenichen and A Schrell "The Harvard Onco-mouse in the Opposition Proceedings before the European Patent Office" [1993] 9 EIPR 345.

something which is inherently immoral). This raises a fundamental question about the meaning of the morality provision. Is something moral if it can be justified in the interests of humanity or is it moral if it is not inherently wrong;

the subject matter of the patent was an affront to the dignity of mankind;

the patenting of a human oncogene is one step nearer to patenting the human genome and hence an affront to the dignity of mankind;

general arguments about the unknown risks of genetic engineering;

that parts of the patent related to the treatment of the animal body by therapy and was therefore not industrially applicable and were unpatentable under Articles 52(1) and 52(4);

religious, political and moral doubts under Article 53(a); and denying a patent would discourage this type of research and hence protect public order.

In February 1993 the Green group in the European Parliament put forward an emergency motion which called for the revoking of the Onco-mouse patent by the EPO. This resolution was carried by a majority of 178 to 19 (with 27 abstentions), and declared the "resolute opposition" of the Parliament to the patent.[137] The outcome of the Harvard/Onco-mouse patent oppositions is still awaited.

F After the Harvard mouse in Europe

The *Upjohn Application*[138] involved a hairless mouse used to test hair restorer. The mouse had been genetically modified to incorporate a

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137 EP Resolution B3-0199, 0220,0249/93.

138 Above n 11, 32.

"reporter gene" which would signal the stimulation of hair growth by producing a readily measurable effect. One such effect was the development of cancer. The Examining Division decided that the benefit to mankind was outweighed by the suffering caused to the animal and rejected the application on moral grounds.[139]

In two recent decisions[140] the EPO has confirmed the narrow interpretations that will be given to the exclusions under Article 53(a) and (b). Hence animals and plants are not generally excluded from patent protection, but the EPO is prepared to reject some applications under the morality exclusion.

G Methods of Medical Treatment

Article 52(4)[141] of the EPC provides that:

> Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

According to White[142] this restraint on the patentability of certain types of pharmaceutical and veterinary inventions is a retrograde step having the effect of retarding the discovery of new remedies for many diseases.

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139 The equivalent application has been allowed in New Zealand in NZ Patent No. 231502. No controversy surrounded the granting of this patent and the Patent Office were not required to make public the reasons for its decision to grant this patent.

140 Opposition to EP-B1 0 122 791 and opposition to EP-B1 0 242 236; discussed in n 136 above, 347.

141 Equivalent to section 4(2) Patents Act 1977(UK).

142 A White "The Patentability of Naturally Occurring Products" [1980] EIPR February, 37, 40.

Article 54(5) relates to novelty requirements and provides that the provisions of paragraphs (1) to (4) of Article 54 shall not exclude from patentability any substance or composition, comprised in the state of the art (ie a known compound), for use in a method referred to in Article 52(4), provided that its use for any method referred to in Article 52(4) is not comprised in the state of the art (ie provided it has not been used in a method of treatment before). The consequence of this is that a first therapeutic use of a known compound will have the requisite novelty to be patentable.

This means that a use-bound-substance claim will be allowed, while the actual use of the substance in a method of medical treatment will not be patentable due to Article 52(4). This can be seen as a compromise position. Methods of treatment are not patentable, but it is desirable to encourage the discovery of medical uses for known substances. The inventor of a medical use for a known substance cannot patent the medical use, and cannot patent the substance itself because it is not new.[143] As a compromise position the EPC has in effect relaxed the novelty requirements for the first medical use of a known substance by rendering it novel under Article 54(5).

Another means by which the inventor of a new medical use for a known compound can gain patent protection under the EPC is by the use of so-called "Swiss-type" claims.[144] A Swiss-type claim is in effect a claim to the method of manufacture of a medicament, which derives its novelty

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143 The inventor of a new non-medical use for a known substance will be able to patent the new process, and so does not need the benefit of Article 54(5).

144 An example of a Swiss-type claim is: "The use of substance (A) in the manufacture of a medicament (B) for the therapeutic and/or prophylactic treatment of a medical indication (C)."

from the new use.[145] Infringement of a Swiss-type claim catches the manufacturer and not the physician. Therefore such claims do not raise the same ethical issues that patents on methods of medical treatment do.

XIII THE PROPOSED EUROPEAN UNION DIRECTIVE ON BIOTECHNOLOGY

A The Emergence of Ethical and Moral Issues

In 1988 the European Commission published a *Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions* (the draft Directive). The Commission observed that within the Community "there is no other field of technology where national patent laws vary on so many points as they do in biotechnology".[146] There was concern that this made the European Union a less attractive place in which to invest in research and development in biotechnology, and that ground was being lost to Japan and the US which had more favourable patent regimes.

In pursuit of a uniform, certain and liberal interpretation of the EPC in relation to biotechnology inventions, the Commission produced the draft Directive.[147] The original draft Directive did not mention moral and ethical considerations because the Commission did not consider them to be relevant.[148]

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145 *John Wyeth's and Schering's Applications* [1985] RPC 545: in this case some *obiter* comments were made to the effect that Swiss-type claims lacked novelty under the Patents Act 1949 (UK) on which the Patents Act 1953 was based. Based on this authority the New Zealand patent office do not allow Swiss-type claims.

146 R Whaite, N Jones "Biotechnological Patents in Europe - The Draft Directive" [1989] 5 EIPR 145.

147 Above n 11.

148 N Jones "Biotechnological Patents in Europe - Update on the Draft Directive" [1992] 12 EIPR 455, 456.

The European Parliament opposed the draft Directive on ethical and moral grounds. Patent protection on human genetic material became a controversial issue as did patents on transgenic animals. The continued exclusion of methods of medical treatment has raised little controversy.

It appears that groups opposed to the Directive employed delaying tactics in the European Parliament.[149] However, in October 1992 an amended draft Directive was adopted by 105 to 82 votes.[150] As a result of the opposition the draft Directive encountered in the European Parliament, moral and ethical issues were addressed in the amended draft Directive.

In December 1993 the Council of Ministers reached political agreement on the draft Directive, and in January 1994 adopted, by a qualified majority, a "Common Position" on an amended draft Directive. It adopted some but not all of the European Parliament's amendments to the original draft Directive.[151] The Common Position was adopted by a qualified majority. Spain, Denmark, Luxembourg and Italy all voted against the Common Position for ethical reasons.[152] The UK vote in favour was subject to the reservation that the draft Directive be examined by the UK Parliament, in particular the Laws and Institutions Subcommittee of the House of Lords.

The patenting of animal life *per se* was objected to by Denmark. Denmark also objects to the Common Position because of concerns that

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149 There is a strong "green" lobby in Europe which believes that no living forms should be patentable.

150 "Parliament Finally Gives OK to Biotech Patent Proposal" (1992) 6 World Intellectual Property Report 329.

151 "Onco-mouse Oppositions Filed as EC Grapples with Biotechnology Directive" (1993) 7 World Intellectual Property Report 62.

152 S Faircliffe "Biotechnology Patent Directive Still Faces Ethical Objections" (1994) 8 World Intellectual Property Report 96.

the text of the draft Directive is not clear enough in limiting the possibility of obtaining patents on the human body. The Danes also appear to be concerned about gene therapy patents due to the unknown future of gene therapy and the consequences of patenting such technology.[153] Spain took the view that all processes for human gene therapy should be unpatentable. Spain also considered that the test of whether a form of gene therapy was contrary to human dignity or not would be impossible apply. Luxembourg agreed with the objections raised by Spain and Denmark.[154]

B The Common Position

1 The provisions of the Common Position

Article 2 of the Common Position makes it clear that patents may be obtained on plants and animals.

Article 2.3 provides that inventions, the publication or exploitation of which would be contrary to public policy or morality, shall be unpatentable. This is virtually identical to EPC Article 53(a), except it uses the phrase "public policy" instead of "ordre public".[155] Paragraphs 2.3(a), (b) and (c) list specific exclusions considered to be contrary to public policy or morality.

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153 Above n 152.

154 M Moynihan "The European Biotech Directive - an End in Sight?" Patent World, April 1994, 24.

155 The significance of this change of wording will be open to debate and may create uncertainty over the continued relevance of precedents decided under the different wording of EPC Article 53(a). Considering that the aim of the Directive is to increase the certainty and uniformity of Community patent law this change of wording in the main morality clause may be unwise.

Under Article 2.3(a) "the human body or parts of the human body as such", are not patentable. Under Article 2.3(b) "processes for modifying the genetic identity of the human body contrary to the dignity of man" are unpatentable. These two provisions appear to contemplate an absolute prohibition from patentability of inventions which fall within them.

"[P]rocesses for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and animals resulting from such processes" are excluded from patentability by Article 2.3(c). The benefit to man or animal must be "substantial". If the benefit is substantial it would seem that the suffering to the animal need not be considered at all. This Article may be viewed as a partial ban on patenting transgenic animals.

Recital 15 states that an invention involving the genetic modification of animals will be unpatentable where the suffering or physical handicaps inflicted on the animal is out of proportion to the objective pursued. This involves using a balancing test as used in the *Harvard Onco-mouse* and *Upjohn* decisions of the EPO. According to the recital even an invention with laudable aims may cause an unnecessary degree of suffering. Recital 15 requires the suffering of the animal to be taken into account. In employing a balancing test paragraph 2.3(c) is different from paragraphs 2.3(a) and (b).

Paragraphs (a), (b) and (c) of Article 2.3 have been criticised for not giving adequate guidance as to how they should be interpreted.[156] For example there is no guidance on what is meant by "contrary to the dignity of man" as used in Article 2.3(b). Article 2.3 of the Common Position, together with the exclusion of methods of medical treatment from

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156 R Nott "The Proposed EC Directive on Biotechnological Inventions" [1994] 5 EIPR 191, 192.

patentability under Article 52(4) of the EPC, indicate the willingness in Europe to tackle the difficult moral issues raised by new technologies as a part of patent law.

2 Genes and DNA under the Common Position

It is proposed that the human body or parts of the human body *per se* should be unpatentable as being contrary to public policy or morality.[157] This raises the question what is a part of the human body? For example are microscopic parts, such as human genes, included within this definition? Recital 10 states that ownership of human beings is immoral, and that consequently a patent cannot be granted over the human body or parts of the human body as such. This includes a human gene, protein or cell in the natural state of the human body "as found inside the human body", including germ cells and products resulting directly from conception. If genes, proteins or cells are isolated from the body, they may be patentable.[158]

3 Transgenic Animals under the Common Position

Article 2.3 of the Common Position provides that inventions are not to be considered to be patentable where publication or exploitation of them would be contrary to public policy or morality.

Concerns have been raised about the possibility of patenting human beings. There seems to be a consensus that this should not be allowed. Articles 2.3(a) excludes patents on the human body or parts of the human body. This should also exclude patents on transgenic humans. Such

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157 Article 2.3(a) of the Common Position on the draft Directive.

158 J Thurston "Recent EC Developments in Biotechnology" [1993] 6 EIPR 187.

patents are also likely to fall foul of Article 2.3(b) as being "contrary to the dignity of man" and possibly also Article 2.3(c).

Article 3 provides that biological material, including transgenic animals, is patentable. However, under Article 2.3(c) processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps on them without any benefit to man or animal are to be unpatentable.[159] Recital 15 indicates that the suffering or physical handicaps inflicted on the animal is to be balanced against the benefits of the objective pursued. The European Parliament has resisted the arguments of those who say that animal welfare considerations should be addressed in laws specifically directed towards that purpose, and have no place in patent law.

4 Methods of Medical Treatment under the Common Position

Methods of medical treatment are not generally patentable under the EPC and did not need to be dealt with specifically by the draft Directive. However, the draft Directive does contain provisions relevant to the new area of gene therapy. Article 2.3(b) excludes from patentability any process which modifies the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man. Some commentators are critical of introducing concepts such as "the dignity of man" into patent law.[160]

Since its first publication with no reference to moral considerations in 1988 the draft Directive has evolved to a position where in 1994 it incorporates significant provision for the consideration of moral issues.

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159 This provision is intended to prevent patents on animals such as the "Beltsville pig": see above n 35 and n 150.

160 Above n 158.

The European Parliament seems to be determined to ensure that moral issues are not shut out of patent law.

C The European Parliament's Response to the Common Position

The Common Position has been referred back to the European Parliament, which referred it to a Committee for consideration in March 1994. This Committee has proposed significant changes to the Common Position. They propose that there be an absolute ban on patenting human genes and gene therapies.[161] The Committee also propose a farmers privilege which includes genetically engineered livestock. The future of the draft Directive may not be settled until 1995 or later.[162]

D Criticisms of the Common Position on the draft Directive

According to Nott the morality and *ordre public*/public policy objections to patentability are so great a burden on the EPO, and to business, that they should be rejected.[163] However, this argument sounds a bit like saying crime is proving to be such a burden on the police, the courts and our prison system that we should stop trying to detect criminals. There may be something to this argument but clearly the real issues are much more complex than this analysis would suggest. Nott makes the standard argument of those opposed to morality clauses in patent law:[164]

> The way in which the problem of animal suffering should be addressed is by the individual Member States relying on their own laws specifically directed to the protection of animals, and the control of the development and release of undesirable animals and plants. Patents cannot control material which is not

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161 Above n 156, 194.

162 R Nott "The European Biotech Directive-An End In Sight? (Reprise)" Patent World, September 1994, 5,6.

163 Above n 156.

164 Above n 156, 192.

> both the subject of the invention and patented, but it is imperative that nature and the environment should be appropriately protected from undesirable genetic manipulation. This can only be done effectively by laws directed specifically to the problems, and not by laws which touch only patented inventions and nothing else.

Nott wishes to see the patent system operate in a vacuum, isolated from any value other than the encouragement of innovation. This argument does not consider the possibility that patent laws can play a role as a part of the wider overall regulation of areas of social concern. For example, the patent system alone cannot address the concerns society has for safeguarding animal welfare. However, the patent system can play a role as a part of a wider system of regulation, which includes specific animal welfare laws, as well as laws in some peripheral areas, such as patent law, which can also impact upon animal welfare. Nott also ignores the issues concerning whether granting property rights in some inventions would be contrary to human dignity.

In January 1994 the Laws and Institutions Subcommittee (Subcommittee E)[165] of the House of Lords took evidence on the Common Position. The Subcommittee supported the attempt in the Common Position to expand the use of ethical criteria in deciding whether biotechnology inventions should receive patent protection.[166] However, it was opposed to denying patents for gene therapy techniques considered to be "contrary to the dignity of man" on the grounds that such a test would be very difficult to apply. The Subcommittee believed that the issues raised by these

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165 A Subcommittee of the Select Committee on the European Communities

166 "Lords panel backs ethical barriers to biotech patents" (1994) 368 Nature 278.

techniques should be debated in the wider medical and ethical context.[167]

The British Biotechnology Group are concerned about increasing the role of ethical considerations in patent law.[168] First, they say that such considerations may reduce the competitiveness of the European biotechnology industry compared to other countries, such as the US, which do not have the same restrictions. This argument seems to be saying that any moral concerns should be cast aside in the interests of improving the competitiveness of the European biotechnology industry. Such an argument may have some merit if, and only if, it can be demonstrated, or at least persuasively argued, that the benefits of such a regime for society outweigh the costs. The British Biotechnology Group make no such supporting arguments.

Secondly, the British Biotechnology Group argue that the morality provisions place an unfair burden on patent officers by requiring them to make ethical judgements. The EPO itself has not complained about this unfair burden on examiners, so presumably this argument can be discounted. Thirdly, the British Biotechnology Group is concerned that the draft Directive will be interpreted differently in different European nations. Even though one of the avowed purposes of the draft Directive is to harmonise Community biotechnology patent law. The interpretation of morality is likely to vary from one country to another. This would appear to be a valid but not insurmountable concern.[169]

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167 A view echoed by Cooke J in the *Wellcome* case (above n 112) where he said at page 391 "the question whether medical and surgical devices should be treated as a special subject in patent law ... [is] ... a question upon which the views of medical professional bodies would seem to be among those deserving of consultation".

168 Above n 166.

169 This concern can be addressed by provisions such as s 91(1) of the Patents Act 1977 (UK) which requires the UK Courts to take judicial notice of European Court decisions in order to achieve the conformity required by s 130(7).

In summary the EPC and the Common Position (if it proceeds in its present form) indicate that the European Union considers it to be appropriate and necessary to tackle the moral and ethical problems raised by biotechnological inventions as a part of patent law. This view has met with support from a House of Lords Subcommittee. In short moral and ethical issues are considered to have a place in patent law in Europe.

XIV EXCLUSIONS ON MORAL GROUNDS IN THE UK

A The Patents Act 1977 (UK)

The Patents Act 1977 (UK) brought UK law close to the European Patent Convention. Under section 1(3)(a) patents are not to be granted for inventions the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour. It has been suggested that the test to apply under subsection 3(a) is "whether use of the invention would offend moral principles of right thinking members of the public, such that it would be wrong for the law to protect it".[170] A similar principle has been applied to the registrability of designs.[171]

B Genes and DNA

Patents have been granted on human genes and DNA in the UK. The morality of such patents has not been questioned by the UK Patent Office. However, DNA and gene patents are vulnerable on other grounds. In *Genentech Inc & Another* v *Wellcome Foundation Ltd* [172] the English Court of Appeal considered the patentability of an amino acid and DNA sequence. The Court held that the patent was invalid on the ground that it

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170 The Chartered Institute of Patent Agents *C.I.P.A. Guide to the Patents Acts* (3 ed, Fourth Cumulative Supplement, Sweet & Maxwell, 1993) 4.

171 Above n 64.

172 [1989] RPC 147.

was obvious to a person skilled in the art and lacked novelty.[173] If gene patent applications become more vulnerable on the grounds of obviousness and novelty then the importance or relevance of moral arguments for their exclusion may be lessened or removed.

C Transgenic Animals

The position in the UK is similar to that under the EPC. Under section 1(3)(b) patents are not to be granted for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a microbiological process or the product of such a process. Patents can be obtained for taxonomic groups other than varieties. Applications are subject to a morality test under section 1(3)(a).

D Methods of Medical Treatment

In 1970 the Banks Committee Report on the British Patent System[174] stated that the courts had consistently expressed the view that a process for the medical treatment of a human being was not patentable. The Banks Committee Report did not recommend that patent protection be extended to such methods. Consequently the Patents Act 1977 (UK), which generally gave effect to the Banks Committee Report, contains a specific exclusion for methods of treatment.

The position with regard to the patentability of methods of medical treatment is virtually identical to that under the EPC described above.[175] Falconer and Whitford JJ have given as the purpose of the exclusion of

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173 S Hird and M Peeters "UK Protection for Recombinant DNA - Exploring the Options" [1991] 9 EIPR 334: M Cohn and I Cohn "Some reflections on the patentability of biotechnological inventions" Patent World, October 1991, 34.

174 Cmnd 4407, paras 237-240, p 67.

175 See Part XII G above.

methods of medical treatment from patentability as being "to ensure that the use in practice of such methods of medical treatment in treating patients should not be subjected to possible restraint or restriction by reason of any patent monopoly."[176]

XV MORALITY AND U.S. PATENT LAW

In the US a strikingly different approach has been taken to the role of morality and ethics in patent law than has been the case in Europe. With some exceptions, the US PTO and courts have not considered ethical and moral concerns to be relevant to their determinations of patentable subject-matter.

A U. S. Patent Law

The US Constitution grants Congress broad power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries".[177] The US Patent Act 1952 (35 USC section 101) defines as patentable "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof ...".

B Genes and DNA: the NIH and MRC applications

The US government has recognised the ethical issues raised by the Human Genome Project by allocating US$7 million a year for research on the

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176 Above n 145, 565.

177 Article I, sec 8, cl 8, Constitution of the United States.

ethics of genome research.[178] In 1992 the Congressional Office of Technology launched a study on the propriety of patents on genes. The debate about the appropriateness and morality of patents on human genes was intensified when the US National Institutes of Health (NIH) applied for patents on hundreds of fragments of human genes.

The NIH is participating in the international research effort known as the Human Genome Project.[179] In 1991 the NIH applied for patents on several hundred [180] partial and complementary DNA sequences, known as expressed sequence tags (EST's). The function of these sequences was not known. These sequences are fragments of larger genes, which code for a particular protein. Some of these fragments could eventually turn out to cover valuable products. The application also claimed the whole gene of which the EST was a part, and the proteins for which they coded.

If the NIH application had succeeded it could have resulted in something of a "gold rush" with biotechnology companies racing to sequence and patent random segments of the human genome until it was all accounted

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178 C Anderson "Genome Project Goes Commercial" (1993) 259 Science 302: The study would appear to have been started as a part of a deal with Senator Edward Kennedy who had proposed a two year moratorium on gene patents. The US Department of Energy has supported the adoption of a new model for the protection of genes. The model involves restricting patent protection to known uses, thus avoiding the problem of the ownership of genes.

179 See Part III B above.

180 Through the use of the continuation-in-part procedure available under US patent law the NIH application expanded to include several thousand sequences, representing 5-15 % of the entire human genome.

for.[181] The holders of the EST patents could then exercise a stranglehold over the biotechnology industry.[182]

The NIH application provoked world-wide criticism from scientists.[183] James Watson, head of the NIH HGP, described the application as "sheer lunacy" and resigned in protest.[184] He felt that the patenting of the ESTs would hinder the free flow of information which was a central part of the HGP. This is an argument with an ethical dimension, ie the ethics of the methodology of scientific research and the free exchange of information in the academic community. France is participating in the HGP and the French Minister for Research and Technology, Hubert Curien, said that patenting the human genome was ethically unacceptable and a "patent should not be granted for something that is part of our universal heritage".[185]

In response to the NIH application the UK Medical Research Council (MRC) reluctantly applied for patents on 1,100 sequences of human DNA it had isolated as a part of the HGP.[186] In August 1992 the US PTO issued an Office Action which raised two substantive objections against the NIH

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181 This gold rush may already have begun. It has been estimated that by 1995 50-60% of the expressed portion of the human genome will have been revealed as EST's: K Murashige "The NIH gene application's fate at the US PTO" (1993) Patent World, October, 15.

182 R S Eisenberg "Genes, Patents and Product Development" (1992) 257 Science 903.

183 Above n 5, 32.

184 M L McGregor "The NIH Patent Dispute: In Brief" (1992) 11 Biotechnology Law Report 127. James Watson discovered the double helical structure of DNA in collaboration with Francis Crick in the 1950s, for which he won a Nobel prize.

185 Letter to Science, (1991) 254 Science 1710.

186 P Aldhous "MRC follows NIH on patents" (1992) 356 Nature 98.

application.[187] First, the utility of the ESTs was said to be inadequate and vague. Secondly, some of the claimed sequences overlapped with previously published sequences. It was said that it would be obvious to a person skilled in the art to use the published sequences as probes to obtain lengths of DNA identical to those claimed. No moral or ethical objections were raised in the Office Action.

The NIH application was most vulnerable on the ground that it was obvious. The NIH had done what would be obvious to a person skilled in the art. The obviousness of the work is demonstrated by the fact that other research teams are using the same technology as the NIH to the same ends.

In February 1994 the NIH and the MRC agreed to withdraw their respective gene fragment applications. The Director of the NIH said that "I do not believe that patenting at this stage promotes technology development, and it may impede important research collaborations here and internationally".[188] Private companies are still understood to have outstanding applications for EST patents.[189]

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187 "Top HHS Lawyer Seeks to Block NIH" (1992) 258 Science, 9 October, 209.

188 "Applications for gene patents 'thrown on bonfire' " (1994) 141 New Scientist 4.

189 "NIH to Appeal Patent Decision" (1993) 259 Science 302.

C Transgenic Animals

1 Diamond v *Chakrabarty*

The decision of the US Supreme Court in *Diamond* v *Chakrabarty*[190] has had far reaching consequences for the biotechnology industry in the US.[191] In *Chakrabarty* the Supreme Court was asked to decide whether a living human-made bacterium, which was capable of degrading crude oil, was patentable subject matter. The Patent Office Board of Appeals had affirmed the patent examiners rejection of the application on the ground that living things were not patentable subject matter under section 101. This decision was reversed by the Court of Customs and Patent Appeals. The Commissioner of Patents and Trademarks appealed to the Supreme Court. The Supreme Court upheld the Court of Customs and Patent Appeals decision by a 5 to 4 majority. The Supreme Court considered that the question before them was a narrow one of statutory interpretation which required them to construe the section 101 definition of patentable subject matter. Did the bacterium under consideration constitute a "manufacture" or "composition of matter" within section 101? These phrases were to be given their ordinary meaning[192] and the Court was not to read into patent law limitations which the legislature had not expressed. By using broad language in section 101 it was clear that Congress contemplated that patent laws would be given a broad scope. The majority had no difficulty in bringing a living human-made bacterium within this

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190 477 U.S. 303 (1980).

191 The decision in *Diamond* v *Chakrabarty* led to a flood of biotechnology applications at the US PTO. In 1978 only 30 biotechnology applications were filed, compared to 11,000 in 1991: G R Peterson ed *Understanding Biotechnology Law* (Marcel Dekker Inc, New York, 1993) 8.

192 This approach is the opposite to that which has developed in Commonwealth courts to the interpretation of the words "manner of new manufacture": see for example above n 93 and 112.

broad scope, the bacterium was a "non-naturally occurring manufacture or composition of matter - a product of human ingenuity".[193]

For the Commissioner it was argued that the enactment of the 1930 Plant Protection Act and the 1970 Plant Variety Protection Act indicated that Congress did not consider living matter to be otherwise within section 101. These Acts extended patent protection to certain plants and specifically excluded bacteria. If living matter had already been patentable under section 101 it was argued that these two Acts were unnecessary. The majority rejected this argument by holding that these Acts were passed to prevent the rigid application of the "products of nature" doctrine and disclosure requirements, which would prevent the patenting of artificially bred plants, and not because living matter was regarded as being unpatentable.

A second argument presented for the Commissioner was that Congress did not have living organisms in mind when it enacted the patent laws. The Court noted that it was in the nature of the patent system that applications would be made for unforeseen inventions. This view must be correct. However, the Court went on to say that it could not address issues related to the morality of such patents (for example whether they might depreciate the value of human life). The majority declared themselves "without competence to entertain these arguments"[194] of high policy which were for the legislature to resolve. These arguments involved "the balancing of competing values and interests"[195] which was the business of elected representatives. This is a strange view for a court to take, since the life-blood of courts is the balancing of competing values and interests. By deciding that their task was a narrow one of statutory interpretation one is

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193 Above n 190, 150.

194 Above n 190, 155.

195 Above n 190, 155.

left with the feeling that the Supreme Court avoided facing up to the moral issues raised by patents on living matter.

The dissenting minority believed that the 1930 Plant Protection Act and the 1970 Plant Variety Protection Act were strong evidence that Congress did not consider living organisms to be generally patentable under section 101. Otherwise these Acts would, in their view, have been unnecessary. The majority were extending the area of patentability to include living matter even though Congress plainly believed this to be unpatentable when it enacted the 1930 and 1970 Acts. This was not the proper role of the Court in this area of unique public concern. If the minority view is correct then the majority in fact adopted the convenient approach of extending the scope of patentability to living matter while at the same time absolving themselves of any responsibility for addressing the public policy and morality issues involved. They disguised this manoeuvre by claiming to be addressing a narrow issue of statutory interpretation.

Although the Court in *Chakrabarty* said that "anything under the sun ... that is made by man" was proper subject matter for a patent,[196] the decision must be restricted by the facts of the case. *Chakrabarty* is only authority for the proposition that living single-celled bacteria are patentable in the US. The decision in *Chakrabarty* was made by the narrowest of margins. It may represent the high-water mark from which subsequent decisions will retreat.

The US PTO have acted upon the *Chakrabarty* decision by granting patents on higher organisms. Issuing such patents has become the practice of the US PTO, however, whether the courts will ultimately support this

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196 One exception from patentability was human beings, as the US Constitution prohibits slavery: Amendment XIII (1865). In New Zealand slavery is on offence under section 98 of the Crimes Act 1961.

practice remains to be seen.[197] US courts have in the past considered moral issues to be relevant in determining patentable subject matter and they could do so again.[198]

In 1985 the US PTO Board of Patent Appeals and Interferences ruled that plants, seeds and plant tissue were patentable subject matter.[199] In 1987 the same Board in *Ex parte Allen,*[200] relying on *Chakrabarty,* determined that a multicellular organism, in that case an oyster, was patentable.[201] In April 1987, shortly after the *Ex parte Allen* decision, the Commissioner of Patents and Trademarks issued a Notice stating:[202]

> The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 USC s 101

The Board of Patent Appeals and Interferences is a branch of the PTO, which is itself an administrative agency of the federal government. Therefore the decisions of the Board (such as that in *Ex parte Allen*), and the Notice issued by the Commissioner, are not binding on US courts faced with the same issue. A court decision could still reverse the position taken by the PTO on the patenting of multicellular organisms. As *Chakrabarty* was concerned with a single-celled bacterium it is not binding authority for the view that multicellular organisms are patentable

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197 R Armitage "The Emerging US Patent Law for the Protection of Biotechnology Research Results" [1989] 2 EIPR 47.

198 *Lowell* v *Lewis* 15 F.Cas. 1018 (CCD Mass 1817) (No. 8568); *Reliance Novelty Corp* v *Dworzek* 80 F. 902, 904 (ND Cal.1897).

199 *Ex parte Hibberd* 227 USPQ 443 (PTO Bd.Pat.App.& Int.1985).

200 2 USPQ 2d 1425 (PTO Bd. Pat. App. & Int. 1987).

201 Although the application in this case was rejected on the ground of obviousness.

202 US PTO Official Gazette 1077 OG 24 (1987).

The decision in *Ex parte Allen* and the Notice were adversely criticised by farm, church and animal welfare groups.[203] Groups representing farmers were concerned that large biotechnology corporations would gain control over the sales of superior patented livestock. Church groups believed that genetically engineering animals was immoral and interfered with God's work. Animal welfare groups felt that the granting of patents on genetically engineered animals was immoral because they would encourage more animal experiments and suffering.

2 *Animal Legal Defense Fund v Quigg*

In *Animal Legal Defense Fund* v *Quigg*[204] a coalition of 6 animal welfare groups, two individual farmers and a farmers organisation, challenged the legality of the PTO Notice on administrative law principles. They sought to have it declared void.

The Federal Circuit Court dismissed the case on the ground that the plaintiffs did not have standing to sue.[205] In US patent law there is no opportunity for pre-grant opposition and the Court was not prepared to create such a right by granting the plaintiffs standing. The problems the applicants faced in gaining standing are in contrast to the greater opportunities for interested parties to oppose patents under the EPC[206] and in New Zealand.[207]

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203 D Kell "The Furore over the Patenting of Animals: *Animal Legal Defense Fund v Quigg*" [1992] 8 EIPR 279.

204 710 F.Supp 728 (DC N. Calif. 1989); appeal transferred: 900 F.2d 195 (9th Cir. 1990); 932 F,2d 920 (Fed.Cir. 1991).

205 For a detailed discussion of why the plaintiffs were refused standing see above n 203, 281.

206 EPC Article 99.

207 Patents Act 1953 sections 21 and 41.

Since the plaintiffs never established standing the Court did not have to consider the question of whether the interpretation of section 101 contained in the Notice was correct. In effect the absence of pre-grant opposition procedures, and the difficulties interest groups face in obtaining standing, are further examples of how the US patent system is shutting out moral arguments. An authoritative court ruling on the patentability of multicellular animals in the US may not occur until a case arises out of an infringement action involving an animal patent, in which the defendant challenges as being unpatentable the subject matter of the plaintiffs patent.

3 Events after the Notice

In April 1988 the US PTO granted the first US patent for a higher organism, for the so-called Harvard Onco-mouse.[208] The same animal patent that was to meet such resistance in Europe.[209]

No further transgenic animal patents were issued by the US PTO for four years.[210] This delay was not due to any shortage of applications as over 100 such applications were pending. These applications were stalled while the US PTO considered the political implications.[211] In December 1992 the US PTO issued three further transgenic animal patents.[212] All three related to strains of mice.[213]

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208 Although the patent is generally described as being for a mouse US Patent No. 4736866 is directed towards any non-human mammal genetically modified in the manner disclosed.

209 See Part XII E above.

210 "US PTO breaks log jam on animal patents with three transgenic mice" Patent World, February 1993, 12.

211 Above n 32.

212 US 5175383, US 5175384 and US 5175385.

213 The mouse of US 517383 develops benign prostatic hyperplasia, the mouse of US 5175384 has a defective immune system, while the mouse of US 5175385 produces increased amounts of interferon and has higher resistance to viral infections.

Transgenic animal patents are being granted in the US apparently without the application of any kind of morality test. However, voices of opposition have raised moral arguments against such patents in Congress[214] and the courts.

D Methods of Medical Treatment

In an 1883 application the US Patent Office rejected claims to surgical instruments for the treatment of haemorrhoids, on the grounds that methods of treatment of disease were not patentable.[215] This decision was overruled in 1942.[216] In 1954 in *Ex parte Scherer,*[217] the US Patent Office Board of Appeals issued a statement that medical or surgical methods were patentable. Such methods are a "process" within section 101. According to White since the decision in *Ex parte Scherer* many such patents have been issued in the US, with no apparent ill effects or public outcry.[218] Others have noted that patents for exclusively medical treatments (ie patents for medical processes which are not conjoined with a drug or medical device) remain relatively uncommon in the US.[219] Between 1975 and 1984 at least twenty-eight patents were granted in the US for medical processes which were not related to a new drug or device.[220]

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214 A Watts "A Matter of Life and Patents" (1991) 129 New Scientist 41: Between 1988 and 1991 at least eight Bills on patenting animals were introduced into the Congress.

215 *Ex parte Brinkerhof* 24 Ms. Dec. 349 (P.O. Comm. 1883), JPOS Vol.27, p. 797 (1945).

216 *Canadian-American Pharmaceutical Co.* v *Coe* 126 F.2d 847 (1942).

217 103 USPQ 107.

218 Above n 31.

219 T J McCoy "Biomedical Process Patents: Should They be Restricted by Ethical Limitations?" (1992) 13 J Legal Medicine 501, 508.

220 G F Burch "Ethical Considerations in the Patenting of Medical Processes" (1987) 65 Texas Law Review 1139.

The US courts and the US PTO have in recent years consistently refused to consider moral or ethical issues as a part of the patent system. The US approach has involved a mechanical application of the patent statute. However, there have been dissenting voices from some members of Congress[221] and public interest groups.[222] The absence of a court ruling specifically on the patentability of higher organisms means that this issue cannot be taken as having been finally settled even in the US.

XVI EXCLUSIONS PERMITTED BY INTERNATIONAL AGREEMENTS

The General Agreement on Tariffs and Trade (GATT) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been described as a major breakthrough in the international protection of intellectual property.[223] According to GATT-TRIPS to be patentable an invention must be new, capable of industrial application, and involve an inventive step.[224] The Agreement allows, but does not require, exclusions for diagnostic and therapeutic methods (but not pharmaceuticals) for the treatment of animals or humans, animals and plants, and essentially biological processes for the production of animals and plants.

Under Article 27(2) Members may exclude from patentability "inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality." This includes protecting human, animal or plant life or health and avoiding serious

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221 "Hatfield Introduces Bill Mandating 2-Year Moratorium on Animal Patents - Human Cells, Tissues, and Fluids Also Covered" (1993) 12 Biotechnology Law Report 249: M J Lane "Patenting Life: Responses of Patent Offices in the US and Abroad" (1991) 32 Jurimetrics Journal 89.

222 Above n 34.

223 J Worthy "Intellectual Property Protection After GATT" [1994] 5 EIPR 195.

224 Article 27(1).

prejudice to the environment. Under Article 27(3) Members may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals, and plants and animals other than micro-organisms.

DNA, genes, transgenic animals and methods of medical treatment could all be denied patents in individual cases on the traditional patentability grounds included in Article 27(1). Gene and DNA patents are also potentially excluded from patentability under Article 27(2) if such patents were considered to be contrary to morality.

Signatories are allowed to exclude transgenic animals from patentability under Article 27(2) and/or 27(3)(b). Methods of medical treatment may be excluded under Article 27(2) and/or Article 27(3)(a).

The GATT TRIPS Agreement makes ample provision for the consideration of ethical and moral issues in patent law. GATT TRIPS does not require New Zealand to exclude ethical and moral considerations from its patent law.

The World Intellectual Property Organisation[225] (WIPO) produced a Draft Patent Law Treaty in 1984, with the aim of harmonising world patent law.[226] Agreement on what, if any, exclusions should be allowed under the WIPO Draft Patent Law Treaty has not yet been reached.[227]

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225 An agency of the United Nations

226 H C Wegner *Patent Harmonisation* (Sweet & Maxwell, London, 1993).

227 Above n 22, 9.

XVII EXCLUSIONS ON MORAL GROUNDS IN NEW ZEALAND

A Section 17 Patents Act 1953

Under section 17(1)(b) of the Act, inventions the use of which would be contrary to law or morality, may be refused by the Commissioner of Patents.

B Section 6 of the Statute of Monopolies

Section 6 of the Statute of Monopolies forms part of the definition of an invention in New Zealand.[228] Section 6 contains three limitations on patentability. Patents must not be: contrary to the law; mischievous to the State by raising prices of commodities at home or hurt trade; or be generally inconvenient.

C Genes and DNA

Applications to patent genes and DNA may be declined because they relate to a discovery and are therefore not an invention. DNA sequences which have been modified or created by human manipulation will not be a discovery. If naturally occurring DNA or genes have been isolated and/or purified and have a commercial use, then this may bring them within the definition of invention. DNA sequences are commonly granted patents in New Zealand. In 1990 the Assistant Commissioner of Patents set out some of the criteria for the granting of patents on DNA sequences:[229]

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228 See Part IV above.

229 K B Popplewell, Assistant Commissioner of Patents, "Protein Sequences" 13 June 1990.

> Claims to protein [and DNA] "sequences" are therefore allowable provided that a method for their production is disclosed, the claim is fairly based, and the product is defined sufficiently for a skilled addressee to be certain that he or she has the claimed product. Examples of "sequence" claims which may be allowed are: "A DNA sequence coding for (a well defined substance)"

Section 10(7) of the Act provides that claims to a new substance found in nature shall be construed as excluding that substance when found in nature. In practice the patent office require claims to explicitly exclude the substance when found in nature.[230] Moral arguments do not appear to have been raised to try to exclude patents on human genes or DNA in New Zealand.

D Transgenic Animals

The New Zealand patent office have granted patents on microorganisms since at least 1970,[231] and have now allowed patents on genetically modified plants and higher animals.[232] There has been no suggestion that the patent office have considered refusing applications on moral grounds.

E Methods of Medical Treatment

In the *Wellcome* case the New Zealand Court of Appeal confirmed that methods for the medical treatment of human beings were not patentable. The Court decided that for ethical reasons a method of medical treatment was not the proper subject of letters patent according to the principles

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230 K B Popplewell, Assistant Commissioner of Patents, "Naturally Occurring Micro-organisms" Memorandum 2 April 1991.

231 NZ Patent Office Ruling "Patentability of Micro-organisms" H. Burton, Assistant Commissioner of Patents, 6 October 1980.

232 NZ Patent Number 231502 Transgenic Mammals for the Analysis of Hair Growth (1987); NZ Patent Number 224576 Herbicide Resistant Crop Plants (1988).

which have been developed by the courts for the application of section 6 of the Statute of Monopolies.

However, there have been suggestions that the exclusion might now be based on one of the express limitations listed in section 6 of the Statute of Monopolies.[233] The Court of Appeal in the *Wellcome* case indicated that if this exclusion could no longer be based on the meaning of the words "manner of new manufacture" then it might come within the closing words of section 6 of the Statute of Monopolies. That is allowing such patents might result in "raising prices of commodities at home" or be "generally inconvenient". Also in the *Wellcome* case the Court of Appeal stressed the ethical objections to such patents. By stressing the ethical considerations the Court of Appeal has moved a long way from the decision in *C & W's Application* in which the Solicitor-General expressly excluded such concerns from his mind.

In *Wellcome* Cooke J cited with approval a passage from Kahn J, who, in discussing Israeli patent law, said that a basis for excluding medical treatment patents could be found in the Israeli equivalent to section 17(1)(b). It would seem that over the years there has been a change in the basis of the exclusion of medical treatment patents. A time might be approaching when it could be squarely based on section 17(1)(b), such patents being contrary to morality.

XVIII THE PROPOSED NEW ZEALAND REFORMS

Reform of New Zealand's patent legislation offers an opportunity to address the problems raised by biotechnology inventions with regard to moral issues. Should New Zealand follow the US ("pure patentability") or

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233 See for example *Eli Lilly & Co.'s Application*, above n 100.

the European ("morally-responsible") approach?[234] Will this opportunity be taken to address the issues at all?

A Proposed reforms to the New Zealand Patents Act.

1 Repeal of the definition of an invention

In 1992 the Ministry of Commerce produced some "proposed recommendations" on the reform of New Zealand's patent law.[235] The Ministry recommended that the current definition of an "invention" be repealed. This would remove the limitations currently imposed upon patentability by section 6 of the Statute of Monopolies. Instead of having a definition of "invention" patentability would be determined by the application of three criteria, namely: an invention would have to be new; involve an inventive step; and be industrially applicable. This course was favoured because the Ministry believed that it would represent a clear break from the overly restrictive old definition and would increase certainty with regard to what was required to obtain a patent. Also this simplification might result in lower costs for applicants,[236] and would be consistent with international obligations. The Ministry propose that there should be no specific exceptions to patentability. Methods of medical treatment would be rendered patentable.

The main reason for the proposal would seem to be to establish a more liberal patent regime in which new technologies were not excluded from patentability by the requirements of the current definition of an invention. As the Ministry put it this new approach would be:[237]

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234 Above n 32 .

235 Above n 22.

236 No empirical data was provided to support this speculative claim.

237 Above n 22, 7.

> A clear break from the present approach. Any possibility of being restricted by previous practice would be removed. This approach should also overcome recent difficulties which have arisen in respect of the extent to which new technologies are eligible for patent protection.

The cryptic reference to "recent difficulties" is perhaps a reference to the Harvard Onco-mouse patent and other biotechnology inventions. These difficulties are to be "overcome" by a more permissive patent regime. The Ministry have decided that the patent regime should be more permissive without articulating the reasons for this policy stance, except in the broadest sense. The argument would appear to be that under the current regime some new technologies will, in some instances, be unpatentable, and that therefore patent laws should be liberalised to "overcome" this "difficulty". This is rather a shallow treatment of the issues involved.

The present Act does not have a definition of what is an infringement of a patent. It is proposed that such a definition be included in any new Act. It has been suggested that this definition could contain some exclusions. For example while methods of medical treatment may be rendered patentable by the removal of the definition of an invention, the actual use in treatment of such a method would be excluded from the definition of infringement. [238]

In the *Wellcome* case Cooke J commented on the deep-seated sense that the art of the physician or the surgeon were outside the scope of patentability.[239] Somers J said that the treatment of human ailment was of a special character.[240] The Ministry of Commerce propose to "overcome" this "difficulty" by removing the definition of invention from the Act and having no specific exceptions from patentability, without apparently

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238 Above n 22.
239 Above n 112, 388.
240 Above n 112, 404.

having undertaken the wide range of inquiries on the relative social and economic merits of such a move which the Court of Appeal in *Wellcome* suggested was necessary. If methods of medical treatment are rendered patentable, then their use should be excluded from the definition of infringement. The better approach would be to specifically exclude methods of medical treatment from patentability in the first place. This would send clearer, and more certain, signals to those using methods of medical treatment.

2 Repeal of section 17

To implement the proposal that there should be no specific exceptions to patentability section 17 of the Patents Act 1953 would need to be repealed. This would assist in overcoming the difficulty that a biotechnology invention might fall foul of the "contrary to law or morality" provision contained in section 17(1)(b).

3 Impact of the proposed reforms

These proposed reforms would have little impact on current New Zealand practice in relation to DNA and transgenic animal patents. However, there would no longer be the option of declining patent applications in these areas on the grounds that their use would be contrary to law or morality. There is also room for argument that current New Zealand practice is not what it should be with regard to the morality provision in section 17(1)(b).[241]

In relation to the repeal of section 17 the Ministry noted that "inventions contrary to law or morality can be controlled by the law against which the

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241 For example the granting of the Upjohn application for a transgenic mouse to study hair growth in New Zealand when it was rejected on the grounds of morality in Europe.

invention is contrary ".[242] This view is open to challenge.

First, this statement makes no attempt to address the long standing and widespread entrenchment in intellectual property law, including patent law, of exclusions based on illegality and immorality.[243] The exclusion from patentability of inventions which are contrary law has existed continuously in England since at least 1623, and has always been a part of New Zealand law. The Patents Act 1977 (UK), the EPC and the proposed European draft Directive on Biotechnology all contain provisions relating to morality. A House of Lords Sub-Committee has recently expressed support for continuing to consider ethical considerations in patent law.[244] If New Zealand were now to change its position one would at least expect to find careful arguments in support of this change. The Ministry of Commerce have not provided any such arguments.

Secondly, as Davison CJ observed in the *Wellcome* case in the Supreme Court "[i]t would be absurd if by one law patents might be granted to reward persons for providing the means of violating any other law".[245] This argument has the ring of common sense about it. However, it might be argued that, as a matter of practicality, the patent office is not equipped to screen all applications for legality and adherence to certain ill defined moral principles. But if an invention is clearly illegal then does it make sense for the patent office to proceed with a patent application relating to it? One would intuitively think not. There is also the possibility that the only time that the illegality or immorality of an invention comes in for close official scrutiny is during the patent prosecution process. Perhaps

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242 Above n 22, 9.

243 See Parts VIII and IX above.

244 Above n 166.

245 Above n 80, 332.

this opportunity to screen out illegal or immoral inventions should not be lost.

Thirdly, the Ministry of Commerce's argument ignores the fact that there is a group of inventions which occupy the middle ground. That is inventions which are not prohibited by law but on which it is not felt to be appropriate to grant proprietary rights.[246] For example in *Masterman's Design* Aldous J did not consider the design in question to be illegal under any other Act or law, but he still considered that there might be grounds for "preventing the designer from having the proprietary right given by the Act to protect his work".[247] For example it might be considered appropriate to conduct germ-line gene therapy on humans while it would be immoral (or contrary to human dignity) to grant proprietary rights in human beings, parts of human beings or modified parts of human beings.

Also in *Masterman's Design* the hearing officer considered that it would not be proper to give the *imprimatur* of registration to a design which was likely to offend the susceptibilities of a not insubstantial number of persons, although Aldous J disagreed with this suggestion.

Thus it can be argued that the illegality exclusion fulfils a function which cannot be performed by "the law against which the invention is contrary."[248]

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246 The same principle is demonstrated by the non-protection of copyright in immoral works. See Part VII B 1 above.

247 Above n 64, 104.

248 See also Part IX above.

B The GATT (Uruguay Round) Bill

The GATT (Uruguay Round) Bill amends a number of Acts in order to give effect to New Zealand's obligations arising out of the Uruguay Round of GATT Negotiations. Clause 3 of the Bill repeals section 17 of the Patents Act 1953, and substitutes the following section:

> 17.(1) If it appears to the Commissioner in the case of any application for a patent that the use of the invention in respect of which the application is made would be contrary to morality, the Commissioner may refuse the application.
>
> (2) An appeal to the Court shall lie from any decision of the Commissioner under this section.

Thus the Ministry of Commerce's proposed recommendation to repeal section 17 is only to be partially fulfilled. The morality exclusion is to remain[249] and will provide a possible means for denying patent protection to some biotechnology inventions. If the present definition of an invention is repealed then the morality clause may provide a means by which patent protection could be denied to methods of medical treatment of human beings.

C The Patents Bill

It is expected that a further Bill reforming the Patents Act 1953 will be introduced into Parliament in the next few years, possibly during 1995. The form of this Bill is of course unknown at the present time. The Ministry of Commerce's proposed recommendations in 1992 still perhaps provide a guide to the shape of future reforms. However, the retention of a morality provision in the GATT (Uruguay Round) Bill, despite the 1992

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249 It has been suggested that this change of heart was precipitated by representations made by Te Puni Kokiri, who sought to retain this exclusion as a possible means of protecting the intellectual property rights of Maori from appropriation.

recommendation that it be removed, illustrates that we will not know the contents of the Bill until it is actually introduced into Parliament.

If the proposed recommendations are adhered to then the current definition of an invention will be repealed and will be replaced with three criteria for patentability, namely novelty, inventive step and industrial applicability. There would be no specific exceptions to patentability, including methods of medical treatment. However, the use of a method of medical treatment may be excluded from the definition of infringement.

XIX SHOULD MORAL AND ETHICAL VALUES BE A PART OF NEW ZEALAND'S PATENT LAW?

A What Moral and Ethical Values are Involved?

To talk about "morality" can sound outdated in modern society. The knee-jerk reaction is that it has no place in the law. However, with regard to morality provisions in patent laws this reaction is based on a misconception of their role. Morality provisions have a thoroughly modern role to play in patent law today. The importance of this modern role is increased as a result of the emergence of new technologies which have profound implications for our society. The Concise Oxford Dictionary defines "moral" as:[250]

> concerned with goodness or badness of human character or behaviour, or with the distinction between right and wrong ... concerned with accepted rules and standards of human behaviour ... conforming to accepted standards of general conduct.

"Morality" is defined as "the degree of conformity of an idea, practice, etc., to moral principles."[251]

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250 Above n 1.

251 Above n 1.

The use of the morality provision in the EPC in relation to the Harvard Onco-mouse illustrates the modern use of such provisions. The morality provision was used to weigh the benefits and disadvantages of a transgenic organism. The provision allowed consideration of issues such as animal suffering, risks to the environment and benefits to humans and animals.

The morality and public policy provisions of the Common Position on the draft Directive also demonstrate the modern role of "morality" by: prohibiting patents on the human body or parts of the human body as such;[252] by denying patent protection to forms of human gene therapy which are contrary to human dignity;[253] and by introducing a balancing test to determine the patentability of non-human animal gene therapy.[254] The morality test here involves balancing the suffering or physical handicaps caused to the animal against the benefits to humans and animals. These areas raise modern moral issues which need to be addressed.[255] The issue is can they, or should they, be addressed by the patent system.

B Morality in Patent Law

1 Morality provisions do not belong in patent law?

It is sometimes said that morality provisions simply do not belong as a part of patent law. They are somehow out of place in patent law, which is concerned only with the promotion of innovation. This assertion is not supported by the facts. It has been argued above that in fact morality is

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252 Article 2.3(a).

253 Article 2.3(b): arguably the concept of "human dignity" is already included by the morality provision of existing patent laws, for example s 17(1)(b) Patents Act 1953.

254 Article 2.3(c) and Recital 15.

255 The concern modern society has over new technologies is articulated in the reports discussed in Part VI above.

incorporated into our general law, and is by no means an unusual feature of intellectual property law.[256] For centuries morality provisions have been a part of patent law. Even the courts in the US, which have in recent years eschewed the use of morality arguments in patent law, once openly used such arguments.[257] The development of new technologies in the twentieth century has perhaps made the use of such morality exclusions more difficult, but it certainly has not rendered them less relevant. If anything new technologies have made the morality exclusion more necessary than ever before.

As well as explicit morality provisions the patent system intrinsically embodies certain moral and ethical values. This is reflected in section 6 of the Statute of Monopolies 1623 (UK). The section 6 limitations have allowed patent offices and courts to make value judgements on issues of social advantage before granting a patent. For example in deciding whether a patent would be "generally inconvenient" or "mischievous to the State".

2 *Morality provisions are too vague and subjective?*

Those opposed to the incorporation of moral values in patent law argue that morality is too subjective and vague a concept to include in patent laws.[258] Others believe that attempts to incorporate ideas of popular morality and ethics into patent law only cause confusion and legal uncertainty.[259] There is some truth in the comment that morality may be subjective, and can be vague until patterns and precedents are established. However, moral considerations are also important, and cannot be disregarded simply because they raises difficult issues.

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256 See Part VII above.

257 Above n 75.

258 For example see above n 32.

259 Above n 158, 188.

The problems of vagueness and subjectivity can be overcome by setting out in an enactment what shall not be patentable on moral grounds. For example, in the Common Position on the draft Directive Article 2.3(a) states that patents shall not be available on parts of the human body as such This provision is not vague and subjective, although is still requires interpreting.

However, there is more room for vagueness, subjectivity and consequent uncertainty when the patent office is given a discretion to decide whether something is immoral. This problem can be addressed by adding guidelines to an enactment which indicate which considerations can validly be taken into account when assessing morality. For example, in the Common Position Article 2.3(c) and Recital 15 set up a balancing test for assessing whether methods of non-human animal gene therapy are to be patentable.[260] Factors to be weighed include the amount of suffering caused to the animal, the objective of the invention, the benefits to humans, and the benefits to animals. Such a test does leave room for subjectivity and uncertainty to some degree, but the problem is not insurmountable. As cases are settled a clearer idea of what is, and what is not, permitted will emerge.[261]

3 Regulation is best achieved by specific laws

It is also argued that those activities upon which the morality exclusion impinges are best regulated by laws concerned directly with that activity.[262] This argument is deficient in a number of respects. First, it seems entirely appropriate to confront the moral issues raised by new technologies in the system which exists for the reason of encouraging the development of new

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260 See Part XIII B 1 and 3 above.

261 This process is already underway in Europe with the Harvard Onco-mouse and Upjohn cases: see Part XII above .

262 Above n 22.

technologies ie the patent system. Secondly, while it is not possible to protect animal welfare or human dignity solely through the operation of the patent system, that does not mean that the patent system cannot play a useful role in a wider system of regulation. For example the patent system can work in conjunction with other laws designed to discourage socially undesirable activities. Thirdly, concerns directed towards the granting of property rights in particular subject matter, parts of the human body for example, are in fact most appropriately dealt with by the system which grants such rights, ie the patent system.

The use of moral considerations in the patent system can be used to promote or discourage activities which are not contrary to any other law. For example the denial of patents on methods of medical treatment can be used to promote the unhindered use and access to such methods. A property right is denied to encourage the unhindered use of technology. In contrast, the denial of patents on forms of gene therapy considered to be contrary to human dignity, can be used to discourage such research from being pursued in the first place. A property right is denied to discourage the research, and also to make a statement about society's values. These diverse goals are naturally ones which can be pursued through the patent system since they relate to property rights.

To argue that those activities at which the morality exclusion hits are best regulated by laws concerned directly with that activity is to miss the point that the patent system has its own unique contribution to make to a broader regulatory framework.

4 What path do relevant reports suggest?

The principles enunciated by the Canadian Royal Commission on New Reproductive Technologies, "*Proceed With Care*", and the New Zealand Department of Justice Report, "*Assisted Human Reproduction,*

Navigating Our Future",[263] would appear to support the retention of ethical values in patent law. The ethic of care and the concept of human dignity suggest that human tissues should not be made a commodity through the granting of property rights over them in the form of patents. The Canadian report expressly supported the continued exclusion of methods of medical treatment from patentability.[264] The New Zealand report was of the view that there should be no commercialisation of the use of human tissue.[265] Granting patents over human tissue is a form of commercialisation, and may conflict with human dignity.

5 *The patent office is not the proper forum for morality decisions*

It is frequently said that the patent office is not the place for ethical decisions.[266] The patent office is fundamentally structured to promote technology and not to assess it.

However, morality has long been within the jurisdiction of the patent office. In answer to the suggestion that patent offices are not equipped to make moral judgements a distinction can be drawn between absolute and selective moral prohibitions. For example if all methods of medical treatment of human beings are excluded from patentability on ethical grounds, then it is easy for the patent office to apply this test. No one could complain that this involved the mere subjective opinions of patent examiners. An absolute rule like this can be set by the legislature in an enactment, or by the courts when interpreting a legislative provision.[267]

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263 See Part VI above.

264 Above n 38, 721.

265 Above n 46, 29.

266 Above n 219.

267 Examples of absolute prohibitions on moral grounds are Articles 2.3(a) and (b) of the Common Position on the draft Directive.

The problem is greater when the patent office has to exercise a discretion in each individual case. In Europe the EPO Legal Department has acknowledged that in exercising the morality exclusion under the EPC it will be necessary for individual examiners to decide the morality issue for themselves, initially at least, on the facts of each case.[268] This problem can be alleviated by the formulation of guidelines as to which considerations are relevant to the morality question. Such guidelines could be incorporated into an enactment. This approach is being followed by the European Common Position on the draft Directive with regard to Article 2.3(c).

There is no reason why the patent office should not have or develop the competence to make moral judgements in relation to patent applications, particularly if suitable guidelines are produced. The discretion should be exercised judicially on reasonable grounds which are capable of being clearly stated. A test similar to that adopted by the EPO might be considered. Another possibility is that the patent office could form a committee to screen questionable applications for compliance with a morality provision, similar to the ethics committees which screen applications to conduct medical research.

6 *The U.S. approach is to be preferred*

Bennett has suggested, in the context of the transgenic animal debate, that although the EPO position does have "emotional appeal",[269] morality is too vague and subjective a term to be a legal benchmark, and the patent office is not equipped to fulfil this function. Consequently the US approach is "the correct and practical one".

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268 Above n 11.

269 Above n 32.

The arguments as to vagueness and subjectivity have been discussed above. The suggestion that all the European approach has going for it is emotional appeal cannot be sustained. The European approach recognises that the patent system does have a role to play with regard to the morality of new technologies, and attempts to address the issue. The European approach recognises that the patent system does not exist in a vacuum, and can be used to influence the achievement of wider social goals.

B Cultural Issues and Access to and Ownership of Genetic Resources

The claims of indigenous peoples to genetic resources can perhaps be characterised as having a moral element. Governments not bound by law to respect such interests may at least have a moral obligation to do so. The use of genetic resources in biotechnology inventions may be seen as being contrary to this moral obligation.

In New Zealand the possible implications of the Treaty of Waitangi must be borne in mind. In a claim currently before the Waitangi Tribunal the claimants state that;[270]

> Crown policies on patenting and the passage of the 1987 Plant Variety Rights Act have denied Maori those proprietary interests in indigenous flora which are inherent in the exercise of te tino rangatiratanga.

The claimants seek control of indigenous flora and fauna in a manner which recognises te tino rangatiratanga o te Iwi Maori. The morality

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270 Claim Wai 262 "A claim by Haana Murray (Ngati Kuri) and Dell Wihongi (Te Rarawa) and others relating to the Protection, Control, Conservation, Management, Treatment, Propagation, Sale, Dispersal, Utilisation, and Restriction on the use of and transmission of the knowledge of New Zealand Indigenous Flora and Fauna and the genetic resource contained therein." Statement of Claim p 7.

provision in New Zealand patent law may provide a means by which patents could be denied on inventions, the use of which was considered to be contrary to the moral rights of Maori under the Treaty of Waitangi.

C Genes and DNA

On what basis can moral objections be raised against patents on human genes? Some people see no rational basis for finding ethical concerns in the issue of patenting human genes,[271] while to others they are self-evident. First, it can be argued that the ownership and commodification of human genes is contrary to human dignity. This position seems to follow from the arguments made by Atkin and Reid,[272] who state that all human tissue has mana. Secondly, it can be argued that allowing patents on human genes will slow down medical research by inhibiting the free exchange and use of research results. These two themes can be discerned in the arguments put forward by those opposed to patents on human genes.

In the UK four professional organisations representing clinical geneticists have asked for the prohibition of patents on human genes.[273] The Clinical Genetics Society, the Clinical Molecular Genetics Society, the Association of Clinical Cytogeneticists and the Genetics Nurses and Social Workers Association oppose the patenting of human genes on two grounds. The first ground is that it is morally unacceptable to patent an entity found in a natural state in the human body. The second ground relates to the free exchange of research results. It is claimed that the ability to patent human genes has already made researchers reluctant to release research results and share information until the patent is secure. The concern is that this

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271 Above n 181.

272 Above n 46.

273 D Dickson "UK clinical geneticists ask for ban on the patenting of human genes" (1993) 366 Nature 391.

reluctance to share information will slow down the progress of research into the causes and treatment of human genetic diseases.[274]

Charities that are major supporters of medical research in the UK are also campaigning against the patenting of human genes. The Genetic Interest Group (GIG) in the UK represents nearly 100 voluntary groups involved with genetic disorders. The GIG have moral and ethical objections to patents being granted over genes because genes are a basic part of the human body. The GIG are concerned that such patents will slow down genetic research, and are not in the best interests of those suffering from genetic conditions.

There has been talk of an international agreement not to patent human genes.[275] Britain's MRC suggested the possibility during the dispute with the NIH over EST patents.[276] However, no such agreement appears close.

In France the Minister for Research, Hubert Curien, has described patents on the human genome as "ethically unacceptable".[277] Three Bills concerned with bioethics have been discussed in the French Senate. The first of these Bills is aimed at protecting "human dignity and the human race".[278] It proposes a ban on patenting parts of the human body, including the human genome. The Bill proposes banning germ-line gene therapy, but not somatic cell gene therapy.

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274 For example researchers at the Children's Hospital in Toronto were the first to identify the main genetic mutation for cystic fibrosis. They have demanded royalty agreements from British researchers developing cystic fibrosis screening kits.

275 Above n 273.

276 Above n 186.

277 Above n 186.

278 D Butler "How France plans to legislate for bioethics" (1994) 367 Nature 209.

D Transgenic Animals

Why might transgenic animal patents be objected to on moral grounds? And can these objections be appropriately addressed by the patent system, or should they really be addressed by other forms of regulation?

The Guidelines to the EPC state that a fair test to apply to determine whether an invention is contrary to morality is to consider "whether it is probable that the general public would regard the invention as so abhorrent that the grant of patent rights would be inconceivable". This formulation suggests that if an invention is considered to be sufficiently abhorrent it is immoral, and a patent will not be granted. However, in practice the EPO apply a balancing test, in which whether an invention is immoral or not is measured by weighing up the positive and negative aspects of the invention. Morality is thus a utilitarian concept based on the overall good. If one accepts that a balancing test is to be used then what criteria are to be considered as tending towards immorality?

The abhorrence of the general public is apparently the touchstone of morality for the EPO. The EPO consider animal suffering and the risk to the environment to be relevant. Public abhorrence could also include concern about destroying "species integrity", the creation of animal/human hybrids and a devaluation of life.

It has been argued that patents should not be granted on living organisms since this is not what patent law was designed to cover.[279] Most patent laws were written before the advent of modern biotechnology and did not have such technology in mind. This view is supported by the type of language used in the definition of an invention in the Patents Act 1953.

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[279] B Belcher, G Hawtin *A Patent on Life Ownership of Plant and Animal Research* (IDRC, Ottawa, 1991), 17.

Describing a mouse as a "manufacture" does not seem to be quite correct. The system was designed for the mouse trap and not the mouse. However, the courts have rejected arguments of this nature.[280] It is inherent in the concept of a patent system for inventions that the nature of future inventions will not be known at the present time.

Multinational corporations with a stake in biotechnology, working through the International Chamber of Commerce, have sought widespread recognition of the patentability of living matter.[281] They claim that the UPOV Convention provides inadequate protection. Reports by WIPO have supported this view.[282]

Malcolm Eames, Head of Information and Research, for the British Union for the Abolition of Vivisection (BUAV) says that "[a]nimal patents will provide a massive financial incentive to find new ways of exploiting animals. This will inevitably lead to more animal experiments and increasingly unnatural and inhumane treatment of farm animals".[283]

Possible environmental and health implications of releasing genetically modified organisms into the environment are difficult to predict and should also be considered.[284] The BUAV is concerned about the

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280 For example the United States Supreme Court rejected arguments of this nature in *Diamond* v *Chakrabarty* above n 190.

281 United Nations Environment Programme, *ad hoc* Working Group of Experts on Biological Diversity "Relationship Between Intellectual Property Rights and Access to Genetic Resources and Biotechnology" UNEP/Bio.Div.3/Inf.4, 18 June 1990.

282 Above n 282, 6.

283 "Three Nice Mice: PTP Issues More Animal Patents" (1993) 2(1) Biotechnology Law Report, 4,6.

284 United Nations Environment Programme "Biotechnology: Concepts and Issues for Consideration in Preparation of a Framework Legal Instrument for the Conservation of Biological Diversity" UNEP/Bio.Div.3/7, 23 May 1990.

possibility of an escaped transgenic animal interbreeding with wild animals and spreading a gene with unwanted effects, causing cancer for example. The accidental escape of genetically engineered organisms has already occurred in New Zealand[285] and the US.[286] This is perhaps an argument against genetic engineering *per se*, rather than against patents on the products of biotechnology. Biotechnology has been invented and it cannot now be uninvented. The refusal to grant patents on life forms would not stop the use of biotechnology.

It has also been argued that the creation of transgenic organisms is an unacceptable interference with species integrity.[287] This interference is wrong and species should not be crossed. Species have a right to have their genetic composition left alone. Animal patents are simply the latest invasion of animals inherent rights.[288] Religious arguments suggest that people should not tamper with God's creations. Swapping genes about between species is morally offensive.

E Methods of Treatment

Arguments concerning the patentability of methods of medical treatment can be pitched at a number of levels. It is possible to argue that some forms of medical treatment (some types of gene therapy for example) are contrary to human dignity and should be excluded from patent protection for that reason. Such procedures should not be patentable at all. Because the method itself is considered to be undesirable for some reason it is denied patent protection.

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285 Y Cripps "Genetic Engineering - A Problem for the Patent Office?" [1979] NZLJ 232 .

286 Above n 35.

287 Above n 75.

288 For a discussion of the growing recognition of animal rights see: S L Goodkin "The Evolution of Animal Rights" (1987) 18:2 Columbia Human Rights Law Review 261.

On another level, most methods of medical treatment are considered to be acceptable, and the question is should they also be patentable. Separate ethical arguments can be raised as to why these method should not be patented.

1 Arguments for the exclusion of methods of treatment considered to be contrary to human dignity

The emergence of gene therapy strengthens the argument for the exclusion of some methods of medical treatment from patentability because it introduces an area of medical treatment with immense potential for abuse, and the undermining of human values. France has included germ-line gene therapy as a procedure prohibited in a Bill directed at protecting "human dignity and the human race". In Europe the draft Directive on Biotechnology looks likely to include an Article prohibiting patents on gene therapy inventions the use of which would be contrary to human dignity. A European patent application has already been filed for a method of human germ-line gene therapy.[289] The Director of the EPO in Munich, Christian Gugerell, has described this application as the first of its kind in Europe and possibly the world. Gugerell is reported as having said that the EPO would have to decide whether this patent was ethical and that his first reaction was that "it would be highly doubtful whether something like this could be patented".

While the patent system alone cannot be expected to regulate the area of gene therapy it can play a role. It can deny the incentives provided by patents where the method is considered to be undesirable, or where the granting of property rights in the method is considered to be contrary to human dignity. Denial of patent protection would seem to be entirely appropriate in some circumstances. If a method was particularly abhorrent

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289 Above n 18.

then one would expect to find it prohibited by specific laws. However, this does not mean that the patent system does not have a role to play in the overall system of regulation.

2 *Arguments for the exclusion of otherwise acceptable methods of treatment from patentability*

There are ethical arguments against granting patents on methods of medical treatment, where the method itself is not regarded to be objectionable in anyway.[290] Granting patents for methods of treatment allows the monopolisation of the treatment method at the expense of patients. When a drug or medical device is patented there will usually be an adequate alternative drug or device which can be substituted for the patented item. However, in the case of a method of treatment it is more likely that there will be no alternative, and the method will be completely unavailable to some patients. Probably those who cannot afford it. Under most health systems all patients do not have access to all new technologies. However, this does not make it desirable to introduce new barriers to access unless the benefits of allowing method of treatment patents are clear.

Relatively few pure [291] method of treatment patents have been granted in the US. Those which have been granted have mostly been for non-routine procedures, and not for basic medical procedures. The full scope of the potential problems created by method of treatment patents may not yet have been realised in the US. The problems would be more pronounced should patents be obtained over basic general medical procedures.

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290 Above n 283.

291 By "pure" is meant processes unrelated to a new drug or medical device.

Granting patents on methods of treatment could lead to physicians having a conflict of interests. This conflict could be manifested in the manner and timing of the disclosure of research results. Results may not be released until patent rights are secure. Also the prospect of financial reward from licensing a patented method may be reflected by a bias in the reporting of research results. The better the method sounds the more physicians will want to obtain a licence to use it, and the greater the rewards for the inventor. Also, if a doctor has paid a licence fee to use a method they may want to use it as frequently as possible to maximise their return on the licence fee. Although other mechanisms function to regulate the medical profession, these are still unwelcome influences.

Also such patents may interfere with the physicians autonomy and the confidentiality of the physician-patient relationship. Physicians will not be able to use patented methods unless they obtain a licence. The patentee will have to pry into physician-patient relationships to detect possible infringers.

Patents for methods of treatment in relation to reproduction raise constitutional issues in the US. The constitutional protection afforded to the privacy surrounding reproduction would make the monitoring of possible infringement difficult. Such patents may also raise privacy issues in New Zealand.

3 Cost Benefit Analysis

The courts have said that the width of analysis required to determine whether patents on methods of medical treatment should be allowed was more than they could accomplish, and was a job for Parliament with its greater resources.[292]

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[292] Above n 112, 391.

No empirical study appears to have been done on the benefits of method of medical treatment patents. In theory such patents should act as an incentive to the development of new methods of treatment. As a result of the patent incentive new medical advances would be made, which would not otherwise have been made. However, methods of treatment that would have been developed anyway, without the patent incentive, would also be rendered patentable. This is an extra cost which must be outweighed, in addition to the ethical costs related to the physician-patient relationship, before society achieves a net gain from allowing method of treatment patents. Physician autonomy and physician-patient confidentiality are not absolute values, rather they are a means to achieve high quality health care. If the benefits of patents on methods of treatment were sufficient then the ethical concerns could be outweighed.

However, the alleged benefits of allowing method of treatment patents are only theoretical. New Zealand and the UK have always excluded methods of treatment from patentability. Significant medical advances have continued to be made in these countries in the absence of such patents. While such methods have long been patentable in the US, it is not suggested that more advanced methods of treatment have emerged in the US because of the patentability issue.[293]

In the absence of any empirical evidence that method of treatment patents offer society a net gain, it is argued here that such patents should not be permitted in New Zealand. The advantages of such patents are only theoretical, and even then it is not clear that they outweigh the costs.

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293 A possible exception to this is the Surrogate Embryo Transfer (SET) technique which was developed in the US with private funds and has been patented: see above n 220.

4 Mandatory Universal Licensing as a Solution to Ethical Problems

Compulsory licensing is one way in which the potential problems posed by method of treatment patents could be restricted. [294] If a physician knew that the licence application procedure was simple, relatively cheap and that a licence would not be refused, then many of the ethical problems posed by such patents could be ameliorated. However, this may reduce the costs of allowing such patents it does not remove them.

5 The New Zealand position

After the *Wellcome* case on what was the New Zealand exclusion of methods of medical treatment based? It could be based on such methods not coming within the words "manner of new manufacture" or on the limitations contained within section 6 of the Statute of Monopolies. The Court of Appeal based considerable weight on ethical considerations concerning the art of the physician. Arguably, if the definition of an invention were removed from the Patents Act, then methods of medical treatment could still be excluded under the morality provision retained in the proposed new section 17 of the Patents Act 1953 to be enacted by the GATT (Uruguay Round) Bill.

6 Compromise positions

If the decision were made to allow method of treatment patents then there are many intermediate positions in between New Zealand's current position and a blanket allowance of such patents. For example: the definition of infringement could exclude the use of a method of treatment; the duration of patent protection could be reduced for such methods; the

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[294] Above n 220.

experimental use defence could be enlarged to give other researchers greater freedom of action to use the patented method; Swiss-type and/or use-bound substance claims could be allowed instead of allowing patents on methods of medical treatment; a regime of compulsory universal licensing with pricing limitations could be introduced for methods of treatment patents; and there could be specific requirements as to the working of the method in New Zealand. It is argued here that the benefits of allowing method of treatment patents are not sufficiently certain to justify changing their present exclusion. However, if the position must be changed then a compromise position should be considered to limit the costs to society of allowing such patents.

XX CONCLUSIONS

A Moral Arguments Do Have a Legitimate Role in Patent Laws

Moral and ethical arguments do have a legitimate role to play in modern patent laws. They can be used to achieve a number of diverse goals. The patent system does not exist in a vacuum and cannot be allowed to ignore moral values. The approach of the European Union is to be preferred over that of the US. The European approach may be more challenging (some might say less practicable) than the US approach, but developments in Europe suggest that it can be workable, and it does refuse to allow the encouragement of innovation to become an end in itself. It refuses to allow the patent system to exist in a moral vacuum, and refuses to allow human values to be swamped by new technology.

B The Function of Moral Arguments

Moral arguments can be used to achieve different objectives within the patent system. For example they can be used to promote features of society which are considered to be of value, such as physician autonomy,

or to deny an incentive to innovation in areas considered to be undesirable, such as those which result in animal suffering. Patent laws cannot achieve these goals alone, but they can make a useful contribution to a wider regulatory framework.

In areas where the moral concern is directed towards the existence of property rights in particular subject matter, then the patent system has a major role to play. For example if it is considered to be contrary to human dignity to grant property rights in the human body, then this objective can partially be achieved through the patent system.

C Moral Arguments and Methods of Medical Treatment

The exclusion of methods of medical treatment from patentability has a long history. The basis of this exclusion is largely ethical. Many countries, including New Zealand, maintain this exclusion today.

The New Zealand Court of Appeal in the *Wellcome* case resisted the temptation to allow patents on methods of medical treatment, preferring to leave such a change to Parliament. Before the law is changed to allow patents on methods of medical treatment some clear evidence, or at least some strong arguments, must be produced to show that the benefits of the change outweigh the costs. Neither the evidence or the arguments have yet been produced by the Ministry of Commerce to justify the change. The advent of gene therapy has added a new dimension to the debate, and tends to support the exclusion of at least some methods of medical treatment from patentability.

The exclusion of gene therapy could be based on the same grounds as other methods of medical treatment. Arguably, it could also be based on a general morality provision or on a provision relating to the dignity of the human race.

If methods of medical treatment are to be patentable then a system of mandatory universal licensing should be considered to help overcome some of the ethical problems that such patents create. Alternatively, the use of a method of medical treatment should be excluded from the definition of infringement in any new Patents Act.

D Transgenic Animals

The patent system cannot play the primary role in the protection of animal welfare. However, it can play a useful role as a part of the wider regulatory system. A morality clause also allows other factors to be taken into account during the patent prosecution process, environmental issues for example.

Transgenic animals which incorporate human genetic material raise issues that other transgenic animals do not. These animal/human hybrids raise issues which have been categorised as relating to human dignity, and the commercialisation and commodification of human tissue. Ultimately, they also raise issues related to slavery. These are all valid concerns and there is no reason why these concerns should not be allowed to influence the patent system.

It is appropriate that the morality provision is to be retained by the GATT (Uruguay Round) Bill. The current process of reform of the Patents Act 1953 should be used to incorporate a provision which requires the patent office to exercise its discretion to decline transgenic animal patent applications if they fail the morality test. The adoption of a test of morality for transgenic animals similar to that contained in the EPC Guidelines should be considered.[295]

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[295] See Part XII B above.

E Human DNA and Genes

Patents should not be permitted on human DNA and genes when found in the human body. This appears to be the present position in New Zealand.[296] Patents on human genes may also be denied following the application of the standard criteria for patentability, that is novelty, industrial applicability and inventive step.

On one view, human DNA isolated from the body is simply a chemical molecule. Once the sequence has been isolated from the human body it will usually be synthesised artificially. It clearly has particular human significance, but this alone does not seem to be sufficient to deny patent protection. Allowing such patents does provide an incentive to biotechnology and drug companies to identify, isolate and purify useful genes and DNA sequence, and develop these potentially valuable products for the market. The cost of this procedure can be high, and society will benefit from the new medicines which may be produced. The downside ethical costs of allowing such patents are not as clear as they are with transgenic animal and method of treatment patents. Allowing such patents on isolated human DNA or genes may not violate the ethic of care and human dignity principles. An artificially synthesised DNA molecule is not a part of the human body, it is merely another chemical molecule and its commercialisation is not contrary to human dignity.

Isolated human DNA or genes will usually be inserted into some other organism (ranging from a bacterium to a cow) in order to be expressed. That expression system may be a transgenic animal which should be subject to a morality test before it is patentable.

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296 Above n 230.

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