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PATENT PROTECTION FOR BIOTECHNOLOGICAL
INVENTIONS: A STUDY OF LEGAL AND ETHICAL
ISSUES

BY

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requirement for the degree of Master of Comparative
Laws

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ABSTRACT

Tremendous advances in the field of biotechnology that enable the selection and manipulation of genetic materials for various purposes have attracted heightened public interest not only in the commercial uses of living organisms but also in the grant of intellectual property rights on biotechnological inventions. The patenting of plants, animals and genetic materials has raised heated debates and conflicting arguments in favour or against the issuance of such patents, that go beyond the question of their eligibility for patent protection to the question of the ethical desirability of patent protection and the socio-economic impact of patent rights on fundamental biotechnological innovations.

This study analyses some of the legal, ethical and socio-economic considerations raised by the patenting of biotechnological inventions. Shaped by a comparative analysis of the United States' and the European patent law and administrative interpretation, and by decided cases in the jurisdictions, this study observes how the complex issues have been addressed and handled by the patent systems. It also evaluates some of the ethical issues in the light of Islamic law and proposes Islamic principles as determinants of an ethical standard in response to the ethical challenges that confront the patenting of biotechnological inventions.

This study notes that despite the protection provided for (or withheld from certain) biotechnological inventions, many of the issues have yet been fully resolved. Various legal, ethical and socio-economic issues will continue to besiege biotechnology patents as scientific and technological developments continue to grow. The main challenge faced by the patent systems, thus, is to strike a proper balance between the needs and interests of the biotechnology industry and those of society. While there is no clear or easy answer to solving all the issues, appreciation of the complexity of the issues and the significance of the matters is an essential step to face further challenges to come.

ملخص البحث

إن التطور الكبير في مجال التقنية الحيوية من الاختيار لمواد وراثية لأغراض المختلفة لا تقتصر فيه للأعمال التجارية، إنما تعلق أيضاً بمنح حقوق الملكية الفكرية والقانونية لتسجيل براءة الاختراعات العلمية الجديدة في عدة مجالات حيوية سواء أكانت في النباتات أو الحيوانات. وتسجيل براءة الاختراع لتغيير المواد الوراثية في الحيوانات، أثار جدل وتعارض في إصدارها وتسجيلها، وتجاوز عن ذلك استحقاقهم في مسألة تسجيل الحماية الأخلاقية لها، مع تأثرها بعوامل اجتماعية واقتصادية للحقوق المسجلة في إبداع التقنية الحيوية.

وقدمت الدراسة اعتبارات عدة منها؛ القانونية، والأخلاقية، والاجتماعية والاقتصادية في تسجيل براءة الاختراع لمجال تقنية التكنولوجيا الحيوية، مع تقديم المقارنة بقوانين وتفسيرات إدارية مسجلة للقوانين الأمريكية والأوروبية، وسجلت تقاريرها لدى السلطات القضائية، لأن هناك قضايا معقدة في السجل التقني عولجت بالأنظمة والقوانين الأمريكية والأوروبية. ومنها قُيِّمت بعض القضايا الأخلاقية في ضوء القانون الإسلامي، والتي لا تتعارض مع مبادئ الشريعة الإسلامية باعتبار المعيار الأخلاقي لها، وتقييد أجوبة التحديات الأخلاقية بحدود الأخلاق الإسلامية لمجال استحقاق براءة الاختراع في التقنية البيولوجية.

ولوحظت في هذه الدراسة مسائل كثيرة منها؛ انها لم تقدم الحلول الكاملة والمناسبة سواء القانونية، أو الأخلاقية أو الاقتصادية في منح حقوق الملكية الفكرية لبراءة الاختراع في التقنية الحيوية، وبالرغم من وجود قانون حماية الملكية لبراءة الاختراع غير كاملة إلا أن التطور فيه مستمر. والقضية تطرح فيه محصورة كقضايا قانونية، وأخلاقية، واجتماعية، واقتصادية. والتحدي الرئيس الذي يواجه به نظام براءة الاختراع في تضارب ذلك لإيجاد موازنة صحيحة بين الحاجات والمصالح، صناعة التقنية الحيوية مع مصالح المجتمع، مما يزيد تعقيد القضايا مع أنها أمور ضرورية. بالرغم من عدم الإدراك وتعقيد الحلول لكل قضية من القضايا المتعلقة بحماية الملكية الفكرية لبراءة الاختراع في التقنية الحيوية، إلا أن قضاياها جديرة بالذكر لمواجهة تحديات أخرى في المستقبل.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Master of Comparative Laws.

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Dean, Ahmad Ibrahim Kulliyah of Laws

DECLARATION

I hereby declare that this dissertation is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at HUM or other institutions.

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**PATENT PROTECTION FOR BIOTECHNOLOGICAL INVENTIONS: A
STUDY OF LEGAL AND ETHICAL ISSUES**

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In the Name of Allah, the Most Gracious, the Most Merciful

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CONTENTS

Abstract.....	ii
Abstract in Arabic.....	iii
Approval Page.....	iv
Declaration Page.....	v
Copyright Page.....	vi
Acknowledgements.....	vii
Contents.....	viii
List of Cases.....	x
List of Statutes.....	xii
List of Abbreviations.....	xiii

CHAPTER 1: PATENT PROTECTION OF BIOTECHNOLOGICAL INVENTIONS: AN OVERVIEW

1.1 Introduction.....	1
1.2 The Rise of Biotechnology Patents.....	3
1.3 Fundamental Patent Principles in Relation to Biotechnology.....	5
1.4 The Need For Patent Protection.....	9
1.5 The Biotechnology Patent Debates.....	10

CHAPTER 2: LEGAL ISSUES IN PATENTING BIOTECHNOLOGICAL INVENTIONS

2.1 Introduction.....	13
2.2 Legislative Setting.....	14
2.3 Biotechnology As Patentable Subject Matter.....	17
2.3.1 The Concept of Invention, Discovery and Products of Nature....	21
(i) Products of Nature.....	25
(ii) Living Matters.....	32
2.3.2 The Patentability of Genetically Modified Microorganisms.....	34
2.3.3 The Patentability of Plants.....	35
2.3.4 The Patentability of Animals.....	42
2.3.5 The Patentability of Genetic Materials.....	48
2.4 Substantive Requirements Of Patentability.....	55
2.4.1 Novelty.....	56
2.4.2 Nonobviousness/Inventive Step.....	58
2.4.3 Industrial Applicability/Utility.....	66
2.5 Appraisal.....	72

CHAPTER 3: ETHICAL ISSUES IN PATENTING BIOTECHNOLOGICAL INVENTIONS

3.1 Introduction.....	74
3.2 Ethics And Biotechnology Patents: Unfolding The Debates.....	76
3.3 Comparative Approaches In Addressing The Ethical Issues In Biotechnology Patenting.....	80
3.3.1 The US Approach.....	80
3.3.2 The European Approach.....	85
3.3.3 The Biotechnology Directive.....	95

3.4	Addressing the Ethical Concerns According to Islamic Perspectives...	115
3.4.1	The Validity of Intellectual Property Rights.....	115
3.4.2	The General Principles.....	117
3.4.3	The Application of the principle of Masalih al-Mursalah.....	119
3.4.4	The Application of the Principle of Sadd al-DharT'ah.....	122
3.5	Appraisal.....	123

CHAPTER 4: BIOTECHNOLOGY PATENTS AND IMPLICATIONS FOR RESEARCH AND INNOVATION

4.1	Introduction.....	126
4.2	Patents And Genetic Innovations: Economic Incentives vs. Policy Concerns.....	127
4.3	The Conundrum of Gene Patents.....	130
4.3.1	Arguments For Strong and Expansive Patent for the Progress of Research and Innovation.....	132
	(i) The Incentive to Invest.....	132
	(ii) The Incentive to Disclose.....	133
	(iii) The Incentive to Innovate.....	134
	(iv) The Prospect Theory.....	134
4.3.2	Arguments of Adverse Impacts of Patent Rights on Research and Innovation.....	136
	(i) Restriction To Free And Rapid Diffusion Of Information....	136
	(ii) Restriction Of Access To Fundamental Resources Of Innovation.....	137
	(iii) Research Dependency On The Genetic Information Both In The Upstream Level And Downstream End-Product.....	141
	(iv) Threat To The Traditional Function Of The Public Research.....	143
	(v) Threat To Equitable Access To Healthcare Products And Services.....	143
4.4	Potential Solutions.....	146
	(i) Reformation of the Existing System.....	146
	(ii) Enactment of New Legislation.....	147
	(iii) Self Regulation.....	148
4.5	Appraisal.....	149

CHAPTER 5: CONCLUSION

5.1	Introduction.....	150
5.2	Conclusion.....	150
5.3	Recommendations.....	156

BIBLIOGRAPHY.....	160
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LIST OF CASES

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(Directive 98/44/EC)
The European Patent Convention 1973
The Intellectual Property Corporation of Malaysia Act 2002 (Act 617)
The Malaysian Patents Act 1983 (Act 291)
The United Kingdoms Patents Act 1949
The United States Patent Act 1952 (Title 35 of the US Code)
The United States Plant Patent Act 1930
The United States Plant Variety Protection Act 1970

LIST OF ABBREVIATIONS

Alberta L. Rev.	Alberta Law Review
Ariz. St. L. J.	Arizona State Law Journal
art/arts.	article/articles
B.U.J. SCI. & TECH. L.	Boston University Journal of Science and Technology Law
Berkeley J. Int'l L.	Berkeley Journal of International Law
Berkeley Tech. L. J.	Berkeley Technology and Law Journal
BIO	Biotechnology Industry Organisation
Biotech Directive	The European Directive for the Legal Protection of Biotechnological Inventions 98/44/EC
BPAI	The USPTO Board of Patent Appeals and Interference
CAFC	US Court of Appeal for the Federal Circuit
CBD	Convention on Biological Diversity
Columbia L. Rev	Columbia Law Review
DNA	Deoxyribonucleic Acid
e.g.	(exempligratia); for example
EC	European Commission
ECJ	European Court of Justice
EGE	European Group on Ethics in Science and New Technologies
EIPR	European Intellectual Property Report
Emory L. J.	Emory Law Journal
EPC	European Patent Convention
EPO	European Patent Office
EPOR	European Patent Office Report
ESTs	Expressed Sequence Tags
etc.	(et cetera); and so forth
EU	European Union
Fordham Intell. Prop. Media & Ent. L. J.	Fordham Intellectual Property, Media & Entertainment Law Journal
GATT	General Agreement of Tariffs and Trade
Geo. L. J.	Georgetown Law Journal
GRDAA	Genome Research and Diagnostic Accessibility Act
GRUR	Gewerblicher Rechtsschutz und Urheberrecht
GSTIA	Genomic Science and Technology Innovation Act
Guidelines	Guidelines for Examination in the European Patent Office
Hous. J. Int'l L.	Houston Journal of International Law
i.e.	that is
ibid.	(ibidem); in the same place
IDEA	The Journal of Law and Technology
IIC	International Review of Industrial Property and Copyright Law
Ind. Int'l & Comp. L. Rev.	Indiana International & Comparative Law Review
J. L. & Tech	Journal of Law and Technology

Minn. Intell. Property Rev.	Minnesota Intellectual Property Review
n.d.	no date
N.Y.U.L. Rev.	New York University Law Review
no.	Number
OECD	Organisation for Economic Co-operation and Development
OJEPO	Official Journal of the European Patent Office
Para	Paragraph
PPA	The United States Plant Patent Act 1930
PPA	The US Plant Patent Act
PVPA	The United States Plant Variety Protection Act 1970
rev.	Revised
RPC	Reports of Patent Design and Trademark Cases
Santa Clara Computer & High Tech. L.J	Santa Clara Computer and High Technology Law Journal
T. Jefferson L. Rev.	Thomas Jefferson Law Review
TRIPS	Trade Related Aspects of Intellectual Property Agreement
UK	The United Kingdom
UOLTJ	University of Ottawa Law and Technology Journal
UPOV	International Union for the Protection of New Varieties of Plants
US	United States of America
USC 35	The United States Code Title 35
USPTO	United States Patent and Trademark Office
v.	versus, against
vol./vols.	volume/volumes
Wake Forest L. Rev.	Wake Forest Law Review
Wash. U. Global Stud. L. Rev.	Washington University Global Studies Law Review
Wash. U. J. L. Pol'y	Washington University Journal of Law & Policy
Willamete L. Rev.	Willamete Law Review
WIPO	World Intellectual Property Organisation
Wm and Mary L. Rev.	William and Mary Law Review

CHAPTER 1

PATENT PROTECTION OF BIOTECHNOLOGICAL INVENTIONS: AN OVERVIEW

1.1 INTRODUCTION

The 21st Century is hailed by many as "the Biotech Age", wherein biological materials and sciences are set to be the new engines that will drive the economics of the new century.¹ Fuelled by remarkable developments in the field of biotechnology, the lucrative promises of new breakthroughs and innovations, especially in the area of genetic engineering, have sent researchers, corporations and governments scurrying all over the globe in the quest for genetic materials that might have future market potentials, modifying and patenting them as their "inventions." Whilst it is generally acknowledged that patent is a crucial legal tool for the protection of new inventions, and that it provides the necessary incentive to promote research, development and innovation, the race to acquire patent rights to biological processes and products is provoking a heated debate worldwide on a host of legal, ethical and social issues and concerns due to the subject matter's direct connection to living beings and materials.

This study explores and provides a critical insight into some of the issues that surround biotechnology patents. It adopts an analytical and comparative approach in examining the development of biotechnology patent laws in the US and Europe, two regions that have broken new ground for most major changes in the technology and patent law over the past century. This study also analyses Islamic views and perspectives in relation to the moral and ethical concerns raised by biotechnology

¹ Richard W. Oliver, *The Biotech Age: The Business of Biotech and How to Profit from It*, McGraw Hill, New York, 2003, at 1.

patents, and proposes to advance Islamic principles as answers to the ethical challenges that confront the patenting of biotechnological inventions.

The examination of the international developments in this area is beneficial for future review of our existing policies, in view of limited jurisprudence on the issues in Malaysia, and in line with our international obligations under the TRIPS Agreement.² Additionally, the inclusion of Islamic perspectives on the ethical issues is pertinent in the light of the influence of Islamic law either directly or indirectly on the general laws and policies of many Islamic countries³ including Malaysia. A revitalization of Islamic laws and values in many Islamic countries around the world also warrants recognition of its effects and presence.

This study is organized as follows. Chapter 1 guides the foray into biotechnology patenting debates by offering a brief overview of the historical and general background. Chapter 2 analyses the legal issues by examining and addressing the conceptual and technical objections against biotechnology patents. This part focuses primarily on the examination of the requirement of patentable subject matters and the substantive requirements of novelty, non-obviousness/inventive step and industrial applicability/utility; and how these patent requirements have been stretched to accommodate new developments in relation to biotechnology. Chapter 3 shifts the focus to the moral and ethical issues brought about by the patenting of living organisms and the difficulties experienced by the patent laws in responding to the

² Art. 27(1) of the TRIPS Agreement states that patents shall be available for any inventions, whether products or processes, and in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Art. 27(2), however, allows the member countries to exclude from patentability, inventions, the commercialization of which may be against the accepted norms of ethics and morality in their respective countries. Art. 27(3) in addition, allows the exclusion of a number of other subject matters such as diagnostic, therapeutic and surgical methods from patentability. Patent legislations in various countries including Malaysia uphold a general consideration of the spirit of the TRIPS Agreement.

³ Amir H. Khoury, "Ancient and Islamic Sources of Intellectual Property Protection in the Middle East: A Focus on Trademarks," *IDEA*, vol. 43 (2003): 151. LexisNexis Total Research System, via LexisNexis, <<http://www.lexisnexis.com>>.

intricacies posed by the ethical side of biotechnological inventions. This part evaluates some of the issues in the light of the principles of Islamic law and proposes Islamic principles as a determinant of ethical standards in answer to the ethical challenges that confront the patenting of biotechnological inventions. Chapter 4 explores and assesses the arguments for and against patent protection of gene-related inventions and the implications of such patents on research and innovations. Chapter 5 ends this study with a conclusion and recommendations.

1.2 THE RISE OF BIOTECHNOLOGY PATENTS

Biotechnology is defined in a plain and simple way by its two root words: bio — which means the use of biological processes; and technology — to solve problems or to make useful products.⁴ The application of biological processes is not a new phenomenon. Since the dawn of agriculture, we have been using living micro-organisms in fermentation processes for the production of cheese, beer etc. and biological processes to improve agriculture and animal husbandry through selective breeding and crossbreeding.

What is more recent and attracting much attention, however, is the use of cells, genes and other biological elements to solve problems and make useful products.⁵ The identification of deoxyribonucleic acid (DNA) in 1944 and the discovery of its double helix structure by James Watson and Francis Crick in 1953 paved the way for

Biotechnology Industry Organization (BIO), *The Editors' and Reporters' Guide to Biotechnology 2004-2005* (Biotechnology Industry Organization (BIO)) at 1, <<http://www.bio.org/speeches/pubs/er/BiotechGuide.pdf>> viewed on 1 January 2005.

⁵ Biotechnology in this new sense is defined by the Office of Technology Assessment of the US Congress as "any technique that uses living organisms or their products to make or modify a product, to improve plants or animals, or to develop microorganism for specific uses." See Office of Technology Assessment of the US Congress, *New Developments in Biotechnology: Patenting Life—Special Report* (Office of Technology Assessment of the Congress of the United States) at 3, <<http://www.wss.princeton.edu/ota/disk1/1989/8924/8924.PDF>> viewed on 1 January 2005. A more all encompassing definition can be found in Article 2 of the Biodiversity Convention which defines "biotechnology" as "any technological application that uses biological system, living organism or derivatives thereof, to make or modify product or processes for specific use."

the emergence of modern biotechnology in the 1970's. Building upon the discovery, scientists have developed new technologies and products based on the use of cells and biological molecules and have utilized cellular and molecular biology for human needs. Cohen and Boyer's announcement in 1973 of their successful attempt to construct a recombinant DNA molecule containing genetic materials from two different species⁶ introduced the technique of genetic engineering or gene splicing which has been applied to higher life forms producing transgenic animals and plants for increased yield, diversity and quality; and allowing isolation of human genes for the production of pharmaceutical products in microorganisms such as bacterium. Advances in the field of biotechnology have stimulated other innovations such as cloning, bio-catalysis, genetic testing, gene therapy, monoclonal antibodies and so on that offer much hope in research and development in the health, agricultural, food, as well as in the industrial and environmental sectors.

As in other fields of technology, patent law plays a crucial role in the legal protection of biotechnological inventions. The first known patent in relation to living organisms was granted in Finland in 1843 for a yeast ("ferment de poche") followed by Louis Pasteur's patent in the US in 1873 on yeast that was "free from organic germs."⁹ In the ensuing years patents were granted for antitoxic serum, bacterial vaccine, fermentation processes with the aid of bacteria, antibiotics produced with the aid of micro-organisms etc.¹⁰ The patentability of living materials, nonetheless,

⁶ *History of Biotechnology*, (Biotechmedia), <<http://www.biotechmedia.com>> viewed on 1 Jan 2005.

⁷ Phillip W. Grubb, *Patents for Chemicals, Pharmaceutical and Biotechnology*, Oxford University Press, 1999, at 225.

⁸ Biotechnology Industry Organization (BIO), above n. 4 at 3.

⁹ Joseph Strauss, "Biotechnology and Intellectual Property," in *Biotechnology: Legal, Economical and Ethical Dimension*, edited by D. Brauer, VCR, Weinheim, 1995, 281, at 283.

¹⁰ *Ibid.*, Strauss notes that in 1877, a patent was granted for an antitoxic serum; in 1904, for a bacterial vaccine; in 1916, for a viral vaccine in the US; and that from 1877 onwards patents were granted for culturing yeast, fermentation process with the aid of bacteria, and antibiotic penicillin produced with the aid of microorganisms discovered through fermentative method.

seemed to be of limited importance at the time. Only starting from the 1930's, did debates unfold in relation to the patentability of plant breeding processes and new varieties of plants. In order to avoid higher food prices arising out of royalties, plant breeders were provided with a special protective regime, albeit a much weaker protection under plant variety legislation. Such a protective scheme was given an international standing through the International Union for the Protection of New Varieties of Plants (UPOV) Convention 1961.¹¹ In contrast to plant varieties for which a separate scheme of breeder's rights was introduced, no specific animal variety legislation was devised for animal breeding methods. In the 1969 *'Rote Taube'*¹² (*Red Dove*) case, the German Federal Supreme Court recognized the patentability of the animal breeding method and its resulting products, provided the description of the breeding was enabling i.e. it allowed a repetition that would produce the same result. The *Red Dove* case was hardly noticed outside professional circles. However, since the grant of a US patent to Chakrabarty in respect of a genetically-engineered bacterium useful for cleaning oil spills, the laws on the patentability of biotechnological inventions have developed at a rapid rate.¹³

1.3 FUNDAMENTAL PATENT PRINCIPLES IN RELATION TO BIOTECHNOLOGY

Patent has long been seen as an effective legal instrument to protect a wide range of inventions. Patent promotes new research and innovation by ensuring the protection of the fruits of inventive ideas and creativity. A patent may be defined as a grant by

¹¹ Gerd Winter, "Patent Law Policy in Biotechnology," in *Intellectual Property*, edited by Peter Drahos, Ashgate, Dartmouth, 1992, 181, at 183-185.

¹² *'Rote Taube'* case (1969) GRUR 672, 1 IIC 136 (1970) the German Federal Supreme Court case cited in Strauss, above n. 9 at 284.

¹³ Howard Mann, *Intellectual Property Rights, Biotechnology and the Protection of Biodiversity: Literature Review* January 31, 1996 (Industry Canada, Intellectual Property Policy Directorate) at 8, <<http://strategis.ic.gc.ca/pics/ip/mannef.pdf>> viewed on 1 January 2005.

the state of an exclusive right to exclude others from commercially exploiting (making, producing, using or selling) the patented invention for a limited period of time. Patent rights are territorial which means that they are only valid and enforceable within the national jurisdiction that grants the patent.

It is generally accepted that patent confers a negative right i.e. the right to prevent others from doing certain acts in relation to the patented invention without the consent of the patent holder, not the right of the patent holder to exploit the invention. This negative right aspect has been repeatedly used to counter any attack to biotechnology patents especially on ethical grounds. It is interesting to note, however, that the EPO Board of Appeal in *Plant Genetic System*¹⁵ defined a patent as a combination of negative and positive rights. The Board of Appeal stated that:

a patent confers on its owner(s) for a specified time an exclusive right to exploit the subject matter of the claims, i.e. to manufacture, use and market it, and to prevent others from doing the same... the right to exploit the invention is not unconditional. On the contrary, the invention claimed in a patent may only be exploited within the framework defined by national laws and regulations regarding the use of the said invention.¹⁶

The confusing statements on the nature of rights conferred by patents generate debates on the implications of patent protection. Should patents be held responsible for unethical exploitation of biotechnological inventions or is there no tie at all between patent and exploitation? Both sides of the contention have their own arguments and lines of reasoning which deserve another study on its own. What needs to be highlighted at this point is that one does not need a patent to be able to exploit one's own invention. However, the existence of a patent neither gives the patent holder a license to disregard the rights of other

¹⁴ Normally, the period covers 17-20 years but it varies according to the countries. The period may be based on the first to file or the first to invent basis depending on the country.

¹⁵ *Plant Genetic System/Plant Cells*, T356/93, *OJEPO* 1995 545; [1995] *EPOR* 357.

¹⁶ *Ibid.*, at para 18.2.

individuals nor to override public liabilities. The rights conferred by the patent may also be limited by other legislations or regulations or by the existence of other patents.¹⁸

A patent, though an intangible property, may be dealt with in the same manner as a tangible property. It may be sold, leased, mortgaged, assigned etc. to others. However, it is important to distinguish between ownership of an invention or a patent and ownership of goods which incorporate the invention or fall under the patent. The owner of a patent may not necessarily be the owner of the goods that incorporate the patent or invention.¹⁹ In such a case, the respective rights of each owner must be respected. The scope of ownership is one of the points of contention and it has been criticized that "the fundamental distinction between the ownership of patents and the ownership of things which are patented is often misunderstood or deliberately misrepresented, so that for example patents granted for transgenic animals are described as giving ownership of "life" and patents for isolated human genes are described as if they give property rights over human beings."²⁰ One writer was quick to point out that when the US Patent and Trademark Office (USPTO) announced its intention to allow patents on animals in 1987, it was added that human beings were exempt from patentability, because the 14th amendment to the US Constitution prohibits 'ownership' of human beings.²¹ Such a confusing statement only helps to cloud the already grey waters of biotechnology patents.

W. R. Cornish, *Intellectual Property: Patents, Copyright, Trademarks and Allied Right*, 4 edition, Sweet & Maxwell, London, 1999, at 6.

¹⁸ Grubb, above n. 7 at 4.

¹⁹ Ibid., at 5.

²⁰ Ibid.

²¹ Sigrid Sterckx, "European Patent Law and Biotechnological Invention," in *Biotechnology, Patents and Morality*, edited by Sigrid Sterckx, Ashgate, Aldershot, 1999, 1, at 11.

Patent claims may be made for products or processes that result from inventive thought. In the context of biotechnology, the claims may cover three categories, namely the processes for the creation or modification of living organisms and biological materials, the results of such processes, and the use of such results.²² Patent is granted in respect of an "invention" as opposed to a mere "discovery". The question is whether there is really an invention as opposed to scientific discovery. In the context of biotechnology patents this question raises more than one issue on the basis of the prior existence in nature or the product of nature etc.

Biotechnological inventions must also fulfill certain requirements set out in patent legislation. Three universally accepted requirements are novelty, non-obviousness or inventiveness, and industrial applicability or utility. An invention is new if it is not anticipated by prior publication, patent or other ways of disclosure to the public domain.²³ It is considered as involving an inventive step if it is not obvious to a person having ordinary skill in the art at the time the patent application was made.²⁴ Lastly, it is considered industrially applicable if it can be made or used in any kind of industry.²⁵ It has been noted that this third requirement "presents a more significant obstacle to patentability within biotechnology" as scientists sometimes create biotechnological inventions without a precise knowledge of their utilities.

Another important point to note is that patent law usually provides for exceptions to patentable subject matters which relate to materials that might meet the general criteria for patentability but which are still excluded due to certain policy

²² World Intellectual Property Organisation (WIPO), *WIPO Intellectual Property Handbook: Policy Law and Use* (WIPO) at 444, <http://www.wipo.int/about-ip/en/iprm/pdf/detailed_toc.pdf> viewed on 1 January 2005.

²³ Section 14 of the Malaysian Patents Act 1983.

²⁴ Section 15 of the Malaysian Patents Act 1983.

²⁵ Section 16 of the Malaysian Patents Act 1983.

²⁶ John R. Thomas, *An Examination of Issues Surrounding Biotechnology Patenting and Its Effect Upon Entrepreneurial Companies*, 2000 (Franklin Pierce Law Centre-Pierce Law - IP Mall search) at 10, <http://ipmall.info/hosted_resources/crs/RL30648.pdf> viewed on 1 January 2005.

considerations. Variation may occur between different countries' patent legislation. Some countries exclude, for example, methods of doing business, medical treatment, pharmaceutical innovations etc. to suit their own particular socioeconomic situation and to keep the prices of basic necessities such as food, drugs, and agriculture down. It has been noted, however, that rapid changes are occurring in the scope of patentability, with a trend to encompass all products and processes, including living organisms.²⁷

In depth discussion of many of the forgoing fundamentals of patent law as they relate to biotechnology is reserved for later discussion. It has been argued that the patent system was not designed to deal with biotechnology, especially, living organisms. We shall see what steps patent law has had to take to overcome this contention when we come to the legal issues in the patenting of biotechnological inventions.

1.4 THE NEED FOR PATENT PROTECTION

The World Intellectual Property Organization (WIPO) notes that:

As in other fields of technology, there is a need for legal protection in respect of biotechnological inventions. Such inventions are creations of the human mind just as much as other inventions, and are generally the result of substantial research, inventive effort and investment in sophisticated laboratories. Typically, enterprises engaged in research only make investments if legal protection is available for the results of their research. As with other inventions, there is an obvious need for protection of biotechnological inventions, not only in the interest of the inventors, but also in the public interest in order to promote technological progress.²⁸

This statement elucidates, among other things, the significant role played by patent protection for the growth of biotechnological inventions as well as the biotechnology

Belcher and Hawtin, *A Patent on Life: Ownership of Plant and Animal Research*, International Development Research Centre, Ottawa, 1991, at 7.

²⁸ World Intellectual Property Organisation (WIPO), above n. 22 at 444.

industry. Proponents of patent protection see a strong patent protection as essential to attract capital infusion into the industry. The fluctuation of the biotechnology industry related stock market movements as impacted by patent related developments supports their view of the significance of patent portfolio to investors.²⁹ One author even viewed biotechnology as an industry whose wealth resides in its patents more than in its products. ° This is true in the sense that patent rights may be sold, leased, licensed etc. creating income from the intellectual property even if the patentee has yet to market the patented products.³¹

In this regard, it is generally accepted that patents are necessary incentives for the promotion of research, development, innovation and even investment in the biotechnology industry. However, it is important to bear in mind that the objective of patent law is to achieve a compromise between the inventor's/investor's interest in market monopolies and society's interest in the promotion of technological development. For the biotechnology industry, it may be in its interest to maximize the protection, while for society maximizing the disclosure may be more important. This leads to the debate about balancing public and private interest. How to best achieve the balance is still a continuing debate.

1.5 THE BIOTECHNOLOGY PATENT DEBATES

The debates on the legal and ethical problems associated with biotechnology patenting gained momentum in the 1980's and 1990's fuelled partly by the widely known US

Thomas, above n. 26 at 7-8. The writer gives instances where a number of biotechnology companies' stocks prices fell as a result of the Clinton-Blair announcement in 2000 that the raw fundamental data on the human genome should be made freely available to scientists everywhere; and following defeat in a patent case dispute.

³⁰ Ibid., at 7, citing Kenneth J. Burchfiel, *Biotechnology and the Federal Circuit* 818.5 (1995).