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INVENTION OR INTERVENTION? THE PATENTABILITY OF TRANSGENIC LIFE FORMS

by

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1. CHAPTER 1: AN INTRODUCTION TO TRANSGENIC LIFE FORMS.

1.1 INTRODUCTION

“There are only two ways we know of to make extremely complicated things. One is by engineering, and the other is evolution”

Danny Hillis¹

Innovation, exploration and invention have always been of fundamental importance to human society and have resulted in the development of a technologically extensive industry. This in turn has resulted in the requirements of recognition and proprietorship that characterise the intellectual property regime. In addition to proprietorship, intellectual property systems seek to provide a balance between private rights and public welfare.

Essentially, intellectual property regimes are characterised by the incentive to innovate whilst still ensuring that the public benefit from the developments thereof. Novel fields of technology are carving niches for themselves within the realm of intellectual property law and transgenic manipulation is no exception.

Transgenic manipulation denotes the “creation” of a life form as a consequence of genetic intervention in order to exhibit characteristics desired for research or experimentation. This poses the question as to whether a transgenic life form can qualify for patent protection.

Arguably, the landmark decision on the patenting of transgenic life forms is the US case of *Diamond vs Chakrabarty*² wherein the subject of the patent was a bacterium that was genetically modified to degrade crude oil. The US Supreme

¹ American inventor, entrepreneur and author cited in Kevin Kelly “Out of Control The New Biology of Machines, Social Systems, and the Economic World” (2004) 251.

² 447 US 303 1980

Court held that a live, human-made organism is patentable subject matter. The case gave rise to an iconic question of whether transgenic life forms should be patentable?

This dissertation assesses the methods of production of transgenic life forms by DNA micro injection, retro-virus mediated gene transfer and embryonic stem cell-mediated gene transfer. It further pronounces upon the requirements for patentability in terms of the Patents Act 57 of 1978 (hereinafter referred to as the "Patents Act") and its exclusions taking into account applicable international legislation and case law as an interpretational tool in determining whether transgenic life forms are patentable in South Africa.

1.2 TRANSGENIC LIFE FORMS

Transgenic manipulation raises a number of issues relating to the scope and protection of intellectual property rights under patent law. Life forms that are transgenically manipulated or engineered are composed of multiple constructs that are artificially simulated and synthesised into a single organism.³ These organisms do not occur naturally and are as a consequence of genetic intervention.

Transgenic organisms are developed for a variety of reasons which include enhanced food production, medical research, toxicology, biotechnology, molecular biology, the production of proteins and organs and environmental welfare⁴. The utilization of this technology can result in methods of cultivation that are less polluting and more economical and is further important to

³ Saukshmya and Chugh "Commercialising Synthetic Biology: Socio-ethical Concerns and Challenges under Intellectual Property Regime" 2010 Journal of Commercial Biotechnology 135 – 158.

⁴ Buy M (1997) Transgenic Animals. <http://www.acs.ucalgary.ca/~browder/transgenic.html> (accessed 15 August 2015)

developing countries in the combating of epidemic and endemic diseases and in limiting world hunger.⁵

A transgenic life form is found where deoxyribonucleic acid (hereinafter referred to as “DNA”) from other species has been artificially introduced into its genome.^{6 7}

A definition of the term transgenic in the Oxford Dictionary⁸ reads:

“relating to or denoting an organism that contains genetic material into which DNA from an unrelated source has been artificially introduced”.

All living cells contain a nucleus. The most important function of the nucleus is that it stores the genetic information of the cell in the form of DNA. DNA is made up of two strands or chains. Each strand or chain consists of “building blocks” called nucleotides. Genes are specific sequences of nucleotides.⁹

Genes control all aspects of the life of an organism and store information on how it forms and functions. This process is known as gene expression.¹⁰ Technological advancements have allowed society to artificially manipulate these genes in order to bring about or inhibit certain characteristics of the said organism. Organisms that are manipulated in this way are known as transgenic.¹¹

⁵ Directive 98/44EC of 6 July 1998 paragraphs 10 -11.

⁶ WIPO Magazine “Bioethics and Patent Law: The Case of the Oncomouse” Issue 3/2006.

⁷ A genome is the complete set of genetic information in an organism and provides all such information that the organism requires to function. By manipulating the genome, certain characteristics can be expressed or inhibited.

⁸ Oxford University Press, 2015. Oxford Dictionaries (Online).

⁹ Russel PJ (2006) 2-3.

¹⁰ Russel PJ (2006) 4.

¹¹ Margawarti ET (2003) Transgenic Animals: Their Benefits to Human Welfare.

<http://www.actionbioscience.org/biotechnology/margawati.html> (accessed 30 August 2015).

Essentially, and rather simplistically expressed, genes are taken from one organism and then inserted into the genetic code of another organism (called the “host”). The inserted genes are known as “transgenes”. The transgenes are responsible for the expression of a protein that can bring about an intended change that then passes to the next generation when the host organism reproduces¹².

1.3 METHODS OF PRODUCTION OF TRANSGENIC LIFE FORMS.

There are essentially three basic methods for the production of transgenic life forms as subsequently discussed¹³.

1.3.1 DNA MICROINJECTION

This method involves the direct microinjection of a chosen gene construct (either a single gene or a combination of genes) from another member of the same species or a member of a different species into the nucleus of a fertilised egg.¹⁴ The chosen gene construct is then recombined. Essentially this means that copies are made of the gene construct. These copies are made by inserting a DNA fragment into a molecule capable of replication or a “cloning vector”. The resultant recombinant gene construct is then introduced into a host cell (the fertilised egg)¹⁵. The introduction of the recombinant gene construct into the fertilised egg is done *in vitro* and a specific embryonic phase is developed before implantation into the recipient or host female.¹⁶ The chosen gene construct then has a high probability of expressing itself in the offspring of the recipient or host female.

¹² Merges “Intellectual Property in Higher Life Forms: the Patent System and Controversial Technologies” 1988 Maryland Law Review 1051.

¹³ Buy M (1997) Transgenic Animals. <http://www.acs.ucalgary.ca/~browder/transgenic.html> (accessed 15 August 2015).

¹⁴ *Ibid.*

¹⁵ Russel PJ (2006) 175.

¹⁶ Margawarti ET (2003) Transgenic Animals: Their Benefits to Human Welfare <http://www.actionbioscience.org/biotechnology/margawati.html> (accessed 30 August 2015).

1.3.2 RETRO-VIRUS MEDIATED GENE TRANSFER

Not all organisms contain their genetic material in DNA. A retrovirus is a virus that carries its genetic material in the form of ribonucleic acid (hereinafter referred to as “RNA”)¹⁷. RNA is single stranded as opposed to the two stranded or chained DNA. Retroviruses however, rather ingeniously, replicate via DNA.

When a retrovirus infects a cell its RNA is released into that cell (the host cell). By the action of viral reverse transcriptase enzyme a DNA copy of the viral RNA genome is made. This “new” genetic material is referred to as proviral DNA. The proviral DNA is then integrated into the host DNA and commissions the host cell to now express viral genes, essentially using the host cell as a transcriptional “factory” to manufacture essential viral structural proteins¹⁸.

1.3.3 EMBRYONIC STEM CELL-MEDIATED GENE TRANSFER

Stem cells are defined in the oxford dictionary as follows:

“An undifferentiated cell of a multicellular organism which is capable of giving rise to indefinitely more cells of the same type, and from which certain other kind of cell arise from differentiation”.¹⁹

Stem cells are capable of self-renewal.²⁰ They thus have the potential to differentiate into any type of cell and can give rise to a complete organism.²¹

¹⁷ Margawarti ET (2003) Transgenic Animals: Their Benefits to Human Welfare
<http://www.actionbioscience.org/biotechnology/margawati.html> (accessed 30 August 2015).

¹⁸ Russel PJ (2006) 605.

¹⁹ Oxford University Press, 2015. Oxford Dictionaries (Online).

²⁰ Russel PJ (2006) 607.

²¹ Buy M (1997) Transgenic Animals. <http://www.acs.ucalgary.ca/~browder/transgenic.html> (accessed 15 August 2015).

In this method, a desired DNA sequence is inserted into an *in vitro* culture of embryonic stem cells.²² Homologous genes are descendant from a common ancestor and thus have similar nucleotide sequences. Essentially they “code” for the same structure or function in any given species. Examples would be the genes that code for height or an eye colour. The genes are related in an evolutionary sense and share similar functions.²³

When recombined, a genetic exchange takes place between DNA sequences²⁴. This allows for the precise replacement of a gene by another. Cells in which homologous recombination occur must be selected and further used to generate a living embryo.²⁵ The cells can also be selected and transferred into an existing embryo.²⁶ Active genes may thus be replaced by their inactive counterparts which will result in the inactivation of a targeted gene (known as “gene knockout”).²⁷ Similarly targeted genes can be replaced by active genes which will result in the activation of that targeted gene (known as “gene knockin”).

1.4 CONCLUSION

In summary, the methods of production of transgenic life forms are the following:

- a) DNA Microinjection – a sequence of genes is injected into a host cell and incorporated into its DNA so that it may be expressed by the host cell. Theoretically, if one wanted to produce a transgenic sheep with red wool, then a sequence of genes which would code for red pigment from

²² Buy M (1997) Transgenic Animals. <http://www.acs.ucalgary.ca/~browder/transgenic.html> (accessed 15 August 2015).

²³ Russel PJ (2006) 258.

²⁴ Alberts B *et al* (2002) 845.

²⁵ L Houbedine, “The Methods to Generate Transgenic Animals and to Control Transgene Expression” *Journal of Biotechnology* 98 (2002) 145 – 160.

²⁶ Buy M (1997) Transgenic Animals. <http://www.acs.ucalgary.ca/~browder/transgenic.html> (accessed 15 August 2015).

²⁷ *Ibid.*

another animal (eg a red lobster) would be injected into the nucleus of a fertilized sheep egg, creating a high probability that that egg would result in offspring with red wool.

- b) Retro-Virus Mediated Gene-Transfer – a retrovirus is used to hijack the host cell and passes its genetic material to the host cell causing the host cell to express the characteristics of the viral genetic material. In keeping with the example of a sheep with red wool advanced above, a retrovirus which contains a gene which codes for red pigment is used to infect the host. Its genetic material (including the gene which codes for red pigment) would be incorporated into the host's genetic material and ultimately expressed in its offspring.

- c) Embryonic Stem-Cell Mediated Gene Transfer: A specific genetic sequence is introduced into embryonic stem cells. This gene sequence codes for the same characteristic to that which is in the embryonic stem cells and during cell replication may be incorporated into the offspring. In keeping with the example of a sheep with red wool, the specific genetic sequence that codes for red pigment would be introduced into embryonic stem cells and when these cells replicate, may result in offspring with red wool.

2. CHAPTER 2: TRANSGENIC LIFE FORMS IN RELATION TO SOUTH AFRICAN PATENT LAW AND THE ONCOMOUSE DECISION UNDER THE EUROPEAN PATENT CONVENTION

The basic principle of the patent system is premised upon the benefits that technological progress brings about for mankind which is promoted by the granting of a temporary monopoly to an inventor or such person's appointee where after it passes into the public domain for its general utilization²⁸. This allows the freedom to innovate whilst still insuring that the public at large benefits from an invention. This temporary monopoly is called a patent. An invention is the subject matter of the patent.²⁹ The right conferred by a patent is a negative right. This negative right does not entitle the patent holder to use the invention but rather acts as a preventative measure to others from using it.

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The provisions of the Patents Act govern South African patent law. The Patents Act is modelled on various international agreements. These agreements include the Paris Convention³¹, The European Patent Convention (EPC)³², the Patent Co-operation Treaty³³ and The Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS").³⁴

Although the Patents Act is modelled on certain international agreements, its manner of formulation follows the approach of the 1977 British Patents Act, which in turn was formulated on the EPC.³⁵ The comparative formulation of both Acts enables South Africa to turn to UK and European legislation and precedents as rich interpretational sources.

²⁸ Burrell TD (2016) 1.

²⁹ Harms LTC (2012) 244

³⁰ *Op cit*, 247

³¹ Paris Convention for the Protection of Industrial Property, 20 March 1883 (as amended).

³² Convention on the Grant of European Patents, 5 October 1973 (as revised).

³³ Patent Cooperation Treaty 19 June 1970 (as amended).

³⁴ 1869 UNTS 299; 33 ILM 1197 (1994).

³⁵ Klopper *et al* (2011) 268 - 269

The European Patent Office was established in terms of the European Patent Convention. The European Patent Office serves as an examining body for European Patents through its administrative organs, which include the Technical Board of Appeal and Enlarged Board of Appeal. The European Patent Office further possesses a comprehensive set of rules and guidelines called Guidelines for Examination in the European Patent Office (hereinafter called “the Guidelines”) that assist in the interpretation of the European Patent Convention.

Decisions of the European Patent Office do not have a direct impact on South African Patent law but they do influence the judicial interpretation of the requirements of patentability in English law, which in turn is relied upon for guidance from the South African judiciary. They also serve as useful interpretational tools in relation to matters that have not yet reached South African courts.³⁶

Similarly, the 1977 British Patents Act (hereinafter referred to as the British Patents Act) and the Intellectual Property Office’s Manual of Patent Practice³⁷ lend insight into UK interpretation and precedents. Section 76A(1)³⁸ of the British Patents Act and Schedule A2 thereof was introduced to cater for biotechnological inventions. Especially relevant for this dissertation are the Examination Guidelines relating to Biotechnological Inventions in the Intellectual Property Office³⁹ (“British Biotechnological Guidelines”).

In order for an invention to be patentable, it must contain patentable subject matter.⁴⁰ Art 27(1) of TRIPS sets out that an invention consists of a product or a process. A product can be circuitry or a system, equipment or a chemical

³⁶ Klopper et al (2011) 269.

³⁷ 1 July 2014 (as updated).

³⁸ Introduced by the Patent Regulations 2000 (SI 2000 No. 2037).

³⁹ The Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office 2016.

⁴⁰ Buy M (1997) Transgenic Animals. <http://www.acs.ucalgary.ca/~browder/transgenic.html> (accessed 15 August 2015).

product. A process comprises of a series of steps that do not necessarily result in a product⁴¹.

Section 2 of the Patents Act defines an invention as “*an invention for which a patent may be granted under section 25*”. Section 25(1) of the Patents Act specifies the requirements for a patentable invention. The section is drafted in the negative. It does not say what a patentable invention is. Rather it sets out what does *not* fall within its ambit (the intrinsic requirements) and further sets out the validity requirements for a patentable invention (the extrinsic requirements).

The intrinsic and extrinsic characteristics of an invention determine whether it is patentable. The intrinsic requirements determine the eligible subject matter of the invention whereas the extrinsic requirements deal with the legal standards that need to be met concerning the implementation of the invention.⁴²

Intrinsically, an invention shall not be anything that consists of ⁴³:

- I. A discovery;
- II. a scientific theory;
- III. a mathematical method;
- IV. a literary, dramatic, musical or artistic work or any other aesthetic creation;
- V. a scheme, rule or method for performing a mental act, playing a game or doing business;
- VI. a program for a computer;
- VII. the presentation of information.
- VIII. 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 process, or

⁴¹ Klopper *et al* (2011) 271.

⁴² Burrell TD (2016) 27

⁴³ Section 25(2) of the Patents Act.

- IX. A method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body.

Extrinsically, an invention should be⁴⁴:

- I. New or novel;
- II. involve an inventive step; and
- III. be capable of being applied in trade, industry or agriculture; and
- IV. in addition to the above, an invention not be the kind of publication that will be generally expected to encourage offensive or immoral behaviour⁴⁵. This is really an exclusion in the sense of “it must not be” and thus an extrinsic exclusion.

The exclusions under VIII and IX above in being “*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 process*” and “*a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body*” seem to represent inherently patentable subject matter. They are most likely deemed to be unimplementable on the grounds of public policy or ethical reasons and thus falling under the extrinsic requirement of industrial applicability rather than the separate bars to patentability.⁴⁶

The landmark decision on the patenting of a higher order transgenic life form is Harvard’s “*Oncomouse* invention”. Researchers at Harvard’s Medical School in the early 1980’s produced a genetically modified mouse with a heightened genetic susceptibility to cancer by introducing an activated oncogene sequence into the embryo by no later than the eight-cell stage.

Harvard College sought patent protection in the US and various other countries. The United States Patent Office granted Harvard College a patent

⁴⁴ Sections 25(1) and (4) of the Patents Act.

⁴⁵ The “morality clause” embodied in section 25(4)(a) of the Patents Act.

⁴⁶ Klopper *et al* (2011) 290 – 291.

over the process of preparing the affected mice as well as the product of the process (ie: the resultant “*Oncomice*”).⁴⁷ Harvard sought patent protection in the US and various other countries.

The European Patent Office considered the application at length and at various levels of appeal until the patent (in amended form) was eventually granted. The Examining Division held that the intention of the legislator had been to exclude animals in general from patentability and further held that there was not sufficient disclosure to satisfy Art 83 of the European Patent Convention in that it could not be carried out by a person skilled in the art⁴⁸.

This was rejected by the Technical Board of Appeal which remitted the case back to the Examining Division for further examination and consideration⁴⁹.

Further proceedings in the Examination Division lead to the granting of the patent on the 13th of May 1992. Seventeen oppositions were filed against the patent between the period of the 18th of December 1992 and the 13th of February 1993. The oppositions included:

- I. Lack of industrial applicability;
- II. Lack of novelty;
- III. Lack of an inventive step;
- IV. The absence of an invention;
- V. A non patentable method for treatment of an animal body;
- VI. The exploitation of the invention would violate the morality clause contained in Art 53 (a) of the European Patent Convention;
- VII. The patent was for an animal variety; and
- VIII. Insufficient disclosure.

⁴⁷ Patent no. 4 736 866.

⁴⁸ *Board of Appeal of the European patent Office, Decision of 6 July 2004, T 315/03 paragraphs III – IV.*

⁴⁹ *T 19/90 OJ EPO 1990 476.*

The opposition proceedings continued until January 2003 and culminated in the Opposition Division rejecting all oppositions raised, save for the opposition in relation to Article 53 (a) of the European Patent Convention.

The Board of Appeal of the European Patent Office finally adjudicated over the issue and the patent was eventually granted⁵⁰.

The *Oncomouse* decision provides valuable insight into how courts may interpret the wording of the Patents Act in its application to transgenic animals and will be referred to numerous times in the subsequent chapters.

In answering whether transgenic life forms are indeed patentable in terms of the Patents Act, the most relevant enquiries would be the extrinsic requirements of a patentable invention and the extrinsic exclusions relating to essentially biological processes and plant and animal varieties. Same is discussed below with reference to the European Patent Convention and British Patents Act.

⁵⁰ *Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03.*

3. CHAPTER 3: THE EXTRINSIC EXCLUSIONS TO PATENTABILITY AND THEIR APPLICATION TO TRANSGENIC LIFE FORMS

As indicated previously, the Patents Act tells us what shall not be considered as a patentable invention⁵¹.

The most important exclusion pertaining to the patentability of transgenic life forms is contained in section 25(4)(b) of the Patents Act. It stipulates as follows:

“A patent shall not 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 process.”

The section comprises of two sub exclusions. Firstly any variety of animal or plant is automatically excluded. Secondly any essentially biological process for the production of animals or plants is excluded except if such process is of microbiological character. If thus of such microbiological character the product thereof (most likely being of microbiological nature) remains patentable. The provisionality to this sub-exclusion thus represents an exception to the exception. The European Patent Office has defined a microbiological process as any process involving or performed upon or resulting in microbiological material⁵².

It is important to mention that this juncture that certain varieties of plants are afforded protection in terms of the Plant Breeders Rights Act 15 of 1976 and its regulations⁵³. This thesis will thus focus on animal varieties.

This section aims to exclude naturally occurring biological processes. This poses the question as to whether a transgenic life form can be considered essentially biological *enough* to be denied patent protection.

⁵¹ Section 25(2) and (4) of the Patents Act.

⁵² Rule 26(6) of the European Patent Convention.

⁵³ Burrel TD (2016) 38

In interpreting Section 25(4)(b) of the Patents Act and its applicability to transgenic animals, the term “*variety*” and the phrase “*essentially biological process for the production of plants or animals*” must be interpreted.

3.1 PLANT AND ANIMAL VARIETIES

Animal (and plant) varieties are automatically excluded from patent protection. In dealing with transgenic life forms, one would first have to determine if such life form constitutes a variety for purposes of section 25(4)(b) of the Patents Act.

The term variety is not defined in the Patents Act. Guidance is thus sought from Rule 26(4) of the European Patent Convention and Schedule A2 of the British Patents Act that define the term “plant variety” as follows:

“Plant variety” means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and

(c) considered as a unit with regard to its suitability for being propagated unchanged.”

The phrase “plant variety” is also defined in the Oxford English dictionary as follows⁵⁴:

“A taxonomic category that ranks below subspecies (where present) or species, its members differing from others of the same subspecies or species

⁵⁴ <https://en.oxforddictionaries.com/definition/variety> .

*in minor but permanent or heritable characteristics. Varieties are more often recognized in botany, in which they are designated in the style *Apium graveolens (var. dulce)*” and includes “A plant or animal which varies in some trivial respect from its immediate parent or type”.*

The provisions clearly cater for plant varieties however this does not mean that they cannot lend any insight into what may constitute an animal variety. On an interpretation of the rule and the biological definition of the term, the following essential constituents are revealed:

- a) The animal must be classified as forming part of the same species;
- b) There must be the presence of certain characteristics that reveal themselves when a certain set of genes are expressed;
- c) These expressed characteristics must be unique to that particular animal and renders that animal distinguishable from other members of the same species; and
- d) These characteristics remain expressed when the animal reproduces⁵⁵.

The Technical Board of Appeal in decision *T320/87*⁵⁶ (hereinafter referred to as the “Lubrizon decision”) interpreted the meaning of variety in a patent application titled “*A process for the rapid development of hybrid plants and commercial production of hybrid seed*”. The Board followed the approach

⁵⁵ Using an example of a domesticated dog, the genus (the biological name for a taxonomic group covering more than one species) would be *Canis* (Dog). A species is essentially a group of organisms forming part of the same genus that can interbreed and produce fertile offspring. Using the dog example, the species would be *Canis Lupus* and would include a grey wolf. A sub species is essentially would be a subdivision of that species and would include the domesticated dog. A variety is a variation within the subspecies itself that have unique characteristics which are expressed when the variety reproduces. Example: a pug.
M Nyberg “*Canis Lupus Familiaris: The Domestic Dog*”
http://bioweb.uwlax.edu/bio203/s2009/nyberg_mich/Classification.htm <accessed 22 September 2017>

⁵⁶ *Hybrid plants/ LUBRIZOL, Decision of 10 November 1988, T320/87.*

taken in decision *T 49/83*⁵⁷ wherein it was held that the term “plant variety” should be interpreted to mean a multiplicity of plants which possess the characteristics of homogeneity and stability (the former meaning that the plants possess largely the same characteristics and the latter meaning that those characteristics remain the same within specific tolerances after every propagation).⁵⁸

Applying the characteristics of homogeneity and stability to transgenic animals, it becomes apparent that those animals would need to be in possession of characteristics genetically unique to them and that those characteristics would have to remain the same when the animals reproduce.

The Boards of Appeal of the European Patent Office (hereinafter referred to as “the Board”) interpreted the meaning of “variety” contained in Article 53(b) of the European Patent Convention in relation to transgenic mice (the *Oncomouse* decision). The oppositions relating to Article 53(b) encompassed various notions. It was argued that plants and animal species were abstract concepts and not products as such. Animal species existed in a material sense when a specific common feature was present in a number of them. It was argued that excluding plants and animal species as immaterial concepts would be absurd and irrelevant if the subjects of the immaterial concepts - i.e. the animals themselves – could be patentable.⁵⁹

The wording of Article 53(b), which is virtually identical to the wording of Section 25(4)(b) of the Patents Act, states as follows:

“European Patents shall not be granted...in respect of plant or animal varieties or essentially biological processes for the production of plants and animals: this provision shall not apply to microbiological processes or the products thereof.”

⁵⁷ *Propagating material/ CIBA GEIGY, OJ EPO 1984.*

⁵⁸ *Lubrizol* decision, paragraph 13.

⁵⁹ *Board of Appeal of the European patent Office, Decision of 6 July 2004, T 315/03, page 51.*

The Board also referred to Rule 23c(b) of the European Patent Convention that deals with patentable biotechnological inventions and states as follows:

*“Biotechnological inventions shall also be patentable if they concern...plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety”*⁶⁰

It is clear from the rule that if an invention were not confined to a particular plant or animal variety then that invention would be patentable. It thus narrows the application of Article 53(b) to one particular plant or animal variety.⁶¹

The Board analysed the German and French texts of Article 53(b) of the European Patent Convention and found that the former referred to the words “animal species” but the latter referred to the words “animal races”.⁶² Neither text referred to the word “variety” which created an interpretational conundrum. A strict interpretation would thus lead to severe inconsistencies in that any objection based on Article 53(b) would depend on the language of the case.⁶³

The Board referred to the decision of *G 1/98*⁶⁴ (hereinafter referred to as “the Novartis decision”) that enunciated the principle that a claimed invention will not be directed at a plant variety or varieties if there is no specific identification of such variety in a product claim. It was further enunciated that a patent will not be granted for a single plant variety but can be granted if varieties fall

⁶⁰ The wording of Rule 23c(b) is identical to paragraph 4 of Schedule A2 to the British Patents Act.

⁶¹ *Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03*

⁶² *Supra*, page 101, paragraph 11.2.

⁶³ *Supra*, page 105, paragraph 11.7.

⁶⁴ *Transgenic plant/ NOVARTIS II, Enlarged Board of Appeal of the European Patent Office, Decision of 20 December 1999, G1/98.*

within the scope of its claims.⁶⁵ The Board indicated that the same approach should be applied with respect to animal patents.⁶⁶

The Board held further that in interpreting the meaning of the word “variety”, a definition by reference of taxonomical rank would be consistent with the approach taken in the Novartis decision and be in the interest of legal certainty. An assessment can then be made as to whether the technical feasibility of the invention is confined to a particular animal variety and thus excluded under Article 53(b).⁶⁷ Applying the aforesaid, it appears if one of the claims of an invention relate to a taxonomical category that is at least as narrow as an “animal species”, an objection based on Article 53(b) will be upheld.⁶⁸

This approach is endorsed in the UK wherein it was said that animal varieties rank below species and thus does not exclude claims to non-human mammals.⁶⁹

In determining whether a transgenic animal constitutes a species, the Board held that simply because a transgenic animal inherits a certain characteristic does not mean that it constitutes a new species. This is especially true if the “starting material” originates from a whole genus of animals. If the claimed invention could be performed on numerous species, each one of those species would then all become members of a single species if the inherited characteristic manifests.⁷⁰

Oppositions raised further indicated that the legislature did not explicitly indicate the willingness to patent plants and animals of a new species and the

⁶⁵ *Supra*, page 31, paragraph 3.10.

⁶⁶ *Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03* at pages 102 – 103, paragraph 11.4.

⁶⁷ *Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03* at pages 103 – 104, paragraph 11.5.

⁶⁸ *Op cit*, page 128, paragraph 13.3.1.

⁶⁹ British Biotechnological Guidelines paragraph 97.

⁷⁰ *Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03* at pages 128, paragraph 13.3.1.

absence of same indicated that animals, as material manifestations of abstract species, were simply not patentable.⁷¹ This was rejected by the Board who held that Article 53(b) only excludes a limited category of animals and not *all* animals. The Article therefore cannot be interpreted as a general exclusion on animal patents.⁷²

Similarly Schedule A2 of the British Patents Act does not exclude animals in general and the British Biotechnological Guidelines indicate that the same reasoning that is applied to plant patents should be applied to animal patents.⁷³

3.2 MICROBIOLOGICAL PROCESSES OR THE PRODUCTS THEREOF.

Section 25(4)(b) already allows for the patentability of microbiological processes and the resultant products. Such products can include transgenic microorganisms, as they would be considered the products of such processes.⁷⁴

A microbiological process is defined as:

*“Any process involving or performed upon or resulting in microbiological material”.*⁷⁵

The Guidelines further indicate that the term should to be interpreted to cover not only processes performed upon microbiological material or processes resulting in microbiological material but also processes which involve both microbiological and non microbiological steps.⁷⁶

⁷¹ *Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03.* pages 51 – 52.

⁷² *Op cit*, page 128 – 129, paragraph 13.8.2.

⁷³ British Biotechnological Guidelines paragraph 96.

⁷⁴ *Supra*, paragraph 141.

⁷⁵ Guidelines Part G Chapter II-19, paragraph 5.5.1, Schedule A2 to the 1977 Patents Act.

⁷⁶ *Supra*.

Similarly, the microorganism that is derived from a microbiological process can be the subject of a patent as a product claim. The propagation of the microorganism itself is also construed as a microbiological process.⁷⁷

The Guidelines interpret the term “microorganism” as:

*“Including bacteria and other unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and moreover, human, animal and plant cells.”*⁷⁸

In the *Oncomouse* decision, the Board of Appeal held that the proviso relating to microbiological processes did not apply to transgenic mice. The Board relied upon the matter of *Plant Genetic Systems N.V and others vs Greenpeace Ltd*⁷⁹ (hereinafter referred to as the “Plant Genetic Systems matter”). In this decision, traditional microbiological processes and modern microbiological processes were differentiated. It was held that modern microbiological techniques combined traditional techniques with genetic engineering techniques and experimental approaches that are applicable to human, animal and plant cells and which can be grown and maintained in a culture similar to bacteria and yeasts.⁸⁰

Taking into account the developments of modern microbiology, the term “microbiological” can now be interpreted as encompassing technical activities in which microorganisms are made direct use of. These technical activities can include traditional fermentation, biotransformation processes and the manipulation of microorganisms by genetic engineering or fusion techniques.⁸¹

⁷⁷ Guidelines Part G Chapter II-19, paragraph 5.5.1.

⁷⁸ *Supra*.

⁷⁹ *T356/93 OJ EPO 1995 545*.

⁸⁰ *Op cit*, par 33.

⁸¹ *Op cit*, par 35.

In applying modern microbiology to the realm of genetic engineering, one can consider whether the genetic engineering processes carried out on either plant or animal cells may be considered microbiological processes and if the resultant products (transgenic life forms) may be considered as “the products thereof”.⁸²

The answer may lie in the Plant Genetic Systems matter wherein the question was considered as to whether biotechnological inventions which consisted of multiple steps, at least one of the steps being a microbiological process, was enough to consider the process as a whole essentially biological. It was held that technical processes, which include at least one microbiological step, couldn't be equated with the term “microbiological processes”. The products of those technical processes similarly cannot be equated with the term “products of microbiological processes”.⁸³

The British Biotechnological Guidelines indicate that claims relating to microorganisms that have been isolated or obtained by artificially induced mutations are allowed. However, generalizations from the specific microorganisms themselves as novel species would not usually be permitted.⁸⁴ That being said, genetically modified microorganisms may be claimed more readily where the invention lies in the gene introduced. Mutants and variants of the genetically modified microorganisms would also be permitted on the condition that they possess the same inventive property.⁸⁵

In summary, microbiological processes and its resultant products are patentable even if the microbiological process involved non-microbiological steps such as genetic engineering techniques. Conversely, however, biotechnological inventions which include at least one microbiological step is not enough to equate the entire process as a microbiological one and the resultant products from such processes would not be considered the “products

⁸² T356/93 OJ EPO 1995 545 paragraph 35.

⁸³ *Op cit*, paragraphs 37 and 38.

⁸⁴ British Biotechnological Guidelines, paragraph 142.

⁸⁵ British Biotechnological Guidelines, paragraph 142.

thereof". Applying this to transgenic animals, it appears that the products of microbiological processes cannot be in the form of plant and animal varieties (as discussed above) even if microbiological steps were included in the technical process and thus seem to be limited to microbiological material.

3.3 THE EXCLUSION ON ESSENTIALLY BIOLOGICAL PROCESSES FOR THE PRODUCTION OF ANIMALS OR PLANTS

As indicated previously⁸⁶, the wording of section 25(4)(b) of the Patents Act is almost identical to Article 53(b) of the European Patent Convention wherein guidance will be sought in interpreting what constitutes "an essentially biological process".

Rule 26(5) of the European Patent Convention defines an essentially biological process as follows:

*"A process for the production of plants and animals that consists entirely of natural phenomena such as crossing or selection."*⁸⁷

The rule specifies that an essentially biological process must consist *entirely* of natural phenomena. It therefore follows that genetic manipulation or human intervention which would cause a consequence that would not naturally, biologically, arise will fall outside the ambit of an "essentially biological process". If the process occurs naturally and human intervention plays no consequential role, it seems as if the process would be regarded as essentially biological.

The European Patent Convention's Board of Appeal held that when interpreting the exclusions to patentability, they should be construed narrowly and judged bearing in mind what the essence of the invention is.⁸⁸

⁸⁶ Page 20.

⁸⁷ Schedule A2 to the British Patents Act mirrors this definition.

⁸⁸ *Decision T 320/87 (OJ EPO 1990, 71)*.

In the *Oncomouse* decision, arguments presented included that once the oncogene was inserted into the mice embryos there were a vast number of biological steps that had to take place in order to produce the transgenic mice themselves. This was especially evident considering that the natural progeny were only obtained through an essentially biological process, i.e. reproduction.⁸⁹

The Board held that it is self evident that a process will not consist entirely of natural phenomena if it includes genetic intervention.⁹⁰

In the *Lubrizol* decision, the Examining Division indicated that the steps of selection, crossing (sexual combination of two selected individuals) and propagation were common in all classical breeding processes which results in a statistical population that follows Mendel's laws with respect to their phenotypical characteristics. Any process in line with the aforesaid would not be patentable and would be considered biological in essence.⁹¹

The *Plant Genetic Systems* matter endorsed the approach taken in the *Lubrizol* decision in the interpretation of "essentially biological processes" wherein it was held that in determining whether a non microbiological process is essentially biological within the meaning of Article 53(b) of the European Patent Convention has to be judged on the essence of the invention and should further take into account the totality of human intervention involved and its consequences on the result achieved.⁹²

The Examining Division in the *Lubrizol* decision further indicated that the "quantity" of human intervention in a biological process was not decisive in this respect. Rather, the "quality" of the human intervention had to be decisive in determining whether a process was biological in its essence or not.⁹³

⁸⁹ *Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03.*

⁹⁰ *Op cit*, paragraph 13.3.5.

⁹¹ *Lubrizol* decision, pages 1-2 paragraph II.

⁹² *T356/93 OJ EPO 1995 545 paragraph 27, T320/87.*

⁹³ *Lubrizol* Decision *T 320/87 (OJ EPO 1990, 71).*

The subject of the claim in the Plant Genetic Systems matter comprised of plant cells that were genetically engineered to be resistant to glutamine synthetase inhibitors. It was argued that even though there was technical human intervention wherein the plant cells or tissues were transformed with recombinant DNA, the subsequent steps of regeneration and replication were essentially biological and conferred an overall biological character on the process.⁹⁴

The Boards of Appeal, however, disagreed. It was held that the steps of transforming the plant cells with recombinant DNA was an essential technical step which had an impact on the desired final result. It was further held that even though the steps of regeneration and replication were biological in nature, the insertion of DNA into the plant's genome simply could not occur without human intervention. The objection based on Article 53(b) was thus rejected.⁹⁵

The Enlarged Board of Appeal, in decision *G2/07 Broccoli / PLANT BIOSCIENCE* (hereinafter referred to as the Plant Bioscience decision) identified the following elements in determining whether a process does not constitute an essentially biological one⁹⁶:

- a) The amount of human intervention and the impact thereof on the result achieved has to be determined.
- b) The above needs to be judged on the basis of the essence of the invention.
- c) The impact must be decisive.
- d) The contribution must be of a significant nature.
- e) The totality and sequence of the specified operations must not occur naturally or correspond to classical breeders processes.
- f) There should be a fundamental alteration of the character of a known process that may lie either in the sequence of the process or the special sequence of the process steps.

⁹⁴ Plant Genetic Systems matter, paragraph 40.1.

⁹⁵ Plant Genetic Systems matter, paragraph 40.1.

⁹⁶ *G2/07 Broccoli / PLANT BIOSCIENCE*, paragraph 3.2.3.

The following further elements were also identified as possible interpretations to the exclusion⁹⁷:

- I. The process as a whole should have a “biological essence” however the presence of one mere biological feature in the process would not automatically result in the process as a whole being regarded as having an essentially biological character.
- II. Conversely, there should be at least one clearly identified non-biological process step which may carry any number of essentially biological steps into allowability.

The meaning of “*biological essence*” has not been defined, but one could interpret it to mean that an intervention of a non-significant nature that does not result in a decisive impact or a fundamental alteration of a naturally occurring process would not be enough to exclude the process as a whole as “essentially biological”. Similarly, intervention of a significant and decisive nature which fundamentally alters the character of a naturally occurring process would be enough to exclude the process as a whole as “essentially biological” even if biological features are present in such process.

In December 2010 the Enlarged Board of Appeal handed down two decisions that provided clarity on the interpretation of the essentially biological exclusion. The first decision was the Plant Bioscience decision and the second was G1/08 TOMATOES/ State of Israel decision. In both decisions, the following was held⁹⁸:

- a) If a non-biological process for the production of plants consists of the sexual crossing of whole genomes and subsequent selection of plants then that process would be excluded from patentability on the basis that it would constitute an essentially biological process.

⁹⁷ *Op cit*, paragraphs 6.2 – 6.3.

⁹⁸ Order in G2/07 Broccoli / PLANT BIOSCIENCE, Order in G1/08 TOMATOES/ State of Israel.

- b) If the aforesaid process contains a step of a technical nature that assists in the performance of the sexual crossing of whole genomes and subsequent selection of plants then such process would still be considered an essentially biological process.

- c) If however the aforesaid process contains an additional step of a technical nature which introduces a new trait or modifies an existing trait in the genome of the plant produced and this trait is not as a result of the mixing of the genes of the plants chosen for sexual crossing, then the process would not be regarded as essentially biological in nature.

Finally, irrelevant considerations in determining whether a process is excluded from Article 53(b) would include:

- I. If the technical step is a new or known measure;
- II. If the technical step is a trivial or fundamental alternation of a known process.
- III. If the technical step does or could occur in nature; and
- IV. If the essence of the invention lies in the technical step.

The Guidelines also proceed from this standpoint and indicate that a selection of plants and animals based on any processes derived from the sexual crossing of whole genomes will be excluded from patentability on the basis that it would be essentially biological. This would remain the case even if technical steps were present before or after the selection or crossing steps.⁹⁹ The process would be considered to consist entirely of natural phenomena.

It appears that genetic intervention that does not rely on the whole crossing of genomes and subsequent selection of plants or animals would render a process patentable, and not essentially biological. This would be because any

⁹⁹ Guidelines, paragraph 5.4.2, page 671.

process wherein which genetic intervention plays a role cannot be considered to consist entirely of natural phenomena. However human intervention alone is no longer the decisive factor in determining whether a process is essentially biological.

The decisions cited under this sub-heading provide valuable insight into the interpretation of the phrase “essentially biological process”. The UK Intellectual Property Office has relied on these decisions in their own interpretation of the phrase and, whilst not binding in their courts, have indicated that guidance will be sought therefrom.¹⁰⁰

3.4 BIOTECHNOLOGY DIRECTIVES: A SUPPLEMENTARY MEANS OF INTERPRETATION

Rule 26(1) of the European Patent Convention indicates that all inventions that are of a biotechnological nature should be interpreted in accordance with the provisions of Chapter V of the Rules and Directive 98/44EC of 6 July 1998 (hereinafter referred to as the “Biotechnology Directive”) which should be used as a supplementary means of interpretation.

Chapter V of the Rules deals with Biotechnological inventions and extends from Rule 26 to 34. The applicable rules pertaining to transgenic animals are canvassed briefly below.

Biotechnological inventions are defined as:

*“inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.”*¹⁰¹

Biological material is defined as:

¹⁰⁰ British Biotechnology Directive paragraph 106.

¹⁰¹ Rule 26(2) of the European Patent Convention.

*“any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.”*¹⁰²

Rule 27 defines the parameters of patentable biotechnological inventions and stipulates as follows:

“Biotechnological inventions shall also be patentable if they concern:

- (a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;*
- (b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;*
- (c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.”*

Lastly, Rule 28 defines the exceptions to biotechnological inventions, the relevant part thereof indicating that biotechnological inventions will not be patentable if they concern processes for modifying the genetic identity of animals which would be likely to cause them suffering and do not provide any substantial benefit to man or animal. The animals resulting from the aforementioned processes would also not be patentable.¹⁰³ These exceptions have been interpreted as having provided concrete form to the requirements of *“ordre public”* and *“morality”* in biotechnological fields.¹⁰⁴ Further, the substantial medical benefit referred to in Rule 28 has been interpreted to include any benefit concerning research, prevention, diagnosis or therapy.¹⁰⁵

The Guidelines provide that in principle, biotechnological inventions are patentable under the European Patent Convention. The Guidelines further

¹⁰² Rule 26(3) of the European Patent Convention.

¹⁰³ Rule 28(d) of the European Patent Convention.

¹⁰⁴ Guidelines Part G Chapter II-16, paragraph 5.2.

¹⁰⁵ *Op cit.*

indicate that patentable biotechnological inventions referred to in Rule 27 and the list of exceptions referred to in Rule 28 are non-exhaustive lists.¹⁰⁶

The Biotechnology Directive was introduced due to the recognition that biotechnology and genetic engineering now play increasingly important roles in industry and commerce. The protection of these inventions are of fundamental importance for the industry and require high-risk investment in research and development. Adequate legal protection needs to be afforded to such inventions in order to make them profitable and encourage investment in the field of biotechnology.¹⁰⁷

The directive was also formulated to provide clarification on the legal protection of biotechnological inventions and in order to harmonize protection throughout member states.¹⁰⁸ It was further recognized that it was not necessary to create a separate body of law to cater for biotechnological inventions and the rules relating to national patent law remain the essential basis for such inventions but can be adapted or added to in order to take into account the latest technological developments.¹⁰⁹

The Biotechnology Directive indicates that inventions that are new, involve an inventive step and are capable of industrial application will be patentable even if such inventions concern a product that consists of or contains biological material or a process by which biological material is produced, processed or used.¹¹⁰

Article 2 thereof indicates that an essentially biological process for the production of plants or animals is one that consists entirely of natural phenomena such as crossing or selection.

¹⁰⁶ Guidelines Part G Chapter II-16, paragraph 5.2.

¹⁰⁷ Biotechnology Directive paragraphs 1-4.

¹⁰⁸ *Op cit.*

¹⁰⁹ Biotechnology Directive paragraph 8.

¹¹⁰ *Supra*, Article 3.

Article 4 thereof stipulates that plant and animal varieties and essentially biological processes for the production of animals and plants will not be patentable unless the technical feasibility of the invention is not confined to a particular plant or animal variety.

Lastly, Articles 8 and 9 thereof define the scope of protection conferred by the patent. If biological material possesses certain characteristics from the invention then the patent will extend to any further biological material derived therefrom through propagation or multiplication as long as the biological material possesses the same characteristics.¹¹¹

Similarly, if a process enables biological material to be produced that possesses certain characteristics from the invention then the patent will extend to biological material obtained from that process as well as further biological material derived therefrom through propagation or multiplication as long as the biological material possesses the same characteristics.¹¹²

Article 9 indicates that if a product consists of or contains genetic information then the patent shall extend to all material in which the product is incorporated and wherein which the genetic information is contained and performs its function.

Articles 1 – 11 of the Biotechnological Directive were implemented into the British Patents Act by the Patents Regulations 2000.¹¹³ The British Biotechnological Guidelines set out the practice in the Intellectual Property Office and relate to the patentability requirements for biotechnological inventions in the UK. The implementation of the Biotechnological directive into the British Patents Act allows for harmonized protection and clarification on biotechnological inventions between Europe and the UK and accordingly provides valuable sources of interpretation for the South African Judiciary.

¹¹¹ Biotechnology Directive, Article 8.

¹¹² *Ibid.*

¹¹³ SI 2000/2037.

3.5 SUMMARY

In interpreting the phrase “animal varieties” (as an automatic exclusion to patentability) the essential constituents would be: an animal classified as forming part of the same species, with unique characteristics that distinguish that animal from other members of the same species, and that these characteristics reveal themselves when a certain set of genes are expressed and remain expressed when the animal reproduces. Furthermore, biotechnological inventions should not be confined to a particular animal variety.

With regard to whether transgenic animals fall within the meaning of the phrase, “microbiological process or the product of such process”, it appears that the products of microbiological processes cannot be in the form of plant and animal varieties even if microbiological steps were included in the technical process and thus the phrase seems to be limited to microbiological material.

With regard to the exclusion on essentially biological processes for the production of animal or plants, any process which consists of entirely natural phenomena or considered as having a “*biological essence*” would be excluded from patentability. This would be the case where any intervention is of a non-significant nature and does not result in a decisive impact or a fundamental alteration of a naturally occurring process.

Lastly, biotechnology directives are valuable tools and a supplementary means of interpretations. The EPC’s Biotechnology Directive defines “biotechnological inventions” and “biological material” and lists (non-exhaustively) patentable biotechnological inventions and the exceptions thereto. Articles 1 -11 of the Biotechnology Directive has been implemented into the British Patents Act, allowing for harmonized protection and clarification on biotechnological inventions between Europe and the UK, and accordingly valuable sources of interpretation for the South African Judiciary.

4. CHAPTER 4: THE EXTRINSIC REQUIREMENTS FOR PATENTABILITY AND THEIR APPLICATION TO TRANSGENIC LIFE FORMS

It is easy to focus on the contentious issues surrounding biotechnology patenting, such as the criteria for patenting plants and animals, the patenting of gene sequences and morality issues and simply forget that the majority of biotechnology patent applications will still have to be decided on the basic issues of novelty, inventive step and industrial application.¹¹⁴

As indicated previously¹¹⁵, Section 25(1) of the Patents Act hold the extrinsic requirements of patentability and dictate that an invention should be¹¹⁶:

- I. New or novel;
- II. involve an inventive step; and
- III. be capable of being applied in trade, industry or agriculture.

The issues of novelty, inventiveness, industrial application are of significant importance to this dissertation and will be dealt with in greater detail below.

4.1 NOVELTY

Any invention has to be new or novel in order to be patentable. South Africa, has a non-examining system and thus the issue of novelty only arises in applications dealing with revocation or when a lack of novelty is raised as a defence in an infringement claim.

The novelty of an invention is assessed by having regard to all relevant subject matter forming part of the state of the art before the priority date (earliest date of filing) of an application or patent.¹¹⁷

¹¹⁴ Paragraph 7 of the British Biotechnology Directive.

¹¹⁵ *Supra* page 12.

¹¹⁶ Sections 25(1) and (4) of the Patents Act.

The Patents Act defines the state of the art as comprising of all matter (whether a product, a process, information about either, or anything else) that has been made available to the public in South Africa or elsewhere either by written or oral description, by use, or in any other way.¹¹⁸

The state of the art is used for an assessment of both novelty and inventiveness. Subject to certain exceptions¹¹⁹, any matter forming part of the state of the art would invalidate a patent application by rendering the invention not new.¹²⁰

Matter which forms part of the state of the art can be categorized as forming part of three kinds of disclosures:

- I. Matter made available to the public;
- II. Matter contained in a patent application¹²¹; and
- III. Inventions used secretly and on a commercial scale in South Africa¹²².

It is important to mention that for any disclosure to form part of the state of the art, such disclosure must be enabling. This essentially means that the technical particulars of the invention must be disclosed in such a way as to enable a person properly skilled in the art to understand and perform it.¹²³ The British Biotechnological Guidelines indicate that a disclosure will only destroy novelty if the information it contains is enough to enable a person skilled in the art to reproduce it.¹²⁴

If an invention is compared with the relevant prior art and found to be the

¹¹⁷ Klopper *et al* (2011) 280, paragraph 39.2.

¹¹⁸ Section 25(6) of the Patents Act.

¹¹⁹ Sections 26(a) and (b) of the Patents Act.

¹²⁰ Klopper *et al* (2011) 280, paragraph 39.2.

¹²¹ Section 25(7) of the Patents Act.

¹²² Section 25(8) of the Patents Act.

¹²³ Klopper *et al* (2011) 278; *Gentiruco AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 9A) 650.

¹²⁴ British Biotechnological Guidelines, page 8, paragraph 11.

same, the invention is said to be anticipated and thus not patentable.¹²⁵ An assessment of novelty essentially entails a comparison between the elements of the alleged anticipation and the claims of the patent. In this comparison, a small but real difference can be enough to establish the element of novelty.¹²⁶

The principles pertaining to the assessment of novelty have been well established in South African jurisprudence. The application of novelty to transgenic life forms however deserves special consideration in that many of the inventions are based on natural, biological material. Guidance in this regard is sought from the British Biotechnological Guidelines which indicate that a natural substance isolated for the first time and which has not been recognized as in existence previously will not lack novelty simply because it has always been present in nature.¹²⁷

4.2 INVENTIVENESS

An invention needs to be inventive in order to be patentable. A lack of inventiveness would render an invention obvious. Normally, when issues of both novelty and inventiveness arise, our courts have adopted the approach of deciding the issue of novelty first and only thereafter the issue of inventiveness.¹²⁸

Inventiveness can be said to be present if a previously unrecognized technological benefit has been disclosed.¹²⁹ If an invention does not go beyond the normal progress of technology and merely follows logically from the prior

¹²⁵ Klopper *et al* (2011) 280, paragraph 39.2.1.

¹²⁶ *Ibid*, 282 – 283.

¹²⁷ Page 8, paragraph 9 thereof.

¹²⁸ *Ensign-Bickford (SA) (Pty) Ltd & others v AECL Explosives and Chemicals Ltd* 1999 (1) SA 70 (SCA) at 80E-F.

¹²⁹ Klopper *et al* (2011) 284.

art, it would be deemed obvious. The same can be said for an invention which is self evident to a person skilled in the art.¹³⁰

An assessment of inventiveness is normally done through the eyes of a person skilled in the art. This assessment involves the identification of subject matter that forms part of the state of the art and a comparison between the invention and any disclosures.¹³¹

The person skilled in the art is normally reasonably skilled in the art and does not have to be a specialist in the field.¹³² They should have an adequate understanding in the appropriate field of the invention and should be acquainted with the features of the art in the way that a well-informed worker would be.¹³³ The “person skilled in the art” may be a multi-disciplinary team rather than a single individual.¹³⁴ Literature indicates that the person skilled in the art should be wholly unimaginative whilst having the ability to absorb unlimited amounts of new knowledge and mentally gifted enough to distinguish real inventive activity from the ordinary application of the state of the art.¹³⁵

With regards to biotechnological inventions, the European Patent Office identified the person skilled in the art to have the following characteristics:

“...the skilled person in this field is well aware of the fact that even a small structural change in a product (e.g. a vector, a protein, a DNA sequence) or in a procedure (e.g. a purification process) can produce dramatic functional changes. Therefore, the said expert would constantly be conditioned by the prior art and, before taking action, would carefully ponder any possible modification, change or adjustment against the background of the existing knowledge. Under these circumstances, ... the skilled person would adopt a

¹³⁰ Klopper *et al* (2011) 285.

¹³¹ *Ibid*, page 284.

¹³² *Ibid* page 284, paragraph 39.3.2.

¹³³ *Ibid*.

¹³⁴ *Harvard / Fusion proteins OJEPO 1992, 268 (T 0060/89)*.

¹³⁵ Klopper *et al* (2011) 284, paragraph 39.3.2.

conservative attitude. However, this must not be seen in the sense of being reluctant or opposed to modify or adjust a known product or process, but rather in the sense of being cautious."¹³⁶

When assessing if inventiveness is present, one should look at the claims of the invention and not the description bearing in mind that the claims are assessed in the light of the description. The claims define the scope of the invention with clarity and precision and function as to set the parameters of an area wherein which others may not trespass.¹³⁷

Section 25(10) of the Patents Act deals with inventiveness and stipulates that an invention shall be deemed to involve an inventive step if:

- I. It is not obvious to a person skilled in the art;
- II. having regard to any matter from forms part of the state of the art;
- III. immediately before the priority date of the invention.

South African courts have adopted the English law approach¹³⁸ to inventiveness and have identified a four-step test. The enquiries are as follows¹³⁹:

- I. What is the inventive step that is involved in the patent?

¹³⁶ *Decision of 20 June 1994, T 0455/91, OJEPO, 1995, 684, Genentech et al / Expression in yeast.*

¹³⁷ *Ensign-Bickford (SA) (Pty) Ltd & others v AECI Explosives and Chemicals Ltd 1999 (1) SA 70 (SCA) at 77H-78B.*

¹³⁸ *Molnlycke AB and Another v Proctor and Gamble Ltd and Others (No 5) 1994 RPC 49 CA at 115.*

¹³⁹ *Ensign-Bickford (SA) (Pty) Ltd & others v AECI Explosives and Chemicals Ltd 1999 (1) SA 70 (SCA) at 80H-J.*

- II. At the priority date, what was the state of the art relevant to the invention?
- III. In what way does the inventive step go beyond the state of the art?
- IV. Taking into account the previous step, would the inventive step be obvious to the person skilled in the art?

In the *Oncomouse* decision, the invention was also attacked on the basis that it contained no inventive merit. Methods for the introduction of genes into the germ line of an animal at an early developmental stage had already existed and transgenic animals were already produced through such methods.¹⁴⁰ Appellants thus argued that a known method for introducing a known oncogene into the mouse genome could only result in the integration of that gene in at least a few animals. Thus, it was argued, that this integration would be the expected outcome by a person skilled in the art.¹⁴¹

The Board rejected this argument and indicated that at the priority date of the opposed patent, experimentation in mice was not so advanced so as to enable a skilled person to predict the consequences of the introduction of human protein into the animal immune system. Further, the introduction of an activated oncogene that was known to interfere with the regulation of cell division was still under investigation. Consequences such as the death of the animal, the expression of the gene or whether the introduction would have any effect at all was unknown. Accordingly the Board held that the method was not obvious to try and even if it was, there simply was no reasonable expectation of success.¹⁴²

¹⁴⁰ *Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03, page 133.*

¹⁴¹ *Ibid*, pages 16 – 18.

¹⁴² *Ibid*.

4.3 INDUSTRIAL APPLICATION

As indicated previously, Section 25(1) of the Patents Act stipulates that a patent may be granted for any new invention which involves an inventive step and is capable of being used or applied in trade or industry or agriculture (own emphasis).¹⁴³

Simplistically put, the invention must be able to be implemented or put into practice in the relevant fields of human endeavour. The Patents Act also contains certain implementation exclusions involving specific types of subject matter. These inventions would normally fulfil the other requirements of patentability but are deemed unimplementable on public policy or ethical grounds and are thus not industrially applicable.¹⁴⁴

The implementation exclusions are categorized as follows:¹⁴⁵

- I. The application is frivolous because it claims an invention which is obviously contrary to well established natural laws.¹⁴⁶
- II. The use of the invention would be expected to encourage offensive or immoral behaviour¹⁴⁷ (discussed in subsequent chapter).
- III. The use of the invention may be carried out in a way that is contrary to law.¹⁴⁸

¹⁴³ Article 57 of the European Patent Convention and Section 4(1) of the British Patents Act mirror the wording of Section 25(1) of the Patents Act.

¹⁴⁴ Klopper *et al* (2011) 290 – 291.

¹⁴⁵ *Ibid.*

¹⁴⁶ Section 36(1)(a) of the Patents Act.

¹⁴⁷ Section 36(1)(b) of the Patents Act.

¹⁴⁸ Sections 36(2) and 25(4)(a) of the Patents Act.

- IV. The invention claims a plant or animal variety or an essentially biological process for the production of a plant or animal, not being a microbiological process.¹⁴⁹
- V. An invention which claims a method of treatment on the human or animal body by surgery, therapy or diagnosis practiced on the human or animal body is deemed as not being industrially applicable.¹⁵⁰

The Guidelines dictate that the description of a European Patent application should indicate the way in which the invention is capable of being applied in industry. Further, the invention should have a sound and concrete technical basis so as to enable the skilled person to recognize the contribution to the art and to determine if such contribution could lead to practical exploitation in the industry.¹⁵¹

In the *Oncomouse* decision, the Board indicated that the industrial applicability of *Oncomice* resided in their use as animal models for testing materials suspected to be carcinogenic as well as testing materials for the ability to confer protection against the development of neoplasms.¹⁵²

Industrial applicability with regards to biotechnological inventions is a somewhat more difficult process in that unlike inventions in other fields of technology, the industrial applicability of these inventions are not normally apparent from the invention itself.¹⁵³

In *T 0898/05*¹⁵⁴ (hereinafter referred to as the *ZymcoGenetics* matter), the Board considered the meaning of industrial application in relation to a

¹⁴⁹ Section 25(4)(b) of the Patents Act.

¹⁵⁰ Section 25(11) of the Patents Act.

¹⁵¹ Guidelines, Part G Chapter III – 1 – 2.

¹⁵² *Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03*, paragraph 13.8.

¹⁵³ British Biotechnological Guidelines, paragraph 59.

¹⁵⁴ *Decision of 7 July 2006, Hematopoietic receptor/ ZYMCOGENETICS*.

hematopoietic cytokine receptor.¹⁵⁵ The Board pointed out that the notion of the term “industry” has to be interpreted broadly and thus include all manufacturing, extracting and processing activities of enterprises that are carried out continuously, independently and for financial gain.¹⁵⁶ It was held that the concepts of financial or commercial gain and profitable use imply that the criterion of industrial applicability require that a patent application should describe the invention in adequately meaningful technical terms so that it can be expected that the grant of the patent will lead to some financial or commercial benefit.¹⁵⁷

The Board also considered that the need to show a profitable use should not be construed narrowly in the sense of generating more income than expenditure or in creating new or increased business opportunities but rather be construed widely in the sense that the invention should have a sound and concrete technical basis so as to enable the skilled person to recognise its contribution to the art and ascertain how it could be practically exploited in the industry.¹⁵⁸

The Board further indicated that the term “profitable use” should be understood in terms of an “immediate concrete benefit”. This implies that the purpose of the invention should be disclosed in definite technical terms and indicate how it can be used in industrial practice in order to solve a technical problem.¹⁵⁹ The essence of the requirement is described as at least having a real (as opposed to theoretical) prospect of exploitation. This should be derivable from the description of the invention (if it is not already obvious from the background art

¹⁵⁵ Simplistically, hematopoiesis is the production of all types of blood cells by the body. This production process is controlled by cytokines (which is broad category of small proteins) and their receptors.

¹⁵⁶ *Decision of 7 July 2006, Hematopoietic receptor/ ZYMCOGENETICS*, point 2 of Reasons for Decision.

¹⁵⁷ *Ibid*, point 4 of Reasons for Decision.

¹⁵⁸ *Ibid*, point 5 of Reasons for Decision.

¹⁵⁹ *Ibid*, point 6 of Reasons for Decision.

or nature of the invention) and should not be derived from the skilled reader having to carry out a research program.¹⁶⁰

Lastly, the Board indicated that the function of a protein could be seen at different levels which include molecular functions, cellular functions and biological functions. None of these functions is more fundamental than others for the purposes of industrial application as long as a practical application (a profitable use in the wider sense) is derivable in a straightforward manner. This would be the case even if other levels of activity remain completely unknown or only partially characterized.¹⁶¹

More recently, the requirements of industrial applicability in relation to biological material were set out by the UK Supreme Court in the matter of *Human Genome Sciences vs Eli Lilly*.¹⁶² The appeal before the Supreme Court concerned the validity of a patent which claimed the nucleotide sequence of a gene that encoded for a novel protein.

Taking into account European jurisprudence, the UK Supreme Court formulated the requirements of industrial applicability in relation to biological material. The general principles were formulated as follows¹⁶³:

- I. The patent needs to disclose a practical application and some profitable use so that it can be expected to lead to some commercial benefit.
- II. The description of the invention coupled with common general knowledge should disclose a concrete benefit or the inventions use in industrial practice.

¹⁶⁰ *Decision of 7 July 2006, Hematopoietic receptor/ ZYMCOGENETICS*, point 6 of Reasons for Decision.

¹⁶¹ *Ibid*, points 29 – 30 of Reasons for Decision.

¹⁶² 2011 UKSC 51

¹⁶³ 2011 UKSC 51 at paragraph 107.

- III. This use should not be merely speculative or a vague indication of objectives that may or may not be achievable.
- IV. The patent as coupled with common general knowledge should enable the skilled person to reproduce or exploit the invention without incurring an undue burden and without having to carry on a research program.

The Court also formulated certain requirements in the event that the patent discloses a new protein and its encoding gene.¹⁶⁴ They are:

- V. The patent coupled with common general knowledge should demonstrate a real possibility of exploitation as opposed to a purely theoretical one.
- VI. Mere identification of the structure of a protein with the corresponding identification of its role or any practical use thereof will not be sufficient for purposes of industrial application. The same can be said for vague and speculative indications of objectives that may be achieved.
- VII. If there is no experimental or wet lab evidence in respect of the activity of the claimed protein, it will not necessarily be fatal to the patent.
- VIII. A claimed use that is plausible, reasonably credible or simply an educated guess can be sufficient.
- IX. Later evidence can confirm such plausibility however relying on later evidence alone will not be sufficient.
- X. A plausible and specific possibility of exploitation can be evident at the biochemical, cellular or biological level.

¹⁶⁴ 2011 UKSC 51 at paragraph 107.

In summary, the industrial applicability of biotechnological inventions are not normally apparent from the inventions themselves and is a somewhat more difficult process. Decisions of the European Patent Office indicate that in order to be industrially applicable patent applications should be described in adequately meaningful terms to show the expectation of a financial or commercial benefit. This benefit should be in the wide sense by indicating a practical exploitation in the industry. Further, definite technical terms should be used to show the inventions purpose and how it can be used to solve a technical problem in a concrete (as opposed to theoretical) manner and should be readily apparent to the person skilled in the art without undue burden.

Similarly, the UK Supreme Court found that in order for patents in biological material to be industrially applicable, they should disclose a practical, beneficial and concrete use which can be expected to lead to a commercial benefit. Further, the invention should be reproduced or exploited by a person skilled in the art without undue burden.

As indicated previously,¹⁶⁵ UK and European jurisprudence are relied upon as interpretational sources for the South African judiciary and the requirements pronounced upon above are valuable in the interpretation of industrial applicability in relation to biotechnological inventions.

¹⁶⁵ Page 11.

5. CHAPTER 5: THE EXTRINSIC EXCLUSION DEALING WITH A LACK OF MORALITY

Arguably, the most controversial aspect involved in the patentability of transgenic life forms is the host of ethical questions that arise. Opponents to the patentability of transgenic animals argue that an incentive is provided to harm animals for commercial gain.¹⁶⁶ Another view is that society is regressing in viewing animals as soulless, unfeeling creatures that can be treated like machine parts for commercial gain.¹⁶⁷

Section 25(4)(a) of the Patents Act, or the “morality clause”, indicates that a patent shall not be granted for any invention wherein the publication or exploitation thereof would be generally expected to encourage offensive or immoral behaviour. The wording of Section 25(4)(a) is mirrored in Article 53(a) of the European Patent Convention¹⁶⁸ and Section 1(3) of the British Patents Act.¹⁶⁹

5.1 UNDER THE EPC

Article 6 of the Biotechnological Directive gives effect to the morality clause in its application to biotechnological inventions. Article 6(1) reiterates that inventions would be considered unpatentable if their commercial exploitation would be contrary to *ordre public* or morality. The exploitation will, however, not be deemed so contrary merely because some law or regulation prohibits it.

¹⁶⁶ Mauk Dustin “*Animal Patents*” <http://www.animallawsection.org/animal-patents/>.

¹⁶⁷ F B Orlans “*In the Name of Science: Issues in Responsible Animal Experimentation*” Oxford University Press (1993).

¹⁶⁸ The section states that European patents shall not be granted in respect of inventions wherein the commercial exploitation thereof would be contrary to “ordre public” or morality provided that such exception shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states.

¹⁶⁹ The section states that a patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

Article 6(2) of the Directive and Rule 23d of the European Patent Convention list inventions that are deemed unpatentable. They are:

- I. Processes for cloning human beings;
- II. Processes for modifying the germ line identity of human beings;
- III. Uses of embryos for industrial or commercial purposes
- IV. Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal, and also animals resulting from such processes.

The unpatentable inventions identified above have also been mirrored in Section 3 of Schedule A2 to the British Patents Act.

The Biotechnology Directive indicates that the list outlined above cannot be presumed exhaustive and that ethical and moral principles should supplement the standard legal examinations under patent law irrespective of the technical field of the invention.¹⁷⁰

Of particular importance for this dissertation is Rule 23d(d) which deals with the modification of genetic identity of animals that is likely to cause them suffering without any corresponding substantial benefit to animal or man.

In the *Oncomouse* Decision, the Board interpreted both Rule 23d(d) and Article 53(a) of the European Patent Convention and their application to transgenic life forms.

The Board held that the inventions categorised in Rule 23d must *ipso facto* be denied patentability under Article 53(a) and the accordingly the enquiry need not go further. Conversely, a case not falling within one of the categories

¹⁷⁰ Paragraphs 38 and 39 thereof.

justifies further consideration under the Article. Accordingly two quite distinct objections could find application under Article 53(a):¹⁷¹

- I. A Rule 23d objection: this entails an assessment as to whether or not an invention falls within one of the four categories listed in the Rule.
- II. An Article 53(a) objection: this entails an assessment as to whether or not an invention would be contrary to morality or *ordre public*.

With regards to Rule 23d(d), it was held that only a likelihood of suffering was required in order to trigger application of Rule 23d(d). The Rule imposed a balancing test wherein animal suffering was weighed against medical benefit to man or animal¹⁷². The Board also relied upon the Technical Board of Appeal's decision in T 19/90¹⁷³ wherein a similar balancing test was identified but differed to the Rule 23d(d) test in the sense that animal suffering was weighed against usefulness to mankind as opposed to a substantial medical benefit to animal or man.¹⁷⁴ The T19/90 test was accordingly broader and embraced a wider range of benefits. In relation to the T19/90 test and its applicability to a Rule 23d(d) enquiry, it was held that if substantial medical benefit to man was established then it would naturally follow that so would usefulness to mankind.¹⁷⁵

The Board concluded that three matters needed to be evaluated when an assessment is carried out in terms of Rule 23(d)(d)¹⁷⁶:

- I. Is animal suffering likely?

¹⁷¹ Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03, paragraph 6.1, 10.1.

¹⁷² *Op cit*, paragraph 6.2.

¹⁷³ T 19/90 OJ EPO 1990 476.

¹⁷⁴ Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03, paragraph 7.1.

¹⁷⁵ *Ibid*.

¹⁷⁶ *Op cit*, paragraph 9.1.

- II. Has a likely substantial medical benefit been established?
- III. Does the suffering and medical benefit exist in relation to the use of the same animal? (The patent should only extend to those animals whose suffering is balanced by a medical benefit.)

The Board held further that the Rule 23(d)(d) test does not require different levels of proof in assessing animal suffering and substantial medical benefit. All that is required is a likelihood. Accordingly factors such as the actual degree of suffering or the availability of non-animal alternatives need not be considered.¹⁷⁷

Lastly, in relation to a Rule 23d(d) enquiry, such test should be applied at the effective date of the patent or the patent application. This provides uniformity and legal certainty in that it is assessed at the same time as all other criteria for the assessment of patentability.¹⁷⁸ Further, the nature of the evidence relied upon should be confined to the likelihood of animal suffering, the likelihood of a medical benefit and the necessary correlation between the two. Additional evidence may be considered subsequently but such evidence should relate to what the state of affairs was at the effective date.¹⁷⁹

In interpreting Article 53(a), the Board relied on the Plant Genetic Systems matter¹⁸⁰ which differentiated between the concepts “*ordre public*” and “morality”. It was held that each concept represented a separate objection under Article 53(a).¹⁸¹

¹⁷⁷ *Op cit*, paragraph 9.7.

¹⁷⁸ Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03, paragraph 8.1, 8.2

¹⁷⁹ *Op cit*, paragraph 9.7.

¹⁸⁰ Fn 76.

¹⁸¹ *Infra*.

With regards to the former, it was held that the concept covers the protection of public security, the physical integrity of individuals that form part of society and environmental protection.¹⁸²

With regards to the latter, it was held that morality relates to the belief as to what is right or wrong. This belief stems from the totality of natural norms that are inherent in particular cultures. The Board held that the relevant culture would be European society and civilization. Naturally, for purposes of this dissertation, the relevant culture would be South African. Inventions which are contrary to the accepted standards of conduct in South African society would thus be subject to an objection in terms of Section 25(4)(a) of the Patents Act.

However, reliance on cultural norms are potentially problematic in that neither morality nor *ordre public* are defined in legislation. The concepts primarily represent value judgements that are difficult to formulate due to the wealth and diversity of human minds. Further, deeply rooted norms are not necessarily representative of a country's culture. "Non culture" such as slavery, torture or certain medical experiments could be considered deep rooted.¹⁸³ It is for these reasons that the Board in the *Oncomouse* decision was hesitant to place significant reliance thereon. Despite the aforesaid, the Board did however emphasize that the deeply rooted norm of animals not being akin to inanimate objects should be respected.¹⁸⁴

The Appellants in the *Oncomouse* decision further relied upon opinion polls as a representation of public perception on morality. Such polls indicated that the majority regarded the patenting of genetically manipulated animals for cancer research morally reprehensible.¹⁸⁵

¹⁸² Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03, paragraph 10.2.

¹⁸³ *Infra*, paragraph XXV (4).

¹⁸⁴ Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03, paragraph 10.3

¹⁸⁵ *Op cit*, paragraph XXV (5).

The Board once again relied on the Plant Genetic Systems matter wherein it was held that opinion polls cannot be considered decisive when assessing patentability in terms of Article 53(a) for, *inter alia*, the following reasons¹⁸⁶:

- I. Opinion polls are not necessarily reflective of deep-rooted moral norms or ordre public concerns.
- II. The results of opinion polls are unpredictable and can fluctuate within a short period of time. The polls can also be easily influenced depending on a number of factors.
- III. Certain groups of people only reflect their specific interests or biased beliefs and cannot be seen to represent a collective view of society at large.
- IV. An Article 53(a) enquiry has to be considered on a case by case basis. Accordingly opinion polls would have to be conducted on an *ad hoc* basis to cater for the specific facts. This is unfeasible.

The question thus posed is what criteria should be taken into account in an Article 53(a) enquiry? In the Oncomouse decision, the Board held that the starting point for a “real” Article 53(a) assessment is the test formulated in T 19/90¹⁸⁷. The test was set out as follows¹⁸⁸:

“The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand and the invention’s usefulness to mankind on the other.”

¹⁸⁶ Plant Genetic Systems matter, paragraph 15.

¹⁸⁷ Fn 166.

¹⁸⁸ Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03, paragraph 10.5

As indicated previously, this test differs from the Rule 23d(d) test in that it requires animal suffering and environmental risks to be carefully weighed up against usefulness to mankind (as opposed to a substantial medical benefit). The burden of proof in an Article 53(a) enquiry is also different from a Rule 23d(d) enquiry in that the former requires “a careful weighing up” whereas the latter requires only a likelihood.¹⁸⁹

Further, the word “mainly” used in the formulation of the T19/90 test indicates that other considerations can be taken into account when conducting the enquiry.¹⁹⁰

The Board considered three additional considerations. They were¹⁹¹:

- I. The resultant Oncomice posed a threat to evolution.
- II. The grant of the patent would encourage trade in animals and promote an increase in the number of transgenic mice used in cancer research.
- III. Public perception regards the genetic manipulation of animals in medical research morally reprehensible.

A number of factors are identifiable by the Board in consideration of the above contentions. They are¹⁹²:

- I. Arguments that generally relate to the morality of animal patents are irrelevant. One would need to consider the morality of the exploitation of the particular invention in contention.

¹⁸⁹ Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03, paragraph 10.6

¹⁹⁰ *Op cit*, paragraph 10.7.

¹⁹¹ *Op cit*, paragraph 13.2.10.

¹⁹² *Op cit*, paragraphs 13.1.11 – 13.2.21.

- II. Care and consideration for the wellbeing of animals is an accepted tenant of European Culture.
- III. The grant of a patent will not necessarily result in increased use of transgenic mice or encourage animal trade. The monopoly afforded upon the grant of a patent only allows work of the patent by the patentee and it's licensees for the duration of the patent. This may mean that the use of modified mice would be less than it otherwise would be since unrestricted competition usually leads to an increase in economic activity.
- IV. Any objections based on public perception must be substantiated by sufficient evidence. A fact would not be considered sufficiently proven if it is merely alleged in written or oral argument.
- V. The use of animals for medical research and testing is also an established tenant of European Culture.
- VI. Public unease in relation to patents involving animals cannot be elevated to the status of moral disapproval of the use of animals in medical research.

5.2 CANADIAN CASE LAW

The Supreme Court of Canada also considered the patentability of Harvard's Oncomouse.¹⁹³ The court found against Harvard and held that the words "manufacture" and "composition of matter" in the context of the Canadian Patents Act¹⁹⁴ were not broad enough to include higher life forms.¹⁹⁵

¹⁹³ Harvard College vs Canada (Commissioner of Patents) 2002 SCC 76.

¹⁹⁴ R.S.C 1985 c. P-4.

¹⁹⁵ Fn 186, paragraph 153.

The provisions of the Canadian Patents Act do not correspond with British, European or South African legislation and thus provide little guidance on the interpretation of the substantive requirements of patent law in their application to transgenic life forms for purposes of this dissertation. The concept of morality, however, is universal in nature. In this regard the Supreme Court dealt with a number of policy arguments advanced against the grant to the patent. These arguments can be useful in the formulation of “additional considerations” encompassed in the T 19/90 test. The arguments were, *inter alia*, as follows:¹⁹⁶

- I. The absence of a regulatory framework dealing with genetic patents is a clear indication of the legislations intention not to grant patents for genetically engineered higher life forms.
- II. The deliberate engineering of a sentient being to grow painful malignant tumours offend against animal rights.
- III. The grant of the patent would treat life as a commodity in that living entities become commodities.
- IV. Genetically modified organisms pose a threat to the environment.

The Supreme Court concluded that the policy implications for and against patent protection of the Oncomice were vast and varied but declined to formulate any test therefore. Instead the court held that the balance between the competing interests should be regulated by Parliament.¹⁹⁷

5.3 SOUTH AFRICAN LEGISLATION

In South Africa, the regulation of policy implications can be gleaned from the Genetically Modified Organisms Act¹⁹⁸. The Act provides measures to promote

¹⁹⁶ Fn 186, paragraphs 75 – 106.

¹⁹⁷ Fn 186, paragraph 107.

¹⁹⁸ 15 of 1997.

the development, production, use and application of genetically modified organisms in a responsible manner and with adequate levels of protection for biodiversity as well as human and animal health.¹⁹⁹

The Act further provides for the establishment of the Executive Council of Genetically Modified Organisms²⁰⁰ which is tasked with advisory powers on all aspects of genetically modified organisms and further with ensuring that any activities performed are in accordance with the Act.²⁰¹ Section 10 of the Act establishes an Advisory Committee. Members of the committee should be knowledgeable in the fields of science that are applicable to the development and release of genetically modified organisms including their relationship to ecological matters and impact on human and animal health.

The Act further identifies certain aspects relating to genetically modified organisms that require consideration²⁰². *Inter alia*, they are:

- I. Aspects relating to the introduction of genetically modified organisms into the environment.
- II. Proposals for specific projects or activities relating to genetically modified organisms.
- III. Aspects concerning the contained use of genetically modified organisms.
- IV. The importation and exportation of genetically modified organisms.

¹⁹⁹ *Op cit.*

²⁰⁰ Act 15 of 1997, Section 3.

²⁰¹ *Op cit*, Section 4.

²⁰² *Op cit*, Sections 11 and 20.

- V. The classification and types of genetically modified organisms.
- VI. Requirements for laboratory development of genetically modified organisms.
- VII. Facility standards for activities involving genetically modified organisms.
- VIII. Effective waste management.
- IX. Release and marketing of genetically modified organisms.
- X. Classes of genetically modified organisms that should be exempted from application of the Act.
- XI. Information to be supplied in the event of any accident involving genetically modified organisms.

The promulgation of the Genetically Modified Organisms Act signifies a clear intention on the part of the South African legislator to acknowledge the significance of genetically modified organisms and their role in commerce and agriculture and further provides regulatory mechanisms in place governing their control and protection. The Act is also useful in gleaning what policy implementations should be taken into account when conducting an enquiry into Section 25(4)(b) of the Patents Act.

5.4 SUMMARY

The interpretation of the morality clauses forming part of the Patents Act, the European Patent Convention and the British Patents Act (and their

biotechnology directives) provide insight into the host of ethical questions associated with the patentability of transgenic life forms.

In terms thereof, a non-exhaustive list of inventions are deemed unpatentable. They are: processes for cloning human beings; processes for modifying the germ line identity of human beings; uses of embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal, and also animals resulting from such processes.

Any patent falling within one of these categories will be *ipso facto* denied. However, cases that do not fall under one of the unpatentable categories would require further consideration. Factors to be considered in such enquiry include a balancing test wherein animal suffering was weighed against medical benefit or usefulness to man or animal; the protection of public security, the physical integrity of individuals that form part of society and environmental protection (as part of an enquiry to *ordre public*); and inventions that are contrary to the accepted standards of conduct in the relevant society substantiated by sufficient evidence (as part of an enquiry into morality).

The Supreme Court of Canada declined to formulate a test in relation to morality and indicated that any balance between competing interests should be formulated by parliament.

The South African judiciary has yet to adjudicate on the patentability of transgenic animals (and any morality considerations associated thereto) but The Genetically Modified Organisms Act signifies a clear intention on the part of the South African legislator to acknowledge the significance of genetically modified organisms and their role in commerce and agriculture. Its provisions are thus useful in gleaning what policy implementations should be taken into account when conducting an enquiry into Section 25(4)(b) of the Patents Act.

6. CHAPTER 6: CONCLUSION

The biotechnology revolution is fuelled by human ingenuity. This attracts patent protection in that the ingenuity is rewarded whilst still ensuring that the public benefit from the developments thereof.

A patent is an important instrument for the field of technological research. The patent, however, does not give its holder a license to practice the invention without any regulatory control. The invention claimed may only be exploited, for a limited period of time, within the framework defined by national laws and regulations.²⁰³ It is for these reasons that a patent cannot be equated to ownership²⁰⁴ but is rather an intangible property right.

The patent protects the invention by preventing the unauthorized use by others for a limited period of time from exploiting the information so disclosed. It also provides a *quid pro quo* in that persons skilled in the art can stand on the shoulders of those who have gone before and help to further advance the frontiers of knowledge. It is for this reason that innovation is the lifeblood of modern economy and we neglect rewarding it at our peril.²⁰⁵

As discussed above,²⁰⁶ there are a number of ways to “create” transgenic life forms. However this can only be done through the manipulation of already existing organisms. It has been said that inventors of genetically modified organisms are not inventors in the true sense of the word but rather tinkerers.²⁰⁷ That being said, it is the extent of this intervention that gives the invention value and brings the application of patent law to the fore.

²⁰³ Plant Genetic Systems matter, paragraph 18.2.

²⁰⁴ E Hurter “*No One ‘Owns’ the Genome: The United States Supreme Court Rules that Human DNA Cannot Be Patented.*” (2013) 6 South African Journal of Bioethics and Law.

²⁰⁵ Harvard College vs Canada (Commissioner of Patents) 2002 SCC 76, paragraph 20.

²⁰⁶ *Supra*, Chapter 1.

²⁰⁷ Lacey and Lamont “Should genetically modified organisms be patentable?” Australian Association for Professional and Applied Ethics 12th Annual Conference 28–30 September 2005, Adelaide.

Biotechnological inventions require careful analysis because many natural substances are selected and adapted for industrial, commercial and medical use.

Natural material is thus changed by human intervention and the resulting invention is not the same as that which exists in nature.²⁰⁸ Further, due to the rapidly advancing pace of technology, the benchmarks used to assess the patentability of biotechnological inventions are forever changing.²⁰⁹

South African courts have not yet adjudicated upon the patentability of transgenic life forms. The requirements of patentability in terms of the Patents Act and their application to transgenic life forms have been interpreted above having specific regard to precedents in comparable jurisdictions.

In determining whether a transgenic animal will be patentable in South Africa, the following assessment is proposed:

- I. Determining whether the invention is excluded on the basis that it constitutes a plant or animal variety. Rule 26(4) of the European Patent Convention and Schedule A2 of the British Patents Act provide valuable insight in what constitutes a plant variety. These provisions can be expansively interpreted in relation to animal varieties. The essential constituents of an animal variety would thus be: an animal classified as forming part of the same species, with unique characteristics that distinguish that animal from other members of the same species, and that these characteristics reveal themselves when a certain set of genes are expressed and remain expressed when the animal reproduces. Furthermore, biotechnological inventions should not be confined to a particular animal variety but can be granted if varieties fall within the scope of their claims.

²⁰⁸ Janice McCoy "Patenting Life in the European Community: The Proposed Directive on the Legal Protection for Biotechnological Inventions" *Fordham Intellectual Property, Media and Entertainment Law Journal*, Volume 4, issue 2, page 527.

²⁰⁹ British Biotechnology Directive.

- II. Determining whether the invention is excluded on the basis that it is an essentially biological process for the production of animals or plants, not being a microbiological process or the product of such process. The exclusion on “essentially biological processes for the production of animal or plants” can be interpreted as any process which consists of entirely natural phenomena or considered as having a “*biological essence*”. This would be the case where any technical intervention is of a non-significant nature and does not result in a decisive impact or a fundamental alteration of a naturally occurring process. With regards to the meaning of the phrase “not being a microbiological process or the product of such process” it appears that the products of microbiological processes cannot be in the form of plant and animal varieties even if microbiological steps were included in the technical process and thus the phrase seems to be limited to microbiological material.

In the event that the invention is not excluded in terms of the above, it needs to be evaluated in terms of the extrinsic requirements of patentability. In this regard:

- III. The invention needs to be new or novel by assessing it in terms of the relevant subject matter forming part of the state of the art before the priority date of an application or patent. In this regard, matter made available to the public, matter contained in a patent application and inventions used secretly and on a commercial scale in South Africa form part of such assessment. In relation to transgenic animals or life forms, the British Biotechnological Guidelines indicate that a natural substance isolated for the first time and which has not been recognized as in existence previously will not lack novelty simply because it has always been present in nature.
- IV. The invention needs to be inventive. In accordance with Section 25(10) of the Patents Act, the invention should not be obvious to a person

skilled in the art, having regard to any matter from forms part of the state of the art immediately before the priority date of the invention. In this regard Inventiveness can be said to be present if a previously unrecognized technological benefit has been disclosed. If an invention does not go beyond the normal progress of technology and merely follows logically from the prior art, it would be deemed obvious. The same can be said for an invention which is self evident to a person skilled in the art. For purposes of biotechnological inventions dealing with transgenic animals, the person skilled in the art is well aware of the fact that even a small structural change in a product or procedure can produce dramatic functional changes.

- V. The invention must be capable of being applied in trade and industry. Simplistically put, the invention must be able to be implemented or put into practice in the relevant fields of human endeavour. The invention also needs to be assessed in light of The Patents Act implementation exclusions. As indicated, these inventions would normally fulfil the other requirements of patentability but are deemed unimplementable on public policy or ethical grounds and are thus not industrially applicable.²¹⁰ The implementation exclusions are: a frivolous application because it claims an invention which is obviously contrary to well established natural laws²¹¹; use of the invention would be expected to encourage offensive or immoral behaviour²¹² (discussed below); and use of the invention may be carried out in a way that is contrary to law.²¹³ In assessing the industrial application of inventions claiming transgenic life forms, the decisions of the decisions of the European Patent Office and UK Supreme Court provide valuable guidance. In light of these decisions, industrial applicability seems to turn on a sound and concrete technical basis so as to enable the skilled person to recognize

²¹⁰ Klopper *et al* (2011) 290 – 291.

²¹¹ Section 36(1)(a) of the Patents Act.

²¹² Section 36(1)(b) of the Patents Act.

²¹³ Sections 36(2) and 25(4)(a) of the Patents Act.

the contribution to the art and to determine if such contribution could lead to concrete, practical exploitation in the industry and a financial or commercial benefit.²¹⁴

Lastly, the invention needs to be assessed in light of the extrinsic exclusion dealing with a lack of morality as encompassed in Section 25(4)(a) of the Patents Act.

- VI. The wording of Section 25(4)(a) is mirrored in Article 53(a) of the European Patent Convention and Section 1(3) of the British Patents Act and, as such, provide valuable interpretational tools for South Africa. Both the European Patent Convention and the British Patents Act deem certain inventions unpatentable. This is not a closed list and includes processes for cloning human beings; processes for modifying the germ line identity of human beings; uses of embryos for industrial or commercial purposes and; processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal, and the animals resulting from such processes (the last exclusion being the most important for purposes of this thesis). Any inventions falling within one of these categories will be *ipso facto* denied. All other cases would require further considerations such as a balancing test wherein animal suffering is weighed against medical benefit or usefulness to man or animal; the protection of public security, the physical integrity of individuals that form part of society and environmental protection (as part of an enquiry to *ordre public*); and inventions that are contrary to the accepted standards of conduct in the relevant society substantiated by sufficient evidence (as part of an enquiry into morality). Reliance on cultural norms in any morality enquiry are potentially problematic in that neither morality nor *ordre public* are defined in legislation and represent value judgements that are difficult to formulate due to the wealth and diversity of human minds in modern society and thus the “balancing test” is a

²¹⁴ *Supra*, pp 43 – 47.

more reliable tool (such test to be decided on a case by case basis taking into account the rapidly changing developments inherent in biotechnology). Any competing interests may also be regulated by Parliament. South Africa does not have its own biotechnology directive but acknowledges the regulatory framework required to address this legislative gap in the Genetically Modified Organisms Act ²¹⁵ and its provisions are useful in gleaning what policy implementations should be taken into account when conducting an enquiry into Section 25(4)(b) of the Patents Act.

The patentability of transgenic life forms raise a host of ethical and legal questions which the Patent Act as it stands is wholly illequipt to deal with. Research with animals is necessary and can be described as common practice world wide. That being said, any suffering should be weighted against potential benefits and effective regulatory controls should be put in place to guard against practices and behaviour that causes unacceptable suffering to animals.²¹⁶

Despite the moral concerns and risks inherent in biotechnological patenting, students species formation generally agree that transgenic animal research and commercial application are not as significant a threat to species as land use and destruction of habitats inherent in other human activities. ²¹⁷

The patent relating to Harvard's *Oncomouse* has, *inter alia*, been granted in Australia, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy,

²¹⁵ Act 15 of 1997.

²¹⁶ T Schreuker *et al* "*Ethical Issues Associated with the Patenting of Higher Life Forms*" Westminster Institute for Ethics and Human Values (17 May 1997).

²¹⁷ U.S Congress "*New Developments in Biotechnology: Patenting Life*" Special Report, Office of Technology Assessment (1989).

Luxemborg, The Netherlands, Portugal, Spain and Sweden whilst similar patents have been granted in Japan and New Zealand.²¹⁸

The patentability of transgenic animals has cast a world wide net. Any attempt at harmonization in South Africa should recognize that patent law as a whole does not function in isolation but is merely part of the instruments used to govern the technical and ethical character of society.²¹⁹

Total words: 17 887

²¹⁸ P Campbell "Patentable subject matter in biotechnology: Transgenic animals and higher life forms" Centre for Advanced Study on Research on Intellectual Property (2007) <https://www.law.washington.edu/Casrip/Newsletter/default.aspx?year=2007&article=newsv14i1Campbell#top> <accessed on 15 August 2016>

²¹⁹ *Op cit.*

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