UNIVERSITY OF SOUTHAMPTON

The Fundamental Importance of Morality to the Patenting of Animals under the European Patent Convention

by

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Doctor of Philosophy

FACULTY OF LAW

5 March 2002

To 'Lindy' and Dad

and .....

To a Mouse*

".....
I'm truly sorry Man's dominion
Has broken Nature's social union,
An' justifies that ill opinion,
Which makes thee startle,
At me, thy poor, earth-born companion,
An' felllow-mortal!"

(On turning up her nest, with the plough)
Robert Burns November 1785

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ABSTRACT

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The fundamental importance of morality to the patenting of animals under the European Patent Convention

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Article 53 (a) of the European Patent Convention (EPC) which provides that European patents shall not be granted in respect of inventions whose exploitation is contrary to *ordre public* or morality is generally regarded as one of the less important provisions of the Convention, a view broadly held by the European patenting community. Until relatively recently this provision has had minor impact on the decisions of the EPO and has been regarded by the patenting community generally (including practitioners and the examiners at the EPO) as being little more than a nuisance provision. This thesis argues in opposition to the majority view held by the European patenting community that the morality exception is of great importance, not only in relation to the patenting of animals, but also in respect of all inventions.

The importance of Article 53 (a) EPC has increased considerably over the last decade and a half in view particularly of the developments in research in the field of genetic engineering in relation to animals and plants but also human being, for example, human stem cell and cloning research. The introduction of Dolly the sheep to the world, being the first cloned mammal has resulted in an increased general public awareness and a rise in public concern about the long-term implications for man of the application of such technologies. In Europe the European patent system is the foundation on which such technologies are developed and exploited.

Despite the more conventional view held by European patent practitioners that it is quite inappropriate for a morality provision to be included within any patenting regime, the close linking of 'morality' with the protection of intellectual property rights is not a novel concept. This study shows that morality and patentability under the EPC are inextricably linked however much the EPO and the wider European patenting community may wish otherwise and recommends that an ethical group either in the form of an Ethical Board of Appeal or Ethical Division be established within the EPO for dealing with morality issues. Models for the establishment of either an Ethical Appeal Board or Ethical Division are outlined.

The main focus of this study is the first European patent to be granted by the EPO for an animal, a transgenic mouse, the Harvard Oncomouse. The Oncomouse case is a landmark case in animal patenting in Europe and also in respect of establishing the importance of Article 53 (a) EPC. Prosecution of the European patent application for the Oncomouse, from refusal, to grant and into opposition proceedings is reviewed. Its prosecution before the EPO is compared to prosecution of the application before the US and Canadian Patent Offices. The range of arguments put forward based on the grounds that the patent offends against Article 53 (a) during the examination; appeal and opposition proceedings are analysed.

The thesis is critical of the handling of the Oncomouse case by the EPO particularly the effectiveness of the Oral proceedings before the Opposition Division and the EPO's assessment of the objections raised under Article 53 (a). It is acknowledged that morality issues are not easily addressed but the EPO has a duty to treat Article 53 (a) with the due respect it deserves and to provide an adequate system for doing so. It proposes changes to the structure of the EPO to remedy this failure.

The Oncomouse case is still awaiting a final decision by the EPO 16 years after the filing of the application. This will not be available for some time yet, as the pending decision of the Opposition Division will almost certainly be appealed. In addition it is unlikely that the matter will rest there. If the patent is challenged directly in the national courts of some EPC Contracting States and if these States differ in their interpretation of the morality exception, (which in view of the differences in the religious, political and animal welfare positions adopted by certain of the EPC Contracting States they undoubtedly would) this could result in the undermining of the authority of the EPC as a means of harmonising patent protection in Europe.

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ACKNOWLEDGEMENTS

This thesis would not have been possible without the assistance and goodwill of a number of people.

My greatest debt is owed to my supervisor Jonathan Montgomery without whose advice, guidance and endless patience this thesis would not have been written and for which I do thank him.

I should like to acknowledge the assistance of other members of the Law Faculty particularly Dr. Elizabeth Fisher of the Law Faculty (now at Oxford University) and Dr. Stephen Saxby.

My very great thanks go to Compassion in World Farming and the British Union for the Abolition of Vivisection. Particularly Peter Stevenson, Political and Legal Director of CIWF for discussing the Harvard Oncomouse case with me and for allowing me unrestricted access to CIWF files and papers in relation to the Oncomouse case and others and use of the CIWF library and facilities. Also my thanks go to Chnstine Orr, former Political Co-Ordinator and David Thomas at BUAV, Dr. Gill Langley, adviser to CIWF and BUAV and Daniel Alexander, Barrister, for their time in discussing the Oncomouse case with me.

My thanks to Dr. Christian Gugerell of the EPO for his generous help and for his patience in answering all my questions at various times during this study and for whom, like for me, the Harvard Oncomouse has become an integral part of his life. My general thanks also go to the various members of the EPO with whom I have dealt with during the period of this study who have always been extremely helpful in answering various questions and allowing me access to various EPO papers and documents and most particularly to Godehard Nowak, Willi Geuss and Eugen Stohr.

Thanks also go to Professor Stephen Holgate Professor of Allergy and Respiratory Medicine University of Southampton and Dr. David Flavell of the Department of Microbiology and Pathology at the University of Southampton for their help and time in discussing with me the ethical aspects of their research and their views on the patenting of biological materials.

I would like to thank my colleagues at the Centre for Enterprise and Innovation (formerly the Office of Innovation and Research Support) at the University of Southampton who have been a continuous source of encouragement and support whilst I have been working on this study. My thanks to Dr. Peter Hooper, Dr. Tony Raven, Mylene Ployaert, Rosy Jones, Antriana Raymond and Tina Johnson and to my former colleagues Dr. Don Fox , Sean Huggett and Phil Harris. Thanks also go to Janet Leach for her patience and help in deciphering my terrible handwriting and for transcribing the many EPO tapes. Final thanks go to my parents to whom this thesis is dedicated.

ABBREVIATIONS

1977 Act	The Patents Act 1977 (UK)
ACRE	Advisory Committee on Releases to the Environment
APC	Animal Procedures Committee
Art. or A.	Article
ATCC	American Type Culture Collection
Berne Convention	Convention for the Protection of Literary and Artistic Works 9 September 1886, revised Paris 24 July 1971
BINAS	Biosafety Information Network and Advisory Service
BIO	Biotechnology Industry Organisation (USA)
Biotech Directive	European directive on the legal protection of biological inventions
BUAV	British Union for the Abolition of Vivisection
Budapest Treaty	Budapest Treaty signed 28 April 1977 on the International Recognition of the Deposit of Micro-organisms for the purposes of Patent Procedure
CCPA	Court of Customs and Patent Appeals (USA)
CELA	Canadian Environmental Law Association
ch.	Chapter
CIPO	Canadian Intellectual Property Office
CIWF	Compassion in World Farming
C.M.L.R	Common Market Law Reporter
Cmnd.	Command Number (House of Commons)
Community Patent	Patent granted under the Community Patent Convention
Cong. Rec.	Congressional Record (USA)
CPC	Community Patent Convention signed in Luxembourg 1975
C.P.R.	Canadian Patent Reports
DNA	Deoxyribonucleic Acid
'epi' (EPI)	Institute of Professional Representatives before the EPO
EBA	Enlarged Board of Appeal
ECJ	European Court of Justice
E.C.R	European Court Reports
Ed(s)	Editor(s)
EIPR	European Intellectual Property Review
EP	European Patent or PCT code for the EPO
EPC	European Patent Convention, signed Munich 1973
EPO	European Patent Organisation/Office
EPOR	European Patent Office Reports
ESF	European Science Foundation
EU	European Union
European Patent	Patent granted under the European Patent Convention

ABBREVIATIONS

F	Federal Reporter (Circuit Court of Appeals cases USA)
F. 2d	Federal Reporter Second Series (USA)
F. 3d	Federal Reporter Third Series (USA)
F. C.	Federal Court Reports (Canada)
F. Supp.	Federal Supplement (USA)
Fed. Cas	Federal Cases (USA)
G*	Prefix to Decision Numbers of Enlarged Board of Appeal of EPO
GATT	General Agreement on Tariffs and Trade
GMO	Genetically Modified Organism
GRUR	Gewerblicher Rechtsschutz und urheberrecht
GRUR int	Gewerblicher Rechtsschutz und urheberrecht International Section The Protection of Industrial Property and Copyright
Guidelines	Guidelines for Examination in the European Patent Office
H.R.	House of Representatives (USA)
IIC	International Review of Industrial Property and Copyright Law
International Application	Application made under the Patent Co-operation Treaty
LPQ	Intellectual Property Quarterly IPR Intellectual Property Rights Prefix to Decisions of the Legal Board of Appeal of the EPO
L. Ed; L. Ed 2d	US Supreme Court Reports Lawyer's Edition
MAFF[⊗]	Ministry of Agriculture, Fisheries and Food
MMTV	Mouse Mammary Tumour Virus
Myc	Myelocytomatosis
NAFTA	North American Free Trade Agreement
NBAC	National Bioethics Advisory Commission (USA)
OECD	Convention on the Organisation for Economic Co-operation and Development
OJ.	Official Journal of the European Union
OJ. C	Official Journal of the European Union: C series (Communications and notices)
OJ. L	Official Journal of the european Union: L series (Legislation)
OJ. EPO	Official Journal of the European Patent Office
OTA	Office of Technology Assessment (USA)
P (s)	Page(s)
para.	Paragraph
Pans Convention	The Paris Convention for the Protection of Industrial Property signed in Paris on 20 March 1883 and revised Stockholm 14 July 1967
PCR	Polymerase Chain Reaction
PCT	The Patent Co-operation Treaty signed at Washington on 19 June 1970
PPA	Plant Patent Act 1930 (USA)
PVPA	Plant Variety Protection Act 1970 (USA)

[⊗] Functions taken over by Department of Environment Food and Rural Affairs (DEFRA) 2001.

ABBREVIATIONS

PWP	Patents Working Party
R	Recital
R&D	Research and Development
Rep.	Report
RNA	Ribonucleic Acid
RPC	Reports of Patent Cases
RSV	Rous Sarcoma Virus
s.	Section
S.C.R.	Supreme Court Reports (Canada)
S. Ct.	Supreme Court Reporter
Sup. Ct. Rev	Supreme Court Review
SI	Statutory Instrument
Strasbourg Convention	Convention on Unification of certain points of Substantive Law on Patents for Invention, 27 November 1963
T*	Prefix to Decision Numbers of Technical Boards of Appeal of EPO
TAPRA	Transgenic Animal Patent Reform Act (US)
Tr.	Translated by
TRIPs/TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods
UKPO	United Kingdom Patent Office
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organisation
UPOV Convention	Union International pour la Protection des Obtentions Végétales (International Convention for the Protection of New Varieties of Plants 1961 (amended 1972, 1978, 1991)
U.S.	United States Supreme Court Reports
U.S.C.	United States Code
USPQ	United States Patent Quarterly
USPTO	United States Patent & Trade Mark Office
Vienna Convention	The Vienna Convention on the Law of Treaties
vol.	Volume
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation
WWW	World Wide Web

* The letters of the decisions of the Boards of Appeal indicate the nature of the Board. The serial number of the file and after the forward slash the year of the appeal.

Chapter 1

Morality v. Patentability

The Morality Exception under the European Patent Convention

"Yes we are stuck with it and we couldn't even think about deleting this Article now ..... We could live without it. Other countries can, America, for example".

Dr. Christian Gugerell

Director European Patent Office[1]

"Morality" .. ..Ethical wisdom; Knowledge of moral science; Moral truth, moral sense or interpretation. The doctrine or system concerned with conduct and duty."

The Oxford English Dictionary[2]

The Article to which Dr. Gugerell is referring is the Article of the European Patent Convention (EPC)[3] commonly known as the 'morality' exception to patentability. It provides that notwithstanding the fact that the subject-matter of an invention meets all the requirements of patentability (new,[4] involve inventive step[5] and susceptible of industrial application[6]) certain inventions shall not be patentable.

The so called morality exception or exclusion is contained in Article 53 (a) of the Convention which states "that European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to "*ordre public*" or morality, provided that the exploitation 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". The provision does not indicate what is not an invention[7] but simply gives an indication of those inventions which are unpatentable. This is distinct from the provisions of Article 52 EPC which deals strictly with 'non~inventions'.[8]

Both Articles 52 (1)[9] and 53 (a)[10] were subject to amendment at the European Diplomatic Conference for the Revision of the EPC[11] held in November 2000. Article 53 (a) has been brought into line with both Article 27.2 of the TRIPs agreement and with Article 6.1 of the Directive on the Legal Protection of Biotechnological Inventions (also known as the 'Biotech Directive'). The word publication in the current

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1 Taped Interview with the writer on 24 January 2000 at the EPO in Munich (conducted in English).
2 The Oxford English Dictionary, Second Edition, Volume IX, Clarendon Press 1989.
3 No 24 Convention on the Grant of European Patents, Munich, 5 October 1973 HMSO Cmnd. 5656 1974.
4 See Article 54 RPC.
5 See Article 56 EPC.
6 See Article 57 EPC.
7 2632/IV/64-E-Final dated 15 April 1964 - Minutes of Proceedings of the 12th meeting of the Patents Working Party held at Brussels from 26 February to 6 March 1964 p. 22.
8 Note distinction in Minutes of 9th meeting of Working Party held from 12-22 October 1971 BR/135/71dated 17 November 1971 point 100 at page 52.
9 Preparatory documents: CAJPL 6/99; CA/PL PV9; CA/PL 31/00. Article 52 (1) provides that European patents shall be granted for any inventions in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.
10 Preparatory documents: CA/PL 8/99; CAIPL PV9; CA/PL 3 1/00.
11 Revisions to the Convention proposed by the Chairman of the Administrative Council.

version of the Article is to be deleted and replaced with "commercial exploitation". The EPO has confirmed that this deletion entails no change in EPO practice.[12] From an editorial perspective, the French wording of Article 53(a) EPC has been brought into line with the German wording.

With the developments in the techniques for genetic manipulation of animals since the 1980's, scientists have sought to patent the products of their work. Under the Genetic Manipulation Regulations 1989[13] 'genetic manipulation' means the propagation of heritable material, prepared by the insertion of that material, prepared by whatever means outside a cell or organism, into a cell or organism in which it does not occur naturally, either (a) directly or (b) into a virus, microbial plasmid or other vector system which can then be incorporated in the cell or organism. The USA was the first patenting jurisdiction to grant a patent for an animal, a mouse, which had been genetically modified.

When a European patent was sought for the same animal, the applicant, Harvard College in the US, encountered a number of obstacles, of which the morality exception has proved the most difficult to overcome. As will be seen in this study the association of morality and patentability is not new, and this study investigates its particular relevancy when considering the patentability of animals.

As Dr. Gugerell's comment implies the morality exception has not been regarded by the European Patent Office (EPO) as one of the more significant of the substantive provisions of the EPC and until recently has generated comparatively very little attention from the Divisional Boards of the EPO This study will show that the morality exclusion is no longer the Cinderella provision of the Convention and that it is of particular significance and that its association with patentability is not accidental.

Before looking at the background to the inclusion of a morality exception in a patenting convention it is necessary to look at the purpose for which patents were created.

Patents

The prime purpose of a modem patent system is to promote innovation through rewarding the inventor for his efforts. Patents are often seen as a negative right.[14] A patent gives the owner the right to prevent others from copying his invention without his permission. There is a partnership created between the inventor and society in which the inventor agrees to reveal his invention for the benefit of society and for which, in return, he receives a limited monopoly. A patent does not invest the patent holder with a positive right to use the invention but only a right to prevent its unauthorised use by others.[15] Historically patent law in Europe was framed in an industrial context. The European patenting system (as with most other patenting systems) originated from the mechanical field and while the system has adapted itself to new areas such as chemicals and pharmaceuticals, it seems to have experienced far greater difficulties when called upon to cover living and self-reproducing matter. The creation of such rights are seen as a justification of the belief of John Locke[16] that everybody should be entitled to the fruits of their labour and that property rights are based on natural rights.

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12 Preparatory documents: CA/PL 8/99; CA/PL PV 9, points 32 – 34.
13 SI No. 1810 1989 came into force on 1 November 1989.
14 See comments of P. Drahos, Biotechnology Patents, Markets and Morality (1999) 9 *EIPR* p. 443.
15 For general discussion see Chapter 1 W.R. Cornish, *Intellectual Property* (Sweet & Maxwell 1996); F-K Beier, significance of the Patent System for Technical, Economic and Social Progress (1980) *IIC* 1 p. 563.

The main argument of the biotechnology community (including large corporations and institutions) supporting patents is economic, suggesting that funds would not be invested in research in biotechnology without the security of patent protection to guarantee profitability. It is also contended that patenting encourages invention, since the legal protection of intellectual property and obtaining exclusive use of an invention yield incentives for the sort of entrepreneurial investment which is needed to bring new products to the market. Those lobbying on behalf of the biotechnology industry both in Europe and the US have been instrumental in the defeat of proposals to establish temporary moratoria on animal patenting in these jurisdictions

The arguments of proponents of patents for inventions, be they animate of inanimate, is summed up in a statement of Steven Holtzman,Vice-President for Corporate Development of DNX Inc. "Patents are very important to commercial entities. For an emerging biotechnology company, patents can help attract venture capital, collaborative arrangements and new research and development leads. Companies in the private sector simply cannot afford to invest tens of millions of dollars in new inventions unless there is a reasonable prospect for obtaining patent protection, thereby preventing competitors from pirating the innovator's technology. This is especially true for research intensive industries such as biotechnology. To us, patents are paramount. It is quite literally the sole incentive for risk taking".[17]

Most scientists are aware of the importance of patents in relation to their work.[18] Philip Leder one of the 'inventors' of the Oncomouse [19] was unambiguous in his support of the patenting system when he stated "The patent system offers the only protection available for the intellectual product of this research, and thus, the only hope of a fair return against the great financial risks that investment in biotechnology entails".[20] Those opposed to patenting argue that patenting damages the research enterprise by restricting the use of new technologies to only a privileged few.

The debate whether a patent stifles or encourages research will continue for as long as patents exist. The argument that patents stimulate research by encouraging others to engineer around patents[21] and therefore develop new inventions and technologies may be accepted to a limited extent. But it is the restriction of competition that is the prize which is widely sought after by those applying for patent protection.

The EPC and the EPO

The EPC was signed in Munich on 5 October 1973[22] and came into force on 7 October 1977[23] and provides for

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16 English Philosopher 1632-1704. In 1664 Censor of Moral Philosophy at Christ church College, Oxford.

17 Prepared statement of Steven Holtzman, Vice-President for Corporate Development DNX Inc. on behalf of the Industrial Biotechnology Association during Transgenic Animal Patent Reform Act 1989 Hearings before the Subcommittee on Courts, Intellectual Property and the Administration of Justice H.R. 1556 Serial No. 76 Sept 13 and 14 1989. US Government Printing Office (1990) p. 74.

18 Note comments of I. Wilmut and K. Campbell (C. Tudge) in *Second Creation* ps. 216, 222, 224.

19 This case is subject to detailed examination in Chapters 4 and seq.

20 Statement of Philip Leder M.D. John Emory Andrus Professor and Chairman, Department of Genetics, Harvard Medical School day 2, 14 September, before the Subcommittee on Courts, Intellectual Property and the Administration of Justice of the House Committee on the Judiciary, 101st Congress 1st Sess.1989 Transgenic Animal Patent Reform Act 1989 (Washington DC; U.S. Government Printing Office 1990) (H.R. 1556 TAPRA).

21 By virtue of the experimental use exception.

22 Monaco, Liechtenstein and Switzerland were signatories together with all EU Member States.

the granting of European patents in those Contracting States designated by means of a single application.[24] The aim of the Convention was to establish a system of uniform patenting standards in Contracting States.[25] The EPC comprises the main text together with the Implementing Regulations and Protocols[26] that are an integral part of the Convention.

Provisions of the EPC are required to be incorporated into the laws of the various EPC Contracting States. In the UK this has been achieved by virtue of s. 130 (7) of the Patents Act 1977, Articles 53 (a) and (b) EPC being incorporated with almost identical wording into sections 1 (3) (a) and (b) and 1 (4) of the 1977 Act. The association between use and morality is not new in UK law reference being made to morality in the Patents Act 49 (s.10) and the Patents, Design and Trade Marks Act 1883 (s. 86).

The EPC established the European Patent Office in Munich for the administration of the Convention. [27] The EPO is not a European Union institution and is not engaged in national supervisory roles. The EPC is regarded by the EPO as a self contained code[28] and the EPO operates on the principles of good faith, its Boards of Appeal being governed by their own rules of procedure, with the Enlarged Board of Appeal (EBA) being the highest judicial authority of the EPO. There is no requirement under the Convention that the Boards of Appeal have to follow the interpretation of the law as set out in previous Boards of Appeal decisions. However, an informal system of precedent commonly operates at the EPO which serves to maintain consistent jurisprudence. [29] There is included a diagrammatic representation of the steps in the implementation or enforcement of the morality exception under the EPC. This shows implementation through the Boards and Divisions of the EPO after which action may be taken in national courts of the EPC Contracting States and finally through the European Court of Justice.

The EPO acts as an intermediary between society and the inventor and must act in the best interests of both. The EPO is coming under more and more pressure from the biotechnology sector of industry and particularly by the large multinational life and bioscience companies which are seeking the widest application of patents which they see as an effective means of obtaining some return for their research and development investment. The EPO must balance these interests.

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23 EPC subsequently amended (1980) *OJ. EPO* p. 3.

24 Articles 1-3 EPC.

25 The EPC provides a system for a single examination that on grant converts into national patents to be administered and enforced within national jurisdictions. European patents granted will be the same in all the designated states and will be treated as a national patent in each state. T.C. Vinje, Harmonising Intellectual Property Laws in the European Union: Past, Present and Future (1995) 8 *EIPR* p. 361.

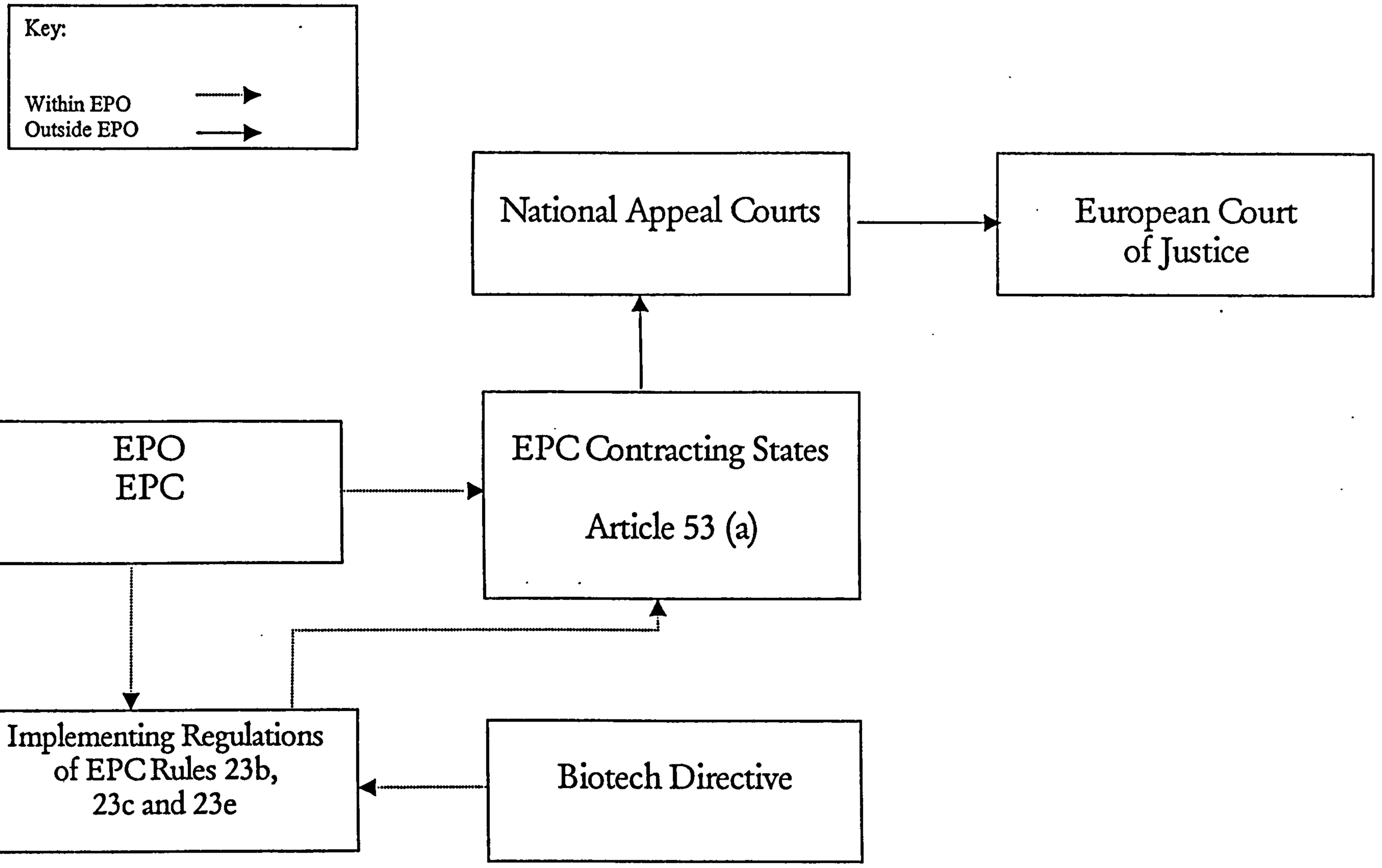
26 Article 164 EPC.

27 An Administrative Council has the overall responsibility for the supervision and operation of the EPO. The EPO comprises four Divisions, the Receiving (section); Examining, Opposition and Legal Divisions organised into 5 Directorates-General (DGs), the latter being further subdivided. For detailed account of the provisions of the EPC see R. Singer and M. Singer revised R. Lunzer, *The European Patent Convention* A commentary (Sweet & Maxwell, London, 1995); G. Peterson, *The European Patent System* (Sweet & Maxwell 1992); K. Goldbach, H.Vogelsang-Wenke and F.J. Zimmer, *Protection of Biotechnological Matter under European and German Law* (VCH 1997); I. Muir, M. Brandi-Dohrn and S Gruber, *European Patent Law* (Oxford University Press 1999).

28 J15/80 *OJ. EPO* 1981, 213.

29 G. Paterson, *The European Patent System* (Sweet & Maxwell 1992) (First Supplement).

Implementation of Article 53 (a) EPC



A patentee will be looking for the broadest protection as possible for his invention. The EPO on behalf of the public interest, will on the other hand be seeking to restrict the breadth of the patent claims as far as possible in order not to stifle ongoing research, development and exploitation of other inventions in any particular scientific field. Criticism has been levelled at the EPO that patent claims have become too broad with the resultant undermining of the whole purpose of the patenting system. This is exemplified later in this study in considering the granting of the Oncomouse patents.

Whilst the EPO has developed its own precedential system in its decisions relating to cases which come before it, it is not as robust as some EU Member states' national legal systems. This may not be surprising in view of the fact that some patenting systems have been in existence for many years.[30] There is potentially flexibility open to the Appeal Boards including the Opposition Division of the EPO to look at each case on its merits but as will be seen in the discussions of the Oncomouse[31] application later in this study this flexibility has not been exploited fully by the EPO.

Morality and Patentability

Dr. Gugerell[32] is the EPO's senior spokesperson on biotechnological matters and particularly relating to the patenting of animals, having been involved as a primary examiner in the Oncomouse European patent case[33] which was the first European patent to be granted for an animal by the EPO. He is also a member of the Opposition Division of the EPO which is still considering the opposition against the Oncomouse patent[34] some 16 years after the date of the filing of the application.

As may be gauged from Dr. Gugerell's comment which opens this chapter the morality exception had been regarded as having relatively minor importance. Dr. Gugerell's comment is particularly revealing and also disturbing as it reveals the attitude that has been adopted by the EPO towards the interpretation of this provision over the last decade and a half.

Whilst the European patenting system is not unusual within patenting jurisdictions in incorporating a morality exception within its provisions it is the first in which detailed debate of the provision in relation to animals has taken place. Morality exceptions to patentability are found in the patent laws of China[35] (Article 4 ('No patent shall be granted for any invention-creation that is contrary to the laws of the State or social morality or that is detrimental to public interest'); India[36] ('Non-patentable inventions shall include an invention the primary or intended use of which would be contrary to law or morality or injurious to public health) and the Philippines[37] (Sec 22.6 Exclusions from patentability 'anything which is contrary to public order or morality'). The Patent legislation of China, India and the Philippines also contains exceptions to the patentability of animal and plant

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30 For example, in England The Statute of Monopolies 1623; the first patent statute in the United States was in 1790.

31 ONCOMOUSE is the US trade mark of E.I. du Pont Nemours and Company, for International Class 31- live laboratory mice or rats.

32 Dr. Christian Gugerell is the Director of Directorate-General 2 Chemistry at the EPO.

33 European Patent Application No. 85 30 44770.7 filed on 24 June 1985 entitled 'Method for producing Transgenic Animals' by President and Fellows of Harvard College.

34 See Chapters 4-6.

35 Adopted at the 4th Session of the Standing Committee of the Sixth National People's Congress on 12 March 1984 as amended on 4 September, 1992.

36 Patents Act 1970.

37 Intellectual Property Code of the Philippines, Republic Act No. 8293.

varieties. Other jurisdictions that contain morality exceptions include Argentina, Bolivia, Peru, Brazil and New Zealand.[38]

It is noteworthy that a morality exception is not found in the statutes establishing patenting regimes in, for example, the US, Australia and Canada. Of particular importance is the USA, being the largest and most prolific of the world patenting jurisdictions and which was the first to take the lead and issue a patent on a living organism although as will be seen in chapter 4 the concept of utility in the USA for example has been developed to included more than just 'industrial application' as is seen under the EPC.

The question has been asked why have a morality criterion for determining patentability of inventions under the European patenting system if the USA, one of the leading patenting jurisdictions functions quite successfully without one? Is Europe more socially aware of its 'moral' responsibilities? Are companies in Europe engaged in research in biotechnology less commercially aware? The answer is no to both questions but as will be shown the US is extremely protective of its competitive position in the global market.

Background to the inclusion of the Morality Exception in the EPC

The wording of Article 53 (a) EPC is almost identical to the wording of Article 2 (a) of the earlier Strasbourg Convention[39] which states that the Contracting States shall not be bound to provide for the grant of patents in respect of inventions the publication or exploitation of which would be contrary to "*ordre public*" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by a law or regulation.

The Strasbourg Convention[40] arose from a proposal of the Council of Europe in the late 1950's. At the time that the wording of the Strasbourg Convention was being finalised, the Co-ordinating Committee and the Patents Working Party[41] (PWP) were in the process of reviewing the first preliminary draft of the EPC. Background papers are unable to throw any light on the intention of the legislators in their inclusion of the morality criterion. Unfortunately, the *travaux preparatoires* of the Strasbourg Convention are no longer available and the Reports of Strasbourg Committee meetings have now been destroyed. [42] However, by reviewing the Minutes of the PWP we can gain some insight into how the morality criterion came to be incorporated into the EPC.

The first meeting of the PWP was held in April 1961,[43] and the PWP liaised closely with the Co-ordinating Committee of the Council of Europe to ensure an exchange of information relating to the drafting of the two conventions. The First Preliminary Draft[44] of the EPC contained in its Article 12 the following exception to patentability:

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38 For details see *Patents throughout the World*, Clark Boardman Callaghan (1978) Loose-leaf, updated.

39 Convention on the Unification of Certain Points of Substantive Law on Patents for Invention was signed in Strasbourg in 1963. Cmnd. 2362 HMSO 1964.

40 Also known as the Council of Europe Convention.

41 Relating to a new Convention for the introduction of European Patent Law.

42 E. Armitage and I. Davis *Patents and Morality in Perspective* (Common Law Institute of Intellectual Property London 1994) Footnote 27 p.20 and confirmed by writer's own investigations.

43 17-20 April 1961.

44 IV/2071/61 –1E first Preliminary Draft Convention relating to a European Patent Law, 14 March 1961, Section 14.

"(1) inventions the exploitation of which either in the territory of all Contracting States or in the territory of individual Contracting States would be contrary to morality or "*ordre public*"; and (2) inventions relating to the production of or a process for producing a new plant variety or a new animal species. This provision shall not apply to processes of a technical nature".

These exclusions to patentability were absolute rather than discretionary. In sub-paragraph 2 of this first draft it will be noticed that there is a distinction drawn between plant 'varieties' and new animal *'species'* rather than the more ambiguous term of 'variety' being used.

At its first meeting, the PWP set itself the task of asking certain fundamental questions in relation to the inclusion of a morality exception in the EPC:

- Is it really necessary to provide for such exceptions to patentability in the European Convention?
- How is morality defined?
- Is there a "European" definition of morality?
- Should national definitions be applied or is it necessary to distil the common features of them all?
- If national definitions are used is an invention patentable if it is contrary to morality in only one of the Contracting States?

In answering these questions, the PWP confirmed that an invention contrary to morality should not be patentable and recognised that there was no 'European' definition of morality. During discussions the German delegation and the Chairman, indicated that they preferred to refer to 'national' concepts of morality, however, the majority of the PWP members felt that if such a position was adopted, it would give too great a prominence to 'national' concepts in a European Convention which would ultimately undermine the fundamental principles for the establishment of such a convention, namely harmonisation of patenting provisions. The PWP unanimously agreed that the interpretation of the concept of morality should therefore be a matter for the European Institutions and the Working Party concluded that it was acceptable to mention the concept of morality on the convention but without going into any further detail.[45]

As the debate progressed[46] the Chairman pointed out that the wording of Articles 11 to 18 (of the draft convention) had strongly influenced the parallel decisions being taken by the Council of Europe on the draft of the Strasbourg Convention and in view of this fact the PWP decided that it would not be appropriate to alter the wording of these articles to any further degree or at all as otherwise they would have to inform the Council of Europe of any changes, especially since the text agreed at Strasbourg had been by this time already submitted to national governments for final approval. The PWP took the line of least resistance and decided to endeavour not to make any changes which would deviate from the text agreed in the Council of Europe.[47] The Working Party confirmed its adoption of the wording used in Article 2 (2) of the draft of the Council of the Europe.

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45 IV/2767/61 - E Proceedings of the 1st Meeting of the Patents Working Party held 17 to 28 April 1961 Section 5.

46 During the Proceedings of the 5th meeting of the PWP 2-18 April 1962.

47 3076/IV/62 – E Proceedings of the 5th meeting of the PWP held 1-18 April.

The general principles of the proposed European Patent Convention were later adopted by representatives from 17 European States at a meeting in Brussels on 21 May 1969. The PWP confirmed that the amendments to the Preliminary Draft Convention relating to a European Patent Law were now as appears in the Convention,[48] the Minutes of the meeting of the Working Party held 8-11 July 1969 recording that Article 10, as it had now been renumbered, the exceptions to patentability, corresponded to Article 2 of the Strasbourg Convention.[49]

The European patenting community was thus endowed with two patenting conventions both of which had ambiguous morality exception provisions. The relevant provisions of the Strasbourg Convention, the EPC and the Patents Act 1977 are set out at 1.1 in the Appendix for ease of comparison.

Unfortunately at the time that the Strasbourg Convention and the EPC were being drafted, those whose role was to do the drafting were not blessed with the gift of foresight and were not able to predict how biotechnology would develop over the next quarter century. At this time it was the general understanding that both plants and animals were not patentable subject-matter.[50] Also, it was understood in principle that under the laws of most of the countries of Europe at this time that micro-organisms were patentable which was to be later confirmed by the EPO.

Although the EPC did not come into force until 1977, it can be seen that the wording of what was to become Article 53 (a) EPC had already been agreed prior to the Strasbourg Convention coming into force. At this time the US patent to be granted to H. Boyer and S. Cohen[51] of the University of California was still awaited and the polymerase chain reaction[52] had not yet been developed.. The morality exception may have been included as a 'catch all' provision to satisfy those interest groups (animal welfare, religious, etc) which considered that some check should be put in place. But the question that both the EPC and the Strasbourg Convention fail to answer is how is morality to be determined?

The EPO did issue 'Guidelines' to assist in the interpretation of the articles of the Convention although stating "that these Guidelines are issued by the President of the EPO for the benefit of those the staff concerned with the procedure".[53] The Guidelines provided that the purpose of the exclusions under Article 53 (a) EPC was to "exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour;[54] obvious examples of subject-matter which should be excluded under this provision are letter-bombs and anti-personnel mines. In general, this provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the inventions as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case objection should be raised under Art 53 (a); otherwise not".[55]

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48 23535/IV/65-E 22 January 1965 Section 1. Note Pre-Diplomatic Conference of November 2000.

49 Minutes of Inter-Governmental Conference for the setting up of a European System for the Grant of Patents Secretariat BR/7/69 29 July 1969.

50 DocIV/2071/61-E of Working Party part of travaux preparatoires.

51 US Patent 4,237,224 Process for producing Biologically Functional Molecular Chimeras.

52 Known as 'PCR' reaction whereby gene segments are amplified by the replication of defined sequences of DNA.

53 http://www.european-patent-office.org/ap-gd/intro.htm (last visited 17 September 2001).

54 See 6.2.1 EPO Grounds for Decision Howard Florey Institute EP Patent No. 0 112 149 p.12 reference to "universally be regarded as outrageous".

55 Guidelines for Examination at the European Patent Office Part C, Chapter IV 3.1.

Before going on to consider 'morality' under Article 53 (a) it is appropriate to look firstly at '*ordre public*' and the qualification in the section of this Article in order to see the close although separate meaning of these terms and their relationship with existing regulations.

'*Ordre public*'

It is generally accepted that the concept of "*ordre public*" covers the protection of public~security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53 (a) EPC, inventions the exploitation of all which is likely to breach public peace or social order (e.g., through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to "order public".[56]

The concept of *ordre public* in particular has wider significance in community law. It is used in the French Text of the Treaty, although it is usually rendered 'public policy' in English. Various Articles of the Treaty of Rome[57] all refer to *ordre public* (as a means of restricting free movement of goods, workers, etc). Three interpretations have been offered by D. Beyleveld and R. Brownsword on the concept of '*ordre public*' being the concept of 'public order'; public morality or the structure of social relations governed by the Rule of law.[58] *Ordre public* is more than just public order[59]even though the phrases are often read as synonyms or as alternatives.[60]

Article 30 contains reference to *ordre public* and relates to the free movement of goods. The phrase was considered in *Henn and Darby*[61] and *Conegate Limited v HM Customs and Excise*[62] which held that each Member State was to determine the requirements of public morality in its territory. In *Re Bouchereau*[63] reference was made to the fundamental interests of society being included under *ordre public* which includes the preservation of the environment. In the *PGS* case[64] the Technical Board of Appeal in T356/93 held that *ordre public* covered the protection of public security, physical integrity of individuals as part of society and also covers protection of the environment.

"provided that such exploitation 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"

This qualification means that the grant of a patent shall not be refused and a patent shall not be invalidated on

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56 Reason for Decision T356/93 paragraph 5.

57 Articles 30, 39 (3), 46 (1) and 58 (1) (b) formerly Articles 36, 48 (3), 56 (1) and 73d (1) (b).

58 See D. Beyleveld and R. Brownsword, *Mice, Morlaity and Patents* (Common Law Institute of Intellectual Property 1993) p.54.

59 ibid. p. 59.

60 ibid. p. 91.

61 (1979) *Henn and Darby* Case 34/79 (1980) *E.C.R.* 3795; (1980) *C.M.L.R.* p. 246.

62 (1986) *E.C.R.* p. 1007.

63 Case 30/77 *Bouchereau* (1977) *E.C.R.* p. 246. A Member State may not rely on grounds of public morality within the meaning of Article 36 of the Treaty in order to prohibit the importation of certain goods on the grounds that they are indecent or obscene where the same goods may be manufactured freely on its territory subject only to an absolute prohibition on their transmissions by post, a restriction on their public display and, in certain regions, a system of licensing of premises for the sale of those goods to customers aged 18 and over.

64 *PGS* 356/93 Plant Genetic Systems case discussed in Chapter 3.

the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law. It would appear that the main reason for including such a provision was that it was thought that the restriction may be temporary or be removed and also that the patent might then be the basis for further patents which did not fall within the restrictions.[65] The proviso is also seen in the Strasbourg Convention and the earlier Paris Convention,[66] the latter convention in Art 4 *quater* providing that the "grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from the domestic law".

Animals and Genetic Engineering

Developments in the field of genetic engineering have led to the creation of transgenic and cloned animals and the question being asked is whether the results of such work are, or ought to be, patentable inventions under the Convention. The question is of great importance to the biotechnology industry resulting in some of the larger biotechnology companies exerting commercial pressure on European governments for clarification regarding the patenting of both plants and animals. As will be seen in Chapter 2 of this study as a result of concerns expressed by many sections of the biotechnology industry and by the European Commission itself, it was considered appropriate for the patenting of biotechnological inventions to be considered as a separate case which led to the introduction of a Directive to deal specifically with the legal protection of these types of inventions. The results of research particularly in the fields of genomics and cloning in relation to both animals and plants and the wish of enterprises to commercialise the results of their research in these areas has led to fears being expressed by the public as to how safe the resulting plant or animal products are and whether patents are an appropriate means of enabling such enterprises to commercialise the results of such research.[67]

Traditionally new varieties of animal and plant species were produced by the selective cross-breeding of individuals having known characteristics. Genetic engineering, being a more precise way to manipulate genes than Mendelian breeding, allows traits that might not have occurred in hundreds of years of selective breeding to be introduced in one generation.

Public concerns about genetic research have led to the scrutiny of the research work of geneticists and embryologists throughout the world and dire warnings have been issued by various interest groups about the consequences of such research. Since concerns in Europe with regard to the release of genetically modified organisms into the environment and the growing of genetically modified crops[68] are being more widely expressed, experiments leading to the creation of 'new' living organisms are coming more and more under the spotlight. The disclosure of research into the cloning of animals the introduction to the world of Dolly[69] the sheep in 1997, an animal which was cloned from a sheep's somatic cells, whilst a great scientific breakthrough has caused alarm bells to ring in certain quarters. Almost all cases which have come before the EPO in relation

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65 See Bureau international de la propriété intellectuelle (now WIPO) *Convention de Paris – La protection de la propriété intellectuelle de 1883 à1983* (Bureau international de la propriété intellectuelle 1983).

66 Article 4 *quater* added by the 1958 Lisbon Conference Revision.

67 (2000) *Nature* vol. 405, p. 5, 4 May; (1999) *Nature* vol. 398, p.651 22 April ; NOP Solutions Research carried out for British Union of Vivisection on Animals and Genetic Engineering April 1998.

68 Charles, Prince of Wales, (1999) *Daily Mail* 1 June p 1,4,0, 11; (1999) *Science* 285 16 July p 367-391; *Genetically Modified Crops: the Ethical and Social Issues* (Nuffield Council on Bioethics 1999).

69 I. Wilmut, A.E. Schnieke, J. McWhir, A.J. Kind and K.H.S. Campbell, (1997) *Nature,* 27 February.

to animal patents relate to genetically modified animals, the Oncomouse case being the first in which the EPO looked in detail at the patentability of animals, the review and the analysis of which forms the nucleus of this study.

Since 1973 the techniques known as gene technology and gene recombination have enabled parts of chromosomes from donor cells of plants and animals to be introduced into cells of host plants and animals. Genes of one organism are liberated using biochemical techniques from their structural complex and introduced as an independent genetic unit into the host organism. The essential feature of the technique is that certain enzymes, known as restriction enzymes, can cut DNA strands into specific segments that can be manipulated and other enzymes can join these DNA strands together. As a result new DNA molecules (known as recombinant DNA) are formed. Recombinant DNA may be created from DNA from different sources and because all organisms use a similar process to express their DNA, it becomes possible to transfer DNA from one organism to another. Various methods have been developed to introduce foreign DNA into another organism's genome including microinjection,[70] retroviral infection and *in vitro* establishment of embryonic stem cells which are subsequently injected into host blastocysts.

Genes can be introduced between unrelated species, for example, human genes into mice or from animals into plants. The technology was originally developed in mice but has since been applied to a variety of mammals including sheep, pigs and cows.[71] There is, therefore, great scope for altering the genetic properties of both plants and animals in order for them to exhibit certain specific predetermined characteristics. The first patent to be granted for an animal was in the USA in 1988 (and in Europe) was for a transgenic mouse, the Oncomouse, carrying a human cancer-promoting gene or oncogene.

Concerns regarding the genetic engineering of animals, particularly farm animals, have been voiced on the basis of animal welfare considerations. Whilst animal husbandry has been known for many centuries and animal breeding programmes recognised and widely accepted, genetic modification of farm animals in order to make them grow faster, bigger and leaner[72] is seen by some animal welfare groups as abhorrent. For example, the rapid growth in broiler chickens has caused crippling deformities of the limb bones and joints[73] and the now infamous transgenic Beltsville pigs, created at the US Department of Agriculture's research facility at Beltsville, Maryland, suffered from lameness, lethargy, bulging eyeballs, degenerative joint disease and heart problems.[74] Transgenic animals have also been used to provide experimental models for research purposes and for the obtaining of certain enzymes being secreted in their milk, the latter use being often referred to as animal 'pharming'. The Roslin Institute in Scotland, where Dolly[75] was created, has undertaken work on the genetic

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70 See Animal Procedures Committee *Report on Biotechnology* HMSO London June 2001) p. 8.

71 I. Wilmut, Methods for genetic modification of farm animals and humans: present procedures and future opportunities in A. Holland and A. Johnson (Eds) *Animal Biotechnology and Ethics* (Chapman & Hall 1998) p. 13.; See Animal Procedures Committee, *Report on Biotechnology* (HMSOLondon June 2001) p.8.

72 Note European Patent No 3 095 599 B1 Method for producing transgenic pigs; European Patent Application No 90311 209.2 Transgenic fowl expressing bovine growth hormone.

73 J. Webster, Animal Welfare and genetic engineering in P. Wheale and R. McNally *The Bio-revolution, Cornucopia or Pandora's Box* (Pluto Press London 1990).

74 V.G. Pursel, R.E. Hammer, D.J. Boldt, R.D. Palmiter and R.L. Brinster, Integration, and Germ-line transmission of growth-related genes in pigs (1990) *Journal of Reproduction and Fertility* Supplement 41 p. 77; The Frankenstein Syndrome, (1988) *Agscene*, May p. 3.

75 Subject of international patent applications PCT/GB96/02099 and PCT/GB96/02098.

modification of sheep to enable such transgenic animals to produce the blood clotting proteins Factor VIII and Factor IX which may be used in the treatment of patients with, respectively, heamophilia A and B. Tracy, a transgenic sheep also created by the Roslin Institute[76] was one of the first 'pharm' animals having a human gene introduced which produced the enzyme alpha-I-antitrypsin (ATT) in her milk which could be used as a source of the enzyme for use in the treatment of emphysema and cystic fibrosis.[77]

It is not surprising that the researchers using such techniques (and the companies and Institutions for which they work) look to the patenting system to protect the animals that they have 'created'. Some interest groups have called these techniques unethical and have opposed applications for patents for transgenic multicellular organisms on the grounds that such inventions are excepted from patentability by virtue of the exception to patentability set out in Article 53 (a) of the European Convention.

The patenting of transgenic animals is a relatively new science and it is not uncommon when a particular science is in its infancy that earlier patents are granted with broader claims than those that follow. This will be seen later in this study in the analysis of the Oncomouse patents. This can be expected to some extent as there is no prior art against which to set a boundary. Often claims on 'early' patents cover ideas underlying what the inventor has done and may be excessively broad. But too broad claims in animal patents may give too much away to the patent holder and may be dangerous.

The number of patent applications in respect of genetically engineered animals has increased steadily since the early 1980's. Analysis of published animal patent applications at the EPO increased from I in 1982, to 12 in 1988 and 63 in 1994, 55% of the total coming from the USA. The majority of the applications related to use in antibody production, the creation of 'customised' laboratory animals to be used as disease models and animals to be used in molecular pharming.[78] In 1998 the EPO granted 36,700 European patents of which 3.2% related to biochemistry and genetic engineering, an increase of 15.8% over 1997. It is interesting to note that there was no accompanying increase in the number of oppositions filed during that year.[79] Does this mean that this technology is being accepted or that patent drafters are becoming more skilled in avoiding those areas of potential difficulty in the provisions of the EPC?

The Morality Exception

In view of the morality exception the granting of a patent by the EPO might presuppose that the subject of the patent is to some extent 'morally' acceptable. The morality exclusion must be considered in respect of all applications and in the granting of a patent for an invention by the EPO it could be assumed that the invention has met some 'morality standard' set by the EPO. But as this study will show, the difficult question for the EPO to adequately answer is how is this standard judged? This study highlights the problems encountered by the

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76 Formerly the Animal Breeding Organisation and the Institute of Animal Physiology and Genetics Research.

77 See I. Wilmut, K. Campbell and C. Tudge, *The Second Creation*, chapter 2, p.35, (Headline Book Publishing 2000).

78 Dr. Crescential Freudling of the Gen-ethics Network, Berlin. Overview of Animal Patent applications in Europe and worldwide and a first analysis of these applications. Source: Compassion in World Farming 1995.

79 EPO Annual Report 1998. The EPO releases a variety of statistics each year in its Annual Report, including the number of patent applications received, the number of patents granted and the nationality of the applicants.

EPO in determining such a standard and suggests how the application of the morality exception might be dealt with in the future.

Whilst the morality exception should be considered in relation to all types of invention and not just those of a biotechnological nature, it is only in biotechnological field that the morality exception has been considered by the EPO. Whilst the Harvard Oncomouse case which is regarded as a landmark case in respect of the patenting of animals under the EPC will be analysed later in this study other cases have come before the EPO in which the morality exception has been considered.

An attempt was made to invoke the morality exception in the Relaxin case[80] in 1995. This involved an opposition by the Green Party of the European Parliament[81] to the Howard Florey Institute of Experimental Physiology and Medicine patent for a DNA fragment encoding human H2-preprorelaxin.[82] In this case the opponents argued that the patent teaches that in order to repeat the invention, tissue is to be taken from a pregnant woman. The isolation of the DNA relaxin gene from tissue taken from a pregnant woman constitutes an offence to human dignity by making use of a particular female condition (pregnancy) for a technical process oriented towards profit. Furthermore that the patenting of human genes such as that encoding H2-relaxin amounted to a form of modem slavery since it involves the dismemberment of women and their piecemeal sale to commercial enterprises throughout the world. This was an infringement of the human right to self-determination. It was also argued that the patenting of human genes meant that human life was being patented which was intrinsically immoral. In the Upjohn case, the pharmaceutical giant was unsuccessful in its attempt to patent a hairless mouse.[83] Both cases are considered further in Chapter 7 of this study.

There have been relatively few cases in which the morality exception has been examined. However, the lack of cases may be questioned rather than applauded. As will be shown in this study until recently the EPO has been able to avoid giving any detailed guidance on the morality exclusion. The EPO has successfully been able to do this by virtue of most of the early genetic or transgenic patent applications being in relation to plants where Article 53 (b) was used as the main line of argument against the granting of such patents. The morality exception being pushed to the background. But today, particularly in the light of the Biodiversity Convention and the TRIPs Agreement this should no longer be the case.[84]

The morality exception to the patentability of inventions has now been part of European patent law for almost forty years. Developments in genetic engineering have been no less than revolutionary during the period that the EPC has been in force. Animal patenting in Europe is only relatively recent and has arrived at it present position as a result of the culmination of a number of scientific, administrative, and political events. Some of the most significant of these are set out in the summary at 1.3 in the Appendix.

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80 Hormone Relaxin Opposition (1995) *OJ. EPO* p. 338.
81 Fraktion der Grunen im Europaischen.
82 Howard Florey/Relaxin (1995) p.541. Decision of 8 December .
83 Transgenic mice for the analysis of hair growth. European Patent Application No 89913146.0, The Upjohn Company of Michigan Filed on 17 November 1989. Refused on 25 July 1993 and deemed withdrawn.
84 Discussed in Chapter 2.

Patents are valuable assets and the European Biotechnology industry is highly patent sensitive. The 'pharming' of animals is seen as a profitable alternative source of certain pharmaceuticals for use in the treatment of humans and animals. The traditional farming of transgenic animals is also seen as a means of increasing food production. Religious, environmental and animal welfare groups have vociferously opposed the patenting of animals for a number of years but it is only in the last few years that the concerns surrounding the growth and use of genetically modified crops voiced by such organisations as Greenpeace and Friends of the Earth that these concerns have been taken seriously by governments and international organisations and indeed the EPO. But as we will see in the following chapters the EPO is under extreme pressure to grant such patents or risk applicants seeking to exploit their technologies outside of the European Union.

Whilst the question of the genetic modification of organisms had begun as a relatively closed debate in the late 1970's, it has over the last decade been taken up by environmental, animal welfare and religious groups, and today it has been transformed into an overt international political issue commanding a high profile. The EPO as hard as it might try to distance itself from this issue it has not been able to do so.

The reference to morality is not new in European legislation. Article 36 of the Treaty of Rome[85] provides that Articles 30 to 34 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

Recently the morality citation in Article 36 of the Treaty of Rome was sought to be evoked by two animal welfare groups in a case before the High Court. In an action, the Queen v The Minister of Agriculture Fisheries and Food *ex parte* 1. The Royal Society for the Prevention of Cruelty to Animals and 2. Compassion in World Farming before the High Court[86] where a declaration was sought that, despite the EU's free trade rules, the UK was entitled to rely on Article 36 of the Treaty of Rome to prohibit an immoral act, namely the export of calves in veal crates.

In the action on a reference to the European Court of Justice the Advocate General's Opinion [87] concluded that whilst the UK could not rely on the public order or health and life of animals aspects of Article 36 of the Treaty of Rome, if the health of animals has become a matter of public morality in a particular Member State, then that Member State could, subject to certain provisos, prohibit the immoral act from continuing, namely the export of calves in veal crates.

Morality and patentablility are thus inexorably linked under the EPC. Whilst this has come about historically it would seem that this linkage is even more important today than it was in the past in view of the present

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85 Following the entry into force of the Amsterdam Treaty the numbers of the article to the EC Treaty changed. Article 30 of the EC Treaty becoming Article 28 EC and Article 36 becoming Article 30 EC Articles 3 1-32 repealed by the Treaty of Amsterdam.

86 CO/2084/95.

87 Reference to the European Court of Justice under Article 177 EC Treaty case C-1/96. Opinion Mr. Leger,

explosion in research being undertaken in the field of genetic engineering, particularly of animals. This importance was recognised by the European Commission and Chapter 2 will consider some of the external factors which have and will in the future influence the interpretation of the morality exception by the EPO.

Advocate General. Source: Compassion in World Farming.

Chapter 2

External Factors Influencing the Interpretation of the Morality Exception

"Having regard to Article 53 (a) EPC it is agreed that the patenting of animals is a controversial area and any consideration in this respect is difficult in view of the complete absence of guidance by case law under the EPC"

Response of Examining Division in Oncomouse case of 28 March 1989[1]

"Efficiency and quality, legal certainty and flexibility; these are the attributes on which the success of the European patent system had been built. Globalisation of the economy and dynamic technological change offer the European Patent Organisation prospects for growth, but they also represent major challenges which need to be mastered if the European patent is to continue functioning as a high-grade property right."

Ingo Kober President of European Patent Organisation 1999[2]

The European patenting system under the EPC cannot be viewed in isolation but must be considered in conjunction with other intellectual property legislative provisions of the EU and international intellectual property related treaties and conventions. Since the time that the EPC and the Strasbourg Convention came into force a number of significant events have occurred both in Europe and other countries of the world, notably in the USA, which have influenced the interpretation of the morality exception under the EPC.

It was the USA which took the lead in the patenting of living organisms including animals, being the first jurisdiction to issue patents on such 'inventions'. In Europe, the most significant events were the coming into force of the Biotechnology Directive[3] and the granting of and subsequent opposition to, the first animal European patent[4] by the EPO. Internationally, the coming into force of a number of treaties and conventions, particularly the TRIPs[5] Agreement and the Biodiversity Convention[6] were noteworthy.

This chapter looks at what influence these events have had or may have in the future on the interpretation of the morality exception of the EPC in relation to the granting of European patents on animals.

The United States (USA)

In the United States[7] until the 1970's the patenting of living organisms was widely resisted in the belief that living organisms were products of nature and therefore unpatentable. Title 35 United States Code s. 101 provides: "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

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1 First Examination p.3 of Communication to the Applicant.
2 Foreword to EPO Annual Report.
3 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. (1998) *OJ.* No. L 213/13, 30 July.
4 EP Patent No. 0169672 relating to a transgenic mouse known as the Harvard Mouse. See Chapters 4, 5 and 6 post.
5 Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods.
6 Signed in 1992.

It was not until 1980 in a decision of the Supreme Court that the question of whether a living organism was patentable was answered. In a now extensively reported decision, *Diamond* v *Chakrabarty*,[8] the US Supreme Court confirmed that genetically altered bacteria were 'manufactures' or 'compositions of matter' and were held to be patentable inventions.[9]

In the late 1960's A. M. Chakrabarty genetically manipulated four types of pseudomonas bacteria which were found to be able to digest the hydrocarbons in crude oil. The potential use of such bacteria in the clearing of oil spillages was thus immediately apparent. In 1971 application was made to the USPTO for a patent which was initially rejected on the basis that animate life forms were not patentable. On appeal by the applicants to the Court of Customs & Patent Appeals (CCPA), in a 3 to 2 decision, the appeal was allowed. In its decision it was held by the CCPA that "The fact that micro-organisms ... are alive ... [is] without legal significance". The USPTO appealed the decision to the US Supreme Court which did not decide the case immediately but referred the CCPA back to an earlier decision, *Parker v. Flook*[10], which had advised that courts must proceed with caution if there is to be an expansion of patent rights and if there is no clear signal from Congress.[11] The CCPA upon referral confirmed its earlier decision. The USPTO once again appealed to the Supreme Court. Following presentation of all the arguments,[12] the Supreme Court on 16 June 1980 granted certiorari and upheld the CCPA decision that the micro-organisms were patentable.[13]

This decision was based again on a small majority (5 to 4), however, all judges agreed that this case was interpreted very narrowly.[14] Judge Baldwin dissenting commented "I believe that the essential nature of the unpatentable organism with which the applicant started was its animateness or life. Appellant has not changed this essential nature; he has not created a new life. Rather, he has merely genetically grafted an extra plasmid on the organism and, thereby, made the organism better at cleaning up oil spills".[15]

It was further held in this case that a statute is not to be confined to the particular applications contemplated by the legislature and this is especially true in the field of patent law. A rule rendering unanticipated inventions unpatentable *per se* would conflict with the core concept of patent law that anticipation undermines patentability.[16]

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7 and in Europe.

8 447 US 303, 206 USPQ 193 (1980), 484 PTCJ A-1, D-1.

9 Prior to this decision the patenting of the results of microbiological studies was known. For example, in the USA Louis Pasteur was granted a patent in 1873 in the field of microbiology which included a claim to a pure culture of a micro-organism.

10 437 US 584 [57 L Ed 2d 451,98 S Ct 2522] 438 US 902, 57 L Ed 2d 1145, 98 S Ct 3119 (1978).

11 Before hearing the case the Court advised the CCPA to examine of recent Supreme Court decision in the *Parker v Flook* in which it was stated "(*the courts*) must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress"(Quoted in A. Kimbrell The Human Body Shop San Francisco Harper p. 193 1993).

12 The claim which caused the main difficulty in this case and which was ultimately upheld was the following: "A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway".

13 US Patent No. 4 259 44. The *Chakrabarty* decision was "distinguished" from the earlier decision of the Supreme Court in *Funk v Kalo* (1948) where the Court invalidated a microbiological patent because the subject matter was a "product of nature"[13] and did not "constitute" an invention or discovery within the meaning of the patent statutes.

14 Ananda Chakrabarty in People Magazine shortly after the Supreme Court Decision said "I simply shuffled genes, changing bacteria that already existed. Its like teaching your pet cat a few new tricks".

15 Re: *Chakrabarty* 197 USPQ 72 (CCPA 1978)

16 *Diamond v Chakrabarty*, 447 US 303, 100 S Ct 2204; U.S. Supreme Court Reports 65L ed 2d p. 144, 16 June 1980.

Unlike the EPC, US Patent law does not contain any exclusion of an invention from patentability on the grounds of is use or exploitation is against morality or public order. However, in a very early US decision, *Lowell v. Lewis*, Justice Story stated "All that the law requires is, that the inventions should not be frivolous or injurious to the well-being, good policy or sounds morals of society ... For instance a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention".[17]

In the later case of *Rickard v. DuBon*[18] in 1900 it was held that the treatment to make tobacco appear to be a higher grade than it was, was not patentable. Thus in the under the US exclusion of an invention from patentability on the grounds of morality appears to be associated with their use in misleading or fraudulent acts, which is a relatively narrow interpretation.

Following the *Chakrabarty* decision the USPTO through the Board of Patent Appeals confirmed that plants, and seeds and plant-tissue cultures altered to contain increased levels of tryptophan were patentable subject-matter.[19] In 1987 the Board ruled that a genetically altered oyster, made sterile to increase size and flavour, constituted patentable subject matter under section 101 although the application was rejected on the ground of obviousness.[20] On the 7 April 1987, within days of the decision in *Ex parte Allen*, Assistant Secretary and Commissioner of Patents and Trademarks, Donald J. Quigg, issued a notice in the USPTO's Official Gazette which included the following statement: "The Patent and Trademark Office now considers that non-naturally occurring non-human multicellular living organisms, including animals, are to be patentable subject matter within the scope of 35 U.S.C. s. 101".

On 28 July 1988, following the grant of the Oncomouse patent in the US, [21] a broad coalition of plaintiffs, encompassing animal welfare groups, instituted a direct legal challenge to the USPTO's notice of the 7 April 1987 in *Animal Legal Defense Fund v. Quigg*. In this case the plaintiff's claimed that the USPTO notice was void being in violation of procedural requirements and that the Commissioner had acted *ultra vires* in issuing the notice in excess of his statutory authority under the patent statute. This case, as one commentator has observed "serves to illustrate the difficulties faced under US law by third party interest groups attempting to challenge in the courts the patenting of controversial technologies..... US courts, and hence also Patent Office examiners, deny any competence to entertain under section 101 arguments grounded in policy and Ethics".[22] The Commissioner filed a motion to dismiss the action on the alternative grounds that the plaintiffs lacked standing to sue and that the claims failed to disclose the cause of action for which relief could be granted[23]. The ruling significantly excluded human beings from patentability. This restriction on the patenting of human beings

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17 *Lowell v Lewis* 15 F. Cas. 1018 (C.C.D. Mass 1817) (No. 8568).

18 103 F.2d 868 (2d. Cir.).

19 *Ex parte Hibberd* 227 USPQ 443 (USPTO Bd.Pat. App. & Int.) 1985. New Developments in Biotechnology; Patenting Life - Special Report, US Congress Office of Technology Assessment, OTA -BA 370 (Washington, D.C. US Government Printing Office, April 1989), 37.

20 *Ex parte Allen* 2 USPQ 2d 1425 (USPTO Bd. Pat. App. & Int.) 1987.

21 which is discussed further in Chapter 4.

22 D. Kell The furore over the Patenting of Animals: Animal Legal Defense Fund v Quigg 8 *EIPR* p. 279 1992.

23 The US District Court for the Northern District of California concurred with The Commissioner on the second ground whilst giving no opinion on the first.

was based on the USPTO's interpretation of the 13th Amendment of the American Constitution (the Anti-slavery Amendment) which prohibits ownership of a human being.[24]

Following the granting of the first US animal Patent on 12 April 1988,[25] attempts were made to try and limit the monopoly allowed in respect of granting a 'farmer's privilege' but two attempts to do so were unsuccessful.[26]

The *Diamond v Chakrabarty* decision in the USA created a paradigm shift in the thinking of the USPTO which on the strength of this decision proceeded to routinely award very broad patents on hybridised and recombinant organisms. The *Chakrabarty* decision was not only important in the USA but had a far-reaching influence on other official opinion worldwide with regard to the patentability of micro-organisms. Following the decision the patenting policy in the USA was seen to allow the exclusive ownership and use of animals having certain characteristics. After *Chakrabarty* there appeared under USA law to be no patentable distinction between living and non-living compositions.

As the greatest filer of European patent applications, the USA has sought since the early 1980's to exert pressure on the European patenting and biotechnology community to lift the restrictions to patentability and to persuade European authorities to adopt the more liberal approach of the USA. Suggestions that unless such an attitude is adopted research and development by corporations might be undertaken outside Europe and the USA's attitude towards TRIPs and the Biodiversity Convention makes it clear where its interest lies.

<u>Europe</u>

The biotechnological community had been unhappy for a while about the European Patent Convention's woolly references to "morality" and "public order" and that it didn't specifically allow gene patenting and was even more unhappy that the EPO kept issuing contradictory decisions on biopatents in general.[27] As will be seen in the following chapters the interpretation of the patenting criteria of the EPC by the EPO has not been consistent and on a number of occasions the EPO has failed to act to clarify the interpretation of a number of specific provisions of the EPC in relation to the field of biotechnology, including Article 53 (a) and (b). As a result of the difficulties being experienced in this area the European Commission felt that reference to concepts of "*ordre public*" and "morality" needed to be supplemented by more precise guidelines and that it was appropriate for a directive to be introduced in this area to assist the patenting community, including regulatory bodies, to fairly

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[24] There are several problems with the human exception. For example, under the USPTO's 1987 ruling, embryos and foetuses, human life forms are not presently covered under the 13th Amendment protection, and are therefore patentable, as are genetically engineered human tissues, cells and genes.

[25] US. Patent No. 4.736,866.

[26] Transgenic Animal Patent Reform Act H.R. 4970, 100th Cong., 2d Sess. (1988), reintroduced H.R. 1556, 101st Cong., 1st Sess. (1989). Section 2 of the Bill 1556 proposed to amend Section 271 of 35, United States Code, adding a new subsection: "it shall not be an act of infringement for a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animals in the farming operation or sell such animal all the offspring of such animal. It shall be an act of infringement for a person to sell the germ cells, semen or embryos of a patented transgenic farm animal. The term transgenic farm animal means a farm animal whose germ cells contain genetic material originally derived from another animal other than the parent of the farm animal and the term farm animal means any animal used or intended for use as food or fibre".

[27] Article -How US muscle bent the rules in Europe James Meek and Paul Brown Wed 15 November 2000, *The Guardian* Special Report Patenting life p.11.

apply the existing European patent system to biotechnological inventions. On 31st July 1998 the Directive on the Legal Protection of Biotechnological Inventions (the Biotech Directive) came into force.[28]

The Biotech Directive

The function of the Biotech Directive confirms that its function is to harmonise the national laws of Member States of the European Union (Recitals 3 and 9) and to clarify the distinction between what is patentable and what is not and the legal framework for the patenting of biotechnological inventions (Recital 4). It was hoped that the Directive would encourage long-term investment in biotechnology and increase the European Union's competitiveness(Recitals 1, 2 and 5). The Biotech Directive broadly regards everything in creation as potentially an invention, unless it can be shown to fall under any of the exclusions. It establishes that biological material is patentable (Recital 13, Articles 1 to 7),[29] sets out the scope of protection of patented biotechnological inventions (Articles 8 to 11,[30] Recital 13), provides for dependency licences for plant varieties (Article 12,[31] Recital 13) and regulates the deposit, access and re-deposit of biological material which cannot be described in a patent application (Articles 13 and14,[32] Recital 13).[33]

The Directive had a long and difficult passage before the legislative bodies of the European Union from its first draft in the proposal of October 1988[34] until finally approved by the European Parliament in 1998. At the beginning of its life the first version of the proposal was relatively widely drafted and did not include a comparable morality exclusion to that in Article 53 (a) EPC. Morality was also not referred to anywhere within the proposal. Political lobbying of MEPS by religious, animal welfare and environmental groups and representations to the Council and the Commission resulted in the inclusion of the qualification to the morality exception to patentability based on morality. The Economic and Social Committee which was consulted by the Council stated "While endorsing the patentability of living matter with the exception of plant and animal varieties, the Committee would point out that this new situation of extended patentability could raise ethical problems in respect of some applications, e.g. those involving animals where possible secondary effects should

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28 Due to be implemented by Member States of the European Union by 31 July 2000.

29 The patenting of the cloning of human beings is explicitly outlawed (Article 6(2)(a)), but the following are held to be patentable: biological materials including plants and animals and parts of plants and animals, but not plant and animal varieties as such (Article 4(1)(a)); plant and animal materials which do not constitute a variety as such (Article 4(2)); uses of plant or animal varieties and processes for their production other than essentially biological processes for the production of plants and animals (Articles 1(1)(b), 8(2)); and microbiological processes, including processes consisting of a succession of steps provided at least one essential step of the process is microbiological (Article 4(3)). Essentially biological processes for the production of plants or animals are not patentable (Article 4 (1)(b)).

30 A "farmer's privilege" is confirmed in the Directive. Farmers are authorised to use the product of their harvest from patented reproductive material for reproduction or multiplication within their own operation. They may also use patented animals for reproduction on their own farms to maintain their herds (Article 11).

31 Conditions are set out in the Directive for compulsory licensing in cases of dependency between Plant Variety Rights and patents.

32 Obligations in respect of the disclosure of inventions and their deposit with a recognised institution acting as a depository are set out. Time limits for the application for a patent and other information related to an institution acting as a depository are specified (Article 13 and 14).

33 *Marleasing v Comercial Internacional de Alimentacion* (1990) *E.C.R.* p. 4135. A European directive is binding, as to the result to be achieved, upon each Member State to which it is addressed, but leaves to the national authorities the choice of form and methods of implementation. To test whether a State has implemented a directive, proceedings may be brought before the European Court of Justice by the Member State or the Commission. A directive, being addressed to Member States, does not have the same direct effect on the rights and obligations of individuals but may be applied in the clarification and interpretation of national law.

be taken into account, especially the pain which the animals may suffer".[35] There is included at 2.1 in the Appendix a summary of the main changes to the Recitals and Articles of the Biotech Directive as it passed through its various stages to grant. As will be seen initially there was no reference to a morality criterion in the Directive which was later introduced and was then diluted down in the final version of the Directive. The changes reflect the influence of the various interest groups which were engaged in lobbying against the Directive.

The first draft Proposal in 1988 was mainly technical in nature and was merely aimed at facilitating the patenting of relevant inventions and did not consider the ethical dimension. These aspects were later considered and introduced by the Council and Parliament amendments and incorporated in the Common Position. It is interesting to note that the first proposal for the Directive for the legal protection of biotechnological inventions did not contain any reference to the morality or animal exceptions to patentability[36] within any of its Recitals or Articles. The first draft of the proposal confirmed that only uses of plant or animal varieties and processes for the production thereof "shall be considered patentable subject matter" (Article 4).

The morality exception was included in the European Parliament Opinion of 29 October 1992[37] and as the Directive passed through its various stages the wording of the exception changed. From the anti-patent lobbyists point of view the morality exception became less restrictive as it passed through its various stages. The reference to animals suffering "physical handicaps" being removed and "substantial medical benefit to man" being added.

On 1st March 1995 the European Parliament rejected[38] the text of the Directive which was almost identical to that of the final Directive because they deemed it unethical. In the Parliamentary debate MRP Mezzaroma (FE) (IT) in proposing that the Directive should be rejected stated " The limits on the patentability of the procedures for the manipulation of genetic identity are, in consequence practically non-existent, being weak and irrelevant in legal terms. There is only a bland and general reference to respect of human dignity without reference to the values of the life of a person during his lifetime as such. The materialistic, organistic and biological approach of the document undermines any ethical, aspect, any moral consideration and any consideration of genuinely human nature". Following one of the largest lobbying campaigns of the multinational biotech industries the European Parliament was persuaded in 1998 to adopt a revised version of the Directive.

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34 No C /103 *OJ* European Communities 13.1.89.

35 Point 2.15, Opinion on the proposal for a Council Directive on the legal protection of biotechnological inventions. (1989) *OJ.* No C 159 26 June p. 10.

36 (1989) *OJ.* No C 10/3. 13 January p. 3.

37 (1992) *OJ.* No C 305, 23 November p. 173.

38 (1995) *OJ.* No C 68 p. 26. Euro MPs voting against the law one by a majority of 56 with 23 abstentions. Following the rejection of the last draft proposal by the European Parliament in July 1995, the European Commission presented a new draft on 25 January 1996 which was approved on 16 July 1997 by the European Parliament. A Common Position was reached at the 27 November 1997 Internal Market Council Meeting which was formally adopted by the Council on 26 February 1998 and forwarded to the European Parliament for its second reading under the Co-decision Procedure. On 12 May 1998 the European Parliament voted in favour of the Common Position and on 6 July 1998 the Council formally adopted the text. The Netherlands voted against and Belgium and Italy abstained. The Directive was published in the Official Journal of the Communities on 30 July 1998 on which date it entered into force. Member states were due to introduce into national laws the regulations and administrative provisions necessary to comply with the Directive within 2 years from that date (Article 15 (1)).

Unfortunately the Biotech Directive seemed unable to break away from the archaic language of Article 53 (a) EPC. Article 6.1 of the Directive provides that "inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation".

It is now, however, made express (Article 6 (2)) that on the basis of Article 6.1 the following, in particular, shall be considered unpatentable: processes for cloning human beings;[39] processes for modifying the germ line genetic identity of human beings;[40] uses of human embryos for industrial or commercial purposes;[41] and in Article 6 (2) (d) " processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes".

On a first reading, Article 6.1 does not seem radically different from Article 53 (a). The only change from the Article 53 (a) text is the omission of the word "publication". Article 6.2 is a new provision which is intended to provide guidance on the meaning of '*ordre public*' and morality. However, it creates some additional uncertainty to that already experienced in trying to interpret Article 53 (a) EPC. Any change from previous known wording is bound to cause some uncertainty as the existing precedent established by the EPO under the EPC is to some extent thrown away.

Articles 3 and 5 provide that patents are in principle available for products consisting of or containing biological material ("material containing genetic information and capable of reproducing itself or being reproduced in a biological system") and for processes by means of which biological material is produced, processed or used. Whilst the standard criteria for patentability will still have to be met,[42] it is expressly stated that biological material previously occurring in nature, when isolated from its natural environment or produced by a technical process, may be the subject of an invention (Recitals 22, 24).[43]

Article 2 is a helpful definition clause confirming the meaning of "biological material", "microbiological process" and an "essentially biological process" and the concept of "Plant Variety" under the Community Plant Regulation 2100/94. There is thus some attempt to bring some consensus to the terms being used. But there is no definition of 'animal variety'.

Article 4 of the Biotech Directive provides that (a) plant and animal varieties and (b) essentially biological processes for the production of plants and animals shall not be patentable. Also inventions which concern plants or animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

Article 7 of the Biotech Directive confirms that the Commission's European group on Ethics in Science and New Technologies will evaluate all ethical aspects of biotechnology. Patent groups had lobbied for some time

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39 Article 6.2 (a).
40 Article 6.2 (b).
41 Article 6.2 (c).
42 Namely, there has to be an invention, other than a mere discovery, that it must be new, involve an inventive step and be capable of industrial application.
43 Gene patents are available in all fields of biotechnology. For recombinant DNA inventions, the patent will claim the nucleotide sequence coding for the protein expression product; vectors, micro-organisms or

for the creation of an Ethical Committee and to this end the Group of Advisers on the Ethical Implications of Biotechnology[44] was set up in 1991. The remit of the Committee was to identify ethical issues in biotechnology and to assess the ethical impact on the Commission's activities in the biotechnological field. However, it is not the intention that this Group will intervene in any proceedings pending before the EPO or act as an EPO Board of Appeal and will only be consulted on a basic level.[45]

Certain provisions of the Biotech Directive have been incorporated into the EPC by virtue of the EPC Implementing Regulations[46] which were amended following a detailed examination by the Committee on Patent Law (instructed by the Administrative Council in 1998) on the implementation of the Biotech Directive in European patent law. A new chapter VI entitled "Biotechnological Inventions" was inserted in Part II of the Implementing Regulations of the EPC and which came into force on 1 September 1999.[47] This Chapter is based on the provisions of Chapter I of the Biotech Directive and introduces into the EPC definitions of "biological material", "plant variety", "essentially biological" and "microbiological process". However, as with the Biotech Directive there is no definition of the term "animal variety". Rule 23d provides that "under Article 53 (a) European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following" and there is then reiterated Article 6.2 of the Biotech Directive.

Challenge to the Biotech Directive

Not all members of the EU were happy that the Directive had been approved by the European Parliament. On the 19th October 1998[48] the Dutch Government filed suit, Case C-377/98, with the European Court Justice seeking a declaration that the Biotech Directive violated international treaties on the grounds which included the use of the wrong legal base, failure to respect the principles of Human Rights and subsidiarity and conflict with international treaty obligations. Norway (6 July 1999) and Italy (21 January 1999) intervened in the appeal.[49] In an opinion of Advocate General Jacobs delivered on 14 June 2001 the appeal was rejected.

The Biotech Directive has provided a morality standard, namely a cost/benefit standard (suffering against substantial medical benefit to man or animal). As will be seen in Chapter 7 such a standard is not new in European law. But how badly does an animal have to suffer to be excluded from patentability under Article 6.2? There are no generally accepted criteria for measuring and defining suffering. How is "substantial medical benefit" to be realistically established when the patent application is filed? At this stage an invention has to be

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higher organisms transformed with the sequence and in appropriate cases the expression product itself.

44 Comprises nine members it is independent of the Commission and acts in an advisory capacity.

45 Confirmed in interview with the writer by Dr. Christian Gugerell, Director, EPO. On 24 January 2000. "Article 7 ...says that we will have to observe what they say, we will take it into account.... We have the Patent Office and we do the job and it is our legal obligation that we do it and we do not give it outside for something. Of course we shall observe what this Ethical Committee says. We also observe what other Ethical Committees say, for example, the Nuffield Committee. That is quite clear, but we will not set up a morality group". Interview in English.

46 Article 164 EPC Implementing Regulations and Protocols.

47 Notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the EPC (1999) *OJ. EPO* 8-9 p. 573. Explanatory Memorandum (1996) *OJ.* No. C 296 p. 4.

48 (1998) *OJ.* No. C 378 5 December p. 23.

49 Italy had earlier abstained from the vote on the Proposal for the Directive in the European Council of Ministers on 27 November 1997.

new. A possible benefit can therefore not be seen. What are the standards to be applied for weighing up suffering against medical benefit? Here, too, there are no existing criteria.[50]

At the heart of the matter is whether morality should play a part in the determination of a grant of an intellectual property right at all or if it should be more properly found outside intellectual property law. For example, once granted, an intellectual property right can be subjected to other restrictions by way of regulation, this regulation thereby controlling the exploitation of the protected material, for example, the Plant Variety Rights system. Some hold the view if certain novel organisms are considered morally and environmentally undesirable, then this should be addressed in the usual way in legislation aimed at regulating the creation or use of such organisms, not in patent legislation concerning the legal protection of the inventions from those who would seek to copy it.

Interpreting the morality exception and *ordre public* has been notoriously difficult for the EPO. The relationship between Article 6 paragraphs 1 and 2 is unclear. Article 6.2 is "on the basis" of Article 6.1 which is a vague way of defining the relationship between the two. The examples in Article 6 (2) are considered unequivocally contrary to public policy. Article 6.2 will therefore have immutable status and developments in these areas which may benefit man and may be seen in time to be morally acceptable will remain unpatentable.

It will be interesting to see how Article 6.2 (d) will be interpreted by the EPO. If the time of judging morality is at the time of the filing of the patent application will this be the time that the medical benefit to man will be assessed? At this time it will be clear if the animals will suffer but it will be unlikely that the medical benefit be able to be assessed. If a patent is granted and is subsequently found not to have any substantial medical benefit, such a patent should logically be revocable. In view of the likely uncertainty in the interpretation of this provision it is anticipated that revocation proceedings will be brought in national courts[51] to test this provision. It will be more than a little interesting to see the EPO's response to such cases.

International

Any discussion of patenting in Europe would not be complete without reference to those international agreements and treaties which may influence on the interpretation of the provisions of the EPC, particularly Article 53 (a).

The influence of the USA on other international patenting systems may be seen when looking at the other international agreements to which Members of the EU and contracting EPC States are also signatories. The most important to be considered in relation to the present study in relation to the patenting of animals are the TRIPS Agreement, the Biodiversity Convention and the UPOV Convention[52] each of which to some extent restricts the US's broad approach.

To put the EPC in political and chronological context there is included at 2.2 in the Appendix a summary of those international conventions and treaties which have or will impact on interpretaion of the morality exception

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50 For further discussion see Chapter 7.
51 Under English law see Patents Act 1977 s. 72.
52 The UPOV Convention is discussed in Chapter 3.

by the EPO. Some biographical details have been included for background information only. It is not proposed that each will be the subject of a detailed review.

The TRIPs Agreement

The Uruguay round of the General Agreement on Tariffs and Trade (GATT)[53] created a subsidiary Agreement on Trade Related Aspects of Intellectual Property Issues (TRIPs)[54] which provides a global system for the protection of intellectual property rights and the recognition of national rights by all signatories.[55] Any country ratifying GATT accepts the obligation to establish minimum standards of intellectual property protection. Patents are to be available in all fields of technology except in certain circumstances. The Agreement is administered by the World Trade Organisation (WTO).[56]

The TRIPS Agreement[57] in Article 27 contains a provision similar to the EPC morality exception. The introduction of Article 27 was supported by a number of signatories to the Agreement with the exception of the US but despite such support the US is trying to exert pressure to have Article 27 removed, which if successful could lead to the unfettered exploitation of biotechnological inventions by the wealthier more patent-aware countries in those countries which have utilised the inventions for centuries.

During the negotiation of the TRIPs Agreement during the Uruguay round in 1987, various countries submitted proposals advocating some form of moral check on the patentability of such inventions. To show how wide these proposals were there is included at 2.3 in the Appendix a summary of those put forward by certain of the Contracting States. As might be expected the US was opposed to any such restrictions.

Article 27 of the TRIPs agreement provides:

"(2) Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal and plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

(3) Members may also exclude from patentability:
(a) .....
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide

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53 GATT established in 1947 led to WTO. For further information see The GATT Agreement on TRIPS Trade-Related Aspects of Intellectual Property Rights, *EIPR*. vol 16 Issue 11 Supplement Nov. 1994; C.M. Correa,The GATT Agreement on Trade-related Aspects of Intellectual Property Rights: New Standards for Patent Protection; (1994) 8 *EIPR* p 327.

54 TRIPs Agreement came into effect on 1 January 1995. Developing countries have until 2001 and the last developed countries until 20045 to harmonise provisions.

55 For detailed analysis see C.M. Correa and A.A. Yusuf (Kluwer Law International 1998); GATT TRIPS Agreement: Supplement (1994) 11 *EIPR* p. 1.

56 htpp://www.wto.org/ (last visited 17 October 2001).

57 See D.J. Gervais, The Trips Agreement Interpretation and Implementation (1999) *EIPR* p. 156; (1994) *OJ.* No. L 336 23 December p. 213; and The Intellectual Property Institute *'TRIPs and the EC'* (The Intellectual Property Institute 1995).

for the protection of plant varieties either by patents or by an effective *sui generis* [58]system or by any combination thereof".

Thus the TRIPs Agreement allows signatories to apply moral and ethical norms to justify exclusions from patentability should they so wish providing an appropriate system is in place for the protection of plant varieties. In opposing this, the economic pressures exerted by the USA on certain contracting States signatories produced a great deal of international interest in the WTO Ministerial Conference held in Seattle in November 1999. However, the conference did not achieve all it had hoped and the meeting was suspended, although work is still underway to consider proposed revisions to the agreement.[59] One of the main areas of contention which arose was that the USA was seeking removal of the morality provision and was pressing members to agree with its proposals.[60]

The Biodiversity Convention

The Biodiversity Convention was enacted in June 1992 at the UN earth summit in Rio de Janeiro.[61] Its objectives were stated as enabling "a conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources".[62]

The Biodiversity Convention has sought to change the legal and institutional treatment of indigenous genetic resources. The Convention guarantees States sovereignty over their genetic resources and seeks to regulate their appropriation without prior consent. The USA has not signed the Convention and is insisting that there is no need to regulate trade in genetically engineered organisms and USA's negotiators are lobbying for the weakest possible terms. The Biodiversity Convention is seen by many as being in direct conflict with the TRIPs Agreement as the granting of such sovereign rights would appear to contradict patenting principles. The Convention on biological diversity also mandates negotiations for a protocol on biosafety.

A Biosafety Protocol (Cartagena Protocol) was the first treaty based on the Convention being agreed in January 2000 and requires exporters to identify genetically modified organisms and thus enable importing countries to determine whether they pose any health or environmental risks.[63]

The European patenting system is seen as 'competing' with other international patenting systems. As the US files the greatest number of European patent applications annually[64] and is potentially one of the largest sources of investment in Europe there is pressure on the EPO to keep as closely in step with US patenting principles as

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[58] Latin of their own kind. A sui generis system does exist for the protection of new, distinct, uniform and stable plant varieties in the form of the International Convention for the Protection of New Varieties of Plants (UPOV).

[59] WTO Press release, 7 December 1999.

[60] M. Ho *Genetic Engineering Dream or Nightmare* (Gateway Books 1998). Commercial pressures exerted by US in cancelling of trade benefits with Ecuador and Ethiopia. Complaints filed with WTO in respect of India, Pakistan and Denmark. Also the US limited trade with Panama and Paraguay.

[61] Came into force in 29 December 1993.

[62] See F. McConnell *The Biodiversity Convention* (Kluwer Law International 1996); Annex A to Council Decision 93/626/EEC of 25 October (1993) *OJ.* No. L 309 p.1.

[63] This is of particular interest in the light of Monsanto's claims that that the acreage of transgenic crops plants in 1999 had increased by almost 44 % beirg mainly in China, Argentina, Canada and South Africa. (*Nature* Vol. 403, p. 403, 3 February 2000).

[64] Annual Report 1998.

possible. As the number of European patents filed annually by US corporations increase so will the pressure on the EPO to fall into line with US standards. Dire warnings have been issued that Europe is lagging behind the US in its patenting policy and that "if European biotechnological companies are to be competitive with their American and Japanese counterparts, they must be given the same possibilities to protect the results of their research and development through patents".[65]

Provisions of the Biotech Directive are now part of the EPC and are seen by many as giving a green light to the patenting of animals not withstanding the amber light of Article 6.2 (d). It has been suggested that its very existence will generate public opposition to biotechnological research. "It also sends an aggressive signal to developing countries, particularly those with high levels of genetic diversity, that Europe is about to join the US line on intellectual property rights within the WTO in elevating industrial patents over all forms of social and economic regulation and reward".[66]

Certain companies have sought to capitalise on the exploitation of agricultural biodiversity in certain countries of the world without any benefit to local populations and some countries are attempting to resist this exploitation by devising their own legal systems to safeguard public access to traditional knowledge and biological and genetic resources. The Biotech Directive is regarded as legitimising such 'biopiracy'. It is feared that the Directive will effectively foreclose on the few potentially democratic opportunities within the WTO[67] for countries to negotiate over the most fundamental of rights to use biodiversity and knowledge directly to meet food and medicinal needs. By permitting the patenting of living material, the Directive pre-empts a full and open discussion of this by WTO. It is thought that it will intensify the already substantial pressure on some of the third world countries to adopt a US-style patent legislation and undermine their bargaining power within the negotiations.

The USA's attitude to patenting is encapsulated in the phrase of the Supreme Court which noted in the House and Senate Committee Reports concerning the 1952 Patent Act, that [patentable] subject matter is to "include anything under the sun that is made by man".[68]

The *Chakrabarty* decision acted as a catalyst for the patenting of living organisms not only in the US but also in other patenting jurisdictions. As the *Chakrabarty* case progressed it became apparent during the appeal that the microbe would not perform its function in open seas and that the applicant (General Electric) was treating the matter purely as a commercial test case. It was a case which the USPTO was ready to decide, and was inevitably going to decide as it did. The USA could be seen as the bully of the patenting world, showing by its influence on the TRIPs Agreement and failure to sign the Biodiversity Convention that its main concern is to establish the US as the leading worldwide competitive force in the field of biotechnology. The USA exercises aggressive diplomacy to persuade other governments to implement intellectual property rights that exceeds what is required by the WTO. Several nations have contested patents granted by the UPTO in relation to biological materials with limited success.[69] American law is felt by the rest of the world to be too biased towards the

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[65] Council of Europe. Parliamentary Assembly; Committee on Agricultural and Rural Development. Introductory Memorandum on the Patenting of Biotechnological Inventions Strasbourg 29 January 1996 doc\1996\aa2.96.

[66] Article – Greenpeace deplores EP vote on Bio Patent Directive, Campaign for Food Safety, 16 July 1998.

[67] http://www.wto.org/wto/intellec/intell2.htm (last visited 17 October 2001).

[68] S.Rep.No.1979, 82nd Cong. 2d Sess. 5 1952; H.R. Rep. No. 1923, 82nd Cong. Sess. 6 1952.

[69] For example, Bolivia in respect of quinoa and India in respect of the neem tree.

influence of large corporations.[70] The US can be seen as biotechnology scavengers, having resources to undertake research in the poorer countries of the world and then patenting the results in the USA.

Having the financial resources to exploit biotechnology in the less prosperous countries of the world the USA is anxious to have in place a patenting system but one which is as broad as its domestic system. The restrictions of TRIPs and the Biodiversity Convention do not lie comfortably with achieving this. The US has therefore exercised aggressive diplomacy to persuade other governments to implement intellectual property rights that exceed what is required by the World Trade Organisation. The USA has threatened to impose commercial sanctions on those countries which do not fall into line. But it is feared that if such countries implement their own patenting systems without appropriate protections and checks in place that US corporations will restrict the use of the products of such research in the very countries where the inventions originated.

Europe is looked towards as an example of having under the EPC a relatively sophisticated patenting system where a morality exception to patentability exists. How the EPO interprets this clause in relation to the patenting of animals will thus have importance beyond European shores but will impact on a number of third world countries. The EPO cannot hide its head in the sand as it has done in the past[71]in considering the interpretation of article 53 (a) EPC. Despite economic pressures the EPO must take a firm stance in relation to the interpretation of Article 53 (a) EPC which is now of even greater importance in the light of recent advances in genetic engineering of animals leading to the analysis of the genetic make up of a vast number of animals. Before considering the interpretation of the morality exclusion in the Harvard Oncomouse case, the next Chapter considers the patentability of animals generally under the EPC in the light of Article 53 (b) EPC.

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[70] Andrew Brown (2000) *The Guardian* Nov 15 p 11 Special Report Patenting Life p.11. See also article – How US muscle bent the rules in Europe James Meek and Paul Brown Wed 15 November 2000, *The Guardian* Special Report Patenting Life p.11

[71] See Chapters 5 – 7.

Chapter 3

Why consider the patenting of animals at all if Article 53 (b) of the EPC states that European Patents shall not be granted for animal varieties?

"European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."

The European Patent Convention, Article 53 (b)

"Transgenic animals are a radical departure from both evolutionary history and classical breeding practices. Never before in history have scientists had the tools to bypass species boundaries altogether and create novel creatures by combining genetic information from across the expanse of the biological kingdom"

Jeremy Rifkin 1998[1]

One may ask why is this study looking at the patenting of animals when the European Patent Convention clearly provides that animal varieties are not patentable?[2] As this chapter will illustrate the determination of the patentability of animal varieties, and indeed plant varieties, has not proved an easy task for the European Patent Office. This chapter will consider how the EPO, has attempted to interpret this exception by reviewing some of the recent decisions of the EPO in relation to plants and animals.

Historically, most of the earlier cases in relation to Article 53 (b) EPC to come before the EPO for consideration related to plants due mainly to the fact that it was recognised very early on, unlike the situation for animals, that plant breeders needed some form of protection for their plants. As a result of this the protection of intellectual property rights in plants developed in a quite different way to that for animals. These differences have not fully been recognised by the EPO where it will be seen that it has been assumed that assumptions and decisions made in respect of plants apply equally to animals.

The UPOV Convention

Selective breeding of new varieties of crops to give increased yields has always been important to farmers. Over the past centuries selective breeding has produced new varieties of plants but more recently with the developments of genetic engineering techniques, new varieties including transgenic varieties, can be created directly using standard laboratory techniques.[3] The significance of selective breeding was widely recognised in a most countries of the world, including the US and Europe, and led to certain countries putting into place their own national systems for the protection of new plant varieties, known as plant breeders' or plant variety rights. A desire for international recognition and harmonisation of these rights led to the signing in 1961 of the

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1 From *Biotech Century* (Penguin Putnam Inc. 1998) at p. 101.

2 For good review see A. Christie, Patents for Plant Innovation (1989) *EIPR* 11 p. 394.

3 For detailed accounts see V.L. Chopra, V.S. Malik and S.R. Bhat, *Applied Plant Biotechnology* (Science Publishers Inc, 1999); Shain-dow Kung and R. Wu *Transgenic Plants Vol 1*, (Academic Press, Inc 1993; A. Hiatt, *Transgenic Plants Fundamentals and Applications*, (Marcel Dekker, Inc. 1992).

International Union for the Protection of New Varieties of Plants (the UPOV Convention)[4] and later in EU Member States the introduction of national plant breeders rights.[5] The level of harmonisation was extended even further in the EU, almost thirty years later, by the implementation of Council Regulation (EC) No 2100/94 of 27 July 1994[6] on Community Plant Variety Rights.[7] To avoid confusion with the implementation of the UPOV Convention and to avoid double protection,[8] the EPC excluded patentability of plant varieties.

The UPOV Convention originally arose as a result of certain European countries[9] seeking to provide plant breeders with an internationally recognised plant variety right.[10] Prior to this time, in Europe, patent law was originally considered unsuitable for protecting new varieties of plants developed by traditional breeding methods. Thus the patenting of plants had not been possible and plant breeders in Europe were frustrated that little was being done to protect their rights. Part of the frustration may be attributed to the difficulty for breeders in showing an inventive step and reproducibility were difficult to establish. Also the understanding of these concepts were different in European countries during the formative years of the UPOV Convention than they are today. In other patenting jurisdictions such as the US and Australia, steps had already been taken to protect these rights. In the US, the Plants Patent Act was introduced in 1930 which provided protection for asexually reproducing plants. In 1970 Congress passed the Plant Variety Protection Act (PVP) for the protection of sexually reproduced cultivars and inbred parents of hybrids.[11]

Article 2 (1) of the UPOV Convention provided that "Member States may provide for a right according to the provisions set out in UPOV Convention using either a patent or a plant variety right but not both for any one species or genus. The Convention was revised in 1978 and 1991. The 1991 Revision[12] removed the dual protection with the result that if UPOV Members were not constrained by the bar contained in Article 53 (b) EPC, they could permit plant varieties to be protected under either patent and/or plant variety rights. This revision also provided a tighter definition of what a 'variety' actually was namely, "a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the

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4 First signed 2 December 1961. Derived from Union internationale pour la protection des obtentions vegetales. Revised in 1972 and 1991. For background and text see http://upov.int/eng/dgtext.htm (last visited 8 September 2001).

5 In UK by Plant Varieties and Seeds Act 1964 and The Plant Varieties Act 1997. See Guide to the Plant Varieties Act 1997, Ministry of Agriculture, Fisheries and Food, Plant Variety Rights Office, December 1997.

6 (1994) *OJ.* No L 227 11 September p. 1.

7 For detailed account see P.A.C.E. van der Kooij *Introduction to the EC Regulation on Plant Variety Protection*, (Kluwer Law International 1997).

8 Up until 1991 when UPOV Convention revised.

9 Originally signed by Belgium, France, Italy, Germany and Netherlands and the following year by Switzerland, Denmark and the UK.

10 Article 1 UPOV Convention 1961 provided "the purpose of this convention is to recognise and to ensure to the breeder of a new plant variety, or to his successor in title, a right the content and the conditions of exercise of which are defined hereinafter".

11 For account see P.S. Baenzinger, R.A. Kleese and R.F. Barnes, *Intellectual Property Rights: Protection of Plant Materials*, (Crop Science Society of America Inc., CSSA Special Publication Number 21, 1993); B.E. Caldwell and J.A. Schillinger, *Intellectual Property Rights Associated with Plants*, (Crop Science Society of America Inc., ASA Special Publication Number 52, 1989).

12 For an informative account of background and changes in 1991 revision see N. Byrne, *Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties*, (Centre for Commercial Law Studies, University of London 1996).

grant of a breeder's right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combinations of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics, and considered as a unit with regard to its suitability for being propagated unchanged".[13]

There is no equivalent in the 'animal breeders' world' to the UPOV Convention providing for animal variety rights.

The Biotech Directive

The Biotech Directive was an attempt to clarify the position of the patentability of animals and plants by providing some guidance, including various definitions, and whilst it has done little to assist in the understanding of what an animal variety is, it does assist to some extent with regard to plant varieties. Article 4.1of the Biotech Directive provides that the following shall not be patentable: a) plant and animals; b) essentially biological processes for the production of plants or animals.[14] Inventions which concern plants or animals shall be patentable if the technical feasibility of the inventions is not confined to a particular plant or animal variety (Article 4 .2).

The Directive's Article 2 provides some useful definitions, including that of plant varieties. Plant variety' is defined in the Biotech Directive by reference to by Article 5 of Regulation (EC) No 2100/94 (Article 2.3).[15] But there is a striking absence of any attempt to define an 'animal variety'.

The Implementing Regulations of the EPC have been expanded to accommodate the use of the Biotech Directive as a supplementary means of interpretation of the EPC.[16] New Rules 23 (b)-(e) inserted in Part II of the Implementing Regulations to the EPC Chapter VI and coming into force on 1 September 1999. The amendments to the Rules mirrored the wording of the Directive[17] but the Rules were not expanded to include a definition of 'animal variety' or 'microbiological material'.

It is the writer's view that the original intention of the drafters of the Strasbourg Convention and the EPC was that both plants and animals were to be excluded from patentability. Because the entity which is of commercial interest to the plant breeder is the 'variety' the drafters of the Conventions used this taxonomic term in their drafting. The *travaux preparatoires* referred in the earliest drafts of the EPC to animal 'species' but then adopted the Strasbourg

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13 UPOV 1991 Article 1 (vi).

14 Article 4.1 (b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

15 Up until now the EPO Boards of Appeal had always used the UPOV Convention's concept of variety as the basis for interpreting Article 53 (b) EPC. Article 5 EU Variety Rights Regulation is based on the 1991 UPOV Convention definition but making reference to breeder's right.

16 Chapter VI Rule 23 b (1).

17 Rule 23 b (3) incorporated Article 2.1 (a) of the Directive 'biological material'; Rule 23 b (4) incorporating Article 2.3 of the Directive 'concept of variety'; Rule 23b (5) incorporating Article 2.2 of the Directive 'essentially biological'; Rule 23b (6) incorporating Article 2.1 (b) 'microbiological'; Rule 23c (b) incorporating Article 4.2 of the Directive 'technical feasibility'.

Convention wording referring to 'plant and animals varieties'. In animal classification systems the term 'variety' is not applied to animals as widely as it is to plants. The term variety in relation to animals is often used (incorrectly) interchangeably with 'species'.

TRIPs

The Trips Agreement[18] is far more simply worded than either the Biotech Directive or the EPC in respect of the exclusion from patentability of animal and plants: Article 27 3. TRIPs providing that "Members may also exclude from patentability (a)... (b) plants and animals other then micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof".

As will be noted the requirement is discretionary rather than mandatory as in the EPC.

Examination of Article 53 (b) EPC in the Harvard Oncomouse Case

The Harvard Oncomouse case was the first European patent application for an animal in which Article 53 (b) EPC was scrutinised by the EPO. The application was filed by Harvard College in the USA from which it takes its name.[19] The invention was entitled a 'Method for producing Transgenic Animals'. The Application No 85 30 4470.7 was filed at the EPO on 24 June 1985[20] and claimed priority from the US Application No 623, 774.[21] The application contained both method and product claims[22] covering the introduction of an oncogene into non-human animals (mammals) to produce transgenic animals for use in cancer testing.

For ease of reference there is included in Chapter 4 at page 63 of this study a diagrammatic representation of the stages in the prosecution of the Harvard Oncomouse European Patent Application.

The Examining Division (1)

The application was considered initially by the Examining Division[23] which issued a notice of its objections to the granting of the patent on the basis that the application did not meet the requirements under Articles 53 (b) EPC, Article 53 (a) EPC and Article 83 EPC.[24] The objections raised under Article 53 (b) EPC related to the fact that the

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18 See Chapter 2.

19 See post Chapters 5 and 6.

20 Designated states AT, BE, CH, DE, FR, GB, IT, LI, LU,NL,SE claiming priority from US Patent Application No. 623774 22 filed at the USPTO on 22 June 1984 by The President and Fellows of Harvard College.

21 Filed at the USPTO on 22 June 1984.

22 See 4.3 Appendix for summary of the claims.

23 See Guidelines C. VI.

24 Communication of 20 April 1988 from the Examining Division pursuant to Article 96 (2) and Rule 51 (2) EPC - Primary Examiner Christian Gugerell. Art. 96 (2) provides 'If the Examination of a European patent application reveals that the application or the invention to which it relates does not meet the requirements of

application contained a claim (claim 17) directed to animals *per se*, namely, " a transgenic non-human eucaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10, said animal preferably being a rodent". The Examining Division interpreted this provision as referring not only to those cases where a specifically designated variety is claimed but also cases where varieties are covered by a claim.

The application was also considered under Article 83 EPC[25] (sufficiency of claims to the invention) and Article 53 (a) EPC (is invention contrary to public order or morality). Commentary in this chapter will be limited to consideration of Article 53 (b) EPC arguments only whilst Article 53 (a) and Article 83 EPC are discussed in Chapters 4 and 5.

The Examining Division referred to the TBA's earlier decision in *Ciba-Geigy* T49/83, which excluded from patentability only plants in the form of a 'plant variety'. The Examining Division acknowledged that in this decision a restrictive interpretation of plant variety as meaning only plants in the genetically fixed form of a plant variety was justified in view of the requirement to avoid the situation of double protection[26] by excluding from patent protection only such subject matter which was eligible for plant variety protection under the UPOV Convention, namely plant varieties. Furthermore, in the light of the Lubrizol decision[27] the exception was to be construed narrowly and judged on the basis of what comprised the essence of the invention. In this case the essence of the process invention under consideration was the introduction of an oncogene into an animal by a technical means such as microinjection. As this was clearly not 'essentially biological', no objection to the process claims was raised under Article 53(b) first sentence, EPC.

With regard to product claims 17 and 18[28] the question arose as to whether they came under the exclusion provisions of Article 53(b) second half-sentence, EPC.[29] They contained two different process steps; namely the non-biological and a purely breeding step. The two steps resulted in two different products. Animals that had been genetically manipulated themselves were products of an essentially non-biological process, whereas further generations were the product of sexual and thus exclusively biological reproduction. The latter were non-patentable under Article 53(b) first half-sentence, EPC. Even if the Examining Division was to accept Harvard's argument that the process as a whole was essentially non-biological, this would not make the product claims allowable. Claims 17 and 18 were held to embrace subject matter excluded from patentability by Article 53 (b) and were held not to be allowable. The Examining Division believed that the second half-sentence, had to be

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this Convention, the Examining Division shall invite the applicant, in accordance with the Implementing Regulations and as often as necessary, to file his observations within a period to be fixed by the Examining Division.

25 Article 83 EPC provides that the European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

26 Article 2 (1) UPOV.

27 T320/87 *Lubrizol/hybrid plants*. (1990) *OJ. EPO* p.71.

28 Claim 18 – A chromosome of an animal as claimed in claim 17, which comprises an oncogene as defined in any one of claims 3 to 10.

29 This provision does not apply to microbiological processes or the products thereof'.

considered in conjunction with the first. Thus if the product of a process was manifestly excluded under the first part of the Article, the second part could not be interpreted in such a way as to set aside the first.[30]

In considering the meaning of the term animal varieties the Examining Division commented that "In Article 53 (b) EPC it is stated that European patents shall not be granted in respect of animal varieties. This provision is interpreted by the Examining Division to refer not only to these cases where a specifically designated variety is claimed but also to cases where varieties are covered by a claim. It is true that the Board of Appeal has interpreted the term plant variety in the same paragraph as excluding from patentability only plants in the genetically fixed form of a plant variety (T49/83).[31] This conclusion was based on the purpose of the provision. The legislators of the EPC wanted to have plant varieties protected by a special industrial property right according to the UPOV Convention double protection was to be excluded according to Article 2 (1) of the UPOV Convention".[32]

The main claims in the Oncomouse patent covered: any individual animals having the oncogene in question; groups of individual animals having the same or a very similar appearance; and groups of animals forming varieties. The Examining Division in reaching its decision stated that when interpreting Article 53(b) it had to be borne in mind that its text was drawn virtually word for word from the earlier Strasbourg Convention.[33] In interpreting Article 53(b) the Examining Division believed that it was necessary to consider what the legislators' intentions had been at that time.

The Examining Division noted "Moreover, if Article 53 (b) EPC is considered in the three official languages it is apparent that with regard to plants the legislator used identical designations in all three languages whereas this is not the case with respect to animals. The German version "Tierarten" is definitely different from the English "animal varieties" and the French "races animals". This is a further indication that the legislators' intention was not the exclusion of some particular group of animals but rather the exclusion of animals in general.[34]

The Examining Division acknowledged that "in scientific language there is no uniform term which would give a clear and reliable basis for the application of Article 53 (b) EPC".[35] It took the view that by artificially combining a breeding and a non-biological process the applicant was seeking to avoid the exclusion under Article 53 (b) first half-sentence EPC particularly since the two processes would give rise to different products. The Examining Division confirmed that it was "therefore quite in conformity with the purpose of the law to reject not only the

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30 With regard to the interpretation of the meaning of 'microbiological' the Examining Division stated "the second part of Article 53 (b) EPC can scarcely be understood to set aside the first part. If a plant or animal variety is made by a microbiological process, this process is eligible for patent protection but not the product thereof, i.e. the plant or animal variety, because this is manifestly excluded by the first part. The second part of Article 53 (b) EPC must not be interpreted in a way which contradicts the basic concept of the first part".

31 *Ciba-Geigy* Decision T49/83.

32 Decision of Examining Division 14 July 1989 p. 4.

33 See Chapter 1. Article 2 of the Strasbourg Convention provides that The Contracting States shall not be bound to provide for the grant of patents in respect of (a) inventions the publications or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by a law or regulation; (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes and the products thereof.

34 Decision of Examining Division 14 July 1989 p. 5.

claims to a specific variety but also claims covering any variety".[36] Moreover the term animal variety would not give sufficient criterion to delineate patentable from non-patentable subject matter.

It was "up to legislators to evaluate the diverging interests whether or not to protect animals *per se* and if so, whether or not by patents or *a system of special protection*".[37] This was the first time the EPO suggested that another form of protection might be available for animals.

Harvard responded to the objections[38] raised by the Examining Division and filed a new set of amended claims. Claim 17 was amended to refer to non-human animals. However, the broad main claim 1 was not amended. Whilst Harvard noted that the Examining Division appeared to be suggesting that claim 17 would be allowable if restricted to rodents, it did not agree that if so worded the claim would differ from the present claim. Harvard alleged that there were errors in the reasons contained in the communication from the EPO but confirmed its agreement to the term 'animal' being broader than 'animal variety', stating "the Examining Division's lack of certainty as to the meaning of the term animal variety is noted. However, one thing is quite clear, and that is that "animal " is broader than the term "animal variety".[39] Harvard in addition argued that the present application related to a microbiological process and that in view of the fact that first half sentence of Article 53 (b) EPC did not apply to microbiological processes, there could be no objection under this section. Harvard went on to propose that it considered that there was no particular difficulty in drawing a parallel between plant varieties and animal varieties.

Notwithstanding Harvard's arguments the Examining Division maintained its objections.[40] The main area of contention still remained the interpretation of the second part of Article 53 (b) EPC. The Examining Division insisted that this must not be interpreted in a way that contradicted the basic concept of the first part.

The Examining Division considered it unfortunate that "there is no uniform use of this term (*animal variety*) in scientific language which would give a clear and reliable basis for the application of Article 53 (b) EPC".[41]

Oral proceedings[42] followed and even though a number of third party observations had been filed and were taken into account,[43] the application was refused.[44] Following the issue of the notice of refusal to grant the Oncomouse patent Harvard appealed to the Technical Board of Appeal (TBA) against the decision.[45]

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35 Communication of 20 April 1988 p. 3.
36 Communication of 20 April 1988 p. 2.
37 Writer's own emphasis. Communication of 20 April 1988 p. 3.
38 By letter of 22 December 1988.
39 Response of Applicant of 22 December 1988 p. 4.
40 Communication of Examining Division sent to Applicant 28 March 1989 and 12 May 1989.
41 Decision of Examining Division 14 July 1989 p. 6.
42 Held on 26 June 1989. Note in relation Article 116 (1) - (4) EPC - Common provisions governing Oral Proceedings.
43 Art. 115 EPC.
44 (1989) *OJ. EPO*, 14 July p. 451.
45 Grounds of Appeal and Amendments being filed on 13 November 1989. See EPC Part VI Appeals Procedure Articles 106 – 112.

Boards of Appeal

Appeals in respect of Decisions of the Examining Division (and Opposition Division) rest with the EPO Boards of Appeal, Technical and Enlarged. The Technical Boards consists of a minimum of three members of which at least one is required to be a legal member, in the interests of building up a body of case law.[46] The Enlarged Board of Appeal comprises five legally qualified members and two technically qualified members, one of the legal members acting as chairman.[47] The Boards of Appeal have the capability to review or reverse an existing decision without referring back to the Division of first instance. The first instance Division is bound by the *ratio decidendi* of the Board of Appeal "in so far as the facts are the same".[48]

The EPC contains nothing which requires individual Boards of Appeal to follow interpretations of the law under the EPC as set out in previous decisions of individual Boards of Appeal. However a system of precedence does exist between the Boards which is clearly desirable in order to maintain a degree of legal certainty. However, this need for legal certainty must be balanced against the need to review previous interpretations of the provisions of the EPC, and the need to change such interpretations where appropriate. The need for flexibility is important to take account of the changes in technology.

But it must be remembered that the Enlarged Board of Appeal is not a further instance of appeal but it decides points of interpretation and questions of principle. The role of the Enlarged Board is to provide a uniform interpretation of the EPC. There is no subsequent appeal from the Enlarged Board. A decision of the Enlarged Board has a binding effect on the Technical Board from which it is referred. The binding effect applies only to the matters of law actually decided by the Enlarged Board. Any *obiter dicta* or observations are not binding.

Article 16 of the Rules of Procedure of the Boards of Appeal[49] provides that if a Board of Appeal considers it necessary to deviate from an interpretation or explanation of the EPC contained in an earlier opinion or decision of the Enlarged Board, the question is to be referred to the Enlarged Board. The aim being to ensure a consistency in adhering to points of principle decided by the Enlarged Board. The Enlarged Board has the discretion to take into account written statements filed by third parties.[50]

Technical Board of Appeal

In its appeal Harvard took the opposite stance to the Examining Division. Harvard proposed that the interpretation of the exclusion clause under Article 53 (b) EPC should be interpreted narrowly in accordance with the decisions T385/86[51] and T49/83.[52] Applying the strict principle of narrow construction to Article 53 (b) EPC, Harvard

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46 Article 21 EPC.
47 Article 22 EPC.
48 Article 111 (2) EPC. The binding effect of a decision extends back only to the section or Division to whom the decision is referred back.
49 10 December 1982, (1983) *OJ. EPO* p. 3; (1989) *OJ. EPO* p. 362; (1994) *OJ. EPO* p. 443.
50 Rules of Procedure of Enlarged Board of Appeal (1994) *OJ EPO* p. 443.
51 T385/86 *Bruker/Non-invasive measurement* (1988) *OJ. EPO p.* 386; (1989) *EPOR* p. 85.
52 T49/83 *Ciba-Geigy/* Propagating material.

proposed that the invention and the matter defined in any of the claims under consideration could not be seen to be expressly directed to or equatable with "animal varieties" (as opposed to "animals") and therefore such claims should be allowable under Article 53 (b) EPC. As there was no general exclusion of animals in the language of the EPC Harvard proposed that any interpretation of any such general exclusion would be contrary to the *Ciba-Geigy* decision T49/83. The claimed process being microbiological fell within the ambit of Article 53(b) second part EPC and was therefore patentable.[53]

During the appeal proceedings Harvard requested that two questions be referred to the Enlarged Board of Appeal for consideration,[54] namely

"In so far as the exclusion of Article 53(b) first part EPC refers to "animal", to what extent is animal protection possible under Article 53(b) EPC (if at all)?" and "What is the meaning of article 83 EPC in terms of the required extent of evidence of performability of embodiments of the invention covered by a claim by a person skilled in the art?[55]

The TBA reported its decision T19/90 on 3 October 1990[56] and gave a detailed account of the reasons on which it based its finding. The TBA held that

- The decision of the Examining Division was to be set aside;
- The case was to be remitted to the Examining Division for further examination;
- The request that certain questions be referred to the Enlarged Board of Appeal was rejected; and
- The application was to be referred back to the Examining Division for re-examination.

The essential arguments that assisted the TBA to reach its decision in respect of Article 53 (b) EPC are considered below under the various elements of Article 53 (b).[57]

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[53] Grounds of Appeal and Amendment dated 13 November 1989, J, (3) p. 30.

[54] Article 112 (1) provides that in order to ensure uniform application of the law, or if an important point of law arises: (a) the Board of Appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes. If the Board of Appeal rejects the request, it shall give the reasons in its final decision; (b) the President of the European Patent Office may refer a point of law to the Enlarged Board of Appeal where two Boards of Appeal have given decisions on the question. Article 112 (2) In the cases covered by paragraph 1(a) the parties to the appeal proceedings shall be parties to the proceedings before the Enlarged board of Appeal. Article 112 (3) The decision of the Enlarged Board of Appeal referred to in paragraph 1(a) shall be binding on the Board of Appeal in respect of the appeal in question.

[55] Grounds of Appeal and Amendments 13 November 1989, J (3), p. 30.

[56] T19/90 (1990) *OJ. EPO* 12, p. 476; (1990) *EPOR*, 7, p. 501; (1990) *World Intellectual Property Report* Vol 4, p.62; (1990) *Intellectual Property in Business* Vol 2, issue 6, p. 25. Board notified Harvard by issuing an Official Communication on 11 December 1990.

[57] For arguments in relation to Article 53 (a) see Chapter 5.

"Plant and Animal Varieties"

Harvard had argued that EPO Board of Appeal case law had consistently shown that patents should be granted for any invention meeting the general requirements of the EPC and that wherever the law was not clear the Boards had taken the line that exceptions to patentability should be construed narrowly. The contested decision departed from this principle by placing a wide construction on the exclusion under Article 53 (b) EPC which ran counter in particular to Decision T49/83 which held that no general exclusion of inventions in the sphere of animate nature could be inferred from the EPC.

The TBA took the view that the invention in the present case was clearly a "microbiological process". The dominant feature of both process and product was genetic manipulation, which the Technical Board considered was unquestionably of a microbiological and technical nature. In addition, that the Examining Division's view that one exclusion provision could not be countermanded by another was wrong in law. It could not be right for subject-matter expressly declared patentable under Article 53 (b) EPC - microbiological processes and their products - to be refused protection on the basis that the products in question were excluded elsewhere in that provision.

The TBA noted that the Examining Division had in their earlier deliberations pointed out that the three texts of Article 53 (b) EPC differed in terminology as to area of non-patentability. In particular, the German term "Tierarten" was broader than the English "animal varieties" and the French "races animales".[58]

The TBA felt that the present application provided an opportunity to develop this case law, as the meaning of Article 53 (b) EPC was uncertain.

Article 177 EPC lays down that the English, French and German texts of the EPC are all equally authentic. However there was an area of conflict with regard to Article 53 (b) and the TBA in considering the present case felt that there was a need to establish their common meaning through interpretation of the EPC in order to determine to what extent animals were excluded from patentability under Article 53 (b), first half-sentence, EPC.

The Examining Division had interpreted Article 53 (b) EPC as excluding not only certain groups of animals from patentability but in fact, animals as such. The TBA did not accept this interpretation and held that the Examining Division had not take into account that Article 53 (b) EPC was an exception, for certain kinds of inventions, to the

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[58] The first half-sentence of Article 53 (b) EPC reads as follows in English, French and German:
European patents shall not be granted in respect of:
(a) .....
(b) Plant or **animal varieties** or essentially biological processes for the production of plants or animals;
Les brevets européens ne sont pas délivrés pour:
(a) .....
(b) les variétés végétales ou les **races animales** ainsi que les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux;
Eurpäische Patente werden nicht erteilt für:
(a) .....

general rule under Article 52 (1) EPC. that European patents "shall be" granted for all inventions which were susceptible of industrial application, which were new and which involve an inventive step and that any such exception must be narrowly construed. The Technical Board held that the Examining Division had given no convincing reasons for deviating in this particular case from this principle of interpretation, nor were any such reasons apparent to the Technical Board.

The Technical Board was not convinced by the argument by the Examining Division stating "the possibility that the reference to certain categories of animals rather than to animals as such was simply a mistake by the legislators could be ruled out. Nothing in the legislative history of either the EPC or the Strasbourg Convention whose Article 2 (b) was taken over and incorporated into Article 53 (b) EPC, supported such an assumption".[59]

The Technical Board held that the Examination Division had erred in concluding that the different terms used in the three official languages of the EPC referring to the non-patentable subject-matter clearly showed that the legislators' intention had been to exclude animals generally and stated that had this been the case the legislators would have said so in unambiguous terms.

The TBA confirmed that it was now the task of the EPO to find a solution to the problem of the interpretation of Article 53(b) EPC with regard to the concept of 'animal varieties', providing a proper balance between the interest of inventors in the biotechnology field in obtaining reasonable protection for their efforts and society's interest in excluding certain categories of animals from patent protection. The Board noted that it should be borne in mind that, unlike for plant varieties, there is no other industrial property right available for the time being for animals.

The Technical Board stated "In contrast to the exclusion of 'plant varieties' from patentability under Article 53(b) EPC, the preparatory documents to this provision are completely silent as to the purpose of excluding 'animal varieties' from patentability. The purpose of a law is not merely a matter of the actual intention of the legislators at the time when the law was adopted, but also of their presumed intention in the light of changes in circumstances which have taken place since then".[60] Whilst not giving any indication of the meaning of 'animal variety' the Technical Board concluded that the Examining Division had been wrong in refusing the application on the ground that Article 53 (b) EPC excluded the patenting of animals as such.

<u>"Essentially Biological Processes"</u>

The invention contained process claims for the production of transgenic, non-human mammals.[61] The Examining Division's finding that the claims did not relate to "essentially biological process" within the meaning of Article 53 (b) EPC[62] was confirmed by the TBA.

(b) Pflanzensorten oder **tierarten** sowie für im wesentlichen biologische Verfahren zur Züchtung von Pflanzen oder Tieren.

59 Decision T19/90 Form 3002, 4.6, p. 16.

60 Decision T19/90 Form 3002, 4.7, p. 16.

61 Having an increased propensity to develop neoplasms through chromosomal incorporation of an activated oncogene sequence into the genome of the non-human mammal, the oncogene being inserted by technical means into a vector (e.g. a plasmid), which was then microinjected at an early embryonic stage.

62 Decision T19/90 Form 3002, 4. 9.1, p. 18.

Claim 19 of the application[63] covered both transgenic animals produced according to the process claims, making use of microinjection, and the descendants of such animals. Whilst the former were the result of a non-biological process, their descendants could be the outcome of a biological process based on sexual reproduction. The Examining Division had taken the view that by artificially combining a breeding and a non-biological process the applicant was seeking to circumvent the exclusion under Article 53 (b), first half-sentence, EPC, particularly since the two processes would have given rise to two different products. However, the TBA doubted whether the latter point was legally correct as the products of the two processes, at least from the point of view of patent law, could not be distinguished from each other in respect of the transferred gene. The Board suggested that this question could be left open since it viewed the basic assertion that Claim 19 circumvented Article 53(b) EPC was wrong in any case. Claim 19 was a product claim and in the absence of any other definition, the product claimed was defined in terms of the process by which it is produced. Claim 19 was thus a product-by-process claim. But a product-by-process claim remains a product claim irrespective of the process it refers to.[64] A successful Claim 19 would result in a product patent, not a process patent. Thus since Article 53(b) EPC excludes only processes for the production of animals, with which Claim 19 is not concerned, the Board took the view that this provision is no bar to patenting the product.

"Microbiological processes and the products thereof"

The Examining Division had not confirmed in its earlier decision whether the present invention involved a microbiological process, as it had taken the view that Article 53 (b), second half-sentence, EPC did not apply if the product (in this case the animal) was excluded under the first half-sentence on the grounds that the second part of the provision could not be interpreted in a manner which would set aside the first part.

This interpretation was not shared by the Technical Board which confirmed that Article 53 (b), first half-sentence, EPC was an exception to the general principle of patentability contained in Article 52 (1) EPC and the second half-sentence was an exception to this exception, thus ensuring that the patentability bar did not cover microbiological processes or the products thereof. Consequently, patents could be granted for animals produced by a microbiological process.

The Enlarged Board of Appeal

In response to Harvard's request to refer the two questions to the Enlarged Board of Appeal, the TBA stated that it considered that it would be premature to refer any of these questions to the Enlarged Board of Appeal before the

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63 See Appendix 4.3.

64 A claim to a product which is defined in terms of the process for its preparation is allowable having regard to article 84 EPC (the claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description) only if the product fulfils the requirements of patentability and there is no other information available in the application which could enable the applicant to define the product satisfactorily by reference to its composition, structure of some testable parameter.

department of first instance had reconsidered the basic problem of interpreting Article 53 (b) EPC[65] in the light of the Technical Board's decision. The request was rejected.

In view of the importance of this matter and the desirability of having it considered by at least two instances, the Board exercised its powers under Article 111(1) EPC[66] and remitted the case to the department of first instance for further prosecution. The case was referred back to the Examining Division for further prosecution.

The Examining Division (2)

In a communication of 11 December 1990[67] the Examining Division sought further observations from Harvard. Harvard filed a lengthy submission in response[68] confirming the earlier arguments. In considering Article 53 (b) EPC Harvard once again confirmed its opinion that there should be a narrow interpretation of the exclusion clause. Harvard reviewed the use of the term animal variety and confirmed its opinion that German term "Tierarten" meant the same as "species" in English whilst the French term "races animales" seemed to relate to animals constituting a sub-group of a species and proposed that "in such circumstances, consistent with the observations of the Technical Board of Appeal in Decision T19/90, it would be perfectly proper for the Examining Division to decide that absence of clarity in the exception to patentability is alone sufficient to enable the Harvard claims to go forward to grant". [69] Harvard suggested that "the Examining Division have it within their power, consistent with Decision T19/90, to decide this case in favour of the Applicants without providing a definition of "animal varieties" and equivalent terms in German and French as used in EPC".[70]

Following further consideration by the Examining Division the patent was granted,[71] mention of the grant of the patent appearing in the EP Bulletin of 13 May 1992.[72] The Rule 51 (4) EPC Communication[73] issued by the EPO indicating the Examining Division's intention to grant a patent was unusually accompanied by additional written comments[74] on the main issues considered and which sheds some light on how the Examining Division interpreted Article 53 (b) EPC. The Examining Division stated that "the term animal variety is not entirely clear, in particular in view of the differing wording in the three equally binding languages of the EPC". Nevertheless, it could "be stated with certainty that rodents or even mammals constitute a taxonomic classification unit much higher than species ("Tierart"). An 'animal variety' or 'races animales' is a sub-unit of a species and therefore of even lower

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65 and Article 53 (a) EPC.

66 Following the examination as to the allowability of the appeal, The Board of Appeal shall decide on the appeal. The Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution.

67 Issued pursuant to Article 96(2) EPC and Rule 51 (2) EPC.

68 Response dated 16 April 1991.

69 Response dated 16 April 1991 p. 3.

70 Response dated 16 April 1991 p. 10.

71 (1992) *OJ. EPO* 13April p. 588.

72 92/20 of 13 May 1992.

73 Applicant informed by Examining Division on 4 October 1991 of intention to grant.

74 Annex to Form 2035.3/2004 - Comments, 4 October 1991.

ranking than a species. Accordingly, the subject matter of the claims to animals *per se* is considered not to be covered by the above three terms of Article 53 (b) EPC".[75]

The difficulties experienced by the EPO in the Harvard Oncomouse case in establishing the meaning of animal variety were discussed by the writer with Dr. Christian Gugerell.[76] When asked why the wording of Article 53 (b) EPC in relation to animals was confusing, Dr, Gugerell replied "Forget the German translation which is wrong, this will be changed now in the next Diplomatic Conference because Tierarten corresponds to animal species, but this of course is nonsense. So the French and the English version, one could argue that it is not exactly the same, but it is at least almost the same, and in the German version with plants it is OK but the animals is entirely wrong the translation. Tierarten is just simply wrong, but it is quite clear that the whole thing was taken over from the Strasbourg Patent Convention, which existed in English and French and it was quite clear what was meant."

Opposition Division

Opposition proceedings followed the granting of the Oncomouse patent[77] during which the objections on the grounds of unpatentability under Article 53 (b) EPC were overtaken by more vociferous objections being raised on the grounds of article 53 (a), the morality exception. Arguments were presented by a number of the opponents of the grounds of Article 53 (b). The Opposition Division appeared not to be persuaded, although in the Oral Proceedings held in November 1995 "the Opposition Division declared that no conclusion on Article 53 (b) had been reached".[78] A final decision is still awaited.[79]

Early Plant Cases before the EPO

As already discussed one of the earliest plant cases[80] to come before the Technical Board of Appeal (TBA) of the EPO was *Ciba-Geigy*/Propagating material T49/83.[81] The invention which was the subject of the application related to the chemical treatment of propagating material (seeds) for plants in order to make the plants resistant to agricultural chemicals such as herbicides.

In this decision the Technical Board upheld as patentable claims which embraced plants propagated from seeds chemically treated with an oxime derivative to confer herbicide resistance and held that Article 53 (b) EPC was intended to deny patent protection to plant "varieties" within the meaning of the UPOV Convention.[82] The

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75 Annex to Form 2035.3/20004 - Comments, 2), p. 2, 4 October 1991.

76 See footnote number 1 Chapter 1.

77 Proceedings before the Opposition Division in the Oncomouse case are discussed in detail in Chapter 5.

78 Minutes of oral Proceedings p.9.

79 See Chapters 5 and 6.

80 For commentary see Hans-Rainer Jaenichen. *The European Patent Office's Case Law on Patentability of Biotechnological Inventions*, (Heymanns, 1993).

81 T49/83 (1984) *OJ. EPO* p. 112; (1979-1985) *EPOR* vol C, p. 758; (1984) *GRUR Int.*, p. 301.

82 The Board found in subsequent opposition proceedings that the claims merely referred to propagating material having a particular chemical treatment and not a new plant variety. Article 53 (b) EPC did not apply as there was no claim to a plant variety *per se*.

TBA also expressly stated that no general exclusion of inventions in the sphere of animate nature could be inferred from EPC.

A few years later in the decision of the Technical Board of Appeal, T320/87 Lubrizol/hybrid plants,[83] the Board held that a gene technological (cloning) process for the manufacture of seedcorn/plants was not excluded from patenting under Article 53 (b) EPC. In support of its position the Board argued that the end product, namely, the seedcorn/plant, was not a plant variety because the seedcorn/plant was not stable in reproducing consecutive generations. The Board also maintained that the process was not essentially biological.

It was from this background in 1985 that the EPO was forced to look at the later GM plant cases and attempt to clarify what an 'animal variety under the EPC actually was.

The Plant Genetic Systems Case

Whilst the Harvard Oncomouse case became embroiled in Opposition proceedings another case involving transgenic plants came before the Technical Board of Appeal for consideration, the Plant Genetic Systems/Glutamine Synthetase Inhibitors (*PGS*) case[84] in which a number of points of principle relating to the patenting of both plants and animals were considered. In this case the Technical Board made some contentious findings in respect of the interpretation of both Article 53 (a)[85] and 53 (b) EPC.

Because of the controversial nature of this case questions were referred to the Enlarged Board of Appeal for consideration. During the Opposition proceedings in the Oncomouse case the Opposition Division invited[86] observations from the parties on the opinion of the Enlarged Board of Appeal in the *PGS* Decision G003/95 in respect of an appeal from the Technical Board Decision T356/93 as the Opposition Division felt that "this opinion may have a bearing on the present decision and the opinion of all parties to these proceedings, particularly the opinion of the Patentee (*Harvard*) is requested of G3/95".[87]

In the *PGS* case the invention at issue concerned a method for rendering plant cells resistant to a specific herbicide, by inserting into the cell genome a gene coding for an enzyme, which protects the cells when in contacted with the herbicide. The patent was granted with claims including: a) a process of controlling the action of the herbicide in plant cells and plants by genetically modifying the genome of the plant cells; b) a process for producing a plant or reproduction material of said plant resistant to the herbicide, comprising genetically transforming cells or tissue of said plants, regenerating plants or reproduction material from the plant cells or tissue; and c) biologically replicating plants or reproduction material, genetically transformed plant cells and transformed plants and seeds.

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[83] (1990) *OJ EPO*, p. 71; (1990) *EPOR* p. 173; (1990) *GRUR Int*, p. 629.

[84] *Plant Genetic Systems/Glutamine Synthetase Inhibitors*. Opposition by Greenpeace, (1995) *EPOR* p.357; (1995) *OJ. EPO* 8, p.545 ; (1997) *IIC* Vol 28, No 1 p.75. Decision of Technical Board of Appeal dated 21 February 1995.

[85] Findings raised in respect of Article 53 (a) are considered in Chapter 5.

[86] On 15 April 1996.

[87] Annex to Form 2323 dated 15 April 1996.

The patent was subsequently opposed by Greenpeace[88] on the grounds that the use of the claimed invention was contrary to Article 53 (a) EPC and that the process for making the transgenic plants but not the plants and seeds themselves was patentable under EPC Article 53 (b). In the first instance the opposition was rejected by the Opposition Division. Greenpeace appealed this decision. The Technical Board found that the claims directed to transgenic plants and seeds *per se* were not patentable under Article 53 (b) EPC. As a result the patent was upheld in amended form (conferring protection which was apparently commercially useful) without claims to the transgenic plants *per se*. However, the Board found that the claimed process for producing herbicide resistant plants by genetic engineering methods was patentable as it was not an "essentially biological process" under Article 53 (b) EPC even though the claimed process included the final steps of biologically regenerating plants from the transformed cells or tissue and replicating such plants or seeds derived therefrom.

More controversially the Technical Board went on to determine the meaning of "Microbiological" in Article 53 (b) EPC and determined that 'microbiological' was to be interpreted according to objective technological criteria and qualifying technical activities in which direct use is made of micro-organisms. Micro-organisms included all unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory.

The extract from the headnote to the *PGS* decision summarises the Technical Board's main findings:

- The concept of "plant varieties " under Article 53 (b) EPC refers to any plant grouping within a single botanical taxon of the lowest rank [89]which is characterised by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics.

- The term "micro-organism" includes plasmids, viruses and all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory.

- The concept "microbiological processes" under Article 53 (b) refers to processes in which micro-organisms (or their parts) are used to make or to modify products or in which new micro-organisms are developed for specific uses. Consequently the concept of "products thereof" under Article 53 (b) EPC encompasses products which are made or modified by micro-organisms as well as new micro-organisms as such.

- "Technical Processes including a microbiological step" may not simply be equated with "microbiological processes". Nor can the resulting final products of such technological processes (e.g. plant varieties) be defined as "products of microbiological processes" within the meaning of Article 53 (b) EPC.

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[88] For review see M. Llewelyn, Article 53 Revisited, Greenpeace v Plant Genetic Systems NV, (1995) 10 *EIPR* p. 506.

[89] Irrespective of whether it would be eligible for protection under the UPOV Convention.

- A claim is not allowable if the grant of a patent in respect of the invention defined in said claim is conducive to an evasion of a provision of the EPC establishing an exception to patentability. Hence, a claim which encompasses plant varieties is only allowable, if the exception to patentability under Article 53 (b) EPC concerning plant varieties, does not apply, because the subject-matter of the claim is to be regarded as the product of a microbiological process.

Neither the biotechnology industry, nor it would seem, the Technical Board of Appeal were happy with this decision which marked a surprising departure from previous practice which up until this time was believed to be relatively well established. The Decision was self-contradictory, as it denied patent protection for transgenic plants under one part of the EPC, but did so in a way that extended patent protection for the same plants under another section of the EPC. As a result of the view held by the EPO in determining patentability and with the support of the industry, the President of the EPO on 28 July 1995 referred a question to the Enlarged Board of Appeal[90] for determination

"Does a claim which relates to plants or animals but wherein specific plant or animal varieties are not individually claimed contravene the prohibition on patenting in Article 53 (b) EPC if it embraces plant and animal varieties?" [91]

In reasons accompanying the referral, the President explained that he considered that different Boards of Appeal had given different decisions on the referred question, in particular the *PGS* Decision T356/93[92]was in conflict with Decision T49/83 *Ciba-Geigy*[93] and the Harvard Oncomouse Decision, T19/90. [94]

The *Ciba-Geigy* decision T49/93 as referred to earlier in this chapter concerned an appeal from a decision of the Examining Division which had rejected an application under the first half-sentence of Article 53(b) EPC. The patent application in this case contained two product claims. The description included examples of such chemical treatment carried out on certain known plant varieties, which made it clear that the two claims related to the propagating material of any cultivated plants which had been chemically treated in accordance with the invention, that is, including known cultivated plant varieties which had been so chemically treated. The Examining Division consequently held that the subject-matter of these two claims was excluded from patentability under Article 53 (b) EPC, which was regarded as applicable both to new and to known plant varieties. However, the Technical Board of Appeal allowed the appeal, on the basis that Article 53(b) EPC was intended only to exclude new individual plant varieties from patentability. The Board of Appeal held that even though the two claims included within their scope the propagating material for all kinds of cultivated plants and plant varieties which had received the defined chemical treatment, nevertheless, the subject-matter of the claims was not an individual variety, and there was therefore no contravention of Article 53 (b) EPC.

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90 Pursuant to Article 112 (1) (b) EPC "the President of the European Patent Office may refer a point of law to the Enlarged Board of Appeal where two Boards of Appeal have given different decisions on that question".

91 Writer's emphasis.

92 Decision issued on 21 February 1995 by Technical Board of Appeal 3.3.4.

93 (1983) *OJ. EPO* p.112 decision issued on 26 July 1983 by Technical Board of Appeal 3.3.2.

94 which had been issued by the Technical Board of Appeal 3.3.2 on 3 October 1990. See Chapter 5.

The *Ciba-Geigy* Decision confirmed that 'plant varieties' in Article 53 (b) included cultivated varieties, clones, lines, strains and hybrids which can grow in such a way that they are clearly distinguishable from other varieties, sufficiently homologous and stable in their essential characteristics.

In its decision the EBA determined that there were essentially two lines of argument in relation to the relevant wording of Article 53 (b) EPC. The claim under review in the *PGS* case was claim 21. This claim referred to "a plant, nonbiologically transformed, which possesses, stably integrated into the genome of its cells, a foreign DNA nucleotide sequence encoding a protein having a non variety-specific enzymatic activity capable of neutralising or inactivating a glutamine synthtase inhibitor under the control of a promoter recognised by the polymerases of said cells". The first line of argument of the Enlarged Board was that the claim 21 was not allowable under Article 53 (b) EPC because the claim included within its scope established plant varieties which had been modified by the inclusion of the herbicide resistant transgene and could be infringed by a plant variety. The second line of argument put forward by the Enlarged Board was that the subject matter was unpatentable because claim 21 was directed to a plant harbouring a stable transgene in its genome that was enough to make the claim define a 'plant variety' within the meaning of the revised UPOV Convention.

The EBA held that there was no conflict between the *PGS* decision T356/93 and the Harvard Oncomouse T19/90 and that there was nothing in the Harvard Oncomouse Decision which actually dealt with the meaning of "animal variety" in relation to Article 53 (b) EPC other than to say that animals as such are not prohibited from patentability by the EPC. The referral was held by the EBA to be inadmissible.

However, there may be a flaw in the argument which is directed at the proposition that claim 21 actually defines a plant variety. But the Technical Board in its earlier Decision T356/93 stated at point 23: "thus, in the Board's judgement, the concept of "plant varieties" under Article 53 (b) EPC, first half sentence, refers to any plant grouping within a single botanical taxon of the lowest known rank...". Using this definition the claimed genetically modified plant was itself a new "plant variety" and therefore not patentable under Article 53 (b) EPC.

This was consistent with the definition of plant varieties under the UPOV Convention. However, the claim was set at the taxonomic level of kingdom (plantae). Thus it would seem that claim 21 was not actually directed to a specific plant variety *per se*, as it is directed to a taxon far higher than the lowest known rank. The Technical Board recognised this stating at point 40.3 of its Decision "As regards claim 21, it is noted that this claim is not drafted in terms of a variety description because there is no reference to a single botanical taxon of the lowest known rank...". The Technical Board realised that claim 21 did not define a variety. Thus the conclusion that the Technical Board found claim 21 bad because it embraced a plant variety was the opposite of the conclusion in the *Ciba-Geigy* case T49/83. Thus in reality there was a conflict between the Technical Board's decision in T356/93 and that in T49/83 which the Enlarged Board should have resolved in reaching its decision. The EBA may have considered that claim 21 defined a set of varieties as there are no embodiments of claim 21 which are

not plant varieties. Even if such an approach could have some narrow validity, it was unhelpful of the Enlarged Board not to deal with an issue that users of the patent system would like to see clarified.

Thus in the *PGS* case although transgenic plants *per se* were not patentable, the Technical Board did allow patent claims to plant cells and seeds. These were permitted under the second portion of Article 53 (b) as the products of a microbiological process. The Board explained that plant cells and seeds were 'micro-organisms' because they were single cells capable of reproduction, just as bacteria, yeast, fungi, algae and protozoa.

The *Novartis II* Decision

The second case of note to come before the Technical Board for consideration of Article 53 (b) EPC following the Decision of the Technical Board in the Oncomouse case was also a transgenic plant case, *Novartis* AG/Plant varieties (T1054/96).[95]

The Technical Board in this case released its written reasons for its refusal on 6 July 1998 and it is interesting to note that this decision took into account the coming into force of the UPOV Convention 1991 provisions and the passing into force of the Biotech Directive.[96] This is an acknowledgement by the EPO of the importance not only of both these pieces of legislation, but the need to ensure that the Enlarged Board decision was not at variance with any of the provisions contained in them.

In this case the TBA referred the following questions to the Enlarged Board;

1. To what extent should the instances of the EPO examine an application in respect of whether the claims are allowable in view of the provision of Article 53 (b) that patents shall not be granted in respect of plant varieties or essentially biological processes for the production of plants, which provision does not apply to microbiological processes or products thereof, and how should a claim be interpreted for this purpose?

2. Does a claim which relates to plants but wherein specific plant varieties are not individually claimed *ipso facto* avoid the prohibition on patenting in Article 53(b) even though it embraces plant varieties?

3. Should the provision of Article 64(2) EPC[97] be taken into account when considering what claims are allowable?

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95 *Novartis AG/Plant varieties* T1054/96 (1998) *OJ. EPO* p. 511; R. Nott, The Novartis Case in the EPO, (1999) *EIPR*, p. 33; (1998) *EIPR*, 11, pN-193.

96 The Technical Board of Appeal in this case refused the Appeal on similar grounds to that proposed in the *PGS* case. The Board considered that: 1. It was the duty of judges to apply the law and not create it; 2. It was illogical to determine from the wording of Article 53 (b) EPC that a patent may not be granted for a single variety but may be granted if its claims cover more than one variety.

97 Article 64 (2) "If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process".

4. Does a plant variety, in which each individual plant of that variety contains at least one specific gene introduced into an ancestral plant by recombinant gene technology, fall outside the provision of Article 53 (b) EPC that patents shall not be granted with respect of plant varieties or essentially biological processes for the production of plants, which provision does not apply to microbiological processes or the products thereof?

Unlike in the *PGS* case the Enlarged Board of Appeal could not avoid answering these questions this time. Because the reference to the Enlarged Board was from a Technical Board and not a referral by the President in respect of inconsistent Appeal Board decisions, the Enlarged Board could not deem the reference inadmissible for the reason it did so in the *PGS* decision.

The EBA issued its opinion G0001/98 on 20 December 1999. Questions 2-4 were answered directly by the EBA, which commented that it considered that the answers to these questions " will demonstrate that a separate answer to question 1 is not required".

In answer to question 2, 3 and 4 the EBA confirmed that a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53 (b), EPC even though it may embrace plant varieties.[98] When a claim to a process for the production of a plant variety is examined, Article 64 (2) EPC is not to be taken into consideration. The exception to patentability in Article 53 (b), 1st half-sentence, EPC applies to plant varieties irrespective of the way in which they were produced. Therefore, plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability.

<u>So are animals patentable Inventions?</u>

Despite the wording of Article 53 (b) animals '*per se*' do appear to be patentable under the EPC. Animals are biotechnological inventions and biological material and can be produced either by an essentially biological process or by a microbiological process. Animals are patentable if their technical feasibility is not confined to a particular variety. An animal variety obtained from a microbiological or technical process, or the microbiological or technical process itself producing the animal variety is not patentable. An animal obtained from a microbiological or technical process, or the microbiological or technical process itself is patentable.

The purpose of the wording of Article 53 (b) EPC followed that of Article 2 of the Strasbourg Convention taking into account the existence of plant breeders rights and the requirement to prevent double protection.[99]

It is believed that it was the intention of the drafters of the Strasbourg Convention to prevent animal patenting *per se*[100] and the use of the term 'animal variety' has been more than a little unfortunate. The term animal variety in

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[98] The EBA commented " clearly, it is not the wording but the substance of a claim which is decisive in assessing the subject-matter to which the claim is directed. However, it does not follow that the subject matter of a claim may be equated with the scope of a claim. In assessing the subject matter of a claim, the underlying invention has to be identified. In this respect, it is relevant how generic or specific the claimed invention is" 3.3 at p. 16.

the Strasbourg Convention seems to have been used by the legislators for good measure without giving proper thought to its taxonomic significance in relation to animals. At this time animals were generally agreed to be unpatentable in Europe. The taxonomic term 'variety' is well known in relation to plants and is an accepted term in the horticultural industry. The writer is not convinced by the comment of the Technical Board of Appeal in the Harvard Oncomouse case that it was not the intention of the legislators to exclude the patenting of animals *per se.*[101]

The situation with regard to the taxonomic terminology in relation to plants is different to the situation with animals. The difference has been highlighted with the recognition of plant breeders' rights, the latter being evidenced by the UPOV Convention 1961. Because of this historical difference plant varieties are a recognised group and can be clearly defined. Unlike the case for animals equivalent terms are also used in the three languages of the EPC to describe plant varieties.

The International Code of Zoological Nomenclature adopted by the XV International Congress of Zoology in London in July 1958 does not recognise the term 'variety' as a taxonomic group. However, the term is used informally and viewed as a sub-subspecific category. In it's generic use the term 'animal variety' means 'type, kind or breed'. However, the terms tierart and race animale do have scientific as well as generic meanings the former being respectively equivalent to 'species' and 'subspecies'.[102]

However, it did not seem to make any difference to the EPO that there was no equivalent to plant variety rights for animals but nevertheless the principles determining patentability of plants were applied in the same way to animals. In view of the existence of UPOV and the amount of information associated with plant breeders' rights in respect to plants, the EPO had considerably more information to draw on in relation to plants than for animals.

A fundamental flaw did exist in the EPC whereby the definition of the terms 'animal variety', ' race animales' and 'tierarten' were not equivalent taxonomic or generic equivalent terms, being in contravention of Article 117 EPC which provides that English and French and 'German versions of the text are equally valid. The term 'species' is understood to mean a reproductive community being a genetic unit consisting of a large intercommunicating gene pool.[103] A species can comprise breeds or varieties but not vice versa. If the legislators had intended to exclude species reference could have been made to 'especes' in French and 'species' in English but they did not choose to do so. The generic meaning of tierarten, races animales and animal varieties all mean the same thing, animals in general. This situation has now been corrected to some degree. The Diplomatic Conference[104] held at the end of

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[99] Report on the Preliminary Draft Convention Report by the British Delegation, 25, p. 25.

[100] See Chapter 1.

[101] D. Beyleveld and R. Brownsword, *Mice, Morality and Patents*, (Common Law Institute of Intellectual Property, London 1993) p. 18.

[102] V. Vossius, Patent Protection for Animals (1990) *EIPR*, 7, p.250; D. Beyleveld and R. Brownsword, *Mice, Morality and Patents*, (Common Law Institute of Intellectual Property Law, London 1993).

[103] Paper submitted to EPO by V. Vossius by letter dated 16 March 1990, Patent Protection for animals Including reference E. Mayr *Populations, Species and Evolution*, (The Belknap Press of Harvard University Press Cambridge, Massachusetts, 1970).

[104] EPC revision conference held in Munich from 20-29 November 2000 convened by Administrative Council

November which considered the Basic proposal for the Revision of the European Patent Convention has sought to clarify the difference in terminology between the three different languages of the EPC by bringing the German wording of Article 53 (b) EPC into line with the Biotech Directive and Rule 23c (b) EPC.

Plant breeders' rights have been highly successful in their own sphere of application. However, animal breeds produced by traditional methods have no equivalent legal (or '*sui generis*') system for their protection. Whilst the Boards of the EPO have referred in passing to animal variety rights, it may now be an appropriate time for the European commission to look at this further.[105]

The drafters of the Biotech Directive should have learnt something from this. However, they appear not to have done, the wording of the exclusion from patentability in respect of plants and animals following the earlier wording of the EPC, although assisted by the inclusion of definitions. Despite this we are still kept guessing as to the meaning of 'microbiological material' and will still have to rely on past EPO decisions. The drafters of the TRIPs Agreement seem to have learnt a valuable lesson from the difficulties experienced in the interpretation of the two European conventions, the wording of Article 27 being more transparent in excluding "plants and animals" other than micro-organisms.

The EPO was severely criticised for its handling of both the Harvard Oncomouse case and the *PGS* case. The *PGS* case represented the first time that the EPO had restricted protection for a specified plant. Because the finding of the Enlarged Board was so precise in its interpretation of Article 53 (b) EPC, it was difficult to imagine how this decision could be distinguished to allow patenting of other transgenic plants or animals. The Enlarged Board in this case was further criticised because it did not try to find a solution to the problem. By issuing its opinion without hearing experts in plant and animal genetics, the Enlarged Board raised concerns that it exceeded its powers or at least did not act within the spirit of the Convention. The case revived discussion about the position and function of the Enlarged Board of Appeal. Some have even called for a revision of the EPC in order to create an independent tribunal that can review decisions from the Appeal Boards. However, any negative effects of the decision T356/93 Plant Genetics Systems do not result from the Appeal Board's giving incorrect interpretation of the law.

The *PGS* case is regarded as a decision which had best be forgotten. In discussing the *PGS* Decision with Dr. Christian Gugerell[106]he commented: "In the *PGS* case we failed as you may know, in G1/83 or whatever number. This was not really the best decision I would say, which was handed down, because it said it was not admissible, because there was no contradiction, but there was a clear contradiction in our eyes. It was very strange, so we had better forget about that decision. I don't want to talk about that decision, as this is the Enlarged Board decision, but it was not a good decision. So what we had to do in the end was to refuse another case, that was the *Novartis* case then. Well I must say this was luckily enough this was referred by the Technical Board, probably because the Technical Board also realised that the criticism which was raised

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of EPO.

105 See Chapter 8.

106 Taped interview with writer on 24 January 2000.

everywhere, so they felt more or less obliged to. But as you know this referral decision was again very negative and confirmed *PGS*".

Whilst the *PGS* case has now been dismissed by the EPO Dr. Gugerell's comments are telling.[107] The *Novartis II* decision, which is believed to be better law, has confirmed the ludicrous situation whereby if a plant variety is named it will not be patentable whilst if the plant or plants are named at a higher taxonomic level it or they will be patentable. One thing that the *Novartis* case did appear to emphasise was that the correct form of protection for plant varieties is by plant breeders' rights.

Despite the alleged clarification provided by the amendments to the Rules of the EPC there is a lack of logic in the reasoning of drafters of a legal provision which permits animals to be patented but not specific varieties (or do we mean species?). Thus in the Oncomouse case it is 'acceptable' for the claims to relate to rodents but not to mice. The principle of narrow construction of exclusion clauses is widely accepted, however, in the case where taxonomic standards underpin the determination of the exclusion clauses it does lead to a confusing result. It has been likened in the arguments put forward in the *PGS* case to a law allowing polygamy but outlawing monogamy.

It may be argued that one solution to the problem associated with the patenting of animals would be to cancel Article 53 (b)'s exclusion of plant and animal varieties from patentability. Since there are no special protection laws for animal varieties, there is even less justification for Article 53 (b)'s excluding animal varieties from patent protection than is the case for plants. While this would be welcomed by the large biotechnology corporations it is believed it would strongly opposed by various religious, environmental and animal welfare groups.

There is a basic assumption that the findings in respect of the Article 53 (b) of the EPO in relation to plants transpose directly to animals. Whilst the patent provisions of the EPC should apply to all inventions equally from whatever sphere they may originate the patentability of animals does need to be regarded as a special case. It is not by accident that the Biotech Directive does not give a definition of an animal variety when it includes a detailed definition of plant variety. Representations that the patenting of animals should be regarded as a special case will be considered further in Chapter 8 after a detailed review of the Oncomouse case before EPO which now follows.

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[107] See Chapter 7.

Chapter 4
The Harvard Oncomouse
The First Animal to be granted a patent

"I .... believe the ability to define a transgenic animal invention at the molecular level is almost trivially easy. The molecular definition of an inserted gene in a particular animal can be defined chemically in such a way that would be absolutely unambiguous. The properties of the animal and all others like it that would be produced, in general would conform to the properties that had been defined in any patent claim".

Professor Philip Leder in 1989
Co-inventor of the Harvard Oncomouse[1]

"Ethics are essential for scientists who have to place their work in perspective".

Professor Robert Edwards
Emeritus Professor of Human Reproduction at Cambridge University 2001[2]

Following the *Chakrabarty*[3] decision in the US it was inevitable that a patent application would be filed for an animal. This indeed happened and on the 12 April 1988 the USPTO granted the first patent on a living animal to the President and Fellows of Harvard College.[4] The patent was granted in respect of work undertaken by the inventors, Professor Philip Leder and Timothy A Stewart, which had led to the creation of a mouse containing a variety of foreign genes from other species, including chickens and humans. These foreign genes were engineered into the mouse's germ line in order to predispose it to developing cancer and thus enabling it to be a more sensitive research animal. The rate at which the animal develops cancer can be used as a means of testing whether a certain compound is carcinogenic or if certain materials can halt the onset or rate of development of cancer. Because of this predisposition it is claimed that the amount of substance needed to be used in such tests could be reduced to levels more approximate to naturally occurring levels. The media nicknamed the patented animal the "Harvard Oncomouse".

Recombinant DNA technology or genetic engineering is a means of introducing foreign gene sequences into an organism's, be it a micro-organism, plant or animal, genetic code. As a result of genetic engineering techniques the genetic properties of multicellular plants and animals could be altered by expressing foreign genes within them. It was soon realised that there was great scope for altering the genetic properties of both plants and animals in order for them to exhibit certain predetermined characteristics. Animals (and also plants and microorganisms) that have acquired a new gene in this way are called 'transgenic' and the introduced gene a 'Transgene', the term first being used by Gordon and Ruddle in 1981.[5]

Transgenic models have been used to study neurodegerative diseases, in cancer research[6] and as a tool in the

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1 Statement of Philip Leder M.D. John Emory Andrus Professor and Chairman, Department of Genetics, Harvard Medical School on 14 September (Day 2), before the Subcommittee on Courts, Intellectual Property and the Administration of Justice of the House Committee on the Judiciary, 101st Congress 1st Sess.1989 – Transgenic Animal Patent Reform Act 1989 (Washington DC; U.S. Government Printing Office 1990) (H.R.1556 TAPRA).

2 Article Steve Farrar (21 September 2001) *The Times Higher* p.5.

3 *Charkrabarty v Diamond* 571 F 2d p. 40 (CCPA) 1978; 477 U.S. p. 303 1980. Discussed in Chapter 2.

4 Patent number 4,736,86,6 in respect of an application filed at USPTO on 22 June 1984.

5 J.W. Gordon and F.H. Ruddle, Integration and stable germ line transmission of genes injected into mouse pronuclei (1981) *Science* 214, p. 1244.

6 D. Murphy and D.A. Carter (Eds), Chapter 3, *Transgenic Animals and the Study of Cancer* in *Transgenesis*

study of genetic diseases[7] but the technology has since been applied to a variety of mammals including sheep, cows and pigs. The commercial potential of transgenesis techniques was immediately recognised in the fields of animal and plant agriculture[8] where such things in animals as body growth, leanness of meat, milk yield and wool growth are commercially significant.

Application for a transgenic mouse was first filed in the US. Other applications then followed within the year claiming priority from this US application.[9] Whilst the application had a relatively easy passage through the procedures of the USPTO, the applications before the EPO and the Canadian Intellectual Property Office (CIPO) experienced greater difficulties and appeal decisions are pending in respect of both.

This chapter reviews the prosecution of the US, Canadian and European applications for the same invention', namely the Harvard Oncomouse. The prosecution of the application before the EPO is examined in detail particularly with regard to discussions relating to the morality exception. As will be seen the applications were treated quite differently in these jurisdictions.

The writer has used as her primary source of reference EPO files and materials and has been greatly assisted by the EPO being given access to information, documents and background papers. In the chapters which follow for ease of discussion the writer has referred to 'the President and Fellows of Harvard College' simply as 'Harvard', whatever role it is taking i.e. the proprietor, patentee or appellant.

<u>The 'Invention'</u>

Leder and Stewart designed a DNA hybrid consisting of a gene called c-myc (myelocytomatosis), implicated in cancer, that is attached to another gene expressed in breast tissue. It had been known for a number of years that most malignant tumours in both man and mice arise through mutations in genes that, in their normal forms, play essential roles in controlling cell division and growth. Tumour initiation appears to depend on the accumulation of several such mutations in different genes, but if a mouse is created in which one of the mutant genes (oncogenes) is present from birth the chance of the conditions for tumour formation arising during the lifetime of the mouse is greatly increased.[10] The Oncomouse harbours two different oncogenes in different strains. Each strain develops cancers at a certain age in a predictable way, when the two oncogenes are combined in one strain by cross-breeding, the onset of cancer is strongly accelerated. Thus in the Oncomouse model system, as the investigator generates a transgenic mouse that already carries a mutation in one oncogene, the animal begins life part way down the path to cancer.[11]

The main advantage cited by Harvard that their invention had over other mice was the mouse's increased susceptibility to developing tumours and so favouring its use as a tool for studying cancer and therapeutic

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Techniques, Principals and Protocols (Humana Press 1993).

7 R.D. Palmiter and R.L. Brinster, Germline transformation of mice (1986) *Annual Review of Genetics* 20 p. 465.

8 V.G. Pursel, C.A. Pinkert, K.F. Miller, D..J. Bolt, R.G. Campbell, R.G. Palmiter, R.D. Brinster and R. E. Hammer, Genetic Engineering of Livestock (1989) *Science* 244, p. 1288.

9 In Europe at the EPO and in Canada and Japan.

10 See L.M. Silver *Mouse Genetics Concepts and Applications* (Oxford University Press 1995) p. 114.

11 Statement of John B. Fagan Professor of Molecular Biology Maharishi International University, Fairfield, IA, USA filed with Opposition Division prior to Oral Hearing of Oncomouse patent.

effectiveness of possible cancer treatments. The animals could be used to test material suspected of being carcinogenic by exposing the animals to the potentially carcinogenic material and determining neoplastic growth as an indicator of carcinogenicity. Because the response was more predictable, it was suggested that fewer experimental animals would be required than with the usual breeds of laboratory mice available. In addition it was proposed that the animals could also be used as a source of cells for cell culture.

The Summary of the Invention in the application filed at the USPTO on 22 June 1984 described the invention as follows:

"In general, the invention features a Transgenic Non-human Eukaryotic animal (preferably a rodent, such as a mouse) whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal, or an ancestor of the animal, at an embryonic stage (preferably the 1-cell or fertilized oocyte stage, and generally not later than about the 8-cell stage). An activated oncogene sequence, as the term is used herein, means an oncogene which, when incorporated into the gene of the animal, increases the probability of the development of neoplasms (particularly malignant tumours) in the animal".[12]

Governing Statutes[13]

The origins of patent law of the USA and Canada are grounded in English common law. The provisions under the relevant acts in the USA and Canada are virtually identical, neither having a morality exception.

United States

In the USA the Patent Act of 1952 (Title *35*, Patents, of the United States Code) as amended is the governing statute in which section 101 provides:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

There is no statutory equivalent in the USA of Article 53 (a) EPC. Unlike the position under the EPC there is no opposition process before the USPTO. Re-examination is only possible on the basis of the review of prior art patents and publications. No express standing is granted to the public or other third parties. However, parties may apply to intervene in any court proceedings, as for example did Jeremy Rifkin the American activist and founder of the Foundation of Economic trends in the US in the *Chakrabarty* case.[14]

The *Chakrabarty* case did not specifically address the question of whether animals were patentable, however,

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12 US Patent 4,736,866 p. 1, lines 30 -42.

13 For general overview see A.J. Jacobs (Ed) *Patents throughout the World* Clark, Boardman Callaghan (Loose-leaf) Fourth Edition (as updated).

14 For a historical discussion of US patenting and discussions on US patentable subject matter see KD Sibley *The Law and Strategy of Biotechnology Patents* (Butterworth-Heinemann 1994); M.J. Lane Patenting Life: Responses of patent offices in the U.S. and Abroad (1991) *Jurimetrics Journal* 32 p. 89; See *Re Bergy* 596 F. 2d 952, 201 USPQ 352 (CCPA 1979) Judge Rich; and W.T. Goglia, Supreme Court's views as to what is patentable subject matter under Federal Law as "Process", "Machine", "Manufacture" or "Composition of Matter" (1981) 65 L Ed 2d p. 1197.

following two cases *Ex parte Hibberd*[15] (which confirmed that plants and seeds and plant tissue were patentable) and *Ex parte Allen*[16] (which confirmed that multicellular animals were patentable) the USPTO in 1987 issued a statement confirming that it now considered non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.[17]

It is interesting to note that during the years following the *Chakrabarty* decision in the US an attempt was made to pass in Congress a Bill preventing animal patenting but failed.[18]

Canada

In Canada the Patent Act Revised Statutes of Canada [R.S.C.] 1985, Chapters P - 4 and 33 (3rd Supp.) as amended is the relevant statute. This Patent Act was first enacted in 1869 and was modelled on the US patent statute of the time.[19] As in the USA and Europe, the Oncomouse patent application was the first filed for an animal at the Canadian Intellectual Property Office.

Section 2 of the Canadian Patent Act provides in the 'Definitions' section that:
"invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."

Prior to 1993 section 27 (8) of the Patent Act contained the following provision:

"No patent shall issue for an invention that has an illicit object in view, or for any mere scientific principle or abstract theorem". However, this provision was repealed by the Intellectual Property Law Improvement Act 1993 by deletion of the first part of the sentence. It was reported by CIPO that this amendment was made to facilitate administrative procedures and was not through a wish to remove moral issues from the sphere of patent law.

The Canadian Manual of Patent Office Practice[20] provides some further assistance. Section 16.05 of the manual entitled 'Living Matter' provides that "Living matter is defined in terms of lower life forms which are essentially unicellular in composition (e.g. bacteria, many fungi (including yeasts), cells in culture, transformed cell lines and hybridomas), and higher life forms which are multi-cellular differentiated organisms (plants, seeds and animals). Lower life forms which are new, useful and inventive are patentable. A process to produce or which utilises these organisms may also be patentable. Higher life forms are not patentable subject matter. However, a process for producing a higher life form may be patentable provided the process requires significant technical intervention by man and is not essentially a natural biological process which occurs according to the laws of nature (e.g. traditional plant cross-breeding)".

But the manual is for guidance only, the foreword of the manual stating "this manual is to be considered solely

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15 (1995) 227 U5PQ443 (Patent and Trademark Office Board of Appeals and Interferences).
16 (1995) 2 USPQ 2d 1425 (Patent and Trademark Office Board of Appeals and Interferences).
17 Statement of Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks 7 April 1987; (1987) 077 Official Gazette Patent Office (US) p. 24.
18 Transgenic Patent Reform Act H.R. 4970.
19 1836.
20 CIPO March 1998.

as a guide, and should not be quoted as an authority. Authority must be found in the Patent Act, the Patent Rules, and in decisions of the Courts interpreting them".

As in the USPTO there is no Opposition procedure before CIPO. Before a patent is granted a third party may file prior art. Re-examination after grant is limited only to a review of the prior art.

Whilst the US and Canadian statutes are similar decisions of the US courts do not have to be followed in Canada and vice versa, however, decisions of one court can provide useful assistance on certain legal points to the other.

The Applications

The United States

The application[21] was filed by Harvard on the 22 June 1984 at the USPTO and had 24 claims, including 12 product claims (to the mammal) and 7 process claims (to the method) and 5 claims referring to ATCC (American Type Culture Collection) Accession Numbers. There is set out at 4.1 in the Appendix details of the claims of the US patent application as originally filed. The US and European Patent Applications claimed priority from this application.

Claim 1 was extraordinarily broad, embracing virtually any species, the claim stating "transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal or an ancestor of said mammal, at an embryonic stage".

Plasmids bearing the fusion genes were deposited at the time of filing of the US application in the American Type Culture Collection, Rockville MD and given ATCC Accession Nos 39745 -39759 inclusive.

During the prosecution the methods and ATCC Accession number claims were dropped.

Canada

There is set out at 4.2 in the Appendix details of the claims of the application filed at CIPO which was entitled 'Transgenic Animals'. Claims 1-12 covered claims directly to an animal (Mammal) whilst claims 13-26 were process claims covering methods of production of the transgenic non-human mammal, cell cultures and methods of testing of carcinogens. The application was filed on the 21 June 1985.

The application was virtually identical to that filed at the USPTO the claims covering all transgenic non-human mammals and all oncogenes. Claims 15 and 17 were particularly broad and it is surprising that no arguments were presented during the proceedings to limit these. Originally the application had 24 claims which were subsequently amended on 14 July 1992 by the addition of two further claims.

Europe

Within the twelve-month priority period from the date of grant of the US patent Harvard filed a European patent

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[21] No 4,736,866.

application[22]with the EPO. There is set out at 4.3 in the Appendix details of the claims filed in the European application.

The application was filed at the European Patent Office for a 'Method for producing Transgenic Animals' Application No 85 30 4470.7 on 24 June 1985.[23] The application contained method and product claims covering the introduction of an oncogene into non-human animals (mammals) to produce transgenic animals for use in cancer testing. The application was not identical with the application filed at the USPTO, claims 1-16 being method claims for producing transgenic eucaryotic animals and claims 17 and 18 being product claims. i.e. being directed to the animals. The US application included 12 product and 6 method claims. The change in the emphasis of the claims being as a result of the more restrictive provisions of Article 53 EPC and to the uncertainties as to their interpretation.

The application as initially filed had 18 claims (which were subsequently amended). The claims around which most debate was later centred were claims 1, 17 and 18, namely:

"Claim 1 A method for producing transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an activated oncogene sequence[24] in a non-human mammalian animal at a stage no later than the 8-cell stage.

Claim 17 A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at a stage no later than the 8-cell stage, said oncogene optionally being further defined according to any one of Claims 3-10.

Claim 18 An animal as claimed in Claim 17 which is a rodent".

These claims have particular significance because they are the first claims for a process for producing an animal with certain characteristics, namely having within its genome an activated oncogene, and the first direct claim for an animal to come before the EPO.

Decisions of the Patent Offices

There is set out at 4.4 in the Appendix a chronological summary of the progress of the US, Canadian and European patent applications for the Oncomouse for ease in comparison.

United States - USPTO

During the prosecution of the application the claims were reduced to 13. The method claims were removed and claim 1 was reduced in scope to include "a transgenic non-human mammal". The US patent contained 12 product claims directly to the transgenic non-human mammal containing the oncogene sequence. Reference is

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22 No. 85304490.7.

23 Designated states AT, BE, CH, DE, FR, GB, IT, LI, LU,NL,SE claiming priority from US Patent Application No. 623774 22 filed at the USPTO on 22 June 1984 by The President and Fellows of Harvard College 'Method for producing Transgenic Animals'.

24 An activated oncogene sequence means an oncogene which, when incorporated into the genome of the animal, increases the probability of the development of neoplasms in the animal.

made in claim 12 to an embodiment being a mouse. The patent claims of the granted patent are set out at 4.5 in the Appendix.

Whilst the US system did not provide for an opposition process representations were made to the USPTO against the patenting of the Oncomouse by various groups which included the following: The Massachusetts Society for the Prevention of Cruelty to Animals, The Foundation of Economic Trends, The Humane Society of the United States, American Legal Defense Fund Inc, American Fund for Alternatives to Animal Research, American Anti-Vivisection Society, American Farm Bureau Federation, National Farmers Union, American Agriculture Movement, Animal Welfare Institute, Animal Defense Council Inc, American Society for the Prevention of Cruelty to Animals, Friends of the Earth, United Farmers Organization and the Union of Concerned Scientists. The USPTO's decision to allow the patenting of an animal created much controversy leading to proceedings being taken (unsuccessfully) against the Commissioner of the Patent Office by various animal rights groups and individual farmers alleging violation of administrative procedures.[25] For a judicial view on patenting of animals after Oncomouse see comments of Chief Justice Helen Nies.[26]

In the USA the Oncomouse patent was granted on the basis that Harvard University had created a non-naturally occurring life-form which was argued would prove invaluable in cancer research. The actual extent of that value could not be determined at the time of the patent grant. In Europe the value of the Oncomouse was seen in terms of it being able to provide a benefit to the public, this benefit being a transition from the potential to produce a benefit to an actual benefit being supplied. DuPont claimed in 1989[27] that it had received 10,000 preorders for the Oncomouse. However, following the grant of the patent in the USA, DuPont[28] failed to get any of its competitors to take out licences to use the invention and reached agreement with Charles River Laboratories[29] to distribute the Oncomouse. However, the fee structure was not encouraging to potential customers. Reach through clauses were included which meant that royalties would be payable to DuPont in respect of any products developed using the Oncomice. According to a report,[30] researchers eager to use genetically engineered animals found themselves 'confronted by a thicket of patents, high fees and restrictions on how they could use the materials'.

On 18 January 2000 DuPont signed an agreement[31] with the US National Institute of Health which will now enable academic researchers to use the Oncomouse technology for non-commercial research. Use of the mouse by commercial entities will still attract a royalty.

Canada - CIPO

Upon examination of the patent application C1P0[32] rejected claims 1-12 to the animals but allowed the process

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25 Patents, House Panel hears Testimony addressing Animal Patenting Issues (25 September 1989) *Daily Report for Executives* (BNA Publishers USA) p. 184 A-6; Firm seeks royalties for Patented Animals (29 October 1989) *Newsday* p.62.

26 *Animal Defense League v. Quigg* 932 F. 2d 920, 18 USPQ2d (Fed. Cir. 1991).

27 OTA *New Developments in Biotechnology Patenting Life* 3 (Office of Technology Assessment 1989) Pub. No. 5, 101st Cong. 1st Sess.

28 E. I DuPont de Nemours & Co ("DuPont') as sponsor of the research work undertaken by the Harvard researchers and were granted an exclusive worldwide licence to exploit the Oncomouse.

29 Charles River Biotechnical Services (a Bausch and Lomb company).

30 (1993) *Science* vol. 260, 2 April p.23.

31 http://www.nih.gov/od/ott/oncomous.htm (last visited 7 September 2001).

32 Examiners Final Action dated 24 March 1993.

claims 13-26. Harvard argued that the invention fell into the category of composition of matter. However this view was not supported by CIPO, the Commissioner relying on an earlier plant case, *Pioneer Hi-bred v. Canada (Commissioner of Patents)*[33] in 1987, where it was held that higher life forms were not patentable. The Commissioner separated the process into two phases, firstly the preparation of the plasmid and secondly the introduction in the uterus of the host mouse. At all stages the Commissioner considered that the invention was required to be under the control of the inventor and to be reproducible in a consistent manner. Only the presence of the oncogene was under the control of the inventor.

This case distinguished the earlier Canadian case *Re Application of Abitibi Co.*[34] where it was held that micro-organisms such as yeast, mould, fungi, bacteria, actimomycetes, unicellular algae, viruses or protozoa were patentable. Harvard appealed this decision to the Patent Board of Appeal, which on the 4 August 1995 following oral representations upheld the Commissioner's decision. Harvard further appealed this decision to the Federal Court Trial Division which confirmed that while the application met the patentability requirements (being new and useful) it was held that the mammal was not an invention as defined by s.2 of the Patents Act. It was held that the inventors could not exert sufficient control over the invention i.e. mouse independent of human intervention after introduction of oncogene and that the animal was not sufficiently reproducible to be considered 'composition' of matter or article of manufacture. The Canadian Environmental Law Association (CELA) applied to intervene in the proceedings.[35]

Nadon J, in this case[36] before the Federal Court was persuaded by the minority decision (4-5) of the US case *Diamond, Commissioner of Patents and Trademarks v. Chakrabarty.*[37] Nadon J looked at the invention and the extent to which the inventors could control the end product of their invention. He stated that "On even the broadest interpretation I cannot find that a mouse is raw material" which was given new qualities from the inventor. Certainly the presence of the gene is new, but the mouse is not new nor is it a "raw material" in the ordinary sense of that phrase".[38] Also "a complex life form does not fit within the current parameters of the Patent Act without stretching the meaning of the words to the breaking point, which I am not prepared to do. However, if Parliament so wishes it clearly can alter legislation so that mammals can be patented".[39]

He concurred with the view of Mr. Justice Brennan, with whom Justices White, Marshall, and Powell joined in dissension in the *Chakrabarty* case who stated that "It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern".[40]

Nadon J concluded in his judgement "even if a mouse were found to be within that the realm of patentable

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33 (1987) 3 F.C. 8, affirmed 1989 1 S.C.R. 1623. Case involved the cross-breeding of soybeans in which there was no direct intervention at the genetic level. In 1986 11 *CPR* (3rd) p. 311 the Commissioner refused plant and seed outside definition of invention; in 1987 14 *CPR* (3rd) p. 491 on Appeal to Federal Court which upheld Commissioner's ruling; and File No: 20388, (1989) 25 *C.P.R.* (3rrd) p. 257 application refused due to lack of sufficient disclosure.

34 (1982) 62 *C.P.R.* (2d) p. 81. Case concerning yeast culture. The application was directed only to micro-organisms and the patentability of higher life-forms (plants and animals) was not at issue in this case.

35 See http://www.web.net.cela. (last visited 17 October 2001).

36 President and Fellows of Harvard College v Canada (Commissioner of Patents) (1998) 3. F.C. 510.

37 See Chapter 2.

38 Page 15.

39 Page 22.

40 447 U.S. 303, 65L.Ed., 1000 S.Ct.22O4 at p. 158.

subject-matter it would give the inventor no additional protection in this instance. The inventor has already received a patent for the creation of the plasmid and the injection thereof into the mouse oocyte. The appellant can exclude all others from participating in any activity which infringes that which is already patented. Even to stretch the definition of invention would not to enhance the protection already accorded the appellant".

Harvard appealed the decision to Canada's Federal Court of Appeal which on 3 August 2000, in a 2-1 decision[49] (Rothstein J.A. and Linden J.A. with Isaac J.A. dissenting) sent the matter back to CIPO with the direction to include in the grant the transgenic animal claims. Justice Rothstein giving the written decision held that the animal was eligible for protection as it constituted a composition of matter and acknowledged being persuaded by the majority decision in the US *Chakrabarty* case. Nothing in the term composition of matter excluded higher non-human life forms. The *Pioneer Hi-bred* case was distinguished it being held that a transgenic animal required inventive ingenuity and intervention at the genetic level and the creation of a specific new life form. The appeal was nothing more than interpreting the Act to determine whether the product was patentable. Policy issues should be addressed by parliament, through elected representatives.

In Canada, the Patent Office, supervised by the Court, does examine as to inventiveness, and an applicant may appeal to the highest court. Moreover, in the particular class of case with the which we are here concerned dealing with drugs and medicines, there is considerable public interest at stake, and the Commissioner should most carefully scrutinise the application to see if it merits the grant of monopoly privileges and to determine the scope of the monopoly available". Isaac A.J further concluded "Judson J. affirmed the Commissioner's right to consider the public interest in interpreting section 2 of the Act". He further stated "the foregoing clearly demonstrates that not everything which is new, useful and inventive is *a priori* patentable subject matter. The Commissioner of Patents had both a right and an obligation to consider the public interest in the granting of a patent".

The Canadian government on the 2 October 2000 lodged an application in the name of the Commissioner of Patents seeking leave to appeal the decision of the Federal Court of Appeal decision.

In Canada as will be seen in Europe the question 'are animals patentable?' has still not been answered.[41] Canada has adopted a very cautious approach, unlike its North American neighbours, and seems to be taking its moral responsibilities seriously setting up in September 1999 the Canadian Biotechnology Advisory Committee to advise on biotechnological matters. Canada is under heavy commercial pressure from the USA to allow patents on animals. Also, Canada like the European Union, has responsibilities under the TRIPs agreement (as does the USA) and has a duty to implement fairly its intellectual property regulations in accordance with the provisions of that agreement.

Europe - EPO

Before the Examining Division

Following the preliminary examination a partial European Search Report under Rule 45 EPC was issued by the

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41 For a general review see M. Perry and P. Krishna, Making sense of Mouse Tales: Canada Life Form Patents Topsy-Turvy (2001) *EIPR* p.196.

Examining Division on 25 October 1985. The application was published on January 1986 in EP Bulletin No 1986/05 under publication Number 0169672. The main areas in respect of which the application was examined by the Examining Division[42] were under Article 83 EPC (sufficiency of claims to the invention), Article 53(b) EPC (does invention constitute and animal variety or result from a biological processes) and Article 53 (a) EPC. These provisions are set out for ease of reference at 4.7 in the Appendix.

There is also included a schematic representation of the stages of the progress of the Oncomouse patent before the EPO indicating the present stage that has been reached and possible stages in the future. A chronological summary of the stages of the application is also set out at 4.6 in the Appendix.

The Examining Division issued a notice[43] of its objections to the granting of the patent on the basis that the application did not meet the requirements under Articles 53 (b) EPC, Article 53(a) EPC and Article 83 EPC.[44] The Examining Division objected to the application under Article 53 (b) EPC in view of the fact that the application contained a claim (claim 17) directed to animals *per se*. The Examining Division interpreted this provision as referring not only to those cases where a specifically designated variety is claimed but also cases where varieties are covered by a claim.

The arguments put forward under Article 53 (b) EPC are discussed in Chapter 3.

Objections were raised in respect of claims 1-10, 12 and 13 under Article 53 (a) and Article 83 EPC as "they embrace a method for making human beings".[45] The Examining Division stated "For this reason the subject matter of the application which is not sufficiently disclosed under the terms of Article 83 cannot be accepted. This applies to the subject-matter appearing in claims 1 to 7 (and claims dependent thereon) and in all claims in so far as they are generally directed to animals. With regard to the latter aspect it is suggested that the application be directed to rodents, a preferred feature of present claim 7".[46] This was the first time that the Examining Division indicated that claims should be directed to rodents.

The Examining Division also commented that the idea of patenting higher organisms had encountered severe criticism for ethical and economic reasons. In refusing the application the Examining Division amongst other points argued that with regard to Article 53 (a) EPC patent law was not the right legislative tool for regulating problems arising in connection with the genetic manipulation of animals.

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42 See EPO Guidelines C. VI.

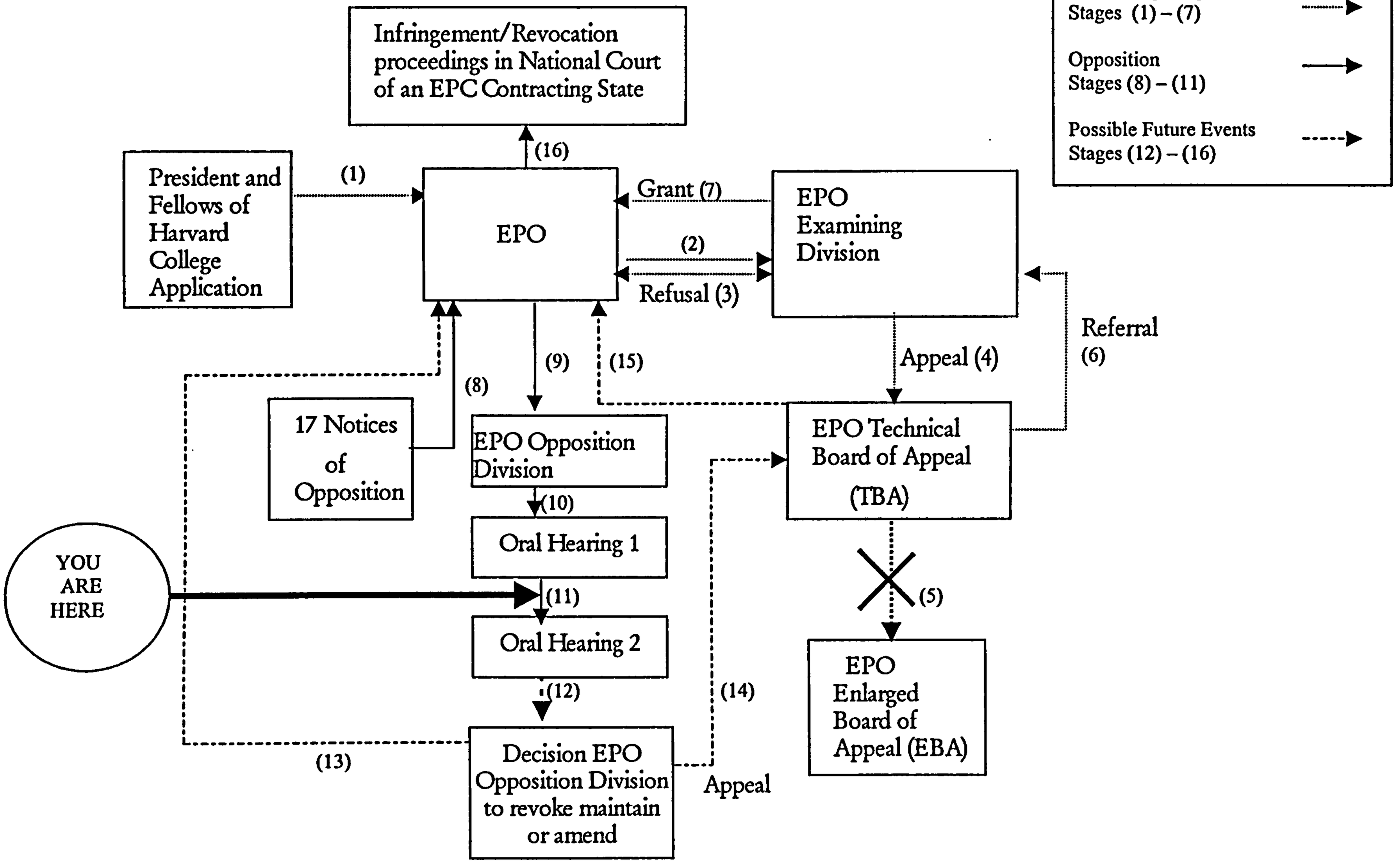
43 20 April 1988.

44 Pursuant to Article 96(2) and Rule 51(2) EPC - Primary Examiner Christian Gugerell. Art. 96 (2 EPC provides 'If the Examination of a European patent application reveals that the application or the invention to which it relates does not meet the requirements of this Convention, the Examining Division shall invite the Applicant, in accordance with the Implementing Regulations and as often as necessary, to file his observations within a period to be fixed by the Examining Division".

45 Communication of 20 April 1988 p.3.

46 ibid. p. 4.

Representation of the stages in the prosecution of the Harvard Oncomouse European Patent Application



Harvard responds

Harvard responded to the objections raised in the notice of 20 April 1988 by letter of 22 December 1988 and further sets of amended claims were filed which are set out at 4.8 in the Appendix.

Claim 17 was amended to refer to non-human animals. However, main claim 1 was not amended as suggested by the Examining Division. Whilst Harvard noted that the Examining Division appeared to be suggesting that claim 17 would be allowable if restricted to rodents. Harvard did not agree that if so worded the claim would differ from the claim at present under consideration.

Reference was made by Harvard[47] to the Guidelines for Examination in the European Patent Office Section C IV 3.1[48] which states that the purpose of the term '*ordre public*' is to exclude from protection inventions 'likely to induce riot or public disorder or lead to criminal or other generally offensive behaviour'.

With regard to objections raised by the Examining Division under Article 83 ECS Harvard proposed[49] that there was no requirement for all embodiments covered by the invention claimed in a European patent application to be reproducible.

Harvard further argued that "exclusions from patentability such as set out in Article 53 must be interpreted in a restrictive and narrow fashion if a fair reflection is to be given to the development of the technology in the context of a fixed code of law (as is the case with the EPC)".

Harvard went on to state "it is also stated that a fair test to apply is "whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable".[50]

Despite Harvard's representations the Examining Division maintained its objections[51] under Article 83 EPC referring to Decision T226/85 *Unilever/Stable Bleaches* which stated that substantially any embodiment of the invention, as defined in the broadest claim, must be capable of being realised on the basis of the disclosure.

Oral Proceedings

Harvard applied for Oral Proceedings before the Examining Division the Oral Hearing being held on the 26 June 1989.[52]

Upon opening the proceedings the Chairman informed Harvard that the Division had been enlarged by the addition of a legally qualified examiner. Harvard submitted an amended set of claims (which are set out at 4.9 in the Appendix) and requested the granting of the patent on the basis of these claims. An additional amendment was also sought namely that in claims I and 17 the word "non-human" was to be inserted before "mammalian animal". As an auxiliary request Harvard asked to substitute the words "8-cell stage" in claims 1 and 17 by "1-cell stage".

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47 Response of Applicant of 22 December 1988 p.7.
48 Published by EPO, September 1989, p. 12.
49 Response of Applicant of 22 December 1988 p. 10/11.
50 ibid. p. 7.
51 Communication of Examining Division sent to Applicant 28 March 1989 and 12 May 1989.
52 Article 116 (1) - (4) EPC - Common provisions governing Oral Proceedings.

Harvard[53] justified patent protection for the treatment of animals the subject of the application on the basis of the 'highly moral' purpose of the invention. In considering Article 53 (a) EPC Harvard replied that the rights of man had to be balanced with the rights of the animal. Negative effects on them had to be accepted as a necessary evil in order to achieve improvements in the treatment of cancer. Asked to comment on the justification of treating animals as a mere object of human activity and of considerable intervention in the genome in vivo, Harvard was of the opinion that the high morality of the nature of the invention justified specific measures.

The sufficiency of the disclosure of the invention under Article 83 EPC was further discussed.

Harvard confirmed that Oncomice were not intended for release into the general environment. They were specialised animals for a specified limited purpose and would be handled only in laboratories licensed to do so and with staff possessing appropriate skills.

Decision of the Examining Division

In July 1989 the Examining Division issued its decision[54] to refuse the application. [55] A considerable number of third party observations had been filed and were duly noted.[56]

The decision of the Examining Division followed consideration of Articles 53 (a) and (b) and Article 83 EPC.

The Examining Division had not found consideration of Article 53 (a) EPC an easy task and appeared to want to avoid giving any indication of it interpretation of Article 53 (a) EPC and concluded "in considering all the above, particularly also considering that the present invention might have a beneficial effect on mankind, the Examining Division concludes that the patent law is not the right legislative tool for regulating problems which may arise in view of the dangers mentioned in paragraph 10.1 (genetic manipulation of animals) Article 53 (a) EPC is, consequently, not used to refuse the present application".[57]

Article 83 provides that a European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The Examining Division made reference to Decision T226/85[58] in which reproducibility of the invention was ruled upon. This latter Decision confirmed that Article 83 EPC was satisfied only if any embodiment of the invention as defined in the broadest claim could be carried out on the basis of the specific disclosure. In the present case Harvard had carried out experiments with one oncogene, the mouse myc gene, by using a mouse as the non-human mammalian animal. The invention, however, broadly relates to any oncogene and any conceivable mammalian animal. In the present case the Examining Division held that the claims in the application related in the description to non-human mammalian animals and not only mice. Other animals, e.g. anthropoid apes, elephants, had a widely varying

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53 Harvard's UK patent agent, Mr. Richard Bizley, attended on behalf of Harvard.

54 Article 113 (1) EPC provides: The decisions of the European Patent Office may only be based on grounds or evidence which the parties concerned have had an opportunity to present their comments.

55 (14 July 1989) *OJ. EPO* p. 451.

56 Article 115 EPC.

57 Decision of Examining Division 14 July 1989 p. 11.

58 T226/85 Unilever/Stable Bleaches (1988) *0J. EPO* p. 336; (1989) *EPOR* p. 18.

number of genes and differently developed immune systems. It could not therefore be assumed that the sole example described in the application, that of mice, could be extended to all other mammals.

The Examining Division considered that the success with the transgenic mouse could not reasonably be extrapolated to all mammals. Therefore the decision with regard to disclosure in T226/85 applied. The Examining Division held that the application contained subject matter not sufficiently disclosed under the terms of Article 83EPC. The Examining Division would consider it a reasonable extension in this respect if the Claims 1 and 19 were directed to rodents rather than to non-human animals.

It is thus interesting to note that at this stage consideration of Article 53 (a) EPC had not taken prominence in the arguments unlike that case during the Opposition proceedings where Article 53 (a) came to dominate the discussions.

On 14 July 1989 the Examining Division issued a notification confirming its decision to refuse the application.[59] following which Harvard appealed to the Technical Board of Appeal against the decision.

Before the Technical Board of Appeal [60]

With the statement of grounds of appeal Harvard filed four sets of Auxiliary claims requests,[61] Set A being the main request and Sets B, C and D Auxiliary Claim Requests 1 to 3 respectively. Sets C and D contained the claims refused by the Examining Division. The claims are set out at 4.11 in the Appendix.

In Set A Harvard claimed the chromosomal incorporation of an activated oncogene sequence into the genome of a non-human mammalian animal, and in Set B the introduction of an activated oncogene sequence into a non-human mammalian animal at an embryonic stage. Lines 4 to 14 on page 2 of the description as originally filed supported these amendments. Although this part of the description did not actually contain the word "genome" now being used in the main claim of the main requests, that concept was thought implicit in the reference to the oncogene sequence being incorporated "chromosomally" or "into the chromosome", the genome of higher organisms being the totality of their chromosomes. Harvard sought review of these sets of claims and the granting of the patent on the basis of the new independent claims.

General Observations[62] and comments on case law in respect of Article 83 EPC were submitted. In considering Article 83 EPC, Harvard referred to the decision T226/85 Unilever/Stable Bleaches a chemical composition case in which the Technical Board held that substantially any embodiment of the invention as defined in the broadest claim, must be capable of being realised on the basis of disclosure. In the decision T281/86 Unilever/Preprothaumatin [63] the Board held that there was no requirement under Article 83 EPC to the effect that a specifically described example of a process must be exactly repeatable. This is in contrast to the finding in T226/85 in which it was held that Article 83 EPC must be construed carefully and be viewed in the context of

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59 (1989) *OJ. EPO* 11, p.451; (1990) *EPOR* 1, p. 4.
60 For discussion of operation of EPO Boards of Appeal see Chapter 3.
61 13 November 1989.
62 The Grounds of Appeal and Amendments being filed on 13 November 1989.
63 T281/86 Unilever/Preprothaumatin (1989) *OJ. EPO p.* 202; (1989) *EPOR* p.313.

the particular form of invention under discussion. In decision T292/85 Genentech/Polypeptide expression[64] (a recombinant DNA invention) the Board held that an invention is sufficiently disclosed if at least one way is clearly indicated enabling the skilled person to carry out the invention. In T301/87 Biogen/Alpha-interferons[65] (a recombinant DNA invention) it was held that the special character of the invention must be taken into account.

Article 64 EPC was considered,[66] Harvard arguing that they were entitled to claims to their animals as well as claims to the process for making them. Harvard commented "there is unquestionably a degree of illogic in Article 64 (2) providing for a patent to extend to the direct product of a process, and yet those products sometimes not being claimable themselves. The consistent attitude of the Technical Board of Appeal in looking at product claims (e.g. in T248/85[67] and T15O/82[68]) has been to produce decisions creating such situation where the product claims were themselves clearly open to other attacks under the Convention". [69]

The Observations of other interested persons or groups

The prosecution of the application by Harvard had caused a great deal of concern amongst animal welfare groups and other animal rights groups opposed to animal patenting.[70] In excess of 1500 third party observations were filed, a record number being filed which exceeded any known number on any previous single case prior. The strength of public opinion against the Oncomouse patent was mounting. A large number of third party observations were identical but signed by different opposing groups.[71] Unlike opponents in opposition proceedings third party observers do not become a party to the proceedings.

A standard letter had been distributed by the animal welfare groups and had been used by a number of observers. A large number of the letters submitted had multiple signatories. An example of the letter is set out below:

"By this letter I wish to express to you my foremost opposition to the granting of the "Harvard Mouse "patent. The patent application, currently under appeal, must be rejected because the patenting of animals is inadmissible for ethical, social, legal and economic reasons.

In my view, the patenting of animals:

- *is contrary to any form of respect for life,*

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64 T292/85 Genentech/Polypeptide expression (1989) *0J. EPO* p. 275; (1989) *EPOR* p.1.

65 T301/87 Biogen/Alpha-interferons, (1990) *0J. EPO* p. 335; (1990) *EPOR* p. 190.

66 Grounds of Appeal and Amendments 13 November 1989, J (3), p. 30. Article 64 (1) EPC provides that a European patent shall, subject to the provisions of Article 64 (2) EPC confer on its proprietor from the date of publication of the mention of its grant, in each contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State. Article 64 (2) EPC states that if the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.

67 BICC/Radiation processing (1986) *0J. EPO* p. 261.

68 1FF/Claim categories (1984) *0J. EPO* p. 309.

69 Grounds of Appeal and Amendments 13 November 1989, H (2) p. 17.

70 See footnote No. 6 p. 19 in D. Beyleveld and R. Brownsword, Patentability of Genetically Engineered Animals the emerging European View *Asia Business Law Review* No 8, April 1995 p. 19.

71 Third Party Observations filed under Article 115 EPC: 115(1) Following the publication of the European patent application, any person may present observations concerning the patentability of the invention in respect of which the application has been filed. Such observations must be filed in writing and must included a statement of the grounds on which they are based. That person shall be a party to the proceedings before the European Patent Office. 115(2) EPC The observations referred to in 115(1) shall be communicated to the patentee or proprietor of the patent who may comment on them.

- *debases our values as a democratic society,*
- *will promote increases in scientific exploitation of the helpless,*
- *will ultimately lead to the patenting of human beings, our children, our body parts, our spirits,*
- *will promote sickness and pain among countless generations of patented "subjects ·.*
- *will reduce the animal world, of which we are apart, to a sea of objects whose only purpose in this world is to be manipulated for short term profits.*

The first animal patent application at the EPO brings into question these very fundamental principles which, in fact, are steadfast legal conventions in Europe. The European Patent Convention Article 53 (a) excludes from patentability all inventions which are contrary to morality EPC Article S3 (b) prohibits the patenting of animals. The "Harvard mouse" application clearly violates these two articles, as well as others. It was on these very grounds that the patent was originally rejected by the EPO examiners and I fully support this position.

The EPO has the express mandate to honour the principles laid out in the EPC. Those principles must be faithfully interpreted to exclude animals as such from patentability Any failure to respect this reading and the far reaching ethical implications of this patent application will quite certainly give rise to a very strong social reaction in Europe".[72]

The Decision of the Technical Board of Appeal

The arguments put forward by Harvard were duly considered by the Technical Board, which gave a detailed account of the basis on which it based its decision.[73] Those in respect of 53 (b) are considered in Chapter 3.

Article 53 (a) EPC

In the earlier contested decision, the Examining Division had argued that patent law was not the right legislative tool for regulating problems arising in connection with genetic manipulation of animals. The Technical Board considered that the genetic manipulation of mammalian animals was undeniably problematical in various respects, particularly where activated oncogenes were inserted to make an animal abnormally sensitive to carcinogenic substances and stimuli and consequently prone to develop tumours, which necessarily caused suffering. There was also a danger that genetically manipulated animals, if released into the environment, might entail unforeseeable and irreversible adverse effects. Misgivings and fears of this kind were expressed by a number of persons who had filed observations with the Technical Board. Considerations of precisely this kind had also led a number of Contracting States to impose legislative control on genetic engineering.

The Board relied on a form of cost/benefit test concluding that "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 risk to the environment on the one hand, and the invention's usefulness to mankind on the other** *(writer's emphasis).* It is the task of the department of first instance to consider these matters in the context of its resumed examination of the case".[74]

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[72] Example of the standard letter signed by Francois Bausch, Member of the Luxembourg Parliament dated 27 April 1990 (source: EPO).
[73] T19/90 dated 3 October 1990.
[74] Decision T19/90 Form 3002, 5, p. 21.

Article 83 EPC - Sufficiency of disclosure

The Board concluded that the invention had been sufficiently disclosed within the meaning of Article 83 EPC. [75] The Technical Board of Appeal noted that Claim 1 of the main request concerned the incorporation of an activated oncogene sequence into the genome of non-human mammalian animals *in general* and that independent Claim 19 related to non-human mammalian animals *in general,* which have been genetically altered in this way.

Whilst the Examining Division had refused the application, *inter alia,* on the ground that the claims were unrealistically broad,[76] the Technical Board, however, considered that the mere fact that a claim was broad was not in itself a ground for considering the application as not complying with the requirement for sufficient disclosure under Article 83 EPC. Only if there were serious doubts, substantiated by verifiable facts, may an application be objected to for lack of sufficient disclosure. The Board felt that although the Examining Division had been correct in saying that certain non-human mammals other than mice had very different numbers of genes and different immune systems, it did not necessarily follow that the invention could not be carried out on such animals. On the contrary, at least one source [77] suggests that those skilled in the art might very well be able to carry out the invention on non-human mammals other than mice. The Technical Board itself was also not aware of any verifiable facts which could cast serious doubt on the possibility for a skilled person to carry out the invention as claimed.[78]

In the appeal proceedings before the TBA Harvard had requested that two questions be referred to the Enlarged Board of Appeal for consideration[79] namely, the extent to which patent protection for animals is possible under Article 53 (b) EPC and the extent of the disclosure required within the meaning of Article 83 EPC in a case of the present kind. The TBA stated that it considered that it would be premature to refer any of these questions to the Enlarged Board of Appeal before the department of first instance had reconsidered the basic problem of interpreting Article 53 (a) and (b) EPC in the light of the Technical Boards decision and the request was rejected.

A statement was issued by the Technical Board of Appeal which confirmed the Board's findings namely that the decision of the Examining Division was to be set aside; the request that certain questions be referred to the Enlarged Board of Appeal was rejected; and in view of the importance of this matter and the desirability of having it considered by at least two instances, the Board exercised its powers under Article 111(1) EPC[80] and

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75 Ibid. 3.9, p.14.

76 Decision T19/90 Form 3002, 3.2, p. 11.

77 Palmiter & Brinster (1986) *Annual Review of Genetics* 20, p. 465.

78 Decision T19/90 Form 3002, 3.3, p. 11.

79 Article 112 (1) provides that in order to ensure uniform application of the law, or if an important point of law arises: (a) the Board of Appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes. If the Board of Appeal rejects the request, it shall give the reasons in its final decision; (b) the President of the European Patent Office may refer a point of law to the Enlarged Board of Appeal where two Boards of Appeal have given decisions on the question. (2) In the cases covered by paragraph 1(a) the parties to the appeal proceedings shall be parties to the proceedings before the Enlarged Board of Appeal. (3) The decision of the Enlarged Board of Appeal referred to in paragraph 1(a) shall be binding on the Board of Appeal in respect of the appeal in question.

80 Following examination as to whether the appeal may be allowed, the Board of Appeal shall make its

the case was to be remitted to the department of first instance (the Examining division) for further prosecution.

The Technical Board of Appeal reported its decision T19/90 on 3 October 1990[81] and notified Harvard by issuing an Official Communication on 11 December 1990.

The Application is Re-examined

In the communication of the decision of the Technical Board of 11 December 1990[82] observations were sought by the Board from Harvard in respect of a number of questions: Firstly, was the subject matter of the application an animal variety within the meaning of Article 53 (b)? Secondly, did the claimed process constitute a microbiological process within the meaning of Article 53 (b)? Thirdly, was the exploitation of the invention contrary to *ordre public* or morality within the meaning of Article 53 (a) weighing the possible suffering to animals and risks to the environment on one hand against the invention's usefulness to mankind on the other?

Harvard filed a lengthy submission in response[83] by letter dated 16 April 1991 reaffirming its earlier arguments. Article 53(b) EPC was again considered. With regard to Article 53 (a) Harvard sought yet again to persuade the Board and the Examining Division that the Oncomouse invention was 'moral' and would by its use have the effect of reducing the extent of animal testing carried out. Harvard confirmed its opinion that there should be a narrow interpretation of the exclusion clause.

It was only to be expected that upon further consideration by the Examining Division the patent would be granted, which it was.[84] However, the Examining Division would appear not to have been totally comfortable with its decision taking the unusual step of explaining in its formal notification to Harvard its reasons for granting the patent. The Rule 51(4) EPC Communication[85] indicating the Examining Divisions intention to grant a patent was accompanied by written comments[86] on the main issues. The Examining Division does not normally give a written opinion explaining its decisions but it did so in this case because of the interest that the application had generated. The Examining Division commented that like the Technical Board of Appeal it had paid due account to the ethical aspects of the patenting of the claimed transgenic animals and that "In view of the extraordinary attention the present case has attracted from the public and the importance the public attaches to the question of patenting animals in the light of public order and morality, exceptionally in a granting procedure the Examining Division considers it appropriate to make a statement on its position concerning these questions".[87]

With regard to Article 53 (a) EPC the Examining Division acknowledged that new technologies attracted new risks. There needed to be a balance "In the case at hand three different interests are involved and require balancing: there is a basic interest of mankind to remedy widespread and dangerous diseases, on the other hand

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decision. The Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution.

81 T19/90 (1990) *OJ. EPO,* 12, p.476; (1990) *EPOR* 7, p. 501; (1990) *World Intellectual Property Report vol.* 4, p.62; (Nov/Dec 1990) *Intellectual Property in Business* vol. 2, issue 6, p. 25.

82 Issued pursuant to Article 9 6(2) EPC and Rule 51(2).

83 Response dated 16 April 1991.

84 13 April 1992, (1992) *OJ. EPO* p. 588.

85 Applicant informed by Examining Division on 4 October 1991 of intention to grant.

86 Annex to Form 2035.3/2004 Comments, 4 October 1991.

87 ibid. 1), p. 1, 4 October 1991.

the environment has to be protected against the uncontrolled dissemination of unwanted genes and, moreover, cruelty to animals has to be avoided. The latter two aspects may well justify regarding an invention as immoral and therefore unacceptable unless the advantages, i.e. the benefit to mankind, outweigh the negative aspects".[88] The statement confirmed that the published article[89] which had been submitted by Harvard in its submissions on the use of Oncomice as a research tool had been duly considered, as had also the 'purpose' of the present invention.

In conclusion the Examining Division commented "it should be stressed that the above considerations apply

solely *(emphasis that of the Examining Division)* to the present case and that other cases of transgenic animals are conceivable for which a different conclusion might be reached in applying Article 53 a) EPC".[90] Details of the patent claims of the granted patent are set out at 4.11 in the Appendix.

Examination of Article 53 (a) during prosecution of the application was less exhaustive than might have been expected in view of the increasing concerns being expressed by the public in respect of animal patenting. The Examining Division and the Technical Board avoided throughout giving any definition of the interpretation of "*ordre public*" or "morality". Some commentators have endorsed the EPO's failure to avoid exhaustively exploring the ethical factors surrounding the interpretation of Article 53 (a) and endorse the EPO's stand[91] and applaud the EPO's avoidance of contributing towards a 'European critical culture'.

The cost/benefit test proposed by the Technical Board (which is discussed further in Chapter 7) set a precedent for following cases considering the provisions of Article 53 (a) EPC. It is also believed by certain commentators that the cost benefit/test expostulated by the TBA influenced the drafting of Article 4 of the Biotech Directive.[92]

Whilst the test proposed by the Technical Board does give some focus as to those points to be considered it muse be remembered that it is not just a balance of the suffering of the animals but a balance between the use of the invention and other 'moral' or more acceptable means of obtaining the same benefit. Some opponents to the patenting of animals as will be seen in Chapter 5 have argued that any form of animal suffering is fundamentally wrong even if this could lead to benefits to man. Thus any inventions which cause suffering are immoral and should not be granted patent protection under any circumstances. As will be seen in Chapter 7 the cost benefit test is not a new test.

A number of patenting jurisdictions now sanction the patenting of animals. The difference between North America and Europe is that there exists strong ecology or green parties in the European Parliament who are able to make their views heard.

The patenting provisions in the USA are more liberal than in Europe, as are the provisions in other jurisdictions

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88 ibid. 4), p. 3, 4 October 1991.
89 A. Berns (1991) *Current Biology* Oncomice a powerful tool vol. 1, No. 1, p. 28.
90 Annex to Form 2035.3/20004 .Comments, 4) (vi), p. 6,4 October 1991.
91 E. Armitage and I. Davis, *Patents and Morality in Perspective* (Common Law Institute of Intellectual Property, London 1994).
92 Discussions in conference with Peter Stevenson of CIWF, David Thomas (BUAV) and Daniel Alexander Barrister on 26 October 2001.

where animal patenting is sanctioned[93] and the difference between the claims of the US and European patents for the Oncomouse reflects the more restrictive provisions of the EPC particularly those contained in Article 53. This may be seen by a comparison of the claims of the US and European patents for the Oncomouse (set out at 4.12 in the Appendix). Looking at the scope of these claims the Examining Division could have limited the scope of the claims of the patent to the method claims providing Harvard with significant protection. However, the Examining Division did not choose to do this and took the very bold step to grant the patent, leaving many questions as we have seen relating to the interpretation of Article 53 EPC still unanswered.

Unlike in the US the Oncomouse story in Europe does not end there upon grant. As will be seen in Chapter 5 the patent now entered the opposition phase.

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[93] Note Japan and Australia. In Japan the Harvard Oncomouse has been granted a patent Japanese patent Office Publication No. 5-48093.

Chapter 5
Opposition to the Harvard Oncomouse European patent

The granting of patents no longer depends on purely technical considerations: from now on, applications will have to bear scrutiny in respect of their wider social implications.

Editorial - EPO Annual Report 1991[1]

By the expiry of the Opposition period in mid-February 1993 following the grant of the Harvard Oncomouse patent a number of notices of opposition had been filed at the EPO. The opposition was launched simultaneously in 11 European cities by a consortium of some 16 European groups including human and animal welfare campaigners, political and environmental organisations, agricultural bodies and religious associations broadly on the grounds that "genetically engineering animals to develop a painful, lethal disease is morally unjustifiable". A number of the opponents comprised more than one organisation. Most of these opponents had already lodged third party observations at the EPO during the earlier examination stage but upon filing formal notices of opposition these groups now became parties to the proceedings[2] and had the opportunity for the first time to make representations directly against the granting of the first European animal patent.

Following a 4-day Oral Hearing in November 1995 before the Opposition Division of the EPO (to which some notoriety has attached) the opposition continued in writing[3] and is still continuing. A decision of the Opposition Division is not expected until the beginning of 2002[4] after which time it is anticipated that appeals will be lodged against the decision (whatever that decision might be) and that the matter will proceed before yet another appeal board. This chapter reviews the ethical or moral arguments put forward by the various opponents during the opposition proceedings and examines the Oral Hearing in detail and the types of arguments that the EPO will have to be able to assess.

Opposition Proceedings

Opposition Proceedings are governed by Articles 99-105 EPC and Rules 56 to 61 (a)[5] and the constitution of the Opposition Division is governed by Article 19 EPC.[6] The President of the EPO decides on the number of Opposition Divisions and cases are distributed amongst them on the basis of their technical specialisation.[7]

Any person may file a notice of opposition in respect of a granted European patent within the prescribed 9-month time limit, this entitlement requiring no special interest on the part of the person filing the notice.[8] A notice of opposition must contain a statement concerning the grounds upon which the opposition is based, as well as an

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1 Page 9.
2 Article 9(4) EPC.
3 A. Abbot (1995) *Nature* 378, p. 427.
4 Interview with Dr. Gugerell on 24 January 2000 and subsequent personal correspondence and telephone discussions to date.
5 Implementing Regulations of EPC of 5 October 1973 amended by Decision of Administrative Council 13 December 1994; (1995) *OJ. EPO* p. 9.
6 W.R. Cornish European patent oppositions and biotechnology (2000) *Nature Biotechnology* p.899.
7 Rule 9 (1) Implementing Regulations EPC.
8 Article 99 (1) EPC; T635/88 (1993) *OJ. EPO* p. 608.

indication of the facts, evidence and arguments presented to support these grounds. Admissible grounds[9] include lack of novelty,[10] lack of inventive step,[11] lack of industrial application,[12] the subject matter is not an invention,[13] non-patentability[14] and inadequate disclosure of the invention.[15] The statement of grounds must be set out in sufficient detail so that it can be properly understood by the patentee and the Opposition Division and also from the point of view of a reasonably skilled person in the relevant art.[16] The time limit for filing an opposition is 9 months from the date of mention of the grant in accordance with Article 97 (4) EPC.[17] Under the EPC the Opposition process takes place after grant of the European patent and after transfer into the national phase.[18] This enables an injunction to be obtained during opposition proceedings if infringement proceedings have already been started. [19]

The burden of proof of establishing the grounds of opposition rests with the opponent. The rule prevails that the inability to substantiate a matter goes against the person who relies on it. If parties in Opposition proceedings make contrary assertions which they cannot substantiate and the EPO is unable to establish the facts on its own motion, the patent proprietor is to be given the benefit of the doubt.[20] An opponent is required to provide sufficient legal reasoning to support the case for revocation.

The substantive examination of oppositions is confined to the grounds raised by an opponent, however, the principle of examination *ex officio* applies.[21] The Opposition Division is thus not limited to the facts, evidence and arguments provided by the parties. However, a prerequisite is that the opposition itself must be admissible for any investigation to be undertaken on the part of the EPO.

The opposition procedure enables a higher probability of validity than would be possible by examination only, as not all the facts would have been available to the examiners at that time.[22] Whilst it acts as a check the EPO cannot take any action after grant even if an incorrect decision was taken to grant a patent unless instigated by an admissible opposition. The principle of the right to be heard forbids informal discussions between the EPO and a patentee during opposition proceedings since the other parties cannot express an opinion on the content of such discussions.[23]

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9 Article 100 EPC.
10 Articles 54 and 55 EPC.
11 Article 56 EPC.
12 Article 57 EPC.
13 Article 52 (2)-(4) EPC.
14 Article 53 EPC.
15 Article 100 (b) and Article 83 EPC.
16 T228/85 (1998) *OJ. EPO* p.128.
17 The opposition may be filed in any of the three official languages of the EPO and a fee is required to be paid. The grounds of opposition mostly used by opponents in opposition proceedings before the EPO are those of lack of inventiveness and lack of novelty.
18 i.e. when European application has been replaced by individual granted national patents effective within the designated States.
19 If the patent had not been 'granted' no such remedy would be available.
20 T219/83 BASF/Zeolites (1986) *OJ. EPO* p. 211.
21 Article 114 (1) EPC which states in proceedings before it, the European Patent Office shall examine the facts of its own motion; it shall not be restricted in this examination to the facts, evidence and arguments provided by the parties and the relief sought.
22 (1989) *OJ. EPO* p. 417.
23 EPO Guidelines E.III.1.

Opposition Proceedings were originally designed to be investigative in nature[24] and a continuation of the grant proceedings. However, this has slowly changed and opposition proceedings have come to be regarded as contentious proceedings between parties.[25] An opposition is not an extension of the examination procedure and ought not to be misused as such.[26] Whilst the Opposition Division can look beyond the evidence and arguments put forward by the parties it can only do so when the proceedings are properly started by the filing of an admissible Notice of Opposition.

A form of 'opposition' whereby a granted patent may be challenged is also recognised in other patenting jurisdictions. For example, Section 72 of the Patents Act 1977 includes a provision whereby any person can apply for revocation of the patent and such application can be made at any time after notice of grant has been published even after the patent has lapsed or expired. Section 72 (1) sets out the grounds upon which such application may be made. In the US there is no opposition process although provision is made for any person to apply for re-examination of a particular patent.[27]

The Opponents

17 Notices of Opposition were filed against the Oncomouse patent.[28] The Opponents to the Opposition (I - XVII) are listed in the Appendix at 5.1. 15 of the Opponents claimed that the invention was unpatentable being in contravention of Article 53 (a) EPC.[29] In response to the Notices and statements of grounds of Opposition Harvard lodged a detailed submission[30] which considered the grounds of opposition raised by each of the Opponents. Nearly all the Opponents were supported by other associations and groups, for example, Opponent I was supported by 40 animal welfare associations based throughout Europe.

The arguments in opposition to the granting of the patent focused on Articles 52, 53 (a) and (b), 54, 56 and 83 EPC, a number of the Opponents relying on the same arguments.[31] These are summarised at 5.2 in the Appendix. There is also included for ease of reference at 4.7 in the Appendix a summary of the main Articles of the EPC considered during the prosecution of the application and also in the opposition proceedings.

The Morality Arguments

The arguments put forward by the Opponents under Articles 53 (a) EPC may be distinguished into separate headings and those put forward under each are set out below, together with a summary of Harvard's response in rebuttal.

A. Intrinsic Evil of Animal Experimentation

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24 G01/84 Mobil-Oil, (1985) *OJ. EPO* p. 229.
25 G9/91 Rohm and Haas (1993) *OJ. EPO* p. 408.
26 G01/84 Mobil-Oil, (1985) *OJ. EPO* p. 229.
27 Sections 301-307 of Title 35, Patents, of the United States Code constitute the reexamination provisions of Public Law 95-517 effective I July 1981.
28 H-R. Jaechen and A. Schrell The 'Harvard Onco-mouse' in the Opposition Proceedings before the European Patent Office *EIPR* 9, p. 345.
29 One commentator identified three groups of opponents, animal welfare Groups, interest Groups representing for example farmers and a rainbow coalition opposed to genetic engineering *per se*. U. Kinkeldey The patenting of Animals (1993) *IIC,* vol. 24, No. 6, p. 777.
30 17 June 1994.

i. Grounds of Opposition

Opponents II, VI and XII proposed that animals were not created just for the benefit of mankind. Animal experiments were evil and should be viewed as such because animal suffering was an inevitable result and it was therefore not right to weigh that suffering against any potential benefits to mankind. The Opponents recognised that moral values could not be regarded as absolute and rigid. Nor, however, should they be seen as something which can be changed when it is expedient to do so. One of the essences of a moral principle is that it does not shift at the whim of convenience. The fact that a particular piece of animal genetic engineering may be of benefit to humanity does not of itself make it morally acceptable to carry out that procedure.[32] Animal experiments, even on so-called lower forms of life, were felt to be objectionable. The patenting of animals was simply immoral. To allow patenting in the field of genetic engineering was legally questionable, medically impractical and unsuited to achieving its objectives. Biomedical processes could not yet be truly qualified and analysed. Life functions were not governed by the kind of laws that could be unravelled by the natural sciences.[33]

Opponents I and VI proposed that the Board of Appeal had failed to consider sufficiently the suffering of the animals and the suffering inherent in the invention. Morality could not be determined solely by weighing up competing interests. The EPO weighting test used in this case by the Board of Appeal was inappropriate. The scope of the patent was not just restricted to the 'Oncomouse' but extended to any 'onco'-animal. Evidence was that primates particularly could suffer more extensively than other animals.

Opponents VIII-XV and XVII stated that the patenting of animals as such was inadmissible. In the development of the Oncomouse it was alleged that there had been an unethical use of living organisms and that the EPO had dismissed valid ethical principles without proper consideration. Concerns were expressed regarding functionalisation, materialisation and commercialisation of life.

ii. Response of Harvard

With regard to Opponent I Harvard again submitted that the decision of the Technical Board of Appeal in T19/90 was binding on the Examining Division. Harvard stated that the concept of morality was constantly changing. There were few fundamental principles which had gained universal acceptance. Harvard proposed that there is some evidence to suggest that the primary reason for the appearance of morality clauses in patent law was, in part, founded upon the attitudes to sex which characterise earlier times.[34] Harvard submitted that arguments put forward in relation to morality which held an absolutist stance should not be held as persuasive.

Harvard denied that it was creating animals. The fears of funtionalisation and materialisation should not be regulated through the patent system.

B. Ineffectiveness of Animal Experimentation and Efficacy of Invention

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31 Opponents IX to XV and XVII put forward the same reasons as those outlined for Opponent VIII.
32 Submission of 17 October 1994.
33 Opponent XIV Oral Proceedings before Opposition Division.
34 Observations of Harvard (Patentee) dated 17 June 1994, p. 17.

i. Grounds of Opposition

Opponent I argued that both the Examining Division and the Technical Board had overrated the benefit of the invention. Opponent I asserted that there was limited value of Oncomice in testing anticancer drugs because of the serious problem of species difference in tumour development and responsiveness. "The use of Oncomice (or other onco-animals) does not overcome the serious problem of species differences in tumour development and responsiveness to anti-cancer agents".[35] Attention was drawn to the fact that there was now a move away from use of mice in cancer research e.g. US National Cancer Institute. Also there are a number of non-animals procedures which, combined in a battery of complementary approaches would be able to test for carcinogenicity more effectively than rodent bioassays".[36] It was expressed to be an obvious fact that the effect of hormones on the immune system shown by these Oncomice will be murine not human and therefore quite different.

Opponent I suggested that the use of the Oncomouse as a 'research tool' could delay validation and adoption of non-animal alternatives and serve to prolong animal suffering and delay the development of new technologies. The use of such animals resulted in continuing suffering and the human benefits from the use of such animals were greatly exaggerated.[37]

Opponent II proposed that the invention did not exhibit any tangible advantages for human health.

Opponent X wished it to be known that alternative research tools were available.

Opponent VI proposed that genetic engineering brought benefits to only a very small and exclusive section of humanity.

Opponents VI, VIII-XV claimed that transgenic mice were of little value in developing new anti-cancer drugs and that their use was unlikely to lead to the reduction in the number of animals used for experimentation as originally described by Harvard.

Opponents VI and XII objected to the lack of enabling teaching and poor efficiency of the gene transfer methods used in the patent.

Opponent IX proposed that there was only limited benefit in the field of cancer research as a result of the use of these animals. It was also not acceptable that social recognition and financial advantage should come to those who caused prolonged and substantial suffering to animals.

Opponent X claimed that the invention had limited value in the development of cancer drugs.

Opponent XI questioned the value of a 'cancer mouse'.

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35 Opposition under Part V of the EPC Opponent I 8 January 1993 p. 9.
36 Opposition under Part V of the EPC Opponent I 8 January 1993 p.17.
37 Letter dated 13 November 1995.

Scientific Observations were also filed by Opponent I on observations of Harvard on oppositions against the Oncomouse patent in which a number of papers reporting experimentation on Oncomice were cited.[38] Such evidence led Opponent I to question the usefulness of Oncomice in carcinogenicity testing. Spontaneous tumours which commonly arose in such mice without exposure to test carcinogens could be seen to cast doubt on the interpretation of results. The Opponent held that the Oncomouse was not such a sensitive tool as might have been thought.

ii. Response of Harvard[39]

Harvard proposed that reliable proof that primates suffer more extensively than other animals would be difficult to come by. It was true that animals did not respond physiologically in a manner identical to humans, all drugs which are shown to be effective in humans were also effective in at least one animal model. This fact alone was proof that animal models have validity in cancer research.[40] Animals were necessary as a research tool. In AIDS research chimpanzees were used and there had been no public outcry. With regard to the alleged suffering of the animals Harvard suggested that limb deformities caused no pain or discomfort. Harvard confirmed that certain institutions e.g. National Cancer Institute still required drugs and suspected cancer-causing substances to be tested on animals.

C Dignity of Animals and Animal Welfare

i. Grounds of Opposition

Opponent I drew attention to the Petition on the Status of Animals in the EEC presented by Opponent I to the European Parliament on 1 March 1991. Opponent I made reference to welfare requirements taken from the Declaration on the Protection of Animals annexed to the Treaty of the European Union 1992.[41]

Opponent X argued that nature should not be viewed merely as a resource for exploitation of things to the maximum, and hence there could be no justification for using patents to exploit plants and animals. To patent life was to take the reductionist standpoint. While the patenting of genetically altered beings could not be ruled out as a matter of principle, this technology should not be given a helping hand by allowing the patenting of living beings. To exploit reproduction was to seize control of creation for private gain, was to reduce living beings to mere objects, to mere instruments. This stood in stark opposition to the view of our being one part of creation, to the inherent value and dignity of nature.[42]

Opponent IX argued that the patent equated animals with machines, whereas the law recognised the intrinsic value of animals, their individuality and will to live, and thus made an analogy between humans and animals which reflected the considerable degree of similarity between them at the genetic level.[43] Opponent IX referred to the sense of decency of all right and proper thinking people which was exhibited in the Federal Republic of Germany by the passing of the Animal Protection Law of 1986.

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38 1 March 1995.
39 17 June 1994.
40 Submission dated 17 June 1994.
41 Submission October 1994.
42 Opponent X in Oral Proceedings before the Opposition Division.

Opponent XVI endorsed the arguments of Opponent 1 regarding the suffering inflicted on the animals. Animals also developed rules of social interaction, a kind of ethics for their communal relations. It was therefore impossible to strike a balance between the rights of animals and those of society. What was called for was a responsible, moral decision. Patents represented a form of ownership. Ownership represented a means of exploitation.[44]

Opponents VI and XII put forward the argument that treating animals as 'things' did not give any dignity to the animals. Also any consideration of the suffering of animals in any test should not just take account of the 'physical' aspects, but also the mental aspects, as suffering goes beyond the presence of mere physical pain.

Opponent XIII suggested that the benefit to mankind was not absolute and that there could be no ethical justification for manipulating animals to suffer.

ii. Response of Harvard

Harvard submitted that the exploitation of the animals was not inconsistent with use of animals in farming and that the patent system provided a different form of ownership. [45]

D. Public Opinion

i. Grounds of Opposition

Opponents, I, III, V and VI confirmed its view that animals were not suitable subject matter for patenting and which view was believed to be broadly held by the public in general. Bearing in mind that mammals are regularly used in research, this patent could well lead to the creation of the Onco-rabbit, the Onco-dog, the Onco-monkey and the Onco-chimpanzee. Opponent I believed that most members of the public would reject as immoral the production of a dog or chimpanzee designed to develop cancer.

Opponent III claimed that the majority of citizens rejected patent protection on living creatures.

Opponent XVI argued that when patent protection for organisms manipulated by genetic engineering was denied, the incentives to do further research in the field of gene manipulation would be diminished so that no disruption of the public order caused by gene manipulation would occur.

Opponent X expressed the view that the general opinion of the public was against use of such animals and went on to express concerns about the impact of patenting on agriculture and on research.

Opponent I believed that the public would oppose the use of onco-animals if they realised that escaped onco-animals could breed with wild or domestic animals, thereby producing offspring which were highly predisposed to developing cancer.

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[43] Opponent IX in Oral Proceedings before the Opposition Division.
[44] Opponent XVI at Oral Proceedings before the Opposition Division.

ii. Response of Harvard

Assertions on what the public believed could not be substantiated and was based on no strict evidence and no discernible or verifiable facts.

E. Religious objections

:. Grounds of Opposition

Opponent I submitted that the patenting of animals was out of step with modern religious and secular beliefs, not just with much of public opinion, but with all religions, for a respect for life was at the basis of religion and moral philosophy. Religion demands that animals be viewed as part of creation not as objects for humanity to utilise as it chooses. For many with religious beliefs, animals are seen as part of god's creation. At the head of the patenting system is the requirement for an inventive step. A patent is only granted in respect of an invention. From a religious viewpoint it is offensive, even blasphemous, for humanity to claim to have invented an animal; it is god, not Humanity who creates life.

By letter dated 5 February 1993 Opponent I had submitted a paper to the Opposition Division entitled "Created Not Invented" by the Reverend Professor Andrew Linzey, IFAW Senior Research Fellow of Mansfield College, Oxford University. Opponent I drew particular attention to Professor Linzey's comments "the granting of patents involving sentient creatures is wrong because it violates fundamental Christian principles. The view of this paper is that animal patents should not be given; not now, not ever".

Opponent XV said that while the suggestion to restrict patents to animals used in experimentation was worthy, but it also missed the point. To patent animals was unethical and a lethal attack on the relationship between man and animals. To transfer genes meant to form a new creature. It was tantamount to making man God's equal. The beneficiaries should not be the companies whose purpose was to make profits. To patent the building blocks of life was absurd and would confer inordinate power.[46]

Opponent VII proposed that the interpretation of Article 53 (a) EPC should be based on Christian responsibility.

Opponent VII stated that the patenting of living organisms should be viewed in the light of Christian culture. The Opponent expressed the view that it believed that the patenting of the present invention is a step towards the patenting of human genomic material.

Opponent XIII alleged that Harvard was creating altered animals which could be regarded as a precedent for future patenting of humans. The Opponent stated that the industrial exploitation of animals in this way was contrary to general ethical and religious thinking.

Opponent X stated that Christians were very sensitive to the issue of patenting of plants and animals. To allow such patenting would in effect mean legalising a form of technology whose effects on our safety none could

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45 Submission 17 June 1994.

46 Opponent XV Oral Proceedings before Opposition Division.

predict, which would hold considerable sway over agriculture and which had not been the subject of public debate. The creationalist tradition in Christianity presupposed respect for and gratitude to nature as a gift from God if morality and public order were to be maintained. Creation was to be tendered and trusted. To allow patenting was irresponsible as it encouraged interventionism driven by commercial interest.[47]

Opponent VIII said that Article 53 (a) should be interpreted in the light of mankind's decisions on fundamental moral issues as these were reflected in the fabric of society. The EPO had to take account of European society's underlying Christian tradition, even if an understanding of morality and *ordre public* was not the product of a specific religious precept. The patenting of living creatures was only possible where a consensus on basic moral issues had been lost. The justification for altering the germ line of the mouse should be rejected not only on categorical grounds, but also because of the complexity and our limited knowledge of genetic manipulation and its consequences. Purely speculative uses were not sufficient justification. Harvard would unleash a flood of other genetic alterations and make them all commercially interesting.[48]

ii. Response of Harvard[49]

Harvard submitted that the Opposition Division should not presuppose a philosophical condition as the basis of morality. Believers in different faiths or non-believers may have different views. Harvard also proposed that the purported reference to "creating" animal life is wholly misleading and inaccurate; genetic engineering did not "create" life, it merely moulded it in a particular direction, and (hopefully) with rather greater efficiency than traditional breeding methods. Nonetheless, traditional breeding methods had precisely the same objective, namely the production of living things which are tailored to particular human requirements. Whether or not animals have "rights" of their own (they manifestly have "needs"), totally depends upon the philosophical or religious authority (if any) that one views as regulating the conduct of living things on this planet. Since there is certainly no consensus view on this central point, this submission was, for all that it must be respected, quite irrelevant for present purposes.

F. Right to Natural World

i. Grounds of Opposition

Opponent I argued that a growing number of people viewed animals as fellow creatures who shared this world with man, who had just as much right to be here as man had and who should not be regarded as things placed here just for man's convenience. This attitude went hand in hand with the new awareness of man's responsibility to the environment. This new attitude to animals sees patenting as being offensive, as it involves regarding particular animals simply as humanity's inventions. Genetic engineering goes far beyond and is fundamentally different in kind from humanity's traditional uses of animals. Traditional breeding takes place solely within a species and simply involves selecting for breeding animals which have characteristics which it is hoped will be passed on to the next generation. In contrast, genetic engineering allows the genes of one species to be put into an animal from another species. It is that which is so disturbing to many people. Furthermore it was inherently contrary to

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[47] Opponent X in Oral Proceedings before the Opposition Division.
[48] Opponent VIII in Oral Proceedings before the Opposition Division.
[49] Submission 17 June 1994.

morality to alter an animal's genetic make up. Something contrary to morality could not become 'acceptable' simply because it was believed to be useful.[50]

Opponent IV referred to the European Convention on Human Rights. People had a right to a world, which was genetically unaltered which would be put at risk if genetically modified animals were freely available.

Opponent V suggested that man by this invention was 'creating' a form of life, which would ultimately lead to a disturbance in the biological equilibrium.

Opponent X expressed the view that it was immoral to change an animal by means of genetic engineering.

Opponent XI supported premise that the genetic basis of life was the common natural inheritance of the whole of mankind and any claim to ownership of genes or genetic constitution of life-forms should be refused.

Opponent XIII expressed the view that genetic information was the inheritance of all living things and that creation and use of such animals was contrary to moral practice.

Opponent XIV submitted that humans had no right to categorise life-forms. Also human beings had a responsibility to keep animals inviolate in their natural mode of life.

ii. Response of Harvard

It has for many years been the practice of most developed European patent systems to acknowledge patent protection for products in nature whether unappreciated for what they are or for their function. Philosophical assertions can have no real place in the cold legally analytical process to be undertaken by the Opposition Division. There is no requirement under the EPC to know and be aware of all possible consequences for the outside world for any particular invention.

G. Risks Associated with Genetic Modification

i. Grounds of Opposition

Opponent I argued that the Examining Division and the Technical Board had underrated the environmental risk of the genetic modification of animals. If Oncomice did escape they would quire probably breed with wild mice whose offspring could well inherit the oncogene and thus be highly likely to develop cancer. This would lead to premature mortalities in the affected rodent population, thus destabilising the wider ecological balance of the region. The implications of this are hard to assess but may be very serious, especially for predator species for whom rodents are a staple part of their diet. Once genetically engineered animals are released into the environment no one will ever be quite sure of what is going to happen. Living organisms with the capacity to reproduce cannot be simply recalled to the laboratory once released.

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[50] Also argued by Opponent VI.

Opponent V put forward arguments against the use of genetic engineering in general and stated that the long-term risk of genetic manipulation could not be judged although likely to exceed the short-term research results in favour of human health.

With regard to Article 52 EPC, Opponent VI put forward different considerations which essentially referred to possible ecological risks inherent in this technology.

Opponent VII argued that the patenting of living organisms had led to legalising a technology that could not yet be judged as regards its various effects and risks. This would lead in turn to the wide acceptance of the potential risk involved in genetic engineering and thus to a termination of the discussions on the limits of the use of genetic engineering.

Opponent X alleged that there had been an inadequate examination by the Examining Division of the facts available. The assessment by Examining Division of the environmental risks was superficial and conclusions erroneous.

Opponent XII expressed concern about the risks to personnel in handling oncogenes. The Opponent alleged that an activated oncogene sequences could be transmitted in the form of free, biologically activated DNA to competent bacteria and then spread in this manner.

iii. Response of Harvard

Harvard proposed that Opponent I's argument ignores the fact that such animals are kept under conditions prescribed by regulation to prevent their escape. Even if Oncomice did escape, they would have a profound survival disadvantage compared to wild type animals and would quickly die out in the wild. They could not compete not only because they had a propensity to develop cancer, but because they are laboratory animals, which generally cannot live outside the laboratory.[51]

Harvard submitted that the onus of proof that the environmental risks in relation to this technology are such as to outweigh the potential benefits should be on the Opponents. The grant of patent rights is a means of controlling technology and ensured responsible and controlled exploitation. Harvard believed that the risks to the environment were small.

H. Human Dignity

i. Grounds of Opposition

Opponent II stated that the subject matter of the contested patent was an affront to the dignity of mankind. There was an 'inseparable' association between the human dignity and the responsibility for fellow creatures.

Opponent VII argued that the patenting of a human oncogene sequence was one step further in the direction of the patenting of human genomic material and therefore was an affront to the dignity of mankind.

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[51] Submission 17 June 1994.

Opponent XII stated that human beings as a whole were excluded from patentability. Inanimate matter or objects, on the other hand, were in principle patentable. As for the patentability of animals, the question was the extent to which there were similarities in one respect of another and what the ensuing consequences were.

The underlying reason for the unequal treatment of humans and animals lay in the dignity inherent only in human beings by virtue of their being human, which had its deeper roots in the recognition of man's characteristic as a rational being capable of genuine autonomy.

While there should be no blanket preclusion on the granting of any kind of protective rights for intellectual endeavours directed towards genetically altering animals, any right conferred should not identify its holder as the inventor or creator of the animal in question. Patents would therefore hardly seem appropriate. What was conceivable was a separate category of protection, analogous perhaps to the protection of plant varieties. This approach, which would need to be enshrined in the legislation of the contracting states, was also in line with democratic principles. The issue of the moral status accorded to animals and of the relationship between man, his fellow creatures and his environment was of great importance to the longer-term development of human and non-human culture in general and to European culture in particular.[52]

ii. Response of Harvard

Harvard argued that Opponent II associated "inseparably" human dignity with responsibility for our fellow creatures. There is no evidence whatsoever that even the generality of such views constitute the general attitude throughout the Contracting States and, more importantly, there is no evidence that the provision of a means of enhancing investigations into disease such as cancer would be contrary to such views.[53]

<u>The First Oral Hearing before the Opposition Division – November 1995</u>

In the examination, opposition and appeal proceedings before the EPO there is an unrestricted right to oral proceedings,[54] that is the right to make oral representations before the appropriate Division or Board. If a party requests a hearing, the EPO has no right to question whether such a hearing is potentially useful. Any party to the proceedings may make a request for oral proceedings. A number of Opponents as well as Harvard requested an Oral Hearing.

The parties cannot exercise any control over whether a decision will be given initially in written or oral form, or over when it is to be given. The usual practice of the EPO is that if a matter has been fully argued at oral proceedings, then an indication is usually given orally of the decision reached. Some months later a written reasoned decision is sent to the parties. It is possible for the EPO to reserve the decision and a written decision only is given in writing at some time after the oral proceedings. After the conclusion of the oral proceedings, the Opposition Division has the power in appropriate circumstances to invite the parties to make further oral or written submissions, or to ask them to state their position on a particular point.

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[52] Opponent X II at Oral Hearing.
[53] Submission 17 June 1994.

The Opposition Oral Proceedings were held over 4 days between 21 - 24 November 1995. In view of the very sensitive nature and public interest this case had aroused, the EPO employed very tight security for the hearing. The names and addresses of all persons who were proposing to attend were required to be submitted in advance, a limitation being placed by the Opposition Division on the number of representatives who might attend. Harvard was limited to a maximum of 20 seats; the Opponents 10 each, with the exception of Opponent VI which was limited to 150 seats. Admission to the general public was restricted as it was felt that this could have serious and unjustified disadvantages, in particular for a party to the proceedings.[55]

The First Day

The first day of the Oral Hearing (21 November 1995) convened with all Opponents attending. The Opposition Board comprised four representatives: R. Grosskopf (Chairman); C. Gugerell (1st Member); E. Hardon (2nd Member); and B. Gunzel (Legally qualified Member).

The Chairman opened the hearing by making a short statement, requesting the parties to allow everyone the opportunity to make their representations. He went on to refer to the very difficult nature of the decision that the Opposition Division was going to have to make and which would certainly not be acceptable to some of the parties present.[56]

Following this statement the admissibility of certain of the oppositions[57] was considered. Once this had been discussed Opposition Division confirmed that each party could speak on all issues during the proceedings, irrespective of whether they had been raised earlier during the written proceedings. Whilst Harvard objected that this was inconsistent with normal procedures and general considerations of fairness this position was maintained by the Opposition Division during the proceedings. The Opposition Division confirmed that the order in which the various issues would be discussed would be in the following order Article 83, 52, 54, 56, 57, 53(b), and 53(a) EPC.

However, prior to the issues being discussed, Opponents VIII - XV[58] indicated that they did not wish to present their requests before addressing the question of partiality. These Opponents argued that the Oncomouse case was being advanced by the EPO as a test case with the express aim of allowing the patentability of animals.[59] They alleged that Dr. Christian Gugerell[60] was partial due to his earlier involvement in the case and that the Chairman Mr. Rudiger Grosskopf, was biased on the basis of opinions expressed in the written decision concerning European Patent Number 85 105 630. Opponent VI also submitted objections in writing with regard to the partiality of the Chairman. The Opposition Division referred the question to the Principal Director, who held that the objection of partiality was admissible but not well founded. The Opposition Division indicated

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54 Article 116 EPC.

55 Article 116 (4) EPC. Article 116 (4) provides that in certain circumstances, the public may be excluded by the Opposition Division or Boards of Appeal if the "admission of the public could have a serious and unjustified disadvantages, in particular for a party to the proceedings".

56 The full statement of the Chairman and comments thereon are included in Chapter 6.

57 Minutes of Oral Hearing, paragraph 2, page 1.

58 Represented by the same professional representative, Mr. Wilhelms.

59 Minutes of Oral Hearing, paragraph 4 page 1.

60 Dr. Christian Gugerell was the Primary Examiner of the Examining Division in the Oncomouse case. He was also Chairman of the Examining Division in the Genetic Plant Systems and Novartis II Cases (see Chapter 3).

that whilst the question of partiality was not separately appealable any objections against the composition of the Opposition Division could be raised again in any subsequent appeal.[61]

During the rest of Day 1 arguments were heard in respect of objections under Articles 83 and 52(2) and (4) EPC.[62] Due to their availability only on this day, experts appointed on behalf of opponent XII and XV, Professors Mieth and Haiger, made representations[63] in respect of Article 53 (a) EPC. Opponents maintained, with regard to Article 83, that the reproducibility of the invention was questionable and argued that the results obtained with mice could not be extrapolated to other animals in view to uncertainties with respect to the introduction, expression and transmission of the transgene. Opponent I referred to the Guidelines for Examination at the European Patent Office D-V, 4.3 of the European Patent Office in support of its argument that in the present case the burden of proof lay with Harvard that an Onco-horse/dog/guinea pig could be made. Harvard in response cited arguments put forward earlier in representations before the Technical Board.

To conclude Day 1, arguments in relation to Article 52 EPC were heard. Harvard submitted that transgenic animals could not be found in nature, but were the result of a major technical intervention by man. These animals could not be considered a mere discovery.

The Second Day

On the morning of the second day (22 November 1995), the Opposition Division declared that the arguments of the Opponents did not sufficiently support the conclusion that the patent ran counter to Article 83 EPC, and that the claimed invention could not be considered a discovery (Article 52(2) EPC) and that the claimed processes did not fall under the exclusion of Article 52(4) EPC.[64]

The Opposition Division then went on to consider arguments raised under Article 54 EPC (Novelty).

Opponents VIII-XV referred to an article appearing in the scientific journal "Cell"[65] which was published in June 1984. They argued that the journal was available which contained prior art, before the filing of the US patent application from which the present patent claimed priority. Harvard countered the arguments stating that the onus of proof was on the Opponents to show that a member of the public could have obtained the document before the priority date, 22 June 1984. The Opposition Division after deliberations concurred with this position.[66]

During the afternoon arguments were put forward by Opponents VI, VIII-XV and X in relation to Article 56 EPC ("inventive step"). The Opponents argued that the claimed invention represented what was obvious in view of the state of the art prior to the filing of the patent application. These Arguments were refuted by Harvard, reciting the arguments put forward earlier in its written response to objections.

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61 Minutes of Oral Proceedings (prepared by Opposition Division) paragraph 4, page 2.
62 ibid. paragraphs 7-8, ps. 3-4.
63 ibid. paragraph 15, pages 9-11.
64 ibid. paragraph 9, page 4.
65 Brinster et al. (June 1984) *Cell* p. 367.
66 Minutes of Oral Proceedings (prepared by Opposition Division) paragraph 10, page 5.

The Opposition Division announced that it had not been sufficiently convinced the claimed subject matter lacked an inventive step.[67] Article 57 EPC (industrial applicability) was then considered following arguments being presented by Opponents I, II, VIII-XV, X and Harvard. The Opposition Division indicated that no conclusion on allowability under Article 57 EPC had been reached at that stage and that the discussion would be continued with Article 53(b) EPC.[68]

However, before these began Harvard asked to be allowed to make a statement on the availability of the cited article in the scientific journal "Cell". Harvard stated that it had just come to their knowledge that the paper had been received by Boston library on the 22nd June 1994 i.e. the priority date of the patent (the date filed in the US). Whilst the Opponents were given the opportunity to comment, none did so.

On returning to consider requests in relation to Article 53(b) EPC Opponent VI explained that it was illogical to exclude animal varieties from patentability, but to grant patents on animals. A broad claim to animals such as is contained in the present patent must necessarily included genetically engineered animal varieties. The term "variety" must therefore be embraced within any generic claim to animals. Therefore animals *per se* are not patentable. Opponent V further alleged that the EPO collaborated closely with major industrial companies and that it was anti-democratic and showed an attitude of "militarism" "undermining the law".[69]

Opponent I argued Article 53(b) must be interpreted in accordance with legal principles and should not be given an illogical meaning. It should be remembered that the Opponents' arguments had been accepted by the Examining Division when this case was first brought before it. The patent application was rejected on the grounds, *inter alia*, of Article 53(b). Therefore, the Opponents are not asking for a strained interpretation of this Article. If the Opposition Division believed that the patenting of animals was desirable in the public interest, they should seek an amendment of the Convention to allow this, not bend the wording of already existing Articles.

Opponent VII argued essentially that the patent ran counter to Article 53(b) EPC, because it comprised animal varieties. Every animal belonged to an animal variety with characteristic features, patenting of which contravened Article 53(b) EPC.

Opponents VIII-XV argued that the procedure revealed "treacherous depths".[70] Article 53 (b) constituted an absolute prohibition on the patenting of animals.

Harvard responded by stating that whilst Article 53(b) EPC was indeed obscurely written, the distinction between animals and animal varieties must have had a meaning. Animal varieties were to be defined as the mere products of breeding. This was also to be derived from the comparison with the exclusion of plant varieties. The claimed animals were not the result of breeding, but of the application of a technical step on a founder animal which was decisive the end result. Harvard proposed that the Oncomouse was a product of the microbiological process, so even if the product claims in the patent were held to constitute animal varieties under the first half-sentence of Article 53(b), patentability was reinstated under the second half-sentence.

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67 ibid. paragraph 11, page 6.
68 ibid. paragraph 12, page 7.
69 ibid. paragraph 14, page 7.
70 ibid. paragraph 14, page 8.

Further arguments were put forward by Opponents I, VI, VIII-XV and XVII after which proceedings ended for that day.[71]

The Third Day

Proceedings on the third day (23November 1995) opened with the Opposition Division declaring that no conclusion on the Article 53(b) EPC had been reached and that the hearing would continue with arguments under Article 53(a) EPC.

Opponent I argued that Article 53(a) was the most important fundamentally for consideration in this case and that the Opposition Division would require courage to decide in favour of the Opponents. Whilst confirming that Opponent I was not against scientific research as such, Opponent I stated that the essence of the present invention was to cause suffering. Causing suffering for commercial ends could not be justified.[72] It should be noted that a principle of legislation on animal experimentation was that animals should be treated with humanity whenever possible. If the patent were maintained, animal suffering would be being used for commercial ends. Opponent VI argued that any patents granted on living creatures would be used as a means of monopolising markets and shut out potential competitors.

During the proceedings the Opposition Division asked the parties to state whether, in their view, Article 53 (a) EPC allowed the distinction to be drawn between animals used in experimentation and other animals. Opponent VI supported by Opponents VIII-XV replied that such a restriction would make no difference.[73] Opponent XV said that while the suggestion to restrict patents to animals used in experimentation was worthwhile, it also missed the point.[74] The Minutes of the hearing recorded that the Opposition Division indicated that any requests other than those on file would have to be filed on that day. Replying to a question from Harvard as to what exactly the Opposition Division meant and what might be considered acceptable requests, the Opposition Division said there might also be a wish to consider claims not relating to animals other than experimental animals.

Opponents VII-XV said this was a unique situation. Harvard was now being told by the Opposition Division what sort of request it would find acceptable even though Harvard had already had sufficient time to make any requests should it have wanted to.[75]

Opponent I submitted that what the OD was doing was unprecedented. The OD never considered requests unless these had been formulated by Harvard. It was wrong of the Opposition Division to suggest these. On Day 1 Harvard had been asked if it maintained its original position and had responded that it did.

After a break Harvard submitted Auxiliary Claim Requests 1-5 in which Harvard stated it wished to maintain the main request. The following insertion was made immediately before the claims in auxiliary request 2 and 5: "by

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71 ibid. paragraph 14, page 9.
72 Minutes of Oral Proceedings (Prepared by Opposition Division).
73 Ibid. at p.13.
74 ibid. at p.14.
75 From writer's transcription of tapes of Opposition Oral Hearing.

'experimental' we mean herein, permissible for use in animal experimentation under prevailing legislation in at least one contracting state or so permissible in supra-national legislation applying to any such state.[76]

Following these representations and additional arguments by Opponents II, VIII, IX, XII, XV and XIV Harvard spoke in rebuttal of the arguments put forward.[77]

Opponent X further stated that fundamental ethical beliefs were difficult to gauge and subject to change. There was neither binding tradition or legal precedence to fall back on. The public was not prepared to accept that the ultimate taboo on the patenting of plant and animals should fall. To reduce these animals to the status of disease models by allowing them to be patented was an insult to their dignity. Opponent XV said that to patent animals was unethical and a lethal act on the relationship on man and animals. Opponent II commented that what the Opposition Division was doing was unfair.

Harvard responded further by stating that Article 53(a) EPC did not exclude the granting of the patent on the grounds that patenting of animals *per se* was contrary to morality. The exception to patentability under Article 53(a) EPC only applied if the exploitation of the patents would be contrary to morality. In a democratic system the majority viewpoint was not the only relevant factor, democracy involved the delegation of power and responsibility to various public bodies. The EPO derived its legitimacy from the contracting states which are legally ratified by the EPC. Evidence on behalf of Harvard was put forward by Professor Muller relating to the usefulness of Oncomice and research. Opponent I raised objections stating that Professor Muller's evidence should have been provided to the Opponents prior to the Hearing and that the Opponents should be given the opportunity to respond. Opponent 1 stated that it would have had no objection to new evidence being submitted if papers had been circulated in advance and that the submission of this new evidence provided grounds for appeal. The Opposition Division invited the Opponents to respond. Opponent I lodged a formal objection and stated that they had not been given the opportunity to suggest an alternative way to do the research referred to.

Opponent II then requested that the entire "Board" be dismissed on the grounds of partiality, a request endorsed by Opponents VI, IX, X, XII, XIII and XVII. The Opposition Division issued its decision that the request was rejected as an abuse and that its reasons therefore would be given in the final decision.

Concluding the Hearing on Day 3 the Opposition Division announced that the debate on Articles 83, 52, 54, 56, 57 and 53 EPC was closed.

<u>The Final Day</u>

On the morning of the fourth day (24 November 1995) Harvard submitted two more auxiliary requests and altered the order of those filed the previous day. Three auxiliary requests now directed to "experimental animals" (as defined) and three to Onco-animals "being for experimental or testing purposes" and one being directed to Onco-rodents. In each case the claims also covered methods for producing such animals.[78]

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[76] Minutes of Oral Proceedings (prepared by Opposition Division) at p. 16.
[77] ibid. paragraph 15, pages 11-16.
[78] Harvard subsequently confirmed the claims by letter on 28 November 1995.

The representative for Opponents VIII-XV (Mr. Wilhelms) stated that he no longer represented Opponents X, XII and XIII. Opponent I requested that the auxiliary requests be rejected on the grounds of late submission. The representative for Opponents XIII, IX, XI, XIV and XV stated that the EPO was required to abide by the principles of impartiality. Opponents IX and X said that the proprietors had been given help by the Opposition Division in reformulating their claims and rejected all the auxiliary claims. Opponents IX and X then walked out. Opponents VI, XIII and XVII rejected the auxiliary requests. Opponent XVII said that the Opposition Division was prejudiced and suggested that the outcome of the hearing had been decided in advance. Mr. Wilhelms then left the hearing. The auxiliary requests made no substantive change to the claims in the patent. Opponents VI, XII, XIII and XVII then walked out. Opponent II then read out a statement in which it alleged that the EPO was not subject to democratic control and was partial because of career interests. Opponent I stated that the auxiliary requests should be disallowed. Mr. Alexander, representative for Opponent 1, commented that if he had been representing some of his other clients which are large companies, they would not have been treated in the same way. If the auxiliary requests are to be allowed, all opponents must be given adequate time to comment on them.

The hearing concluded with only Opponent I and Harvard remaining.

In closing the proceedings on the morning of Day 4 the Opposition Division announced that the Opponents would have an opportunity to comment on the newly filed auxiliary requests, and that the procedure would be continued in writing. Opponents I said that this decision had been reached without hearing any of the other parties and requested an objection to be recorded in the Minutes. The Opposition Division said that nothing could be recorded in the Minutes as the Hearing was closed. Opponent I commented that the way in which the Hearing had been suddenly terminated was a fundamental abuse of correct procedure.

The representations made by all the parties and the manner of the conclusion of the proceedings are discussed further in Chapter 6.

<u>The Auxiliary Claim Requests</u>

The claims of a patent are the legal definition of the invention. As the application passed through examination to grant and to opposition the scope of the patent claims were slowly narrowed. The claims were amended by Harvard to meet objections raised by the various divisions of the EPO which considered the claims. The most significant changes were those following the oral proceedings before the Opposition Division. During the oral proceedings the Opposition Division had indicated with reference to the claims that it would look favourably upon and Harvard had during and following the proceedings submitted revised claims in accordance with these directions.

Following the termination of the oral proceedings Auxiliary Claim Requests were amended and resubmitted by Harvard.[79] These claims are set out at 5.3 in the Appendix with an analysis of the changes included at 5.4. These claims introduced a new concept of 'experimental and testing purposes'.

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[79] 28 November 1995.

The analysis shows the various changes made to the claims by Harvard to accommodate the suggestions of the Opposition Division. The following changes were made: to claim 1, method for making the animal; claim 19, the animal; claim 23, the chromosome; claim 24, method for a cell culture; and claim 25 a cell for making a cell culture to accommodate the following: transgenic non-human mammals; transgenic non-human mammals for experimental or testing purposes; transgenic non-human mammal whether or not for experimental purposes; transgenic non-human experimental mammal; and transgenic rodents.

In the First Auxiliary request method claim 1 and animal claim 19, in comparison to the Main request, required that the animal in question is "for experimental or testing purposes". Harvard submitted that these words were inherent in the applications of the invention set out in the patent at various points, for example on pages 6 and 10 of the published specification.[80] In the Second Auxiliary Claim Request claims 1 and 22 were stated by Harvard to be intended to be identical with the corresponding claims in the first Auxiliary Claim Request, and therefore import the limitation of the animal in question "being for experimental or testing purposes". Similarly, claim 23 was intended in the First Auxiliary Claim Request and claim 25 to be identical to claim 25 in the First Auxiliary Claim Request. The only difference is that of method claim 24. As part of the claim 24 involves "providing" the relevant animal, it was proposed that claim 24 should also incorporate the "experimental or testing purposes" limitation. The Third Auxiliary Claim Request was intended to be identical to the First Auxiliary Claim Request in general ambit except that in place of the "for experimental or testing purposes" limitation in the single word "experimental" was used in claims 1 and 19. As part of the Request, Harvard proposed to include a "definition" of "experimental" at an appropriate point in the specification, suggesting immediately before the claims as follows: 'By "experimental" we mean herein permissible for use in animal experimentation or testing purposes under prevailing legislation in at least one contracting State or so permissible in supranational legislation applying to any such State". As with the First Auxiliary Claim Request, claims 23, 24 and 24 are not limited. In the Fourth Auxiliary Claim Request claims 1 and 19 are expressly limited to "experimental" animals, as in claim 24 by virtue of the absence of any reference to "but whether or not experimental". Chromosome claim 23 and cell claim 25 are however, broader, in that the "experimental" nature of the animal is not essential. In the Fifth Auxiliary Claim Request claims 1 and 19 are restricted to animals for experimental or testing purposes, and in this Request chromosome claim 23, method claim 24 and cell claim 25 are similarly restricted. In the Sixth Auxiliary Claim Request all claims are limited to "experimental" animals. The Seventh Auxiliary Claim Request now avoids unnecessary terms such as "non-human" and simply limits all claims to rodents.

Following the submission of the Auxiliary Claim Requests Opponent I filed observations thereon with the Opposition Division on 9 August 1996. In these submissions Opponent I stated " the restriction of the claims in Auxiliary Claim Requests 1-6 to animals "for experimental or testing purposes" or to "experimental" animals is an attempt by Harvard to address the criticism that the patent is too broadly drawn in extending to all non-human mammals. This wording could be interpreted in at least three different ways. It could be interpreted as meaning that an animal is "experimental" if: a) under one of the relevant laws it belongs to a species or type which may in principle be used in animal experimentation; or b) under any one of the relevant laws permission has in fact been granted for animals of that species or type to be used in animal experimentation; or c) that particular individual animal may, under one of the relevant laws, be used in animal experimentation.".[81]

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[80] Letter 28 November 1995 Hepworth Lawrence Bryer & Bizley (Representatives of Harvard) to EPO.
[81] Observations of Opponent I dated 9 August 1996 p. 4.

With regard to Auxiliary Claim Request 7 Opponent I stated that if the Technical Board's test was applied there could be no possible argument for granting a patent for any onco-animals other than Oncomice.[82] The class "rodents" was much wider than "mice" and included rats, guinea pigs, hamsters, etc. Harvard had produced no evidence that any Onco-animal apart from an Oncomouse had even been used in medical research let alone what value that research had had.

The addition of the words "for experimental or testing purposes" or "experimental" totally fails to address the criticism referred to in the previous paragraph. In practice it is difficult to believe that anyone would wish to create onco-animals for anything other than experimental purposes. Thus in practical terms the addition of "for experimental or testing purposes" or "experimental " does nothing to restrict the breadth of the patent. Even with the additional words the patent would still, for, example extend to the Oncodog provided that the animal was "for experimental or testing purposes".[83]

On 24 April 1997 Harvard filed further observations in response to the Opposition Division invitation of 15 April 1996 relating to the *Plant Genetic Systems* decision.[84] Harvard withdrew the third, fourth and sixth Auxiliary Claim Requests and the other Auxiliary Claim Requests were renumbered. The definition also of "experimental" for the body of the specification in the patent was also deleted.

Harvard explained in its submission that the proposed reference to "experimental animals" had arisen directly from the recommendation of Opposition Division itself during the Oral Proceedings. The maintenance of claim requests relating to "testing purposes" was also an entirely proper limitation of the relevant claims to subject matter which is suitable for such purposes.

The amended Auxiliary Claim Requests filed by Harvard[85] are set at 5.5 in the Appendix together with an analysis thereof at 5.6.

Whilst Harvard did attempt to qualify the meaning of experimental within the claims there is no European legislation which limits the type of experiments or the species on which they may be done. 'Testing' is usually regarded as seeing if something complies with a standard, for example, toxicity, pregnancy, etc whilst 'experimental' is usually understood to mean investigative work 'to find out something'. Council Directive 86/609/EEC relating to the protection of animals used for experimental and other scientific purposes provides a notification system in respect of experiments to be undertaken for specific purposes[86]. The directive does give definitions of 'experimental animals'[87] and 'experiment'[88] which gives some assistance in determining what is meant by these terms.

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82 ibid. p. 9.
83 ibid. p. 3.
84 See Chapter 3.
85 24 April 1997.
86 See Article 3.
87 means "animals used or to be used in experiments" Article 2 (a).
88 means "any use of an animal for experimental or other scientific purposes which may cause it pain, suffering, distress or lasting harm, including any course of action intended, or liable, to result in the birth of an animal in such conditions, but excluding the least painful methods accepted in modern practice (i.e. 'humane' methods) of killing or marking an animal; an experiment starts when an animal is first prepared for use and ends when no further observations are to be made for that experiment; the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does not place the use of an animal outside the scope of this definition. Non experimental, agricultural or

Representations were made by the Harvard to the Opposition Division by letters dated 24 August 1999 and 6 September 1999. Harvard urged the Opposition Division to make a ruling in view of the fact that the decision of the Administrative Council which came into force on the 1 September 1999 amending the Implementing Rules of the EPC resulted in the *PGS* decision being considered no longer good law. Harvard also pointed out that "in the light of recent developments, it is no longer necessary for the Opposition Division even to address the question of whether or not the Harvard animals are animal varieties. Decision T366/93 has been overtaken by events (and was, in any event, wrong on a point of fundamental jurisprudence as discussed above). Harvard also pointed out that "all tests for patentability are set against a particular point in time. No test for patentability is to be set later than the date of filing of the European application. It would be.wholly improper to allow a "floating" and variable patentability test in relation to morality, which could change as the years go by". [89]

On the 20 September 2000 the Opposition Division issued a communication inviting all parties to file observations on the *Novartis II* decision of the Enlarged Board[90] and the amendment to the Implementing Regulations in the light of the Biotech Directive. The Opposition Division also stated "In view of the above a request for further oral proceedings would not be rejected in accordance with Article 113 and 116 (1) EPC. It should be noted however that any such request would cause a considerable delay before a final decision could be reached by the Opposition Division".

Opponent I filed observations on 11 January 2001 in response to the invitation and following a confirmation of its arguments which had earlier been stated "there has been no change in the legal test to be applied since the date of the Oral Proceedings."

The exasperation of Harvard to this invitation to file oral observations was expressed clearly in Harvard's letter to the Opposition Division of the 29th September 2000 from which the following extracts are taken:

"The history of this case is already unacceptable, and the latest proposals of the Opposition Division bring the system into disrepute".

"It is not appropriate to have an opposition system conducted in such a matter that delays of this nature are experienced, even in the most controversial of cases. The patentee long since made its distaste for this delay apparent."

"What is now proposed adds a further unacceptable layer to that delay, rendering the entire procedure so bizarre as to be open to public ridicule".

".....The proposed procedure of the Opposition Division is inappropriate, inconsistent with the rationale behind the case law of the Boards of Appeal, not in the public interest, and fundamentally lacking in fairness to all parties".

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clinical veterinary practices are excluded". Article 2 (f).

89 Letter Harvard to Opposition Division dated 24 August 1999.

90 G 1/98 (2000) *OJ. EPO* p. 111.

"... The Opposition Division, wholly inappropriately, now propose, not withstanding the above, the further delay of at least four months (the possibility of extensions of time cannot apparently be ruled out). Most astounding of all, they had even indicated the possibility of further oral proceedings. It is manifestly in the public interest for this case to be decided now without further delay, particularly given the existence of an appeal process which can be expected to add yet more years of delay, quite regardless of outcome"

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"Furthermore, it is submitted that the proposed actions of the Opposition Division are contrary to the spirit and intent of the case law of the Boards of Appeal."

" This latest proposal for effectively open-ended further delay is also inconsistent with the fairness generated by an expectation of certainty in legal proceedings; on the contrary, it is consistent with an unwillingness to decide the issues. This is an abrogation of responsibility."

..... further oral proceedings would be a clear abuse of procedure.".

<u>What happens next?</u>

A final answer to the question whether animals are patentable inventions under Article 53 (a) EPC is unlikely to be given for a number of years yet as Opponent I to the opposition proceedings has indicated to the writer that if the Opposition Division maintains the patent, the decision will be appealed.[91] Indeed a final decision may not be reached until such time as the patent is examined before an EU Member national court which is likely to happen in infringement proceedings if the defendant, as is usual in such proceedings seeks revocation of the patent.

There is no remedy of judicial review in English courts in respect of decisions of the EPO.[92] The Boards of Appeal are the final arbiters. The legal position of the EPO Boards of Appeal complies completely with the English notions of a judicial tribunal, the Boards of Appeal arriving at decisions according to the legal rules and principles, rather than by simply finding the most expedient and desirable solution in the public interest.[93]

It has been stated by some "although it is doubtful that refusing to grant a patent for the Oncomouse would inhibit the use of Oncomice, such a refusal is quite likely to have a negative impact on the willingness of commercial sponsors of research and development to invest funds in this kind of work and if this is one of the Examiners' unstated arguments, it should be brought out into the open". In its strongest form, the argument is that it might be the lesser of two moral evils to grant a patent today, even for an invention judged to be immoral, for fear that one might discourage investment tomorrow in research and development that will yield greater moral benefits. If so viewed, granting a patent on the Oncomouse might be treated as a kind of moral "loss leader".[94]

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91 Personal communication between writer and Opponent I.

92 (1996) Lenzing AG's European Patent (UK) Queens Bench *R.P.C.*p.245. See W. Cook (1997) Judicial Review of the EPO and the Direct Effect of TRIPs in the European Community 7 *EIPR* p. 367.

93 W. Cook (1997) Judicial Review of the EPO and the Direct Effect of TRIPs in the European Community 7 *EIPR,* see p. 373 footnote 40.

94 As suggested by D. Beyleveld and R. Brownsword, *Mice, Morality and Patents,* (Common Law Institute of Intellectual Property, London 1993) Chapter 4.

It should be noted that a decision of a Board of Appeal from an Examining Division has no binding effect in subsequent opposition proceedings (or in an appeal therefrom) because the Opponent was not a party to the application proceedings.[95]

16 years on from the filing of the first application for an animal patent a final decision has still not been reached. The patent application for the Oncomouse at the EPO was treated differently than in both the Patent Offices of the US and Canada. Despite the US and Canada having very similar patent laws and neither having a comparable provision to that of Article 53 (a) EPC, the applications were treated quite differently in the two jurisdictions. The Oncomouse patent was granted in the US following relatively limited debate whilst in Canada, the acceptance of a genetically engineered mouse as a 'composition of matter' was not so readily accepted. The matter is still before the courts in Canada and it may be that here a similar half-way position might be taken as is likely to be adopted by the EPO, any grant of the patent being restricted to use for experimental purposes only.

The EPC lays down strict rules for the opposition process and after all submissions have been made the Opposition Division is left with three options. The first is to revoke the patent, [96] the second to reject the oppositions and maintain the patent as granted,[97] and thirdly the patent may be maintained but in amended form.[98]

Almost certainly the Opposition Division will maintain the patent in limited form. The EPO is anxious to salvage what it can from the various auxiliary claims which have been put forward. As noted above during the oral proceedings the Opposition Division encouraged Harvard to amend the claims to the patent by making the method and products claims subject to 'experimental' and 'testing purposes'. The present Auxiliary Claims filed by Harvard before the Opposition Division have restricted method and product claims to 'testing purposes' only and one set of Auxiliary claims limits the animal the subject of claims 1 and 19 to a rodent.

Whilst the claims have been reduced over the period from filing to prosecution (5.7 of the Appendix shows a comparison of the main claims during prosecution before the USPTO and the EPO) the Opposition Division does have the option of confirming the patent but maintaining only certain of the claims, for example, the method claims only or proposing claims which might be acceptable.

There is pressure from the biotech industry on the EPO to grant this patent and to bring Europe into line with other biotechnologically advanced countries. For this reason it is believed that despite the proposals for the interpretation of Article 53 EPC the Opposition Division will seek to maintain the patent for 'testing purposes' and restricting the claim to rodents only.

It must also not be forgotten that just because an invention is not granted a patent this does not mean that it will not be used and exploited commercially. It has recently been reported that in the UK there has been a significant increase in the number of experiments on transgenic animals since 1989.[99] This also puts further pressure on the EPO to maintain the patent.

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95 T167/93 Proctor & Gamble (1997) *OJ. EPO* p. 229.
96 Article 102 (1) EPC.
97 Article 102 (2) EPC.
98 Article 102 (3) EPC.
99 (1999) *New Scientist* p. 5, 31 July.

The Examining Division has been circumspect in confirming its reason for the granting of the Oncomouse patent. This is evident by the fact that the Examining Division took the unusual step of giving a written statement following its decision to grant the patent in which it concluded by saying "it should be stressed that the above considerations apply solely to the present case and that other cases of transgenic animals are conceivable for which a different conclusion might be reached". The Examining Division was aware that it had not resolved the difficulties relating to the interpretation of the provisions of Article 53 EPC and particularly Article 53 (a) EPC.

The EPO must be able to put into place an adequate system for it to deal with the ethical problems surrounding the patentability of animals. A possible improvement to the present system is discussed in Chapter 7 of this study following consideration in the next chapter of how effective the Oral Hearing in the Oncomouse was seen to be by the parties.

Chapter 6

How effective was the First Opposition Division Oral Hearing in the Oncomouse case?

"There can be no question but that the issue under Article 53(a) is the most fundamentally important issue in this case, in that it is the one that has encouraged and incited the people who have lodged Oppositions against this patent to come here and address their arguments to you. Were we merely concerned with technical arguments, it is doubtful whether so many people would have taken the time and trouble to develop presentations on these issues.

Daniel Alexander, Barrister representing Opponent I
Oral Proceedings Harvard Oncomouse 23 November 1995[1]

The Oral hearing in the Oncomouse case presented an opportunity for all the Opponents and Harvard to make representations directly to the Opposition Division and for the Opposition Division to question the Opponents. The EPO originally allocated 3 days for the hearing. On the second and third days the hearing ran on late into the evening, going on until midnight on the third day and extended into the morning of the fourth day. The order in which the arguments were to be presented was set out by the Opposition Division on the morning of the first day and Article 53 (a) EPC was left until last for discussion with the inevitable consequence that time ran out. Whilst the Opposition Division did try and ensure that all opponents had the opportunity to present their case time was a critical factor.

The importance of the Oral hearing to the Opponents appears to have been underestimated by the EPO by its not allocating sufficient time for all the arguments, including those relating to any auxiliary claim requests to be discussed. During the four days of the hearing animal welfare groups and other interested parties demonstrated outside the European Patent Office in Munich and there was a general feeling of tension as well as anticipation surrounding the hearing. Unfortunately no conclusion was reached by the Opposition Division on the objections raised under Article 53 (a) or (b) EPC and the hearing was terminated following the departure of almost all of the Opponents, the matter then going back into the written procedure, where it has remained for almost 6 years. This chapter looks at the effectiveness of the Oral Hearing before the Opposition Division in the Oncomouse case.

During the hearing several of the Opponents raised allegations of partiality on the part of the Opposition Division which were supported by the Opposition Division inviting Harvard on the evening of the third day to file claims addressed to experimental animals. This chapter confirms that the Opposition Division did issue such an invitation and that it was looking for some compromise position whereby the patent could be maintained. given to their views.

Objective of the Oral Hearing

The basic principles governing oral proceedings are set out in Article 116 EPC. Oral proceedings are intended to be as brief or as concentrated as the nature of the case allows.[2] The Board may send with the summons to

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[1] Opening remarks on Article 53 (a) EPC. Day 3 of Opposition Oral hearing

oral proceedings a communication drawing attention to matters which seem to be of special significance, or to the fact that questions appear no longer to be contentious, or containing other observations that may help the Parties concentrate on the essentials during the oral proceedings.[3] If oral proceedings are to take place, the Board shall endeavour to ensure that each case is ready for decision at the conclusion of the oral proceedings unless there are special reasons to the contrary.[4]

On the opening of the Oral proceedings in view of the controversial nature of the subject-matter of the Oncomouse patent the Chairman, Mr. Grosskopf, made a statement which is set out below in full. The statement shows some of the concerns that the Opposition Division had with such a sensitive case.

The Chairman opened the hearing:

"Before we will deal with each of the requests of the parties I would like to make some introductory remarks."[5]

"We are all aware of the specific and sensitive circumstances of the present case. This concerns both the number of parties involved and the public interests in respect of this patent. The Opposition Division is further aware of the fact that whatever the result of the proceedings will be, we cannot satisfy all parties. Nevertheless, we should all try to keep the rules of fairness. In this sense we should especially try to let each of the parties finish their presentation without interruptions by another party or even by people in the auditorium. In view of the time which is set for our proposal I am confident that each of the parties will have sufficient time and possibilities to submit their arguments in detail. Nevertheless, a mere repetition of the written submissions should be avoided."

"Furthermore, although many emotions are involved in this case I would like to ask the parties to present their arguments as objectively as possible. I especially hope that any personal verbal attack will be avoided. I also do not believe that such attacks have any influence on the outcome of these proceedings. As usual in Opposition cases, or in the present case, we are confronted with different interests, but nevertheless you should all show the necessary respect to the other parties."

"It is further clear that during this procedure the discussion will focus on issues where it is not easy to decide, what is wrong or what is right. In this respect it should not be forgotten that the members of this Opposition Division are, let's say, merely technical or legal experts. Nevertheless, we have to take a decision. This decision, however, cannot and should not be interpreted in the manner that would disregard the arguments submitted by the so called losing party or parties, all we can do is trying to find a decision which takes into account the requirements of the Articles of the European Patent Convention. Unfortunately, and this has been demonstrated by the contradictory views of the parties, these Articles are not always completely clear."

"Thus, whatever the outcome of our decision will be it should be kept in mind that this can only be

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2 Guidance for Appellants and their Representatives 2.4.1(1984) *OJ. EPO* p. 376 as amended (1989) *0J. EPO* p. 395.

3 Rules of Procedure of the Board of Appeal Article 11(2). (1980) *OJ .EPO* p. 171 as amended in 1982 and 1989.

4 ibid. Article 11(3).

an interlocutory decision, which may be overruled in each possible direction by internal instances of the EPO, which means the Technical Board of Appeal. In addition the Opposition Division does not presume to take the right decision in this case. I hope all of you understand our feelings concerning the doubts and uncertainties we had during the examination of this case and which we still have. It would be of course much easier for us if we could apply strict and clear rules in order to examine such a sensitive case as the present one. Further cases may bring clarification in this respect. In my personal opinion the answer to the question how to treat similar cases in the future, cannot only be decided by the EPO alone, but should involve other political and social authorities."

Article 53 (a) EPC – Opening Statement

During the prosecution of the Oncomouse application before the Examining Division and the Technical Board of Appeal discussion centred on Article 53 (b) EPC. However, during the Opposition proceedings the main emphasis of the debate slowly altered, with the focus moving onto Article 53 (a) EPC.

Opponent I in its opening remarks at the Opposition Oral hearing seemed to summarise the feelings of the majority of the Opponents:

Opponent I:[6]

"As with any issue of public interest, any issue of morality, it takes a certain degree of courage to take a decision in favour of the arguments that I will be presenting to you. There are always good arguments that may be presented in a technical scientific context which may or may not be persuasive, but in a case of this kind you will have to take your courage into your hands and consider whether the arguments I am putting before you are persuasive and if you do so consider in my respectful submission it is your duty to follow those arguments and decide the case in accordance with your view at the time."

"…. although a large number of Opponents with different views, different perspectives, have submitted presentations, ultimately it is for you to ignore the identity of the various proponents and opponents of these view before you. You are not to decide this matter on the basis of views either pro or con the Opponents or pro or con the Proprietor of the patent. You are charged with the duty of deciding this issue on the basis of principle and on the basis of what you feel is ultimately the right answer. It was said in the *Plant Genetic System's* case that the European Patent Office stands at the crossroads of science and public policy. For better or worse these issues cannot be got around. You are given the perhaps unfortunate task of being in the front line in deciding them and what I hope to do for you this morning is give you some assistance in showing you how and why we say that you should be deciding these issues in favour of the arguments submitted under Article 53(a)".

A Proposal

During discussion of Article 53 (a) EPC, on the third day of the hearing, Dr. Gugerell put a proposal before the parties:

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5 Day 1 of Oral Hearing before Opposition Division 21 November 1995.

6 Represented by Daniel Alexander, Barrister.

Chairman Opposition Division:

"I open the Oral proceedings and I want to give the right to Mr. Gugerell who wants to make a proposal in the name of the Opposition Division".

Dr. Gugerell Opposition Division:

"Yesterday remarks were made regarding the Onco-giraffe and the Onco-elephant and similar things and when we listened to Mr. Alexander's statements today he also referred to the fact that, I think I am not citing you because I don't have the quotations here, but I think I can reproduce the meaning of this, that there is no legislation in England where it would not be provided that animals are to be treated with humanity. You also make the statement that the claims are bad for any other animals and certainly bad for other animals than mice. All these remarks prompted us to request you to consider in the further contributions you make today, whether there would be a difference if all the claims in the relevant passages would refer to non human mammals, but also to experimental non-human mammals. The term experimental at least as we understand it here would mean that it could be used in testing in accordance with national legislation. All I would like to request you is to give your comments in your forthcoming contributions on this idea."

The Opposition Division then went on to suggest that Harvard[7] file auxiliary claims. It is as a result of these suggestions that allegations of partiality against the EPO were raised by certain of the Opponents:

Chairman Opposition Division:

"Under these circumstances Mr. Bizley if you want to submit any requests other than the request presently on file, you should please do it until nine o'clock."

Harvard:

"Mr. Chairman I have a problem with that because it is conventional in opposition proceedings that the Opposition Division give a fair indication to the Patentee of the way their thoughts may be going and often there is a discussion between the Patentee and the Opposition Division as to what might be acceptable requests and without wishing to prejudge the decision in any way shape or form I would be denied that opportunity if I comply with what you have requested."

Dr. Gugerell Opposition Division:

"Mr. Bizley we can only discuss requests when they are there. So we would ask you to consider whether you want to make a request and if there is a request then we can discuss it."

Harvard:

"In that case Mr. Chairman I request an adjournment."

Dr. Gugerell Opposition Division:

"Adjournment of the proceedings?"

Harvard:

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[7] Represented by Richard Bizley European Patent Attorney.

"Temporarily, yes, because I am in no position to offer requests by nine O'clock tonight without sitting down and thinking about it. I take it you mean nine O'clock tonight and not 9 O'clock tomorrow morning. If I might repeat, it is normal in opposition proceedings for there to be some interchange".

Dr. Gugerell Opposition Division:

"A second please. *(Discussion between Opposition Division Members)* Quite simply we for our deliberations, and it is not yet the decision, for our deliberations, which will take place tomorrow and maybe this night, we also wish to have to consider claims which do not refer to animals other than experimental animals".

Harvard:

"In those circumstances may I additionally ask the question as to whether there is any reaction from the Opposition Division to my submission that this was not necessary in relation to cells."

Dr. Gugerell Opposition Division:

"As I have said we have not yet decided. We just for our deliberations would like to have such claims. So there can be no reaction to your submissions."

Harvard:

"I understand Mr. Chairman, may I point out that this is unique in my experience of Opposition Hearings in that it is conventional for an Opposition Division to make a decision on individual aspects of the Convention one by one, and you have decided to lump together the Article 52, sorry, Article 57, Article 53(b) and Article 5 3(a) which does make the structuring of any pattern of requests as it were exceedingly difficult to perform. However, I hear what you say and if you would give us an adjournment in order to prepare such a request, because I am not armed with it now, the only other submission I would make to you is that the request would require some interpretation in the body of the specification and in these unique circumstances some form of definition in the body of the specification and it is the nature of that definition which I am wholly uncertain of. This is why I have a problem. You have made a proposal which many people in this room including many of the Opponents have said they are uncertain about the meaning of. *(CLAPPING FROM THOSE IN AUDITORIUM)* Do you still wish me to go away and consider a request?"

Mr. Gugerell Opposition Division:

"How long would it take you to consider this?"

Harvard:

"To be fair it is not just a question of considering if you wish me to submit a request to help you in your deliberations then it is going to take a little time both to work it out and then to make the necessary copies. So I would have thought at least half an hour to do so and that is not unreasonable in the circumstances."

Opponent II then requested that the entire "Board" be dismissed on the grounds of partiality, a request endorsed by Opponents VI, IX, X, XII, XIII and XVII. Opponent II submitted the following grounds:

"The past two hours of this evening's proceedings have confirmed the impression we already had

that irrespective of the arguments advanced here the Board is intent on finding a way of patenting animals within the framework of Harvard's requests".

Opponent I then went on to comment:

"This is an unprecedented approach of this Division. I have not practised in this field for very long, but I have known others who have and I have some experience here. It is always the case that the Opposition Division does not consider claims or proposal to claims unless they have been formulated by the Patent Proprietor. The Patent Proprietor in this case has had <u>years</u> *(speaker's emphasis)* to formulate auxiliary requests to these claims. He was asked on day one of these proceedings whether he maintained his original position, he said he did. This is the very first indication that the Patentee has given of an indication that he may wish to file auxiliary requests and the result of it is and it has nothing to with the fault of the Opponents that the proposal be that these proceedings be held up yet further. In my respectful submission this is quite unjust. Furthermore, the Patentee has himself admitted that he is unclear about what claims can be formulated and how they should be formulated. In my respectful submission there is nothing he can do to make the claims clear, which is a requirement of Article 84 of the Convention, and nothing he can do to give them support by the description which is also required by Article 84 of the Convention as yell. It is pointless giving him time, half an hour or a day to formulate his claims. It is unjust to the Opponents in the circumstances and I would strongly urge you to get on with hearing these proceedings and deal with this patent as it stands. The Patentee is trying to save a sinking ship as Mr. Wilhelms has said, "all the rats have left the sinking ship" and in my respectful submission they ought to be left where they stand".

Harvard responded:

"May I comment on that. Mr. Alexander should be well aware that it is perfectly normal in Opposition Proceedings for a patentee to submit countless requests and even do that at the very last minute of the very last day on the Hearing. That is normal and it happens a lot. Now I further point out for example in the erythropoietin case the Technical Board of Appeal finally accepted the patent on what I believe was on the 11th auxiliary claim request. So in procedural terms, Mr. Alexander is quite wrong, and with respect displays his ignorance of the procedure that you normally follow in such matters. If you are suggesting to me that your deliberations would be assisted by the filing of requests, this is the first that I have heard of it expressed in such strong terms and if that is the case, natural justice demands that I be given a limited period of time within which to attend to that matter and to provide you with such requests. That being so if you believe that would appropriate to the procedure I request an adjournment in order to do so and that would need to be for obvious procedural reasons at least half an hour, because there are physical exigencies that I am hardly in position to override".

Discussion between Members of Opposition Division.

Harvard concluded:

"With the greatest respect to the legal member of the Division there is a difference, a considerable difference, between the practices you are adopting in this case and what is normal and that is that you have deferred your decision on certain aspects. I, for example, sit here now blissfully ignorant whether or not you agree with the argumentation we have put in. For example, Article 57 and Article 53 (b). I have heard what you say about requests but in view of the furore that I might wish to leave the room for half an hour to generate

claim requests has generated, Can you imagine the response if I put it in and I find you are going to turn me down on Article 53 (b)."

Legal Member Opposition Division:

"As a matter of clarification what we say concerns Article 53 (a) rather."

Harvard:

"That does clarify the matter and I thank the Legal Member for that comment in which case I repeat my request for an adjournment in order that I may assist the Division with a potential auxiliary claim request".

Opponent I spoke further:

"I would accept your decision for an adjournment upon terms that all the Opponents have adequate time to prepare their responses ..... This is quite unprecedented that we have a situation like this where we are given so little time that when an adjournment is granted to the Patentee. The Patentee provides an auxiliary set of requests. We need time to consider it. We are considering here possibly sitting until midnight. It is now 8.45 p.m. and I imagine that the interpreters are getting pretty fed-up with what's going on. In my respectful submission this is simply not on".

Mr. Gugerell Opposition Division:

"We adjourn the proceedings for half an hour."

On re-opening the hearing following the adjournment the auxiliary requests prepared by Harvard were distributed to all parties. Harvard then commented on them:

"Firstly, I maintain the request for grant of the granted claims. I think that is very important and highly appropriate. Two. I file five auxiliary claim requests. Three. I have not finished; I am sorry Mr. Chairman. For auxiliary claim requests numbers 2 and 4, they come accompanied with an amendment to be inserted in the specification immediately before the claims, which reads as follows. If I may read it out. For requests 2 and 4. To just make quite sure that I have not misidentified 2 and 4, they are the requests in which claim 1 has been amended solely by the insertion of the word 'experimental'. Assuming that I have got 2 and 4 the right way round, and I am as it were working on memory by now. The amendment that would accompany sets 2 and 4 is the insertion of the following by "experimental", experimental being in inverted commas, "by experimental we mean herein permissible for use in animal experimentation purposes under prevailing legislation in at least one contracting state or so permissible in supra-national legislation applying to any such state".

Representations were made by Opponents XVI and XVII followed by discussions as to what was to happen on the next day. The Opposition Division indicated that they wished to deal with Article 53 (a). There could only be an extension of the hearing the morning of the next day as there was another matter being heard in the afternoon.

Opponent 1:

"Although I have been asked to address the arguments on Article 53 (a) on the first claim, the main claim I should just make one observation on the submission of these auxiliary requests. We came here to argue

this case on the basis of the main claim and one of the reasons that we did so was because that was set out in the Patentee's submissions at page 109 they say that the Opponent must attack the patent as granted, and that is underlined in the submission, and not some other claims. So that is the reason we were fighting and why I took most strenuous objection to the introduction of these claims at this stage because it is unprecedented in my submission for a patentee to say "fight the claims as granted" and then in the middle of proceedings at 9.30 in the evening to submit a series of auxiliary requests. Mr. Bizley in fact told me a few hours before that he had no intention of submitting any auxiliary requests at all so it came as immense surprise to me when those requests were submitted. We are put in some difficulties in that regard but I shall address you on this later.

This was refuted by Harvard stating that no undertaking had been given.

Opponent I continued:

"If I were sitting here addressing you on behalf of Hoescht or Ciba-Geigy or one of the genetic engineering companies whom I occasionally represent I would respectfully say that if evidence of this kind was presented on behalf of my commercial clients it would be impossible for you to come to any other conclusion than to find in their favour. We do not have here the inventors coming along to defend the necessity of a patent being granted."

..... "This institution is not merely an institution which is concerned with technical and scientific matters. If it were we wouldn't be here and your job would have been considerably easier. You wouldn't have had the trouble you have had over the last few days, we would not be sitting here at 11 O'clock at night. Unfortunately for you, you are in the front line of this case. That is the position you find yourself in. ..... You are here acting as a public body and you are obliged under Article 53 (a) to pay attention to morality and public order and in my submission this is what is at the heart of this case and what sets this case apart from all the other cases on genetic engineering and all the other cases on animal experimentation".

..... "The whole purpose of an opposition is to put arguments that cannot properly be put at an examination stage by people who are able to gather all the evidence and marshal all the arguments."

..... "This is an extraordinary case. This is a case on which the very basis for necessity of advancing a patent has been challenged and we have no one here from the Patentee, no one here from its licensee who can explain to you why all of these people and the population of Europe as you see it in the survey are wrong. In my submission this is a very significant factor that you should take into account. We were told they were going to be here. We might have wanted to ask them some questions. You might have wanted to ask them some questions."

"I started at the outset by stating that this was not an easy case for any tribunal to decide and I stick by that. It is not an easy case. But it is a case where you may be reassured that if you decide this case in favour of the position advanced by the Opponents you will not be allying yourself with, as it were, the fringe but you will be allying yourself with the mainstream of public opinion in Europe and in my respectful submission for an institution which is devoted to public interest in a scientific contest it is absolutely right that it should ally itself with the mainstream of public opinion which is very strongly against the patenting of this invention."

Opponent II commented "The past two hours of this evening's proceedings have confirmed the impression we already had that irrespective of the arguments advanced here the Board is intent on finding a way of patenting animals within the framework of Harvard's requests". Opponent II then requested, endorsed by Opponents VI. IX, X, I, XIII and XVII, that the entire Board be dismissed on the grounds of partiality.

Opponents VII-XV added "We draw attention to the two points in the tape recordings of these proceedings where reference is made to "animals for experimentation". In finally submitting their auxiliary requests, the patent proprietors were responding to those documented repeated references on the part of the Opposition Division, which they regarded as invitations to file such requests. We regard this as evidence of the Board's one-sided bias in favour of the applicants".[8]

On the evening of the third day the Opposition Division announced that the debate on Articles 83, 52, 54, 56, 57 and 53 EPC was closed.

The Final Day

On the following morning additional auxiliary requests were submitted by Harvard and the order of those filed on the previous day altered. Three auxiliary requests were now directed to "experimental animals" (as defined) and three to oncoanimals "being for experimental or testing purposes". One was directed to oncorodents. In each case the claims also covered methods for producing such animals.

The representative for Opponents VIII-XV after stating that he no longer acted for Opponents X, XII and XIII referred the Board to the decision T 173/89[9] which states that "all instances of the EPO and in particular the Boards of Appeal are required to abide by the principle of impartiality, and accordingly to refrain ... from giving one-sided assistance in *inter partes* matters".

Opponents IX, VI, XIII and XVII rejected all auxiliary requests and walked out of the hearing. The representative of Opponents VIII, XI XII, XIV and XV also left the hearing. Opponent II issued a statement and then walked out leaving Opponent I and Harvard before the Opposition Division.

A break was then taken for deliberation following which the proceedings were re-opened and then closed.

Chairman Opposition Division:

> "Gentlemen, I reopen the Oral Proceedings. The Opposition Division has decided to prosecute as follows, bearing in mind the stage of procedure and number of auxiliary requests, the Opposition Division has decided to continue the procedure in writing. The Patentee is requested to file his new requests properly typed. A copy of these auxiliary requests will be sent to all parties for comment, together with the Minutes of the Oral Proceedings. The Oral Proceedings are closed. Thank you very much."

SHOUTING - LOT OF NOISE FROM AUDITORIUM

Further statements were then attempted to be made by Opponent I and Harvard:

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[8] Minutes of Oral Proceedings at p.17.

Opponent 1:

"I would like to comment Mr. Chairman if I may."

Harvard:

Mr. Chairman if that is your decision we of course will abide by it but I wish it to be recorded in the Minutes that this decision was reached without hearing either the parties, either the Patent Proprietor or any of the Opponents on this matter. Will you please record that in the Minutes."

Legal Member Opposition Division:

"There is nothing to record in the Minutes. You can comment in writing if you want, but the Oral Proceedings are closed and therefore nothing can be put in the Minutes. The Oral Proceedings are closed."

LOT OF NOISE - SHOUTING FROM SUPPORTERS OF THE OPPONENTS PRESENT IN AUDITORIUM

Opponent 1:

"I have sat patiently during the course of these proceedings and attempted to make representations to you in accordance with the law, the science and the policy. In so doing I have sought to give this tribunal the benefit of any doubt as to the manner in which this matter is considered. In my respectful submission to reach a decision terminating the Oral Proceedings without hearing the parties and without even entertaining a request that this be recorded in writing is, and I will use this word, and I very rarely use it, a fundamental abuse."

CLAPPING AND CHEERING - A LOT OF NOISE FROM AUDITORIUM

Harvard:

"I would like to dissociate myself in public in the unusual way in which this is being handled and I would also like to add that there was no reason for it to be handled in this way. I would further add that I have not even been given a time limit within which to file my requests, which demonstrates the lack of procedural elegance in the way this has been handled."

LOUD CLAPPING AND SHOUTING AND CHEERING - A LOT OF NOISE FROM AUDITORIUM

The Oral Hearing concluded by the dispersal of the Members of the Opposition Division.[10]

Will the Oral Hearing assist the Opposition Division in reaching its Decision?

The Opposition Oral Hearing was unusual not only because of its subject matter but also because of' public interest that it had generated. The Oral Hearing was one of the largest opposition hearings held at the EPO. From the very outset the Opposition Division was anxious to ensure that each Opponent had every opportunity

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9 T173/89 ICI/Gamma-sorbitol (1991) *EPOR* p. 62.

10 The writer has had the opportunity of reviewing the Minutes and notes of the Oral Hearing recorded by Opponent 1 and the Minutes of the hearing recorded officially by the Opposition Division. In addition the writer has had access to the formal EPO tapes of the Hearing.

to make whatever points they wanted during the proceedings. At the beginning of the proceedings the Opposition Division set out the order in which the arguments would be heard and stated this would follow the order as it appeared in the official communication, Articles 53 (b) and (a) EPC being the penultimate and last Articles respectively to be considered. It is interesting to note that the most controversial Articles to be considered were therefore kept until last. It might be suggested that the correct order should have been reversed. The Opposition Division was aware of the arguments to be presented by the Opponents and in the interests of fairness it would have been more appropriate for those arguments under Article 53 (a) to be considered first. This would have also served to prevent the slow drifting away of the Opponents over the course of the Hearing and particularly on the last day. It would also have enabled all the Opponents to make representations with regard to the auxiliary requests filed by Harvard. However, the Opposition Division would not have taken any decision with regard to Articles 53 (a) or 53 (b) and the matter would still have gone into the written proceedings.

During the proceedings Opponent I stated that the only justification to advance the grant of this patent was found in the methods of Claims 16-18, these being the Onco-animals could be used in carcinogenicity testing and testing for anti-cancer drugs. There could be no attempt whatsoever to justify claims 1-15 or 19-22. It was following these observations that the Opposition Division asked Harvard if it would like to make any auxiliary requests, suggesting that Harvard might like to consider claims directed to "experimental animals" rather than to non-human mammalian animals. The Opposition Division Minutes record "replying to a question from the patent proprietors as to what exactly the Opposition Division meant and what might be considered acceptable requests, the Opposition Division said there might also be a wish to consider claims not relating to animals other than experimental animals".[11]

The quasi-judicial nature of the Oral Hearing is clear from the difference in the weight of the evidence to be given to the various experts called by the Opponents and Harvard. One example is the testimony given by Professor Muller on day 3 of the Oral Hearing on behalf of Harvard. Opponent I expressed a wish to ask Professor Muller a question but was denied the opportunity by the Opposition Division. In response to protests by Opponent I, the Opposition Division explained that Professor Muller's remarks were being viewed as statements by a party and not as evidence. There was no cross-examination of the parties or the witnesses during the Hearing.

On the final day Harvard filed further auxiliary requests. Opponents XVII and IX declared that the Opposition Division had 'led' Harvard into drafting and filing their auxiliary requests. It is clear from the EPO Minutes that the Opposition Division was anxious to find a way to confirm the patent which would be acceptable to the parties. One way which seemed relatively attractive to the Opposition Division was by limiting use by including in the claims reference to experimental and testing purposes but as has been discussed in Chapter 5 such limitation offered no limitation to the Patentee at all.

It is worthy of note that the Members of the Division did not ask many questions of the Opponents during the oral hearing. The Members of the Board made few comments and appeared to want to listen to the Opponents present their evidence. This may have been due to time restrictions or, as the Opponents would allege, a view had already been formed. It does appear that inadequate time was given for the Hearing in view of it going on

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[11] EPO Minutes of Oral Hearing para.16, page 16.

late into the second day and until midnight on the third day. The Opposition Division was fully aware of the interest in this case and the number of people who wished to speak considerably in advance of the hearing date.

It is unlikely that the oral hearing will make any significant difference to any conclusion which might be reached by the Opposition Division. Little new evidence was forthcoming despite protracted discussions on the part of some of the Opponents. However, the Hearing will enable the EPO to challenge any criticism that the Opponents did not have the opportunity to fully make their case. Representatives from DuPont or Harvard were conspicuous by their absence from the Hearing, although they were professionally represented by an English patent attorney, Mr. Bizley. It would have made more of an impact on the case if the 'commercial face' of the patentee had been present.

Following the Oral Hearing both Opponent I and Harvard expressed their concern at the manner in which the Opposition Division conducted the proceedings at the Oral Hearing.

The concerns of Opponent I (Compassion in World Farming Supporters and British Union for the Abolition of Vivisection) were set out in a letter to the President of the EPO[12] an extract of which is set out below in order to give an indication of the strength of feeling relating to the way the oral proceedings had been conducted:

"*While we recognise that this was bound to be a difficult case to hear and determine, these Opponents would like to place on record their view that certain aspects of the procedure were not what would have been expected from a public body exercising a quasi-judicial function in an important case.*

At about 6.30 p.m. on Thursday 23November 1995, the third day of the hearing, the Proprietor submitted five auxiliary requests. We believe that the decision to submit these auxiliary requests was strongly influenced by the invitation of the Opposition Division to submit claims directed to "experimental" animals.

The Opposition Division then required both the Opponent I and the Proprietor to make and respond to arguments and evidence on Article 53 (a) EPC well into Thursday evening, despite protests from both parties that it was inappropriate to require the proceedings to continue at that time. The proceedings on that day, which had begun at 9.00 a.m., only ended at about 11.20 p.m. The Opposition Division indicated during the evening that they wished to hear argument directed to the five auxiliary requests the next morning and Opponent I prepared to address arguments on those requests.

At about 9.30 a.m on Friday 24 November, the Proprietor submitted a further two auxiliary requests and a short break was made at about 10 a.m. to enable the requests to be photocopied for the parties. A number of procedural objections were made by other Opponents. When the proceedings resumed, the Opposition Division announced, without warning and to everyone's astonishment, that the Oral Hearing was closed and that further submissions were to be made in writing

None of the parties were given an opportunity to be heard on the matter and the Opposition Division refused to record that fact in the minutes of the proceedings. The objection to this course was universal - from the Proprietor and Opponents alike. Yet the Opposition did not listen to the objection. Instead, they gathered

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[12] Letter to the Opposition dated 3 December 1995.

their papers and left the room without further comment".

Harvard also made its feelings known to the EPO:[13]

"In terms of substantive discussion, with the exception of presentation from two individuals giving purported evidence on behalf of an Opponent, the Oral Proceedings did not reach the issue of Article 53 (a) until the morning of the ostensibly final day, Thursday 23 November 1995. Such an issue against such a background has never before been discussed at the European Patent Office in an inter partes setting.

In the morning of the 23 November 1995 the Opposition Division made the suggestion that parties should consider the "experimental animal" approach, but this was done before hearing all the parties, before hearing the substantive arguments produced by many Opponents, and in particular before hearing the comments of Harvard.

After Harvard had spoken, the situation was clearly different. Not only did the Opposition Division repeat their suggestion having heard most of the substantive argument on behalf of the opponents and having heard Harvard, that with some difficulty it became clear that the suggestion was being made in the context of claim requests only in relation to the Article 53 (a) EPC issue".

However, to put the proceedings in context, it must remembered that whilst the Oncomouse case was before the Opposition Division a number of events had occurred which will almost certainly have a direct bearing on the outcome of the Oncomouse. case. Firstly, the two transgenic plant cases T356/*93Plant Genetic Systems/Glutamine Synthetase Inhibitors* (*PGS*)[14] case and the *Novartis AG/Plant varieties* (T1054/96),[15] were determined and secondly the EU Directive on the legal protection of biotechnological inventions was approved by the European Parliament in July 1998.[16]

The views of those who were present

In January 2000[17] the writer had the opportunity of meeting and discussing various aspects of the Oncomouse case with Dr. Christian Gugerell, Director of Biotechnology at the EPO. Dr. Gugerell has been involved in the Harvard Oncomouse case since its beginning being part of the Examining Division who initially refused application. He is regarded as the spokesperson on behalf of the EPO for this case. Dr. Gugerell was also primary examiner of the Opposition Division and was also Chairman of the Examining Division in the *PGS* and *Novartis II* cases. Dr. Gugerell's comments views are set out here as told to the writer.

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13 Letter dated 28 November 1995.

14 Plant Genetic Systems/Glutamine Synthetase inhibitors (Opposition by Greenpeace) (1995) *EPOR* p.357; *OJ. EPO* 8, p.545; (1997) *IIC* vol. 28, No. 1, p. 75. Decision of Technical Board of Appeal dated 21 February 1995.

15 *Novartis AG/Plant varieties* T1054/96 (1998) p.511; 1999, R. Nott, The Novartis Case in the EPO *EIPR* p. 33; (1998) *EIPR* 11, pN-193.

16 See Chapter 2.

17 Taped interview with the writer held in Munich. 24 January 2000.

On being asked for his views on Oncomouse oral hearing Dr. Gugerell commented:

"I am a member of the Division, our thinking was that there are different ways of conducting the Oral proceedings. It was not easy. Our main consideration was to let people talk, don't give the impression that their right to be heard was violated. That was one of our basic things to observe, because when you can hold oral proceedings more rigidly you can say no you have had your 10 minutes and go ahead with the next one. We deliberately didn't, in order to avoid any kind of criticism that the right to be heard was violated and I think that we achieved this. Nobody could say that the right to be heard had been violated here. The reason why we went back into the written procedure was that most of the parties had left the room at the end and so we could not have decided anyway in the absent of those people, so the only really practical way was to go back into the written phase. I still think that was the right thing to do. It was a bit difficult also because at the beginning we lost a lot of time for a while due to ignorance by some of these parties...".

"One of the representatives said that one of the Members was partial. There was an elderly lady sitting there for another party who said, "when I listen to that it sounds terrible and if you don't make the request then I do". And then half the day was lost at the beginning to sort that out. That was the way it developed and with all these people there everybody wanted to talk and it was difficult... Not many new things came up. Normally oral proceedings are there in order to look at certain different arguments or even to come up with new arguments. That was not really the case here, everything was in writing anyway. At the end it looked like a disaster because all these parties went out of the room, but in essence I would say no it was not a disaster, it was their right to move out if they don't like it. We continue in writing and we will arrive at a decision, that is quite clear".

At the beginning of the hearing allegations of partiality were levelled against both Dr. Gugerell and the Chairman, Mr. Grosskopf. Although the allegations of partiality were put before the Principal Director they were not held to be well founded. Additional allegations of partiality were raised against the Board during the discussions of Article 53 (a) EPC on the third day. In view of the sensitive nature of this case and the fact that it was regarded generally as a test case it is puzzling why the Opposition Division included as one of its members Dr. Christian Gugerell who had been involved in this case at the Examining stage. Although Dr. Gugerell had extensive knowledge of this case in the interests of impartiality it might have been more appropriate for another member to have been appointed.

Some Opponents felt that the Opposition Division had already made its mind up that the experimental exceptions would be acceptable. On being asked did the Opposition Division give an indication that this was the case, Dr. Gugerell responded "Yes, there was an indication made by the Opposition Division. It is more or less normal practice that if an Opposition Division clearly sees that there is something which probably can be saved it is indicated somehow. Of course it is always the threshold to become partial here."

The writer asked the representatives of Opponent I who attend the oral hearing their impressions of the oral hearing. The representative of the British Union for the Abolition of Vivisection[18] commented "I would not call the Oral Hearing a complete farce. It took two or three days and they did listen to us and our arguments. Some of the other Opponents did make very lengthy arguments but we all did get a chance to say our piece. I think the

[18] Interview with Christine Orr (former Political Co-ordinator BUAV) in London 9 December 1999.

problem was that the Hearing terminated abruptly without some of the Opponents having finished making their points and without any decision having been reached. Also there could be some criticism as to the way it was conducted. On the third day it went on beyond midnight. Towards the end, the Opponents tended to walk out because they thought the Hearing was invalid because the Opposition Division was making suggestions to the lawyers for further amendments to the Claims."

Peter Stevenson of Compassion in World Farming[19] confirmed that "the Hearing did go on for a number of days but I felt that we were able to make all our points. I consider that the Oncomouse Case has been successful. We were always fighting an uphill battle. The Opposition Division did indicate a form of claims that from our point of view was more restrictive than those already existing. Some of the Opponents wished to continue to make the same point and it was felt that the Hearing did end rather abruptly. By the time the Oral proceedings were closed on the final day, all the Opponents that were present except ourselves had left."

A Second Oral Hearing

The Oral hearing as a mechanism for enabling parties to discuss the issues under Article 53 (a) appears to have failed in meeting its objective in the Oncomouse case as far as a number of the Opponents are concerned. Neither did the hearing did fully satisfy the objectives of Harvard. During the 6 years that have passed since the hearing, observations have been filed on the auxiliary claim requests filed by Harvard and on the Biotech Directive and the *Novartis II* decision of the Enlarged Board of Appeal.

The Opposition Proceedings are still continuing. Two Members of the Opposition Division have now been replaced, the 2nd Examiner[20] and the Legal Member. The Legal Member has now been replaced by R. Moufang who has already expressed the view that Article 53 (a) should only be considered in exceptional cases.[21]

In a communication of 28 August 2001[22] the Opposition Division gave in a provisional opinion that it considered that matters under Articles 83, 52(2) - 52 (4), 54 and 56 EPC that the conclusions arrived at previously (as reported in the Minutes of the first Oral proceedings) are correct and that it is "therefore the provisional opinion of the Opposition Division that the opposed patent satisfies the requirements of industrial application".

The Opposition Division continued:

> "Whereas Article 53(b) EPC amongst other things excludes from patentability animal varieties, Rule 23c (b) EPC —which is considered to be applicable to the present case — together with Recital 31 of the Directive 98/44/EC, clarifies the article in that animals are patentable subject-matter if the technical feasibility of the invention is not confined to a particular animal variety."

> "New rule 23c (b) and G1/98[23] have brought about an important clarification of the legal situation.

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19 Legal and political director CIWF, interview 25 November 1999.
20 Replaced by A. Nichogiannopoulou.
21 R. Moufang, Patentability of Genetic Inventions in Animals (1989) *IIC* vol. 20, p. 823.
22 Annex to summons of 9 May 2001.
23 Transgenic Plant/*Novartis* II (2000) *OJ. EPO* 3 p. 111.

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The invention as claimed in claims 19-22 clearly represents the situation as addressed by the new Rule and G 1/98. Therefore it is the provisional opinion of the Opposition Division that the claims to animals *per se* do not violate the stipulations of Article *53* (b) EPC. Even if it could be convincingly argued that G 1/98, relating to plants, is not applicable to animals this would not change the situation in view of Rule 23c (b) EPC."

"The terms "ordre public" and "morality" refer to fundamental legal or ethical principles accepted in the EPC contracting states. In accordance with this the Opposition Division is of the opinion that it should not establish its own standards of morality but rather should be guided by the legal situation in all or at least a majority of the member states to the European Patent Convention. If the legal situation allows for the exploitation of a certain kind of invention, as a consequence this inventions should also be patentable under the provisions of this article."

"... . all categoric or "absolutist" arguments pointing out that patents on living matter or patents on animals are generally bad must fail as a matter of principle. Only arguments applying concrete value judgements i.e. the balancing of pros and cons with respect to the subject-matter of the opposed patent, should, in the provisional opinion of the Opposition Division, be used in a convincing argument".

The Opposition Divisions confirmed that Rule 23d (d)[24] was particularly relevant to the present case and called for a "value judgement' continuing "it is proposed to the parties to concentrate on these issues in the discussions under Article 53 (a) EPC in the oral proceedings".

"Concerning the legal situation in the member states of the EPC the Opposition Division would like to point out that the use of animals for experimental or other scientific purposes is allowed under certain conditions in most if not all of the States being party to the EPC. Directive 86/609/EEC regulates this use for the Member States to the EC and similar provisions presently exist in non-EC countries being party to the EPC. In line with the above considerations it follows that for those animals for which the use for experimental or other scientific purposes is permitted a patent cannot be denied in principle. But this also means that a patent should not be granted or maintained if animals are covered by the claims not belonging to this category. Thus, the maintenance of the broad claims (product and process) of the opposed patent (main request), in the provisional opinion of the Opposition Division, is not likely."

"With respect to the auxiliary requests, in particular auxiliary requests No.2 or 2A (with method claim 24 referring back to claim 19) it should be noted that the claim language "said animal being for experimental or testing purposes" is not considered to limit the claims scope when applying the usual standards see Guidelines C-III, 4.8 A product claim to a substance in terms of patent law is normally not limited by indicating its use. This would only be true in a legal environment providing for use-restricted product protection, which does not exist in Europe, or in a first medical use scenario under the EPC. Nevertheless, it may be discussed whether the above language can be seen as a clarification of the intended use of the animals which would be sufficient for considerations of morality. In summary, it will be necessary for the parties at the Oral proceedings to address, in particular, the question whether the above mentioned value judgement as provided for by Rule 23d (d) EPC when applied to the subject-matter of the claims of auxiliary requests No. 2 or 2A may lead to patentable

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[24] "Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animals, and also animals resulting from such processes" are

subject-matter or not."

Article 23 (d) was held by the Opposition Division as being "particularly relevant with respect to the present Case" and proposed that the parties concentrate on these issues in the discussions under Article 53 (a) EPC during the oral proceedings.

Following the provisional opinion, Harvard filed written submissions in response on 6 September 2001. Harvard sought the right to be allowed during the opposition proceedings the opportunity to amend the auxiliary claim requests if necessary and requested "the normal practice in this respect, particularly given the astonishing past history of this matter, and the developments at the previous Oral Proceedings in November 1995".[25] Harvard requested maintenance of the Patent on the basis of any of the claim requests filed i.e. the Main Request (claims as granted), Auxiliary Request 1 or 1A, Auxiliary Request 2 or 2A, or Auxiliary Request 3 or 3A, or Auxiliary Request 4 and went on to comment that in view of the date of the first substantive preliminary view issued by the Opposition Division that this left "very little time indeed for an assessment of the comments of the Opposition Division".

Harvard confirmed who would be presenting evidence on Harvard's behalf at the hearing to support that there were substantial medical benefits associated with the Harvard animals and discussed the background to Article 53 (a). Harvard further stated that in its view Rule 23d (d) could not legally be applied in the case. Harvard proposed that it was apparent that the Rule relates to the question of 'potential' rather than just matters of fact established at the European filing date. Harvard proposed that this was clear from the qualification of the clause by the words "likely to cause" suffering. Harvard also proposed that the term "medical benefit" should normally and naturally receive a very wide interpretation as evidenced by Recital 45 of the Biotech Directive, namely, "The substantial medical benefit referred to above included any benefit in terms of research, prevention, diagnosis or therapy". Harvard further argued that "a new Rule should not and must not be applied retrospectively in a way which is unfair to the legitimate expectations and rights of a Patentee".

Harvard concluded "should the Opposition Division be inclined to view any of the present requests as contrary to Article 53 (a), the point will be argued that this Article cannot properly be applied to deny the rights of the Patentee in relation to a technology which could not have been envisaged by the legislature or the EPC itself".[26]

Three days have been allowed for the second oral hearing which is due to be held between 6-8 November 2001. Such an action by the EPO is most unusual and is a clear recognition of the importance of this case and of the unsatisfactory nature of the earlier oral hearing. It is hoped that some important lessons have been learnt from the earlier hearing.

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excluded from patentability.

25 Section A. at second paragraph p.1.

26 Section D4 Patentee's Submissions dated 6 September 2001.

Chapter 7

The Implications for the European Patent Office of the Harvard Oncomouse Case

"The thoughtless things that scientists sometimes say do add to public perceptions that they are Frankenstein-like and inhumane. For instance, I have heard distinguished scientists on public platforms saying that the breeding of animals as disease models raised no new ethical issues – because we have always used animals as disease models. Well, if making a transgenic animal with a predisposition to disease is not an ethical issue, what on earth is?"

Bernard Dixon OBE former Editor of New Scientist[1].

"Obviously it would have been much nicer for example if Tracy[2] had been the first case, because then it was not such an awkward case where animals die. Then probably the public perception would have been different and you could have said, well, Tracy must have been a very happy animal or it would have not reproduced, so that would have been much easier if that had been the case, but it wasn't".

Dr. Christian Gugerell
Director European Patent Office[3]

"Absolute morality is the regulation of conduct in such a way that pain shall not be inflicted"

Herbert Spencer[4]

The preceding chapters have given a detailed account of the progress of the Oncomouse European patent application before the EPO and the impact on it of the PGS and *Novartis II* decisions and the coming into force of the Biotech Directive. The present chapter will look at the difficulties faced by the EPO in the interpretation of the morality exception taking into account the existence of competing concepts of morality, the influence of European and national regulations and prior EPO decisions. The implications of these, together with the evasive approach of the EPO in the Oncomouse case, for the future structure of the EPO are discussed and lead to the conclusion that an Ethical Board of Appeal or Ethical Division is required to be established by the EPO in order to deal satisfactorily with morality and ethical issues.

The Scope of the Morality Exception

The principal aim of reviewing the Oncomouse case was not merely to chronicle the arguments put forward by the various parties in the proceedings but to provide the background from which to assess the ability of the EPO to provide an adequate system for consideration of the morality exception in general and in relation to animals in particular.

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1 2001 (February) Arthur Andersen, *Managing risk, building value risk management in the UK life sciences.* (February 2001 Arthur Andersen) Chapter 3, p. 95. Questions and Answers.

2 Transgenic sheep created by PPL Therapeutics and the Roslin Institute, Scotland (creators of Dolly the sheep). Modified to produce alpha-1-antitrypsin in her milk for use as a treatment of the symptoms of cystic fibrosis in humans. EP application 87 904286.9. PCT/GB87/00458.

3 Taped Interview with Dr. Gugerell on 24 January 2000 at EPO in Munich (conducted in English).

4 Herbert Spencer 1891, Essays, Vol. iii p. 152.

The arguments put forward by the Opponents during the Oncomouse case were broadly identified in categories, namely, the intrinsic evil of animal experimentation, the ineffectiveness of animal experimentation and the efficacy of the invention, the dignity of animals and animal welfare, public opinion, religious objections, the right to the natural world, the risks associated with genetic modification and human dignity. Whilst these categories are not proposed to be exhaustive they do provide examples of the type of morality arguments with which the EPO has had and will have to deal. During the prosecution of the Oncomouse patent application, the matter was subjected to a detailed examination by the EPO on four occasions, twice by the Examining Division and once by each of the Technical Board of Appeal and the Opposition Division. Notwithstanding this, the fundamental question 'are animals patentable subject-matter under Article 53 of the EPC?' still remains unanswered.

The EPO's view of its function was summarised by the Technical Board in the *PGS* case:

" The function of a patent office is to grant patents, that is exclusive rights to make use of inventions claimed in said patents for a limited geographical area and for a specified time. The Board agrees with the Appellants' submission that patent offices are placed at the crossroads between science and public policy. However, at this crossroads patent offices are not alone, but finds itself side by side with an increasing number of other authorities and bodies, whose function is *inter alia* to ensure that the exploitation of a given technology, regardless of whether it is protected by a patent or not, takes place within the regulatory framework provided by laws, international treaties, administrative provisions, etc".[5]

The difficulties faced by the EPO in interpreting the patenting provisions of the EPC and particularly Article 53 (a) may be summarised as follows "While in many other situations patent law has been able to accommodate alien concepts within its own logic and procedures, in its encounter with the ethical, patent law is now confronted with a set of problems for which it manifestly lacks not only an appropriate conceptual, procedural, or institutional framework, but also a suitable language".[6]

Patent law in Europe has been described by one commentator as being "a mess" and being "at the centre of the swamp is a largely unaccountable organisation called the European Patent Office, based in Munich. .....The EPO is a dinosaur left over from an earlier age of European Cooperation. .....It is its own court of appeal. In theory it is answerable to Convention signatories, but in practice, it is left to its own devices."[7]

<u>Differing Conceptions of Morality</u>

It cannot be denied that the EPO does have a difficult task in applying the morality exception to patentability. Morality has been examined extensively by philosophers over many hundreds of years and has been succinctly defined as "an informed public system applying to all rational persons, governing behaviour that affects others, and includes what are commonly known as the moral rules, ideals, and virtues and has the lessening of evil or

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5 *PGS*. Paragraph 18.3, page 23, Reasons for Decision T356/93.

6 L. Bartley & B. Sherman, The Novelty of Patenting Life? (1997) Occasional papers Series 2 (*Property Rights in the Human Body*), Eds. K. Stern & P. Walsh Kings College London, Centre of Medical Law and Ethics p. 4.

7 Quoted in article by J. Meek and P. Brown, 'How US Muscle bent the rules in Europe' (Wednesday 15 November 2000 *The Guardian*) Special Report Patenting Life p. 11.

harm of as its goal". [8] By way of additional explanation this commentator stated that "some general kinds of actions are commonly regarded as immoral unless one has a justification for doing them; among them are killing, lying, stealing, committing adultery, breaking a promise, cheating and causing pain".[9] Morality can be seen to exist at different levels, from that of the individual, to that of an organisation, like a company or even an institution like the EPO, to that of an individual country or as in the EU, a group of countries.

Ethics is the application of moral values[10]and different areas of ethics have been distinguished, for example Environmental Ethics[11] and Bioethics. The latter is a term used widely in the biotechnological field and is of particular relevance in considering the Oncomouse case being defined as "the systemic study of human conduct towards life, examined in the light of ethical values and principles".[12]

Consequential ethics deems an action right or wrong because of the effects of its consequences. The consequences of an action vary according to the circumstances in which it is performed.[13] An intrinsic ethical framework deems an action right or wrong in itself rather than as a result of its consequences. A consequentialist approach was adopted by the EPO in the Harvard Oncomouse case. The approach of the EPO in the Oncomouse case being based on arguments put forward against a pre-existing moral background. But how can a consequentialist view be balanced against a deeply held inherent ethical position?

It has been observed that "Biotechnologists and lawyers are wary to talk of ethics". [14] This might be because of the difficulty in defining what this is. Ethics may have many different meanings. A utilitarian argument is most often given by those attempting to justify the patent system or its extension to a new industry.[15] Utilitarianism claims the ultimate good to be the greatest good of the greatest number. Actions are deemed right or wrong depending on their contribution to the general good. Utilitarianism allows a certain amount of suffering to some providing a greater number of others receive a benefit.

D. Beyleveld and R. Brownsword suggested four criteria that EPO examiners might use in determining when an invention is contrary to morality. In summary these are the cultural morality of the Contracting States; some philosophical theory of morality; such subjective criterion as the examiners wish to personally employ; and a criterion consistent with "right thinking" or "reasonable" members of the communities of the EPC Contracting States.[16] These commentators proposed that the criterion of moral permissibility to be assessed under Article 53 (a) EPC was "the critical cultural morality of the emerging European legal community".[17]

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8 G. Gert, *Morality Its nature and justification* (Oxford University Press 1998) p. 26.
9 ibid. p. 111.
10 S. Aldridge, Ethical Dilemmas (1998) *New Scientist* Inside Science No.14 p.1
11 S.F. Sapontzis, *Morals, Reason and Animals* (Temple University Press USA 1987) p. 249.
12 Parliamentary Assembly of the Council of Europe, Forty-Fourth Ordinary Session, Recommendation 1213 (1993) on developments in biotechnology and the consequences for agriculture.
13 P. Singer *Practical Ethics*, (Cambridge University Press 1993) 2nd Edition p. 3.
14 D. Beyleveld and J. Kinderlerer, About Biotechnology Law and Ethics (1995) *BINAS* News vol. 1 issue 2.
15 M. Svatos, Patents and Morality: a philosophical commentary on the conference 'Biotechnology, patents and morality' in S. Sterckx *Biotechnology, Patents and Morality* (Ashgate Publishing Co. 1997) ch. 31 p. 291.
16 See D. Beyleveld and R. Brownsword, *Mice, Morality and Patents* (Common Law Institute of Intellectual Property 1993) p. 64.
17 ibid. p. 73.

But exactly whose morality is acting as the standard for the EPO? As we are dealing with a European Convention is it the cultural morality of every country in Europe? Is there a lowest common denominator against which morality is calculated? Morality like love extends beyond geographical boundaries. Also as we have seen in Chapter 1 morality in each European country is different. The Opposition Division in the *PGS* case[18] attempted to answer these questions. In the Greenpeace *v. PGS* decision[19] the Opposition Division refused to consider morality except only in extreme cases. But the idea that an examiner can only consider morality if the invention is clearly immoral is self-contradictory[20] and more than a little absurd.

A general moral is unchanging and unchangeable; discovered rather than invented. It is not dependant on the will or decision of any person or group of persons.[21] But under Article 53 (a) the EPO will be the arbiter and will have to assess inventions against a moral standard.

Sentientism as experienced by Herbert Spencer in the quote at the beginning of this chapter might be to some an appropriate moral position for the EPO to adopt. However, determining the level of suffering of an animal may be difficult as there may be mental as well as physical suffering. In practical terms a framework is needed for the EPO from which it can consider ethical issues based on other approaches such as biblical principles,[22] environmental ethics, risk/benefit assessment, as well as the social dimension. Alternatively, humanist principles might be adopted which recognise that only human beings have moral rights[23] and that animals are not man's moral equal.[24] Neither of these approaches would satisfy the animal welfare or environmental groups Indeed as one commentator stated "The judgement that human life is more valuable than animal life is purely anthropocentric one. If animals could express their views on the matter, they would have a different story to tell".[25]

Suffering is a central concept of morality. Animal suffering is a constant factor which keeps arising throughout the Oncomouse case; the Opponents claiming that the animals the subject of the invention are bred to suffer and die, Harvard responding that a certain level of suffering is acceptable and the Technical Board producing a weighting or balancing test in which animal suffering does form part of the equation. In view of the fact that animal experimentation in respect of drug approvals is widely undertaken there seems to be a general view by those in medical research and the pharmaceutical industry that some animal suffering is acceptable if a benefit to man is the end result however small. Some Opponents argued in the Oncomouse case that if the use of such animals was considered intrinsically immoral then no degree of suffering could be considered acceptable.

Dr. Gugerell's response when asked if animal suffering was acceptable under Article 53 (a) was not unexpected as his comment at the beginning of this chapter might suggest:

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18 M. Llewelyn, Greenpeace v. Plant Genetic Systems NV (1995) *EIPR* 10, p. 506;

19 (1993) *IIC* vol. 24, 5 p.618.

20 L. Bentley, Sowing Seeds of doubt on Onco mouse Morality and Patentability (1994) *The King's College Law Journal* p. 188.

21 G. Gert, *Morality Its nature and justification* (Oxford University Press 1998) p. 113.

22 ibid p.117. One of the more popular definitions offered to distinguish moral rules from others is religious: moral rules are the rules given by God.

23 S.F. Sapontzis, *Morals, Reason and Animals* (Temple University Press USA 1987) p. 52 and 154.

24 M.A. Fox, *The Case for Animal Experimentation An Evolutionary and Ethical Perspective* (University of California Press 1986).

25 M.A. Fox, *The Case for Animal Experimentation An Evolutionary and Ethical Perspective* (University of California Press 1986) p. 82.

"There are clear cases where an animal is likely to suffer, the Oncomouse would probably suffer before it dies, Tracy will probably not suffer, but there are many cases in between where it will be rather difficult to say whether the animal suffers or does not. And again when you look at this one rule or the Article in the Directive, there are two points namely the suffering aspect and the substantial medical benefit question, where we really only have assumptions and no proof whatsoever and therefore it would be extremely difficult to examine that. Our thinking goes in the direction that we will look at the laws of our Members States what the laws say in this direction. For example when you are talking about test animals, the use of test animals is allowed even by the new Directive, so it would hardly be appropriate for us to say the use of test animals is immoral if it is allowed by the new Directive. To one it is allowed and to the other, the Patent Office would say don't do it, but it would be rather inappropriate to do so if it was allowed on the one hand, we say nobody gets a patent because it is not moral. So that is the basic idea, according to which we will be led to arriving at decisions."

The guiding principle of the EPO must be that it has a duty to search for a common morality code but not to invent one.[26]

It has been proposed by certain commentators that the European Convention on Human Rights (ECHR) being a constitutional legal document in an emerging European Legal order could play a foundational role in specification of European critical cultural morality.[27] This might at first seem strange when considering the patentability of animals but it is proposed that "the values of the ECHR are to be interpreted so as to preclude inventions the development of which cause suffering to animals that are not required to protect more important interests of other animals or human beings, and animals so produced".[28]

Competing Interpretations of the Morality Exception

There is a large consensus that the interpretation of the EPC should, on the one hand, respect the principles laid down in the Vienna Convention on the Law of Treaties ("Vienna Convention")[29] and on the other hand, observe the principle of harmonised interpretation. This latter principle, though not dealt with by the provisions of the Vienna Convention, is of particular importance where, as in European patent law, an international treaty provides the basis for the rights and duties of individuals and corporate bodies and where its provisions have then been incorporated into national legislation.[30]

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26 J. Straus, Patenting of Human Genes and Living Organisms – The Legal situation in Europe in F. Vogel and R. Grunwald (Eds), *Patenting of Human Genes and Living Organisms* (Springer 1993).

27 D. Beyleveld and R. Brownsword, *Mice, Morality and Patents* (Common Law Institute of Intellectual Property 1993. R. Moufang Patenting of Human Genes, Cells and Parts of the Body? – The Ethical Dimensions of Patent Law (1994) *IIC* vol. 25 p. 487.

28 D. Beyleveld, Regulating Morality through patent law. Critique of the EC Directive *Law and the Human Genome Review* 2000 vol. 12, p. 165.

29 G5/83 (1985) *Eisai/Second medical indication OJ. EPO* p. 64. Decision confirmed that whilst the Vienna Convention is not directly applicable to the EPC its principles can be referred to as they recognise international practice.

30 The Enlarged Board of Appeal in *Novartis II* Decision page 2, General rules of interpretation of EPC provisions.

The Vienna Convention provides[31] that

"1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

.....

3. There shall be taken into account, together with the context:

(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;

(b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation".

The Technical Board in Oncomouse case provided a 'weighting' or balancing test to be applied in assessing the morality criterion and which has been expanded further in the Biotech Directive. In addition to the Oncomouse case other cases have come before the EPO in which Article 53 (a) EPC was considered and give additional guidance on how the provision has been interpreted.

As we have seen in the earlier chapters of this study, the Biotech Directive and the European Patent Office Guidelines[32] are of assistance in interpreting Article 53 (a) EPC. The Guidelines provide two distinctive tests, the "public abhorrence" test and the "unacceptability" test.[33] The Biotech Directive expanded the Oncomouse weighting test by confirming in Article 6 2 (d) that processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animals, and also animals resulting from processes shall not be patentable.[34]

Prior to the Oncomouse case all reported cases relating to the genetic modification of living material had related to micro-organisms or plants. However, when considering the patenting of animals the EPO appears to have simply applied these principles directly to animals. Such an approach does not recognise the fact that the legal background to the protection of plants and animals is historically quite different and the fact that additional protection of plant varieties is available to plant breeders by virtue of plant breeders rights. No such additional equivalent right exists for the protection of animals.

This may seem a contradiction to the basic premise that the EPC should be applied in the same manner to all inventions but by virtue of Article 53 EPC animals and plants have been identified as special cases. Prior to the Oncomouse case the morality exception had not been widely used to challenge patentability, but those cases which have come before the EPO in which Article 53 (a) EPC was discussed, do give some guidance.

In a similar case to that of the Oncomouse, *Upjohn's Application,* European patent Application No. 89913146.0, relating to 'Transgenic mice for the Analysis of Hair growth' the interpretation of the morality exception was used to prevent Upjohn from successfully patenting a hairless mouse for the investigation of treatments for baldness. In this case the application was refused in July 1993 on the grounds that the invention

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31 Article 31 General Rules of Interpretation, Vienna Convention on the Law of Treaties 1969.

32 EPO Guidelines C-IV, 3.1. The Guidelines are for guidance only and have no greater authority.

33 A. Warren, A mouse in Sheep's clothing: The Challenge to the patent Morality Criterion Posed by Dolly (1998) *EIPR* p. 445.

34 EPC Implementing Regulation 23.

lacked inventive step and that the invention was not patentable by virtue of Article 53 (a) EPC. The application was later abandoned by the applicant following ongoing objections by the Examining Division.

The Upjohn mice were so engineered to develop tumours in response to being exposed to potential hair restoratives the invention being described as "a transgenic, non-human mammal having a recombinant transgene comprising a promoter sequence from a gene which codes for a hair specific protein and a reporter gene".

The Examining Division in its objections to the application under Article 53 (a) stated:

"The case "Harvard/Oncomouse" relates to transgenic animals (particularly mice) which are useful in testing the carcinogenicity of substances. The animals are exposed to these substances and easily develop cancer if the substances are dangerous in this respect. There is no doubt that a certain amount of animal suffering is involved in carrying out these tests. The present case relates to transgenic animals (particularly mice) which are useful for studying hair growth, in particular the screening agents that influence wool production and hair growth. The animals carry a promoter of a gene coding for a hair-specific protein linked to a reporter gene which may result in an observable phenotype. In one of the specific embodiments of the invention the reporter gene is an oncogene, in particular a RAS gene. The animals transformed with this gene are prone to develop cancer when used in tests, which therefore cause animal suffering. The Examining Division therefore concludes that the present application, to the extent that it refers to oncogenes as reporter genes, has to be considered in the same way as the Board ordered for the Harvard/Oncomouse".[35]

Continuing the Examining Division stated:

"Irrespective of how the Examining Division will decide in the latter case, a negative result is obtained in the present case when the same kind of weighing up is carried out: the limited usefulness to mankind of the present invention does not, in the opinion of the Examining Division, justify the animal suffering".

"The usefulness of the invention lies primarily in the screening of agents which promote wool production or (human) hair growth. Both of these uses, although commercially interesting, do not contribute to mankind something that is urgently needed, as a contribution to the development of a new or improved medical treatment often is. Hair growth and wool production are not connected with any kind of serious thereat to human beings as is for example cancer. Consequently the suffering of animals which is invariably connected with the use of the inventions and which is in principle contrary to the morality under the terms of Article 53 (a) EPC, preponderates over the usefulness of the present invention to mankind. ..... Therefore, the specific features of the invention relating to oncogenesis reporter genes are immoral under the terms of Article 53 (a) EPC."[36]

In the *Upjohn* Decision the Examining Division was rather cavalier in its approach to possible environmental risks as the mice were intended for laboratory use only and that there was no intention of releasing the animals in the wider environment, stating:

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35 Communication of the Examining Division 27 September 1991 p. 3.
36 ibid. p. 4.

"Therefore the risk of an uncontrolled release is practically limited to intentional misuse, or blatant ignorance on the part of the laboratory personnel carrying out the tests. The mere fact that such uncontrollable acts are conceivable cannot be a major determinant for deciding whether a patent should be granted or not".[37]

Notwithstanding the balancing test set out by the Technical Board in the Oncomouse case, in the *PGS* decision the Opposition Division expressly refrained from performing this balancing exercise.[38] The Opposition Division went on to say that "Harvard does not superseded the general approach that Article 53 (a) is to be invoked only in rare and extreme cases but should be regarded as an exceptional case relating only to the patenting of animals".[39] Thus it is puzzling on the one hand that animals are treated as any other object when considering patentability but are regarded as a special case and eliciting its own 'test' when it is convenient for the interpretation of the EPO.

Whilst this case is now regarded by the EPO as an unsound decision[40] the *ratio decidendi* of the Technical Board of Appeal must be borne in mind by the EPO when determining the morality exception. In this case the Technical Board gave an indication of its thinking on the concept of morality as the following extracts from the Reasons for the Decision show:

"As is apparent from the historical documentation, the EPC Working party recognised that "there was no European definition of morality". Its members were, therefore, unanimously of the opinion that the "interpretation of the concept of morality should be a matter for European Institutions.[41] Thus, prior to any assessment of the patentability of the claimed subject-matter under Article 53(a) EPC, the meaning of these concepts must be defined by way of interpretation".[42]

"The concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is not in conformity with the conventionally-accepted standard of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality".[43]

"*.... the question whether Article 53 (a) EPC constitutes a bar to patentability is to be considered in each particular case on its merits*".[44] (writer's emphasis)

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37 ibid p. 5.
38 (1993) *IIC* vol. 24, 5, para. 3.16 p. 624.
39 (1993) *IIC* vol. 24, 5, para.3.7 p. 621.
40 Interview with Dr. Christian Gugerell on 24 January 2000 "This was not really the best decision I would say which was handed down, because it said it was not admissible (before the Enlarged Board of Appeal), because there was no contradiction, but there was a clear contradiction in our eyes. It was very strange, so we had better forget about that decision. I do not want to talk about that decision, as this is the Enlarged Board decision, but it was not a good decision. So what we had to do in the end was to refuse another case, that was the *Novartis* case.... This was luckily enough referred by the Technical Board, because the Technical Board also realised that the criticism that was raised everywhere, so they felt more or less obliged to.... This referral decision was again very negative and confirmed *PGS*".
41 Document IV/2767/61-E, page 7.
42 *PGS* Reason for Decision T356/93 paragraph 4.
43 ibid paragraph 6.
44 ibid page 19.

The Opposition Division continued the debate:

"The-Opposition Division sees no obligation imposed by Harvard[45] to perform an analogous balancing exercise in the present case. Harvard does not supersede the general approach that Article 53 (a) EPC is to be invoked only in rare and extreme cases but should be regarded as an exceptional case relating only to the patenting of animals, moreover - in the specific case in question - of animals used as test or models in an assay where suffering is unavoidable". [46]

and went on further:

"…. the Opposition Division is of the opinion that opposition proceedings before the EPO are not a proper forum for discussing the pros and cons of the genetic engineering of plants in general or the present plants in particular. The present invention does not belong to that extreme category of inventions which could be regarded as so abhorrent to the vast majority of the public as to render the granting of a patent inconceivable and thus excluded under Article 53 (a) EPC. Apart from such clear-cut cases, the EPO has no mandate to refuse patents on the basis of abstract ethical and moral arguments. The Opponents first argument that the patenting of higher life-forms is in principle unethical is a philosophical argument which cannot be accepted in the absence of any standards of absolute morality. As far as the potential risks associated with the exploitation of the invention are concerned, the Opposition Division, in view of the disagreement within the scientific community concerning this point, does not see any possibility of determining the morality of the invention on the basis of what amounts to a risks/benefits assessment. …….. The assessment of risks and the consequent regulation of the exploitation of the invention are a matter for other bodies to consider; they are outside the scope of the EPO. The Opposition Division thus expressly refrains from performing the balancing exercise required by the Opponent and considers that the disputed patent does not offend against the provisions of Article 53 (a) EPC".[47]

Objections under the morality exception were considered by the EPO in two cases which human materials, rather than animals, were involved. In the first, the *Relaxin*[48] decision the patent application was rejected by the Examining Division on the grounds of non-patentability under Article 53 (a) EPC. In this case[49] the Howard Florey Institute was granted a European patent (No. 112,149) for a DNA fragment encoding human H2-preprolaxin a hormone capable of influencing smooth muscle contraction. The patent was granted in 1991 and then opposed. It was unsuccessfully argued in the Opposition proceedings that exploitation of the invention was an offence against human dignity. The exploitation of the condition of pregnancy of a woman was a form of modern slavery and was inherently immoral.

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45 Referring here to earlier Oncomouse case.

46 Facts and submissions 15 February 1993 Opposition Division, paragraph 3.7 page 11.

47 ibid., paragraph 3.16 page 17.

48 Discussed in Chapter 1.

49 Howard Florey/ Relaxin (1995) *EPOR* p. 541. Application No. 83 307 553.4. Howard Florey Institute of Experimental Physiology and Medicine. Appeal against decision of Opposition Division submitted by members of the Green Party in the European Parliament against European patent No 0 112 149. Daniel Alexander (Counsel for Opponent I in the Oncomouse case) acted for Opponents/Appellants. Decision on admissibility of appeal and identity of Appellants interlocutory decision to send to EBA (G3/99) 15 April 1999. Decision to grant patent 1 March 1991.

The second case related to European patent EP 695,351[50] granted in December 1999 to the University of Edinburgh, relating to 'the Isolation, Selection and Propagation of Animal Transgenic Stem Cells'. Certain claims referring to "a transgenic animal". The Decision to grant the patent was issued and dated 28 October 1999 notwithstanding that reference was still made in the claims to transgenic animals. Over 10,000 people filed objections including the governments of Germany and the Netherlands. 13 valid oppositions from five different countries[51] were recorded all raising arguments under Article 53 (a) EPC. However, by a Communication of the EPO dated 14 April 2000 the Opposition Division confirmed that the patentee had filed amended claims to request the words "non-human" be inserted before "animal" in claims 47 and 48.

The weighing up test proposed by the TBA is believed by Opponent I to be the correct test. However, this has been diluted down by the Opposition Division in its further arguments and in its last provisional opinion by stating that if a procedure is allowed by law then it should be patentable. The EPO is clearly sensitive to the lack of clarity even with the cost/benefit calculation being incorporated into the EPC by virtue of the Biotech Directive. A cost benefit calculation is required to be undertaken under Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[52] and is therefore not a new idea. The proposed test but forward by the TBA is not inherently impossible to determine and forms a framework from which the morality exception may be considered.

<u>The EPO and the Oncomouse Decisions</u>

The various decisions of the EPO in the Oncomouse case can be described at best as cautious and at worst evasive. every decision issued in this case by the EPO being qualified by a cautionary statement. This may be associated with the EPO's awareness of the increasing interest and concerns of the general public in relation to the products of genetic engineering and particularly those of religious, environmental and animal welfare groups.

The Editorial of the 1991 Annual Report of the EPO, which was published after the grant of the Oncomouse patent, openly acknowledged the uncertainty surrounding any decision taken by the EPO on animal patenting:

> "The new factor in the present situation is the growing concern of society about a technology which is already established as a legitimate area of scientific enquiry, but which has recently become a subject of public controversy, thereby focusing attention on issues which have so far had little bearing on the European patent grant procedure".[53]

> "In the case of the Oncomouse, this reassessment has not yet been completed. In the course of the forthcoming opposition and appeals proceedings, further insights will doubtless emerge concerning the patentability of transgenic animals and plants. Hence it would seem that the granting of a patent for the Oncomouse is merely a transitional stage in a long-term process whose eventual outcome remains uncertain".[54]

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50 Of priority date 21 April 1993.

51 including Greenpeace Deutschland e.V.; Alliance pour Les Droits de la Vie; Bündnis 90 die Grunen – Bundestagsfraktion; "Kein patent auf Leben", Acktion Leben Österreich.

52 (1986) *OJ.* No. L

53 EPO *Annual Report 1991*, Editorial p. 9.

The reluctance of the EPO to give any definitive view on the patenting of animals was again exhibited on the granting of the patent following the further examination by the Examining Division, the EPO this time taking the unusual step of issuing a communication at the same time in which it concluded "It should be stressed that the above considerations apply solely to the present case and that other cases of transgenic animals are conceivable for which a different conclusion might be reached in applying Article 53 (a) EPC".[55]

The evasiveness of the EPO in the Oncomouse case has led to much criticism, including that the EPO was failing the patenting community by not giving much needed answers to fundamental questions. The EPO's approach being described as being entrenched.[56] But could the EPO's caution be viewed as arrogance in its approach to the interpretation of the EPC? One commentator summarised the position "The culture and tradition of the EPO is such that they are a law unto themselves".[57]

In 1992 during the prosecution of the Upjohn European patent application the Independent[58] newspaper disclosed that the EPO was reconsidering its stance on the patenting of living organisms. This was based on information that it had obtained in a leaked memo from the EPO in which the President of the EPO suspended all communication between his staff and patent applicants referring to animal patents while a review took place. The article stated that the President had told his staff to "use extreme care with regard to any future decisions" in relation to similar subject matter.

The EPO might try to justify its approach in view of what appears to be a change in emphasis in the thinking of the European Parliament and the Council by two Decisions in 1993. In the European Parliament on a Common motion where the following resolution was passed on 11th February 1993, on a vote of 178 to 19:

"WHEREAS the European Parliament has had lengthy debates on this issue and in October 1992, adopted an amendment which states that transgenic animals engineered to suffer "shall at all events be deemed incompatible with public order and consequently unpatentable" whereas the Onco-mammals clearly fall into this category;

1. Declares its resolute opposition to the granting of a patent for the Harvard/DuPont Onco-mammal on the grounds that it contravenes the European Patent Convention;
2. Calls on the European Patent Office to revoke the patent for the Harvard/DuPont Onco-mammal and not grant any further applications for animal patents until the legal uncertainties have been clarified;
3. Calls on the Commission and the Council to support the strongly-held view of Parliament in this matter in relevant EC legislation;
4. Instructs its President to forward this Resolution to the European Patent Office, Commission, the Council, the governments of the Member States, and the governments of the other Contracting Parties of the European Patent Convention".

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54 ibid. p. 16.
55 Annex to Form 2035.3/2004 – Comments, 4 (vi), p. 6.
56 January 2000 *The CIPA Journal* p. 14.
57 Professor Deryck Belyeveld, Head of the Sheffield Institute of Biotechnological Law and Ethics, quoted in article by J. Meek and P. Brown 'How US Muscle bent the rules in Europe (Wednesday 15 November 2000 *The Guardian*) Special Report Patenting Life p. 11.
58 S. Watts, Backlash blocks 'invention' of animals, (30 November 1992) *The Independent.*

Later that year there followed recommendation 1213 (1993) of the Parliamentary Assembly of the Council of Europe in a debate on 12 May 1993 (34th Sitting) which showed the recognition of the importance of bioethics not only by the EPO but by the institutions of the European Community and provided:

"9. The Assembly .... Recommends that the Committee of Ministers:

extend its work on bioethics (that is the systematic study of human conduct towards life, examined in the light of ethical values and principles) to include issues related to the production, release, use and trade of new or modified living organisms, animals and plants or food and non-food products and work for a European harmonisation of legislation in this field;

invite the European Community and the European Patent Office to take part in this work.

10. Furthermore, the Assembly asks the Committee of Ministers to call on governments of Member States and the Commission of the European Communities:

.....

ix. To adopt a cautious policy with regard to the granting of patents for biotechnological inventions and applications so as to take due account of ethical considerations and environmental safety concerns;

x. to encourage the inclusion of bioethics in the training of specialists in the field of biotechnology and favour the development of professional ethical norms for work regarding biotechnologies and their applications – including the setting up of professional bodies at institutional, European and international levels".

The EPO has never felt comfortable dealing with the morality exception, the Examining Division in the Oncomouse case stating:

"In considering all the above, and particularly also considering that the present invention might have a beneficial effect on mankind, the Examining Division concludes that patent law is not the right legislative tool for regulating problems which may arise in view of the dangers mentioned in paragraph 10.1".[59]

The EPO must bear some criticism for the ongoing problems and uncertainties regarding the interpretation of Article 53 in relation to animals that it has inflicted on the biotechnological patenting community. The failure of the Technical Board to seek an opinion of the Enlarged Board of Appeal in deciding that "it would be premature to refer any of these questions to the Enlarged Board of appeal before the department of first instance has reconsidered the basic problem in interpreting Article 53 (a) and (b) EPC in the light of the Board's present decision", [60] the Technical Board did a great disservice to the biotechnological patenting community.

It may be asked why didn't the Technical Board refer these questions to the Enlarged Board. Despite the Technical Board's view that such referral would be premature, there is no satisfactory answer to this unless it was clear in the mind of the Technical Board that the patent would be granted by the Examining Division upon referral.

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59 Decision of Examining Division dated 14 July 1989, p. 11.

60 Oncomouse. Decision of Technical Board of Appeal, 3 October 1990 T19/90 p. 21.

If the Enlarged Board had given an opinion at this critical time it would have been hoped that this would have avoided years of uncertainty. Despite there being as the writer believes a conflict between the decisions of the Oncomouse and the PGS case to justify the referral it would have provided the EPO with an opportunity to take a lead and offer some guidance on the patenting of GM animals.

It is therefore not surprising that following the Oncomouse case there have been a number of calls for revision of the role of the EBA which were again revived after the *PGS* case.[61] One such proposal is that the legal members of the EBA should be national judges[62] and thus would be adequately 'judicially' equipped to deal with any referrals.

As well as the EPO's failure to refer specific questions to the EBA,[63] the EPO may also be criticised for the inordinate amount of time which it has taken to reach a decision on this matter. The Oncomouse patent application was filed in June 1985 and 16 years on the case is far from resolved and a final decision may not be taken for possibly another 4 years.

In discussions with Dr. Christian Gugerell the writer raised the question of the delays encountered during the prosecution of the Oncomouse application.[64] In response to being asked why this case had taken so long to be dealt with he responded:

"We get so many cases where we are under heavy pressure to do PCT examination work and this is so bad that we can't do proper Euro examinations anymore. We are recruiting like mad, but as we recruit we get more and more Chapter II work under PCT and now it is for years that my examiners work almost exclusively under Chapter II. That is different and has nothing to do with this, but it is an explanation why that most of these cases are still untouched and not even assigned to Divisions, and therefore there is no waiting of most of these cases don't wait for being granted because of this problem, they just wait for examination."....."We are recruiting like crazy, and I would say we use 100% of our training capacity already, and as more as we have to train, the least capacity we have for examination, but without recruitment, it is a vicious circle. Without recruitment we will never solve the problem, so at the moment we are in this stage where we have to train people and therefore less time for examination, and the amount of Chapter II work is increasing all the time."

"It has taken a long time, but it was quite obvious that we tried to wait for the *Novartis* decision. One of the major problems and it was known and is still known that we could not introduce a kind of official moratorium because this is not possible, (the EPC) does not allow for that.... Now even with the *Novartis* decision being at hand, we go ahead again. That was the main reason otherwise there was no other major delays".

A further opportunity was missed by the EPO at the Diplomatic Conference held in 2000 to discuss the protection of biotechnological inventions. The Diplomatic Conference[65] was held on 20-29 November 2000[66]

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61 A.W. White and J.D. Brown, EPC Appeal Procedures (1996) 7 *EIPR* p. 419.
62 The Hon. Sir Robin Jacob, The Enlarged Board of Appeal of the EPO: A proposal (1997) *EIPR* p. 224.
63 Including 'Insofar as the exclusion of Article 53 (b) first part EPC relates to "animal", to what extent is animal protection possible under Article 53 (b) EPC (if at all)?' See Chapter 4.
64 In a taped interview in January 2000. See Chapter 6.

under the Chairmanship of the Administrative Council. In a press release issued in Munich on 29 November the Chairman[67] acknowledged "that there are a number of outstanding issues of some significance, in particular the protection of computer programs and biotechnology inventions, which require further attention.....I would like to speak briefly about the protection of biotechnological inventions, although this was not on the agenda for our discussions. No one can dispute that this is a sensitive issue which is very much in the public eye. However, long before the Diplomatic Conference, the member states of the European Patent Organisation decided not to consider it in Munich. In view of the leading political and legislative role of the European Union in this area and of the impending implementation by many countries of the EU Biotechnology Directive, it seemed inadvisable to open up a parallel discussion. As you will see from the conference Resolution...the states represented here are fully aware of their responsibilities and will deal with the subject of biotechnology in a further revision round".

As the press release indicates the bulk of the agenda for the Diplomatic Conference was decided over 18 months prior to the conference.[68] A positive decision had been taken to avoid discussion of the protection of biotechnological inventions which might if this had been discussed, served to give further assistance in the interpretation of the Biotech Directive. Again lip service was given to the sensitive and public nature of the issue of the patenting of biotechnological inventions but nothing positive was done towards assisting in the interpreting relevant provisions of the EPC.

There is a sense of inevitability about the grant of the Oncomouse patent which was reinforced by the Opposition Division during the oral hearing which appeared more than a little eager to find some way of maintaining the patent with appropriate 'experimental' caveats. Dr. Gugerell when asked whether it was inevitable that the European Patent would be granted for the Oncomouse in Europe following the grant in the US and Japan, replied:

> "No, the patent was not necessarily going to be granted. The laws are entirely different, the legal situation is different and unfortunately we do have a lot of exemptions in our law, which is a pity by the way because and this clearly demonstrates the exemption of 53(b) and how things turn around over the years and are still there because you cannot get rid of it. Had the Enlarged Board[69] decided differently we would have had to have changed the law, the whole question of animal patenting and plant patenting would have come up again in all national parliaments, which you will never know what might have happened".

The allegations of partiality on the part of the EPO were raised during the Oncomouse case and particularly vociferously during the Opposition Division Oral hearing. It is not proposed to discuss this again further in this chapter but that the fact that these allegations have been raised at all are a serious indictment on the EPO's handling of the Oncomouse case.

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65 Intergovernmental Conference in Paris in June 1999 (1999) *OJ. EPO* p. 545 requested the EPO prepare an EPC revisions conference to beheld in 2000 under Article 172 EPC.

66 Revision Act adopted by Conference MR/3/00 Rev. 1.

67 Dr. Roland Grossenbacher.

68 Also confirmed to writer by Dr. Christian Gugerell in interview 24 January 2000.

How Might the Present System be Improved?

In 1993 Christian Gugerell had identified one of the problems of the present system, namely that the patent examiners were simply not equipped to deal with morality issues.

" I do not believed that considering the ethics in the Patent office is a very economical way of doing these things because the patent examiner who is, at least in Europe, a technically trained person, does not have the necessary competence for doing it. Of course, you could say we have to recruit people who are capable of doing it, but at least at the moment, its not the case and if you take the conditions of the Oncomouse case into consideration ..... the Board told us that we have to consider the risks of the given invention to the environment. In the case of the Oncomouse it was easy to decide on that. But if you take a case like herbicide-resistant plants and the patent examiner should now assess the risk when the plant is put into the field, - there is no way for him to get the necessary information to do that".[70]

The difficulties for patent examiners in assessing patentability under Article 53 (a) EPC was further highlighted by the Opposition Division in the *PGS* case:

"The technically trained patent examiner, who is **not** (Opposition Division's emphasis) a specialist in ethical issues, will find it even more difficult to evaluate in any meaningful way the morality of an invention in the way demanded by the Opponent."[71]

"It would, however, be intolerable and lead to gross inconsistencies if inventions were to be judged unethical or not solely on the basis of the personal beliefs of individual examiners."[72]

The House of Lords Select Committed described the ideal situation when it stated that

"We recognise, however, that patent examiners should not be faced with complex ethical issues requiring the balancing of conflicting rights or interests where the general public itself is divided. ..... the objective should be legislation which itself provides specific guidance, leaving only questions of application – which in this area may be very complex – to examiners and even eventually to national courts and to the European Court".[73]

Unfortunately this situation has not so far been achieved by European patent law.

The Parliamentary Assembly of the Council of Europe in a debate on 12 May 1993 (34th Sitting) as we saw earlier in this chapter, called upon the governments of Member States and the Commission to encourage the inclusion of bioethics in the training of specialists in the field of biotechnology.

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69 In the *Novartis* case.

70 C. Gugerell Discussion Session 1 in F. Vogel and R. Grunwald (Eds) *Patenting of Human Genes an Living Organisms* (Springer 1993).

71 Facts and submissions 15 February 1993 Opposition Division, paragraph 3.4 page 10.

72 ibid. paragraph 3.10 page 13.

73 Select Committee on the European Communities, Patent Protection for Biotechnological Inventions HL, session 1993 – 94 4th report, (HMSO) at 47 p. 19.

If morality is a criterion to be considered under patent law, which it clearly is under the EPC and the Directive, this must be done fairly and openly by the appropriate national examining authorities and courts and even if such criterion may be constantly changing. Patent examiners should be afforded appropriate training and instruction as to the application of any such criterion.

It is interesting to note that the EPO is also responsible for running a variety of training courses and seminars, the EPO International Academy holding 31 seminars in 2000. It is more than a little puzzling therefore why the EPO has not been able to adequately equip its examiners with the appropriate skills they would need in order to deal with ethical issues. The examiners do have to have sufficient skills to be able to deal with the 'technical' nature of inventions and this causes no problems and appropriate measures should be taken by the EPO to ensure that patent examiners are adequately equipped to deal with morality and ethical issues.

Additional Regulations

The biotechnology industry has argued that denial of patent protection by reference to ethical considerations seeks to impose an inappropriate type of regulation at an inappropriate time and that denial of patent protection only serves to deregulate the invention. Patents are typically sought some time before the benefits of the technology reaches society, and usually before the full benefits of the invention can have been properly explored. It has been suggested that a much more cogent case for regulation, if society deems regulation to be needed, could be made at the point of exploitation of the invention rather than at the point of its protection.

The Opposition Division in the Oncomouse case and the Technical Board in the *PGS* case both indicated that any decisions by the EPO must be seen alongside any existing provisions which are in place under other regulatory systems which govern the use or application of the particular invention. It was proposed that any determination of the morality of the exploitation of an invention should be taken by Parliament or other governmental institution which can then put in place appropriate regulation to govern their exploitation.

Dr. Gugerell when asked by the writer if he considered that morality should be considered under the province of patent law responded:

"…. I think it is doubtful whether patent law is the right place to consider these kinds of questions. We could live without. However, I am fully aware of what went on in the work concerning the EU Directive and I was there very often and there, particularly Parliament, you would have thought morality was the most important Article in patent law and that novelty and inventive step are something which come much later….. I am personally against it, I am fully aware politically that there is no way out….. There are a very limited number of cases where the Article is even useful. Very recently with the Roslin Institute patent, they wanted human cloning included that was useful. We managed to get Roslin Institute to delete this human aspect, the animal aspect is ok, but they had to include non-human.[74] For this it was very useful and sometimes it just so happens possibly because applications don't think, they just include humans in claiming something. Then it is useful to say in accordance with Article 53(a), it includes humans so please limit yourself. There is no question

[74] EP 695,351 granted in December 1999 to the University of Edinburgh included removing cells from human embryos. Over 10,000 people filed objections including the governments of Germany and the Netherlands. 13 valid oppositions from five different countries are recorded all raising arguments under Article 53 (a) EPC.

if we did not have this Article then we could argue differently, as the Americans do with utility, but it would be more difficult than without Article 53(a)".

The conclusions reached in these cases may seem an easy way for the EPO to try and pass any decisions with regard to morality onto other regulatory and administrative bodies. The provisions of Article 53 (a) EPC specifically state.... "that the exploitation shall not be deemed to be so contrary (*to ordre public or morality*) merely because it is prohibited by law or regulation in some or all of the Contracting States". This would imply that the EPO must look beyond such regulations and make up its own mind on patentability. The EPO cannot therefore be let off the hook so easily.

Regarding animals as inventions does raise a number of welfare and environmental issues which should be considered under Article 53 (a) EPC even though regulatory frameworks at both the community and national levels do exist. Various conventions and European directives have been put in place to regulate to a limited extent the use and exploitation of transgenic animals but these are more regulatory than advisory.

For example, the Convention for the protection of vertebrate animals used for experimentation and other scientific purposes provides for the registration and approval by the responsible authority of any establishment for the care and management of animals and purposes for which any procedures may be used. It applies to any live non-human vertebrate animal used or intended to be used in any experimental or other scientific procedure where that procedure may cause pain, suffering, distress or lasting harm. The EC Directive (86/609/EEC) The Council Directive on the approximation of Laws, Regulations and Administrative Provisions of the Member States regarding the Protection of Animals used for Experimental and other Scientific Purposes was adopted 24 November 1986. Article 7 paragraph 2 provides that experiments on animals shall not be performed "if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal is reasonably and practically available".

European Directives on the Contained Use and Deliberate Release of Genetic Micro-organisms are also in place[75] being implemented in the UK by the Genetically Modified Organisms (contained Use) Regulations 1992.[76]

Regulations also exist at the national level which have some influence on the use of genetically modified animals. In the UK for example, genetic modification of animals is a regulated procedure under section 2 (3) of the Animals (Scientific Procedures) Act 1986 and may be undertaken only after the grant of a project licence from the Secretary of State. In granting the licence the Secretary of State is required, amongst other things, to "weigh the likely adverse effects on the animal concerned against the benefit likely to accrue as a result of the Programme" for which permission is sought. The implementation of this Act is overseen by the Animals Procedures Committee which in its recent report offered recommendations in respect of the issuing of licences under the Act, stating that no licences should be issued for trivial objectives such as the cloning pets.[77] It also recommended that there should be a bar on cross-species chimeras between humans and other animals[78] and

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75 90/219/EEC and 90/220/90/219. Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms. Directive 90/219/EEC which covers the contained use of genetically modified micro-organisms (1990) *OJ.* L 117 p. 15.

76 (SI 1992/3217) modified in 1996 (SI 1996/967) and 1998 (SI 1998/1548).

77 Animal Procedures Committee Report on Biotechnology (HMSO London June 2001) recommendation 1.

78 ibid. recommendation 5.

genetic modification of great apes.[79] This Act also contains a cost/benefit clause which has recently been reviewed but as in the Oncomouse case has not found this an easy task.[80]

But despite such provisions the ethical questions are still not asked or answered in the case of the cloning of farm animals which if used on a farm, would no longer be protected by the 1986 Act. Instead they would be regulated by laws designed to protect the welfare of farm animals[81] which make no specific reference to the well-being of cloned farm animals.

Some established research bodies also have their own guidelines for the use of genetically modified animals. For example, the Report of the Royal Society[82] recommends guidelines to be drawn up for researchers using GM animals and the UK Co-ordinating Committee on Cancer Research has produced Guidelines for the Welfare of Animals in Experimental Neoplasia, UKCCC (1997).

The Banner Report[83] in the UK endorsed the view that a morality criterion is appropriate within the context of patent law. The Committee sought to provide an ethical framework setting out principles which govern the treatment of animals and which express the view that the use of animals is permissible providing that the use is humane. Such humane use was believed to respect the following principles:

i. Harms of a certain degree and kind ought under no circumstances to be inflicted on the animal.
ii. Any harm to an animal, even if not absolutely impermissible, nonetheless requires justification and must be outweighed by the good, which is realistically sought in so treating it.
iii. Any harm which is justified by the second principle ought, however, to be minimised as far as is reasonably possible.

The report provided: "We believe, however, that a moral criterion does have a proper place in the consideration of patent applications. The European Union (EU) draft Directive on the Legal Protection of Biotechnological Inventions has such a criterion and denies patents to processes which cause more harm to animals than benefits to mankind or other animals. In line with our stated principles, we would prefer a stronger moral criterion – specifically one that ensured that patents would not be granted where the resultant animal is such that its natural good or integrity has not been respected by the modification".

However, it will be noted that the morality test proposed here is different to that of the weighting test adopted by the EPO in the Oncomouse case.

How Could the EPO more Effectively deal with Morality Issues?

In view of the problems experienced by the EPO in dealing with morality and ethical issues in the Oncomouse case it is clear that the present system requires reform.[84]

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79 ibid. recommendation 6.
80 The Royal Society *The use of genetically modified animals* (The Royal Society 2001) p. 25.
81 Agriculture (Miscellaneous Provisions) Act 1968 and the Welfare of Livestock Regulations 1994.
82 The Royal Society, May 2001 *The use of genetically modified animals* (The Royal Society May 2001) Policy document 5/01.
83 MAFF *Report of the Committee to consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals* (HMSO London.1995).
84 D. Bruce and A, Bruce (Eds), *Engineering Genesis, The Ethics of Genetic Engineering in Non-Human*

The present shortcomings in the system could be overcome by either the creation of an Ethical Board of Appeal or alternatively by the creation of an Ethical Division. These represent the two ends of an ethical review spectrum for the EPO and whilst there may be various permutations in between it is proposed that these offer two viable alternative systems which could effectively provide the ethical review function.

There is included a diagrammatic representation of the proposed mode of operation of an Ethical Board of Appeal. This Ethical Board (ETBA) could operate in a similar manner to the EBA. Its remit would be to receive referrals either directly from the President of the EPO, from the EBA on its own volition or through referral from the Technical Boards and to give its opinion on ethical matters arising out of the interpretation of Articles 52 and 53 and the EPC Implementing Regulations e.g. Regulation 23. The grounds upon which such referrals could be made would be similar to those for the EBA although being restricted to morality or ethical issues.

The Ethical Board of Appeal would be similar to the Enlarged Board of Appeal (EBA) receiving referrals directly from Technical Boards and the President of the EPO. The new Board would need to be more flexible than the EBA to enable it to be able to keep abreast of changing moral standards. It should be composed of both legal and technical members as well as a proportion of members with appropriate backgrounds of ethical issues. Its remit would include receiving information from Ethical Advisory groups of the Commission (e.g. European Science Foundation) as well as national ethical groups (e.g. Nuffield Council on Bioethics, National Bioethics Advisory Committee) together with information from groups advising the EBA such as 'epi' (Institute of Professional Representatives of the European Patent office). As with the EBA the decision should be initially binding on the Board of Appeal from which it is referred. The ETBA would thus act in a similar manner to that of the EBA although its remit would be purely limited to ethical matters. It would be hoped that the process for the decisions of such a Board would generally be relatively short. Referrals to the Board could run in parallel to ongoing proceedings before any of the Divisions if the arguments in those proceedings could be separately considered from the ethical matters.

An alternative approach would be to look to the other end of the ethical review spectrum and for the EPO to create an Ethical Division which would accept referrals directly from the Technical Board of Appeal, the Opposition Division as well as directly from the EBA. There is also shown a diagrammatic representation of the mode of operation of the Ethical Division. Allowing referrals directly from the Technical Board and the Opposition Division would enable any ethical issues to be highlighted at a relatively early stage and would offer the Technical Board and the Opposition Division appropriate support by means of advice and recommendations. Referrals to the Division would be at the discretion of the referring Board or Division and the Ethical Division would provide an advisory opinion on the relevant ethical question. Another advantage of this approach would be that such a Division would have the flexibility needed to respond quickly to ethical matters rather than possibly prolonging the process by an additional layer of bureaucracy.

The advisory opinion would not be binding on the referring Board or Division and non-compliance would not be a ground of appeal although a written statement giving the grounds for differing from any advisory opinion issued could be requested by the parties. The parties could be asked to make submissions. The Advisory opinion would take into account all the information provided by the parties and any specific representations

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Species, (Earthscan Publications Limited 1998) Chapter 8, Patenting Life, p. 241.

made together with information available from Ethical groups and bodies with whom the Division could consult. A preliminary view might also be sought by the EBA on its own motion should it feel that it is appropriate to do so. Such opinion shall not be binding on the Enlarged Board but if any views expressed are incorporated within any opinion given by the Enlarged Board it shall have the same authority as any other decision of the EBA.

It would be envisaged that both the ETBA or Ethical Division would receive information from various European Ethical Advisory Groups including the European Group on Ethics in Science and New Technologies and other National Ethical Committees such as Nuffield Council on Bioethics, International Association of Bioethics, The Danish Council of Ethics and the National Bioethics Advisory Commission. It would also be anticipated that each would set up its own sub-committees allowing specialisation within particular technological areas. Inventions the results of genetic engineering might be distinguished from others as might those relating to pharmaceuticals, photonics, etc. All inventions in respect of which European patent applications have been filed could be subject to scrutiny by the ETBA or Ethical Division.

Whilst both alternatives are attractive they serve slightly different purposes. An Ethical Division would be a more accessible way to obtain a preliminary view through the Technical Board at a relatively early stage in proceedings. The Ethical Division would take on an advisory role whilst the ETBA would have a more judicial role and any opinion would be of attendant status.

The creation of a specific Board to deal with ethical matters should not be an alien concept for the EPO, there being a number of 'dedicated' Technical Boards. A new Board of Appeal in chemistry was created[85] on the 1 October 2000 bringing the number of Technical Boards to 18.

Also EPC Article 143 allows additional tasks may be given to the EPO.[86] Special departments common to the contracting States may be set up within the EPO in order to carry out the additional task and the President of the EPO shall direct such special departments.[87] Unlike amendments to the EPC Implementing Regulations which may be amended through delegated powers the creation of such an Ethical Board would also require amendment of the administrative provisions of the EPC and confirmation by diplomatic conference in which representations of the Commission and the Council would be considered.

The writer asked Dr. Gugerell for his views on the establishment of an Ethical Board or Division. Dr. Gugerell responded

> "We do not have the staff for creating such a group, examiners are not trained in that. It is a hard task and therefore we thought it might be useful to have an advisory group here. But again these were only examiners who were more interested than myself, but were not trained for that".

> "We had a group here internally and I was Chairman. We realised how ineffective this was and we always decided on assumptions and in most cases we have to say yes, it is ok, because we did not know better. It was an informal group it was not provided for under EPC law. We advised Examining Divisions. We did not tell them because according to the law it is the Examining Division which decides, but we advised Examining

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86 Article 143 (1) EPC.
87 Article 143 (2) EPC.

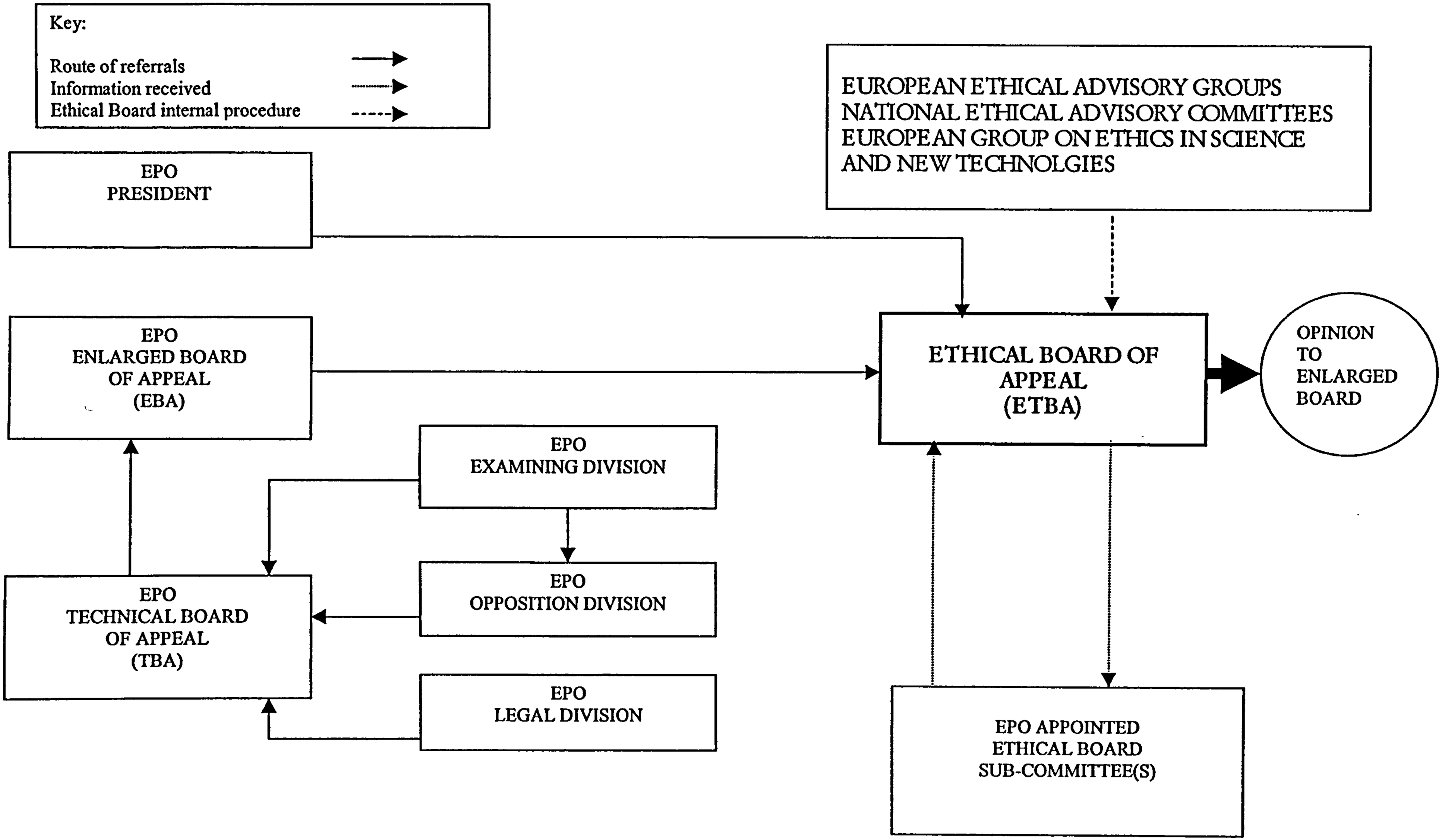
Divisions and it just so happened that the members of this group were primary examiners of this field. It was more or less an advisory thing".

On being asked whether it would be appropriate for such to be set up in the future Dr. Gugerell responded

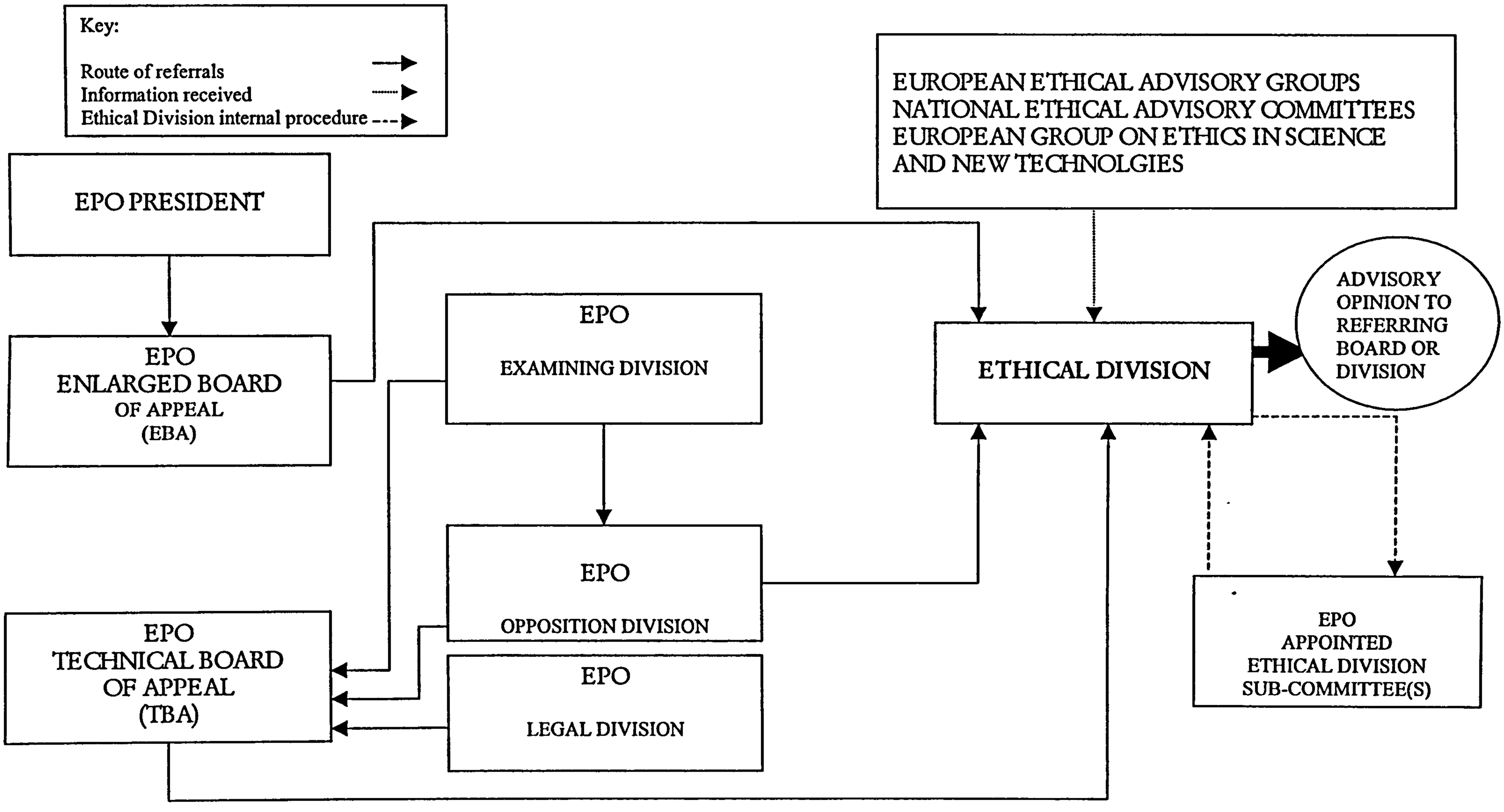
"It was not very effective..... I am still there on the ethical questions and when people have a question I will advise them, along the lines I have just told you".

Dr. Gugerell's reluctance to open up ethical issues for debate within the EPO is understandable in view of the EPO's attitude towards Article 53 (a) EPC in the Oncomouse case. But the writer would suggest that this is rather short sighted.

Representation of the relationship between a proposed Ethical Board of Appeal and Existing Divisions/Boards of the EPO



Representation of the relationship between a proposed Ethical Division and existing Divisions/Boards of the EPO



The problems encountered by Harvard in the prosecution of the Oncomouse patent application would have been resolved far sooner if such a Board had been in existence. The new Board would also be of assistance with the difficulties which are likely to arise under the new Biotech Directive and TRIPs.[88]

In 1991 the European Commission established the Group of advisers on the Ethical Implications of Biotechnology. This was later replaced in 1998 by the European Group on Ethics in Science and New Technologies. The objectives of this Group were to help break down barriers between disciplines in fields which require a multi-disciplinary approach, not only scientific and legal, but also philosophical, sociological and economic and to provide European decision-makers with clear and up-to-date basic information, enabling them to be properly informed in carrying out their duties. The European Group on Ethics in Science and New Technologies was reconvened at the end of April 2001and is now charged with advising the Commission, Parliament and the Council of Ministers, rather than the Commission alone. Article 7 of the Biotech Directive confirms its role as being the evaluation all ethical aspects of biotechnology.

It might be asked why this Group could not take on the role of the ETBA. This would not be satisfactory as any Board to be of any assistance must come from 'within' the EPO and must be dedicated like the other Boards to the interpretation of the EPC. An EU institution would also not be effective when dealing with non-EU countries as would be the case under the EPC as not all signatories are EU Member States.

The EPO is the hub in the wheel of the European Patenting system. The Articles of the EPC and the subsequent development of case law by its Appeal Boards have established the rules. National courts tend to base their decisions on infringement. So far the Commission has put the onus on the EPO to clarify its guidelines on what is patentable, and to simplify the procedure by which protection was obtained but with the introduction of the European Group on Ethics the EPO is now given additional support in assessing bioethical matters. The creation of an Ethical Board of Appeal or Ethical Division would provide a clearly defined mechanism for assessing ethical issues.

However, the image of the EPO as a groundbreaking institution in dealing with animal patenting is far from true. The EPO appears to be travelling (albeit a little reluctantly) down the inevitable path taken by its US counterpart. Throughout the progress of the Oncomouse case the EPO had been very cautious always qualifying any decision that it made. Part of this reluctance was related to its general unease in dealing with the substantive provisions of the EPC relating to moral issues.

In the Oncomouse case the decision of the Opposition Division will be taken by the four individuals of the Opposition Board based on their professional and personal experiences.[89]

The interpretation of the morality exception has not been easy. In the Oncomouse case arguments were put forward by the EPO that whilst it was clearly right to question and prove the morality of using (and indeed, not using) the results of biotechnology in society, patent law was not the appropriate place for this to be undertaken. The EPC is an international treaty and should be interpreted in accordance with the principles of international

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[88] See R. Ford, The Morality of Biotech Patents: Differing Legal Obligations in Europe (1997) 6 *EIPR* p. 315.

[89] Dr. Christian Gugerell will be writing the decision on behalf of the Opposition Division.

law, priority must accordingly be given to the wording as construed in good faith in the light of the purpose of the Convention.[90]

The patenting of biotechnological inventions has been recognised as a special case by the European Commission and Council which is confirmed by the Biotech Directive, although it gave only limited guidance on the patentability of animals. Animals do require different considerations to be taken into account when assessing patentability as stated by one American congressman following the grant of the Oncomouse patent in the USA:

"The patenting of genetically engineered animals may warrant a higher degree of scrutiny than that of other potentially patentable material. The patenting of a machine is different than the patenting of an animal. An animal unlike most other patentable material, has the capacity to reproduce. This provides us with unique health, safety, environmental and ethical concerns".[91]

Notwithstanding that other regulations exist in the EPC Member States which might to a minor extent meet some of the concerns of environmental and animal welfare groups it is not acceptable for the EPO to absolve itself from its responsibility under Article 53 (a) EPC by relying on any ethical decision taken about their use being within the remit only of other regulatory bodies.

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90 Vienna Convention on the Law of Treaties. Signed at Vienna 23 May 1969 entered into force 27 January 1980.

91 Statement of Congressman B. L. Cardin, Subcommittee on Courts, Intellectual Property and the Administration of Justice, 13 September 1989, page 2.

Chapter 8

And so into the 21st Century .....

"By the end of 1991, the EPO's deliberations on the patentability of the Harvard mouse should be complete".

Richard Bizley 1991
European Patent Agent instructed on behalf of
Harvard in Onco-mouse Case before the EPO[1]

"Life is a slippery thing to define, but it consists of two very different skills: the ability to replicate, and the ability to create order".

Matt Ridley

Genome, The Autobiography of a Species 1999[2]

"Of life and property, which is worth more?"

Chinese Proverb[3]

A constant theme to emerge from the foregoing discussions has been the growing importance of the morality criterion in the assessment of animals as patentable inventions under the EPC. Even though it has been agreed in Diplomatic Conference that the EPC should be amended[4] and the Biotech Directive introduced, if biotechnological research continues to develop at the same pace as it has done over the last decade those changes will not be enough to enable the EPC to keep pace with ongoing developments in the biological science, particularly genetics.

Whilst in the future new techniques for genetic manipulation will emerge in the field of human gene therapies and human embryonic research, other developments utilising animals will also emerge. For example, the use of cloning techniques in the field of xenotransplantation; the use of genetically modified animals as sources of drugs (animal 'pharming' defined as agriculture based on the use of plants or animals genetically modified to produce specialised items for human medical use);[5] as well as in the field of animal farming in the more traditional sense. This chapter looks to the future and proposes that it is now time for the European Commission and/or the EPO to formally instigate serious debate as to whether it is appropriate for a new animal intellectual property right to be introduced in Europe and to which the Examining Division of the EPO hinted in its consideration of the Oncomouse application at first instance.

With the increasing research into the genetic modification of animals, researchers and those investing in such work have always sought to protect their results. In respect of the genetic modification of animals and the creation of new 'animal inventions' the patenting system has up to now been called upon to fulfil this function. But as the public is becoming concerned about the genetic manipulation of animals it is believed that it is now an appropriate time for such debate.

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1 In article R.E. Bizley Patenting Animals in Europe (1991) *Bio/Technology* Vol. 9 July p. 619.
2 Chapter 1, *Life*. (Fourth Estate Limited 1999).
3 Believed attributable to Lao Zi, Spring and Autumn Period.
4 See Chapter 1.
5 W.T. Anderson *Evolution isn't what it used to be* (W.H. Freeman and Company New York 1993) p. 126.

The Patenting Debate

The debate whether a patent stifles or encourages research will continue for as long as patents exist. The argument that patents stimulate research by encouraging others to engineer around them[6] and therefore develop new inventions and technologies may be accepted to a limited extent. But it is the restriction of competition that is the prize which is widely sought after by those applying for patent protection.

The handling of the Oncomouse patent application by other national patenting offices, even for jurisdictions which have virtually identical statutory patenting provisions, show quite different approaches in determining whether animals are patentable inventions. We have seen the Oncomouse patent granted in Japan and the US. Australia[7] granted its first patent containing claim to transgenic animals in October 1990 (but not to Harvard for the Oncomouse).[8]

The concept of animals as property and their ownership is widely acknowledged.[9] Intellectual property rights are widely recognised as a means of protecting the products of intellectual endeavour. Patents have been recognised as an effective means of protecting new inventions throughout the world but the use of patents to protect man-made animals as we have seen in the Oncomouse case is not universally accepted.[10]

As we have seen in the arguments put forward by the Opponents in the Oncomouse case, and as the Chairman of the Opposition Division at the Oral hearing confirmed, the patenting debate in relation to animals is unlikely ever to be resolved to the satisfaction of all interested groups. The arguments for and against patenting broadly encompass the grounds of opposition outlined in the Oncomouse case and have already been reviewed by other commentators.[11] It has been suggested that whilst patents have been useful under the current system there is a risk that they may be a barrier to medical progress in the future.[12]

At the time of filing of the Oncomouse patent application at the EPO in 1985 the genetic modification of animals was a relatively closed debate but over the intervening 16 years it has been taken up by environmental, animal welfare, political and religious groups. Since that time genetic modification techniques have revolutionised the thinking of geneticists and this area of research may now be described as having become highly 'fashionable'. However, just because certain procedures may now be possible, it does not mean that they should be or that they should have the benefit of patent protection. One commentator has highlighted the potential problem by stating "There is a tendency in our culture to regard creative genius as an excuse for ethical licence. In a study area where irresponsibility carries grave dangers we should be on our guard against licences of this sort".[13]

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6 By virtue of the experimental use exception.

7 K. Ludlow Genetically Modified Organisms and their products as patentable subject-matter in Australia (1999) *EIPR* 6, p.298.

8 Australian patent No. 597965.

9 See generally J.W. Harris *Property and Justice* (Clarendon Press 1996); S.R. Munzer *A Theory of Property* (Cambridge University Press 1990); J.E. Penner *The Idea of Property in Law* (Clarendon Press 1997).

10 Is this the work of man or nature? (20 November 1995) *The Independent.*

11 S. Sterckx, *Biotechnology, Patents and Morality* (Ashgate Publishing Limited 1997) See Part Five *The case for and against the Patenting of Biotechnological Inventions* p.177-253.

12 (15 February 2001) *Nature* p. 763.

13 A. Holland and A. Johnson (Eds), *Animal Biotechnology and Ethics* (1998) Chapter 10, A. Johnson, *Needs,*

Uses of Genetically Modified Animals

The uses to which transgenic animals will be put will determine their patentability under the morality exception. The use of transgenic techniques[14] in the breeding of animals for food production may be expected.[15] Animals cloned for food production[16] are also a logical development of these techniques; for example, Cyagra Inc in the US has undertaken research into the commercial cloning of cows.

The reasons for using GM animals for biological and medical research[17] have been argued again and again. [18] So also have the reasons against. [19]

The use of transgenic animals as a means of producing human enzymes for application in human disease treatment is widely known. The Roslin Institute in Edinburgh introduced us to Tracy and Dolly the sheep. The method of producing Tracy is the subject of US patent 5,476,995 and as reported by Roslin "secretes about 35 grams/litre of human alpha-1-antitrypsin in her milk, but which is otherwise completely normal".[20] Dolly[21] was the offspring from a cloned adult animal cell[22]. Polly then followed, being the first sheep to be both genetically engineered and cloned, being modified so as to secrete the blood-clotting agent, Factor IX in her milk. As the Scientists who created her said "She [*Polly*] is the one who demonstrates that the genetic transformation of animals other than laboratory mice is truly plausible – that the transformation of farm livestock could become routine and that all animal species might in principle be engineered, if that is what society wants to happen".[23] One witty commentator has suggested that the collective noun for sheep will no longer be a flock, but a 'clone'![24]

We have also been introduced to Herman the first transgenic bull created by scientists in the USA[25] carrying a gene for production of human lactoferrin.

As well as being a source of food and a means of producing chemicals transgenic animals have been suggested as a source of organs for transplantation into humans, the process known as Xenotransplantation. In the UK the Xenotransplantation Interim Regulatory Authority (UKXIRA) was established in 1997 to supervise such research. Almost all source animals used in the procedure will be transgenic and one UK company, Imutran,

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fears and fantasies, p. 133.

14 See US Conference paper Transgenic Animals in Agriculture, Transgenic farm animals get off the ground (1998) *Transgenic Research* 7, p. 73; A.M.Verrinder Giggins, Transgenic Poultry Technology and Food Production (1998) *Animal Biotechnology* 9 (3), p. 173.

15 A. Holland and A. Johnson (Eds) *Animal Biotechnology and Ethics* (1998) Chapter 4, G.E. Seidel Jr, *Biotechnology in animal agriculture*, p. 52; A. Graves Clone Farm (18 August 2001) *New Scientist* p. 4.

16 P. Cohen and D. Concar, The Awful truth (2001) *New Scientist* 19 May p. 14.

17 See Animal Procedures Committee *Report on Biotechnology* (HMSO London June 2001) p.32.

18 M.A. Fox, *The Case for Animal Experimentation An evolutionary and Ethical perspective* (University of California Press 1986).

19 R. Wacks, Chapter 4 in G.K. Becker (Ed) *Changing Nature's Course the Ethical Challenge of Biotechnology* (Hong Kong University Press 1996).

20 Annual Report 1993/4 Roslin Institute Edinburgh, p. 16.

21 WO 97/07668 and WO 97/07669.

22 (1997) *Nature* 385, p. 810.

23 I Wilmut, K. Campbell and C. Tudge, *The Second Creation – The age of biological control by the Scientists who cloned Dolly* (Headline Book Publishing 2000) chapter 11, p. 255.

24 C. Stewart, An udder way of making lambs (27 February 1997) *Nature* (Source: internal article No 4404B, March 1998, J. D'Silva, Director, Compassion in World Farming).

25 Produced by Gen Pharm International Inc.

has indicated that it is in a position to commence clinical trials. The Banner Committee[26] which investigated the ethics of animal-to-human transplants concluded that procedures that failed "to respect the natural characteristics, dignity and worth of animals" would be objectionable.[27]

Transgenic animals and micro-organisms have also been used in Aquaculture and bioremediation of pollution[28] and in the field of biomining bacteria have been used to recover metals from ore. Whilst cloning techniques may be used for the conservation of species[29] and for the benefit of man the cloning of designer pets is more questionable. [30]

A question which the EPO will have to ask in assessing such animals as patentable inventions is have transgenesis techniques in relation to animals gone too far and beyond the limits of what is morally acceptable?

A catalogue of transgenic animals has been created by different scientists. BioTransplant Inc sought to introduce the nucleus of a human cell with a pig egg. Their application for a patent for their creation was challenged by Greenpeace and the company later abandoned the application. Reports of Alba the rabbit,[31] Zombie pigs,[32] and of ANDi[33] the rhesus monkey, the first transgenic primate created by scientists in Portland Oregon in the US may just be the beginning.

Is the introduction of human or animal genes into plants more acceptable or vice versa? In the USA scientists have introduced the human lactoferrin gene into tobacco cells in laboratory tissue cultures and rice has been modified to manufacture the human protein alpha-1-antitrypsin (the enzyme produced by Tracy the sheep). It cannot be denied that it is unnatural to cross such boundaries but this is the science that the EPO is going to have to deal with in the future. With regard to the agricultural impact of such research, the physiological changes produced in transgenic animals are almost certainly different in kind from those achieved by evolution and by traditional breeding activities. In those processes, novelties arise from tiny changes in pre-existing genes, each of which has co-evolved with thousands of others.

But such work has not been undertaken without concerns[34] both ethical and religious[35] as well as those in relation to animal welfare[36] being expressed. An analogy has been drawn between genetic modification and the

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26 Nuffield Council on Bioethics *Animal-to-Human Transplants the Ethics of Xenotransplantation* (Nuffield Council on Bioethics London 1996).

27 ibid. Page 1.

28 R.A. Zilinskas and P.J. Balint, *Engineered Marine Organisms, Environmental and Economic Risks and Benefits* (Kluwer Academic Publishers 1998).

29 A. Coghlan, Raising the Dead (14 October 2000) *New Scientist* p. 5.

30 Man's best friend, *New Scientist,* p.10.

31 See But is it art? (6 January 2001) *New Scientist* p. 34.

32 Zombie Pigs (24 January 2001) *Daily Mail* p.4.

33 Too close for comfort (20 January 2001) *New Scientist* p. 6. See also Animal Procedures Committee *Report on Biotechnology* (HMSO London June 2001) p.20.

34 E.R. Cameron, M.J.A. Harvey and D.E. Onions, Transgenic Science (1994) *British Veterinary Journal,* 150, p. 9; H. Lehman and J.F. Hurnik, Concerns about the Ethics of Genetic Modification (1994) *Proceedings 5th World Congress on Genetics* vol. 20, p. 130; B.E. Rollin, *The Frankenstein Syndrome: Ethical and Social Issues in the Genetic Engineering of Animals* (Cambridge University Press1995).

35 M.J. Reiss and R. Straughan *Improving Nature? The Science and Ethics of Genetic Engineering* (Cambridge University Press 1996) Chapters 3 and 4.

36 T. Grandin and M.J. Deesing, *Genetics and Animal Welfare,* in *Genetics and the Behavior of Domestic Animals* (Academic Press 1998) chapter 11; Farm Animal Welfare Council, *Report on the Implications of Cloning for the Welfare of Farm Livestock* (MAFF December 1998).

atomic bomb,[37] both having the potential capacity to destroy life. Public concern has led to the close scrutiny of such activities, particularly the work of geneticists and embryologists throughout, the world and dire warnings have been made about its consequences.[38]

Animal welfare and ethics are important to us all.[39] But what influence does the attitude of the scientists at the sharp end of the ethical debate have on such issues. Almost always the ethical arguments are conveniently forgotten.[40] However, a surprisingly responsible attitude was shown by scientists in the US. In 1975 at a conference held at Asilomar in California scientists in the field of genetic engineering agreed on a moratorium in respect of certain aspects of their work. Also a bill was introduced in 1987 in the House of Representatives HR 3119 with a view of establishing a 2-year moratorium on such genetic research.[41]

As public awareness of genetic engineering has grown the concerns expressed are being taken more seriously by the decision makers in Europe. At the EU level as we have seen with the coming into force of the Biotech Directive the Commission set up in 1998 the Group on Ethics in Science and New Technologies. Also at the national level, for example, Germany has established a new Council on Bioethics, that will report directly to Chancellor Gerhard Schroder.[42] Assistance may be given by the decision of various ethical groups and it is particularly noteworthy that the Biotech Directive in Recital Articles 7 and 16[43] seeks to keep the application of the morality criterion under constant review.

Harm to animal health and welfare will impact on human health. The treating of animals as mere instruments for human benefit and interest infringes the integrity or the intrinsic value of animals and could lead to the slippery slope of eugenic applications on humans.

Risk Assessment

Assessing the risk to the environment of the release of genetically modified animals has led to a number of methods and theories being proposed.[44] However, environmental risks are difficult to calculate. [45] One commentator has suggested a hybridization approach for analysing the impact[46] of genetic modification. The

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37 J. Bauer (Ed), *Resistance to New Technology* see chapter 16, J. Radkau, *Learning from Chernobyl for the fight against genetics? Stages and stimuli of German protest movements – a comparative synopsis* (1998) p. 335.

38 C. Donnellan, *Genetic Engineering* (Independence, Cambridge England 1994) see chapters1 and 4.

39 L.J. Frewer, *Consumer Opinions on transgenic animals* (1998) *AgBiotech* vol. 10, No. 7, p. 213N.

40 A. Holland and A. Johnson (Eds), *Animal Biotechnology and Ethics* (1998) Chapter 9, J. Burkhardt, *The inevitability of animal biotechnology? Ethics and the scientific attitude,* p. 114.

41 K. W. O'Connor, Patenting animals and other living things (1991) *Southern California Law Review* vol 65, p. 618.

42 (10 May) 2001 *Nature* p.124; (12 May 2001) *The Lancet* 357, p. 1512.

43 Article 7: The Commission's European Group on Ethics and Science and New Technologies evaluates all ethical aspects of biotechnology. Article 16 The Commission shall send the European parliament and the Council: .....(b)within two years of the entry into force of this Directive, A report assessing the implications for basic genetic engineering research of failure to publish, late publication of, papers on subjects which could be patentable; (c) annually as from the date specified in Article 15 (1), a report on the development and implications of patent law in the field of biotechnology and genetic engineering.

44 M. Levin and H. Strauss, *Risk Assessment in Genetic Engineering Environmental Release of Organisms* (McGraw-Hill Inc 1991).

45 E.R. Schmidt and T. Hankeln (Eds), *Transgenic Organisms and Biosafety Horizontal Gene Transfer, Stability of DNA and Expression of Transgenes* (Springer-Verlag Berlin 1996).

46 P.B. Thompson, *Science Policy and Moral Purity; The Case of Animal Biotechnology, Agriculture and*

effectiveness of such theories has been questioned when we have seen in the past what occurs when a new species is introduced into a new area. The introduction of the grey squirrel into Britain from Canada in the late 1800's is an important lesson.[47]

Whilst it has been noted in Chapter 7 that regulations and guidelines do exist for the control of the use of genetically modified organisms at the national [48] (Regulations for the contained use of genetically modified organisms) and international[49] (The United Nations Environmental Programme Guidelines), but the effect of genetically modified organisms on the environment is under particular scrutiny at the present time.[50] The fear that the expression of foreign gene products could disrupt programmed normal development processes and could result in abnormality of reproductive function in both transgenic plants and animals is a very real one as the biological effects of the expression of foreign genes can be quite unexpected.

Public Awareness

There has over the last decade been an attempt by the European Commission to increase public awareness of biotechnology even though it has been suggested that the understanding of developments in genetic engineering are beyond the comprehension of the public.[51]

In the early 1990's the Commission sponsored two Eurobarometer surveys in an attempt to gauge European Public opinion. These results showed a pronounced difference in attitude between countries. More than three-quarters of respondents believed that there should be clear ethical rules about when biotechnology/genetic engineering research involving human beings, animals or plants may not in anyway be undertaken. The perception of risk was highest in Denmark and also very high in Germany.[52]

Over the period 1996-1999 the European Commission spent one Million ECUs to make public aware of biotechnology.

The EPO is charged under Article 53 (a) with the task of assessing the use of genetically modified animals and the risks associated with them, when they are the subjects of European patent applications. As Chapter 6 argued the EPO is not fully equipped to assess such matters which will become increasingly more difficult over the next decade. This reinforces the requirement for the EPO to provide the necessary forum for such issues to be discussed.

Human Values (Kluwer Academic Publishers 1997) 14, p. 11.

47 see K. Wohrmann and J. Tomiuk (Eds.), *Transgenic Organisms Risk assessment of Deliberate release* (Birkhauser Verlag 1993); J. Tomiuk, K. Wohrmann and A. Sentker (Eds), *Transgenic Organisms: Biologicaland Social Implications* (BirkhauserVerlag 1996).

48 The Genetically Modified Organisms (Contained Use) Regulations, 1992 (SI 1992/3217) modified in 1996 (SI 1996/967) and 1998 (SI 1998/1548).

49 UNEP International Technical Guidelines for Safety in Biotechnology 1996. Guidelines provide minimum standards for the safe manufacture and use of modified organisms.

50 See Nuffield Council on Bioethics, *Genetically Modified Crops; the ethical and social issues* (Nuffield Council on Bioethics May 1999).

51 (12-13 May 2001) *Financial Times London* p. 11.

52 Club de Bruxelles, Study written under direction of J. Smith, for the Conference September 1996, with the support of the European Commission (DG XII), *The Future of Biotechnologies in Europe, From Research and Development to Industrial Competitiveness* (1996) p. 34. Surveys in 1991 and 1993.

Is the time now right for consideration to be given to the establishment of a transgenic animal right?

Alternative forms of intellectual property protection have been suggested to protect the results of research using animals, such as trade marks, copyright and trade secrets. [53] Genetic copyright[54] has been suggested as a form of protection, the nucleic acids of the DNA sequence transferred comprising the original literary work. These forms of protection are regarded as less attractive.[55]

One of the difficulties encountered in the interpretation of Article 53 (b) EPC in relation to animals is that unlike the situation for plants, there is no definition of what constitutes an animal variety and the EPO appears to have gone to inordinate lengths to avoid providing such a definition. The new implementing regulations to the EPC aimed at reconciling the Biotech Directive with the EPC also fail to include a definition of animal variety.

The Examining Division hinted in its refusal of the Oncomouse patent application that an animal 'variety' right might be appropriate and Dr. Gugerell, the spokesperson for the Oncomouse case at the EPO also suggested that this was not an unrealistic concept for the Commission to consider.[56] The contribution of the EPO with its experience of a morality standard to any such debate would be crucial. If a new transgenic animal right is to form any part of European biotechnology law in the future within the next two decades, discussions must begin immediately. It is proposed that such debate should be instigated either by the EPO in discussions with the European Commission and the Council[57] or through the auspices of the WTO.

In view of the controversial nature of the animal patenting and the difficulties encountered in agreeing the final version of the Biotech Directive it is likely that the introduction of such a right will encounter opposition. However, the earlier work and debate relating to the Biotech Directive would provide a good starting point from which to discuss a possible new animal right.

It would not be unreasonable to anticipate that in any debate with regard to a transgenic animal right that the model used would be that of the plant breeders' rights.[58] No comparable system of animal breeders' rights to those for plants under the UPOV Convention exists in Europe but notwithstanding this it has been assumed by the EPO that decisions in relation to 'animal varieties' will be on all fours with those relating to plants.

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[53] The law of trade secrets is well known for protection of confidential information and know-how and is recognised in most jurisdictions. The USA more liberal than in Germany and Switzerland . Generally need to show the information must be secret, the owner must demonstrate intention to treat it as confidential and acted with intention of keeping it secret and owner have some interest in keeping the information secret. See A.N. Wise (Ed), *Trade Secrets and Know-How throughout the World* (Clark Boardman Co. 981) vol. 3.

[54] A. Speck, Genetic Copyright (1995) *EIPR.* 4 p. 171.

[55] G.W.G. Karnell, Protection of results of genetic research by Copyright and Design rights? (1995) *EIPR.* 8 p.355; J. Stanley and D.C. Ince, Copyright Law in biotechnology: A view from the formalist Camp (1997) *EIPR.* 3 p.142.

[56] Taped interview with writer on 24 January 2000.

[57] The Commission being the executive body of the European Union is responsible for implementing and managing policy and ensuring that EU legislation is applied correctly by the Member States. In certain areas, such as, competition and trade policy, the Commission has autonomy either by specific powers or delegated authority to take decisions. The commission makes proposals. The Council is the decision making body of the European Union whose members are ministers from member government (and can be Members of the European Parliament). The Ministers of the European Parliament are democratically elected and offer advice to and in some instances decides with the Council on important legislative provisions.

[58] M. Llewelyn, The Legal Protection of Biotechnological Inventions: An alternative Approach (1997) *EIPR* 3 p. 115.

There are mixed views amongst commentators on the effectiveness of the plant variety right system as a means of protection of rights in plants. Whilst some are firm supporters of a plant variety rights system[59] others are far less enthusiastic.[60] Extending comparable Plant variety rights to animals has been suggested but not taken up.[61] One commentator has suggested that an animal breeders' right[62] should be introduced for animals created which are stable, uniform and distinctive. The right owner would have the exclusive right to breed and commercially exploit for breeding purposes animals of the protected description. Exemption from infringement would be established for experimental and non-commercial uses and acts for breeding other varieties. It is proposed that protection afforded by the new right would only be given for certain specific purposes and that there would be the opportunity to include or exclude certain uses. Areas which should be specifically considered are cloning, xenotransplantation, drug pharming, food production and medical experimentation.

Such a right may be the subject of a separate international Agreement or may arise through the modification and expansion by WTO of the TRIPS agreement. From there such rights would be introduced into national laws. In the US legislation was proposed to deal with some of the restrictions likely to arise as a result of patents being granted to transgenic animals, for example the restriction on farmers' rights to breed from their stock but the proposed legislation did not become law.[63]

Such a transgenic animal right based on the principles of the plant variety right of the UPOV Convention could provide the right owner with limited protection from unauthorised exploitation whilst not preventing legitimate use of the animals by farmers and breeders. Such a right is unlikely to be embraced by countries such as Japan, Australia and the US where animal patenting is broadly accepted. Nevertheless those countries with relatively younger patenting systems and third world countries which have legitimate interests in facilitating the development and breeding of animals may find that such a right complements their needs whilst satisfying their obligations under the TRIPs agreement.

A further stumbling block to the introduction of such a right is the amount of time which will be required to be dedicated to the debate of this issue. It might be argued that it is now too late for such a right to be introduced in view of the likely decision of the EPO on the Oncomouse, even though this might not be final for another 5 years. The writer does not adopt this view and consideration should be given to such a proposal which may

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59 M. Llewelyn in *Plant Variety Rights: An outmoded Impediment* (The Intellectual Property Institute 1998) p. 6. The Intellectual Property Institute *Plant Variety Rights: An outmoded Impediment A Seminar Report* (Speakers: M. Llewelyn and T Cook) (The Intellectual Property Institute 1998).

60 The Intellectual Property Institute *Plant Variety Rights: An outmoded Impediment A Seminar Report* (Speakers: M. Llewelyn and T Cook) (The Intellectual Property Institute 1998).

61 See N.J. Byrne, *The Scope of Intellectual Property Protection for Plants and other Life Forms* (Intellectual Property Publishing 1989) endnote No. 46, p. 32.

62 N. Peace and A. Christie, Intellectual Property Protection for the products of Animal Breeding (1996) *EIPR.* 4 p. 213.

63 For a detailed review see D. Manspeizer, The Cheshire Cat, the March Hare, and the Harvard Mouse: animal patents open up a new, Genetically-Engineered Wonderland (1991) *Rutgers Law Review* vol. 43 355 p. 449; E.J. Sease, From Microbes, to corn Seeds, to Oysters, to Mice: patentability of New Life Forms (1988-89) *Drake Law Review* vol. 38 p. 565; M.M. Montgomery, Building a better mouse – and Patenting it: altering the Patent Law to accommodate Multicellular Organisms (1990) *Case Western Reserve Law Review* p. 252; K.W. O'Connor, Patenting Animals and other Living Things (1991) *Southern California Law Review* Vol. 65 579 p. 618.

63 101st Cong. 1st Sess., 135 Cong. Rec. H830 (daily edition 22 March 1989).

63 D.A. Mark, All Animals are Equal, but some are Better than Others: Patenting Transgenic Animals (1991) *Journal of Contemporary Health Law and Policy* vol. 7 p. 245.

serve to meet the need of industry as well as certain interested groups whilst enabling existing international obligations, for example, under TRIPs to be met.

Dr. Gugerell[64] on being questioned whether he felt it was appropriate for an animal variety to be defined commented "No.... that is not necessary. I advise the group in this respect and my opinion is that you do not need to know exactly what an animal variety is or animal line. The kind of inventions we are talking about as you know are in the instances normally all animals or mammals at least can be transformed genetically and transgenic animals cases limited to say a species, just only single animal species, I could not think of any. Therefore, for this kind of application it is not necessary,.....and therefore in the Oncomouse decision we did not define it. We just said rodent and mice are terms which define a group of animals much higher than animal varieties and that is all that we needed. I have never seen a case where, an animal case, and the same is true for plant transgenic plant cases, where an invention was applicable only to one variety. It is extremely unlikely".

The writer asked Dr. Gugerell whether he thought there might be any advantage in having an animal variety right, to which he responded, "OK maybe there might be some use, for example race horses, where such a right would probably be an advantage. But the general interest is not so big, not when you compare it to plants. With plants it is a tremendous potential which is in the plant variety protection in fact, certain crops you can only sell the seed if it is a protected variety, probably in England as well, I know it is in Germany and some other countries. It is necessary, but for animals it is probably not so important as it was never felt that any activities appropriate in this direction."

However, Dr. Gugerell hinted when questioned on whether he considered that it was the intention of the legislators of the Strasbourg Convention to exclude animals that an animal right had been considered:

"No, definitely not, that is not the question here. What happened was this. At the same time the Plant Variety Protection Convention, UPOV, was created. It was the desire to avoid double protection and for this reason the Strasbourg Patent Convention contains the provision that member countries *MAY,* it says may, exclude plant and animal varieties. With animals it was also probably thought that there would be a similar law as for plant varieties in the future. Therefore animals were included in the same label."

"There were investigations made a few years ago, by the Commission and the result was no, it was not worthwhile. But, certainly there are people that would like to have it."

Such a right is unlikely to be widely acceptable to animal welfare groups. When the representative from Compassion in World Farming was asked for his comments he said "I would not support any animal variety right or any other right which gives control over animals.[65]

With or without such a right the EPO has to look to the future. The writer asked Dr. Gugerell how he thought animal patenting in Europe might develop over the next decade:

"You asked me when you look into the crystal ball what will happen. I said as the first step at this Diplomatic Conference[66] not much will happen as far as biotech is concerned. And then we have our law and

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64 Interview with Dr. C. Gugerell on 24 January 2000.

65 Peter Stevenson Legal and Political Director of Compassion in World Farming (Opponent I) in interview 25 November 1999.

we have the national patent laws of course and we have the Directive in the EU and we will see how things develop. Normally laws are changed and adapted to the new, and to meet reality as things develop, as technology develops, normally if had not been so difficult with our law to change it, for example, with transgenic plants, we would have probably would have changed Article 53(a) if it had been easier to do that. Because that is normal if things change, you have to adapt the law to the new circumstances. As far as morality is concerned as this is your prime interest here, I see, it is not only me, but I also see that there might be the need for changing the Directive in consequence and also our rules again, as far as these specific items are concerned[67] on morality, which were introduced in the Directive and are now in our Rules. That possibly the use of embryos which is excluded, which the Brits always disliked very much, because I think until the 10th day you can do research there and then it is human cloning, there is no distinction between reproductive and therapeutic cloning in the law, this will be necessary probably. Even the German morality group learnt only this week, there is issued a paper now on this question, that concluding more or less we have to think about the liability of therapeutic cloning, that is more or less the direction it goes. So even in Germany there is no exception. It is probably moving that way, so in my view the law will have to be changed and the Directive, well I don't know, it is not easy to change the Directive."

"But a discussion will come up and probably national laws will change first of all, not patent laws but the laws prohibiting this technology, with the research on this technology and this will happen first and then they will look at the patent situation and possibly then you will have to say that we have to change that as well. So these two things probably if they ever come true, that you can produce organs for transplantation you probably need the use of embryos, so that is not certain. You could find technologies where you need not call these animals an embryo anymore, it is possible. But certainly you need human therapeutic cloning for that."

During the interview the writer also took the opportunity of asking Dr. Gugerell his views on the proceedings in Canada:

"It was a very strange decision. I did not understand the decision really. I mean it was one of these decisions they had a certain desired result and decided accordingly, and then they found some reason for it."

The EPO in the future will face more difficult questions than it has so far had to deal with or have been posed in this study. Not only will such questions deal with ethical questions relating to animals as inventions but they are also likely to deal with the techniques developed for the genetic testing and therapy of human beings. The patenting of animals may thus prove to be the tip of the ethical iceberg in relation to biotechnological inventions.

As shown in this study it is not possible to excise morality from the EPC. Any attempt to do so would undermine the legitimacy of the European patenting process. The EPO does not have an adequately effective system for dealing with ethical issues which are likely to occur over the next decade and this study suggests a means whereby the present system may be improved.

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[66] Held in Munich in November 2000.

[67] Supported by M. Llewelyn, The Patentability of Biological Material: continuing contradiction and Confusion (2000) *EIPR* p. 191.

However, whether changes are adopted by the EPO or otherwise the morality criterion of the EPC is of fundamental importance to the patenting of animals under the EPC. Article 53 (a) is here to stay and as Dr. Gugerell stated in the opening quote to this study " *we couldn't even think about deleting this Article now*".

Chapter 9
Conclusion

"I would note at the outset that the concepts of *ordre public* and morality have a long and distinguished history as criteria for the lawfulness of the grant or exercise of intellectual property rights".

Advocate General Jacobs

14 June 2001[1]

The patent community has been resistant to seeing their work as influenced by moral rather than economic factors, but the patenting of animals has always been a contentious subject in public debate. As earlier chapters have shown, the Oncomouse case serves to highlight the relevance of these issues through the attention it has drawn to the morality exception in Article 53 (a) of the European Patent Convention. The significance of morality goes further, however, as the patenting of animals is only one example of a field where Article 53 (a) is of relevance. Not only does the provision require due consideration in relation to animals; it is also relevant to all inventions which come before the EPO for examination under the EPC. Despite the reluctance of the European patent community, exemplified by the comments of Christian Gugerell and the ability of non-European systems to operate without a 'morality clause', the writer has argued that Article 53 (a) is due to have an even greater prominence in the future particularly in relation to the protection of the products of the genetic engineering of animals, plants and humans. As a consequence, significant changes are required to equip the EPO to deal with the challenges that Article 53(a) presents and to perfect the weaknesses that the Oncomouse proceedings have exposed.

The attempt to minimize the importance of the morality exception is out of line with the origins and intentions of the Convention. The historical background to the inclusion of the morality exception in the EPC has been reviewed extensively in this thesis, as has the impact of the Biotech Directive and recent EBA decisions relating to transgenic plants. It is the writer's view, although unorthodox when compared to the interpretation of those within the EPO, that it was the intention of the legislators of the Strasbourg Convention that animals *per se* were not to be regarded as patentable inventions. However, the use by the legislators of the Strasbourg and European Patent Conventions of the same terminology in relation to the classification of animals as was used in relation to plants (which at the time of the drafting of these conventions had their own form of plant variety protection by virtue of the UPOV Convention) resulted in only specific animal 'varieties' being held to be unpatentable. Despite both patenting conventions, the Biotech Directive and the Plant Variety Right Regulation all containing numerous definitions of terms, including 'plant varieties' there has been no attempt to define what an animal variety is in the context of the European patenting system. The writer is of the view that if the

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[1] (14 June 2001) Opinion of Advocate General Jacobs in Kingdom of the Netherlands v. European Parliament and the Council of the European Union in C-3777/98 at para. 95.

UPOV Convention had not been under consideration at the time of drafting the EPC that the wording of Article 53 (a) EPC would have mandatorily prohibited the patenting of animals.

Detailed examination of the prosecution of the Oncomouse case highlighted the reluctance of the EPO to engage in discussions or give any guidance on ethical issues. However, the familiar cry of EPO examiners that they "are not trained to deal with such issues" has now been heard too often. It is now time for the EPO to take a firm stand on such issues and to put the appropriate systems in place to efficiently consider such matters. The models for an Ethical Board of Appeal or Ethical Division proposed in Chapter 7 offer a means for the EPO to achieve this.

In the future the EPO is going to have to make some potentially difficult moral assessments. As more and more information is gathered about the Human Genome and as genetic manipulation techniques develop the interpretation of the morality exception is likely to become harder and for those whose job it is to examine patent applications in these areas at the EPO are likely to find their task getting progressively more and more difficult. Even with the 'backup' of the Biotech Directive this task is hard.

Whilst this study is critical of the EPO and its handling of the Oncomouse case it must also be openly acknowledged that this case has not been an easy one and has been dogged with some notoriety. It is undeniable that various members of the EPO have a vast experience and knowledge of such ethical issues, of which Dr. Gugerell is one, but they have no training as 'ethicists'. Their remit, as is that of Dr. Gugerell, is essentially technical. This lack of training may be the major factor in contributing to the reluctance of the EPO to deal with Article 53 (a) EPC head on and which has resulted in effectively the sidelining of this provision. The informal internal 'ethics group' which was set up within the EPO by those interested in this area to deal with such issues was found to be ineffective and was discontinued. But again this may have been due to the lack of experience of those involved in ethical matters rather than a lack of interest in or recognition of Article 53 (a) EPC.

The writer's proposal, made in Chapter 7, for the formation of an Ethical Board of Appeal or Ethical Division provides two models for addressing some of the difficulties that the EPO experienced in dealing with the morality issues arising out of the Oncomouse case and providing a mechanism for dealing with potentially difficult ethical issues which may arise in the future. Both proposals provide that at the grass roots level (at both sub-committee level and above) these matters will be dealt with by EPO 'examiners' or EPO 'Personnel' who have undergone special training in such matters and that they are not merely experts in the technical aspects of the relevant invention but have other skills to bring to the task.

In the Ethical Division model it would be anticipated that any ethical issues would be identified by the Examining Division and referral to the Ethical Division for its opinion made at a relatively early stage. The Ethical Division would act in a purely advisory capacity. The advisory opinion would deal

specifically with Article 53 (a) EPC issues, thus in the Oncomouse case the Ethical Division giving an opinion on Article 53 (a) EPC objections and not on the patenting of animals *per se*.

Whilst any opinion given by the Ethical Division to its referring Board or Division would be advisory there would have to be a very good reason for any Board or Division to deviate from such an opinion. The referral to either the Ethical Division or Ethical Board would be on the grounds that a legal opinion was necessary in respect of the interpretation of Article 53 (a) in relation to the specific case. The advisory opinion of the Ethical Division or the opinion of the Ethical Board would not be appealable by the parties to any proceedings before the EPO, although a request for referral for such an opinion could be made by any party to the proceedings or directly sought at the instigation of the President or the Boards of Appeal themselves. The procedure for appeals and opposition would therefore proceed in the normal way.

Unlike in the Ethical Division model, an opinion of the Ethical Board of Appeal would have the same standing as a decision of the Enlarged Board of Appeal and would be binding on the Board or Division from which it was referred. Unlike the Ethical Division opinion it would not just be advisory but would have a greater precedential authority. The increased standing of such an opinion may make the Board of Appeal model more acceptable to the skeptics at the EPO as the 'advisory opinion' may be regarded as being too weak an authority to have any real influence. In the Oncomouse case such an opinion could have been sought from the Ethical Board at the time that an attempt was made by Harvard to have the matter referred to the Enlarged Board.

If either an Ethical Division or Ethical Board had been in existence at the time of the filing of the Harvard Oncomouse patent application in June 1985 the proceedings would have been considerably shortened and would have also given some definitive guidance in relation to the interpretation of Article 53 (a) EPC, in relation to animals (which the EPO throughout the Oncomouse proceedings sought vigorously to avoid). The Ethical Board model would have had a greater impact on the shortening the proceedings as its authoritative opinion would have resulted in the avoidance of protracted Opposition proceedings based on Article 53 (a) EPC objections.

The length of time that this matter has been before the Opposition Division is an indication that the present system is not operating as effectively as it might. A final decision by the EPO in the Oncomouse case is not likely to be reached for some time yet. The pending decision of the opposition Division can, and almost certainly will, be appealed to the Technical Board of Appeal. But even then that may not be the final chapter in the story. The national courts of the EU Members may be called upon in revocation proceedings to look at the patentability question again in relation to morality and the whole process of reviewing this patent may start again.

No formal decision[2] was given by the Opposition Division following the first Oral Hearing in November 1995 and despite objections by Harvard a second oral hearing was held in November 2001.[3] The writer had the opportunity of attending this hearing before the Opposition Division in Munich. The hearing this time lasted for two days. Three members of the Opposition Division had now changed, although Dr. Gugerell remained as the 1st Member. The patent proprietor sought that the patent be upheld as granted and Auxiliary claim Requests 2, 2A, 3, 3A and 4 be maintained in that order. On opening the proceedings it was agreed that discussion on the issue of Articles 83, 52 (2), 52 (4), 54 and 56 EPC were now concluded and that Articles 57, 53 (b) and 53 (a) EPC would be discussed in that order. Following limited representations on Articles 57 and 53 (b) EPC discussion focused on Article 53 (a) EPC. The earlier arguments under Article 53 (a) were again put forward by the Opponents, as were Harvard's arguments in rebuttal, but additional arguments were put forward with regard to the application and the effectiveness of the invention as a research tool over the last decade and half.[4] Following the representations by the all parties who wished to speak the Opposition Division gave its decision that the 4th Auxiliary Claim Request[5] only met the provisions of the EPC and would be maintained.[6] The Opposition Division also pointed out in concluding the proceedings that the decision could be appealed to the Technical Board of Appeal. Thus a partial success was achieved by the Opponents in the limiting of the breadth of the patent although the restriction to 'rodents' does seem to the writer to be illogical encompassing a group of animals which are unlikely to be used or created in the exploitation of the process (e.g. beavers, squirrels, chipmunks, voles, porcupines). However, this will no doubt be the subject of further extensive debate.

The writer recognises that the opinions expressed in this thesis are controversial in the current European biotechnological and post-Biotech Directive climate and may fairly be described as contrary to the more conventional views held by the majority of the European patenting community. The writer also recognises that such a community will not easily be persuaded to adopt a different view to Article 53 (a). However, it is believed that the final determination of the Oncomouse case whether before the EPO or EU Member's' national courts will result in a greater importance being afforded to the morality exception.

As the writer has indicated a final decision on the Oncomouse case at the EPO may not be available for sometime. Even then this may not be the end of the story. The national patent laws of the majority of EPC Contracting States have provision for revocation proceedings, one of the grounds being unpatentability on the basis that exploitation of the inventions would offend against morality. In the event that patentability is challenged in revocation proceedings on these grounds in an EPC Contracting Member's national court, this matter will be looked at again and could be determine by the national courts differently to that of the EPO. If proceedings are instituted in the national courts of

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[2] Preliminary view given in Annex to Summons issued by Opposition Division 28 August 2001.
[3] 6-7 November Opponents IV, V, VI, XVI and XVII were not represented. Opponent IX had been withdrawn.
[4] Forcefully argued by Opponent I.
[5] Least preferred request of Harvard and relating to rodents see Appendix 5.5 p.211.

Members which are sympathetic to the arguments put forward in opposition to the patent on morality grounds (for example Denmark, Netherlands, Germany) potentially this could result in the undermining of the authority of the EPC as a means of harmonising patent protection in Europe. Whilst the decisions of the EPO are persuasive on the national EPC contracting members' national courts, it is proposed that the Ethical Board opinion (and to a lesser extend the Ethical Division advisory opinion) would assist the national courts in understanding the background to the EPO decision and therefore due account to the arguments already made before the EPO on Article 53 (a) could be given to, and it is hoped would assist, the national courts in their determination and prevent any controversial and inconsistent decisions being made which might lead to the authority of the EPC being brought into question.

[6] Minutes of Oral Hearing issued dated 23 January 2002.

APPENDIX

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APPENDIX Chapter 1

1.1 Articles 1-5 Strasbourg Convention, Articles 52-54, 56-57 European Patent Convention and Sections 1-2 Patents Act 1977.

Strasbourg Convention Signed Strasbourg 27 November 1963	
Article 1 In the Contracting States, patents shall be grated for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. An invention which does not comply with these conditions shall not be the subject of a valid patent. A patent declared invalid because the invention does not comply with these conditions shall be considered invalid *ab initio*.	Article 4 (1) An invention shall be considered to be new if it does not form part of the state of the art.
	Article 4 (2) Subject to the provisions of paragraph 4 of this Article, the state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of the patent application or of a foreign application, the priority of which is validly claimed.
Article 2 The Contracting States shall not be bound to provide for the grant of patents in respect of; (a) inventions the publications or exploitation of which would be contrary to *"ordre public"* or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by a law or regulation; (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes and the products thereof.	Article 5 An invention shall be considered as involving an inventive step if it is not obvious having regard to the state of the art. However, for the purposes of considering whether or not an invention involves an inventive step, the law of any Contracting State may, either generally or in relation to particular classes of patents or patent applications, for example patents of addition, provide that the state of the art shall not include all or any of the patents or patent applications mentioned in paragraph 3 of Article 4.
Article 3 An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry including agriculture.	

1.2 Articles 1-5 Strasbourg Convention, Articles 52-54, 56-57 European Patent Convention and Sections 1-2 Patents Act 1977.

European Patent Convention Signed Munich 5 October 1973	
Article 52 (1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.	Article 57 An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.
Article 52 (2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1: (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information	Article 54 (1) An invention shall be considered to be new if it does not form part of the state of the art.
Article 53 **European patents shall not be granted in respect of:** **(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation 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;** (b) plant or animal varieties or essentially biological processes for the production of plants or animal; this provision does not apply to microbiological processes or the products thereof.	Article 54 (2) The state of the art shall be held to comprise everything made available to the pubic by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application
	Article 56 An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents are not to be considered in deciding whether there has been an inventive step.

1.3 Articles 1-5 Strasbourg Convention, Articles 52-54, 56-57 European Patent Convention and Sections 1-2 Patents Act 1977.

Patents Act 1977 Commencement 1 June 1978	
Section 1 (1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say- (a) the invention is new; (b) it involves an inventive step; (c) it is capable of industrial application; (d) the grant of a patent for it is not excluded by subsections (2) and (3) below; and references in this Act to a patentable invention shall be construed accordingly.	Section 4 (1) Subject to subsection (2) below, an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.
Section 1 (2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of- (a) a discovery, scientific theory or mathematical method; (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever; (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer; (d) the presentation of information; but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.	Section 2 (1) An invention shall be taken to be new if it does not form part of the state of the art.
Section 1 (3) A patent shall not be granted - (a) for an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour; (b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process of the product of such a process.	Section 2 (2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

APPENDIX Chapter 1

1.2 The Contracting States of the European Patent Convention

AT	Austria	BE	Belgium
CH	Switzerland	CY	Cyprus
DE	Germany	DK	Denmark
ES	Spain	FI	Finland
FR	France	GB	United Kingdom
GR	Greece	IE	Ireland
LI	Liechtenstein	IT	Italy
MC	Monaco	LU	Luxembourg
NL	Netherlands	PT	Portugal
SE	Sweden	TR	Turkey

EPC Extension States*

AL	Albania
LV	Latvia
LT	Lithuania
MK	Macedonia (former Yugoslav Republic)
RO	Romania
SL	Slovenia

* States which have concluded Extension Agreements with the European Patent Organisation to allow extension of the protection conferred by a European Patent to those States (dependent on appropriate national requirements being met).

APPENDIX Chapter 1

1.4 The patenting of animals in the context of significant international legislative, administrative and scientific events.

1474 Statute of Inventors (Venice)

1623 Statute of Monopolies

1790 First Patent Act in US

1791 First Patent Act in France

1865 Gregory Mendel published paper on Theory of Inheritance following work on peas

1873 Louis Pasteur granted US patent 'Yeast free from germs of disease as an article of manufacture' (No. 141,072

1883 Paris Convention signed 20 March

1930 Plant Patent Act US

1949 Patents Act UK

1961 UPOV Convention (International Convention for the Protection of New Varieties of Plants) signed 2 December

1963 Strasbourg Convention

1964 Plant Varieties and Seeds Act (UK)

1970 Plant Variety Protection Act (US)

1972 UPOV Convention revised

1973 **European Patent Convention** signed 5 October

1975 Community Patent Convention signed 15 December

1976 *Ex parte Hibberd* Decision (US)

1977 UK Patents Act

1978 EPC into force

US Patent 4,237,224 S.N. Cohen and H. Boyer (Utilising process for inserting foreign genetic material into bacterial plasmid)

UPOV Convention revised

1980 *Diamond v Chakrabarty* Decision (US)

First draft of proposal for Directive for the legal protection of biotechnological Inventions

Cohen-Boyer patent (4,237,224) first in US for recombinant DNA techniques

1981 First transgenic mammals (mice) 'invented' in US

1982 First commercial product based on recombinant DNA technology (human insulin by bacterial fermentation)

1983 Plant Varieties Act

1984 Oncomouse patent application filed by Harvard at USPTO 22 June

1985 Oncomouse patent application filed by Harvard at CIPO 21 June

Oncomouse patent application filed by Harvard at EPO2 24 June

First transgenic pigs generated

1987 USPTO confirms non-naturally occurring non-human animals are patentable subject matter April

Debate on Biotech Directive

1988 Patent granted by USPTO to Harvard for Oncomouse 12 April

First proposal for Directive on the legal protection of biotechnological inventions

1989 Application for Harvard Oncomouse refused by Examining Division of EPO/Appeal against decision filed

1990 Harvard Oncomouse patent granted by Examining Division of EPO following referral back from TBA

Canada enacts Plant Breeders' Rights Act

1991 Oppositions filed at EPO in respect of Harvard Oncomouse patent

March UPOV Convention revised

1992 3 further animal patents granted by USPTO following Harvard Oncomouse U.S. patent Nos. 5,175, 383, 5,175,384 and 5,175.385 claims referring specifically to mice 29 December

1993 First non-murine patent issued by USPTO (for rabbit Patent No.5,183,949) February

EPO issues provisional patent for Harvard Oncomouse 13 May

Tracy the sheep introduced by the Roslin Institute to the world

TRIPs approved in Geneva (15 December)

The United Nations Convention on Biological Diversity enters into force 29 December

1994 Council Regulation (E.C.) No 2100/94 on Community Plant Variety Rights 27 July

NAFTA implemented 1 January

Uruguay round of GATT

1994 Further transgenic mouse patent issued by USPTO Patent No. 5,387,742

Oral Hearing at EPO for Harvard Oncomouse before Opposition Division 21-24 November

Proposal for Biotech Directive rejected by European Parliament

1996 Revisions to Biotech Directive submitted for consideration

1997 Revised Biotech Directive approved by European Parliament

Dolly the Sheep (lamb GLL3) introduced by Roslin Institute and PPL Therapeutics to world (PCT WO 97/07669)

Polly first transgenic mammal to be cloned by Roslin Institute and PPL Therapeutics 24 July

Plant Variety Act UK

1998 Biotech Directive comes into force 30 July

Challenge to Biotech Directive by Dutch and Italian Governments

1999 *Novartis II* decision G1/98 of EBA 22 December

2000 Biotech Directive to be introduced into national laws of E.U. Member States by 30 July

Amendments to Implementing Regulations (Rules 23 b-e) in force 1 September

2001 *Second Oral Hearing of Harvard Oncomouse before Opposition Division of EPO 6-8 November*

Production of Human Clone

2002 *Appeal against decision of Opposition Division in Oncomouse Case*

2004 *Decision of Technical Board of Appeal in Oncomouse Case*

2006 *Challenge to Oncomouse patent in National Courts (Germany or Netherlands?)*

2009 *Ethical Board of Appeal/ Ethical Division established at EPO*

APPENDIX Chapter 2

2.1 Summary of the main changes to the Recitals and Articles relating to the morality exception to patentability at various stages during the progress of the EU Directive on the Legal Protection of Biotechnological Inventions before the Council of Europe, the European Commission and the European Parliament.

Proposal 1988 – Commission Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions submitted by the Commission on 20 October 1988 *OJ.* No 10/3 13 January 1989
Common Position - EC No 4/94 adopted by the Council on 7 February 1994 *OJ.* No C 101/65 9 April 1994
Proposal 1995 – Proposal for a European Parliament and Council Directive on The Legal Protection of Biotechnological Inventions presented by the Commission COM (95) 661 final 95/0350 (COD) Brussels 13 December 1995
Directive - Directive 98/44/EC of European Parliament and of the Council of 6 July 1998 *OJ.* L 213/13 30 July 1998

Recitals

Proposal 1988	-
Common Position	-
Proposal 1995	-
Directive	(36) Whereas the TRIPs Agreement provides for the possibility that members of the World Trade Organisation may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or **morality**, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
Proposal 1988	-
Common Position	(7) Whereas in implementing the Directive regard should be had to existing national patent laws, as amended by the Directive; whereas those laws contain provisions on the criteria for patentability or exclusion from patentability, including provisions to the effect that a patent may not be granted in respect of inventions the publication or exploitation of which would be contrary to public policy or **morality.**
Proposal 1995	(19) Whereas national patent laws for inventions contain provisions as to the criteria for allowing or excluding patentability, including provisions to the effect that a patent may not be granted in respect of inventions whose publication or exploitation would be contrary to public policy or **morality;** (20) Whereas such a reference to public policy and **morality** should be included in the operative part of this Directive in order to bring out the fact that some applications of biotechnological inventions, by virtue of some of their consequences or effect, are capable of offending against them.
Directive	(37) Whereas the principle whereby inventions must be excluded from patentability where their commercial exploitation offends against ordre public or **morality** must also be stressed in this Directive.

Proposal 1988	-
Common Position	(9) Whereas the body of the Directive should also mention a list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to public policy or **morality.**
Proposal 1995	(22) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to public policy or **morality.**
Directive	(38) Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to ordre public and **morality;** whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability.
Proposal 1988	-
Common Position	(8) Whereas it is advisable to include in the body of the Directive such a reference to public policy and **morality** in order to highlight the fact that some applications of biotechnological inventions, by dint of some of their consequences or effects, are capable of offending against them.
Proposal 1995	(21) Whereas it must be determined whether applications offend against public policy and **morality** in each specific case, by means of an appraisal of the values involved, whereby the benefit to be derived from the invention, on the one hand, is weighed and evaluated against any risks associated therewith, and any objections based on fundamental principles of law, on the other hand. (23) Whereas such moral considerations must be given greater weight in appraising the patentability of biotechnological inventions, both on account of the subject-matter of this branch of science, namely living matter, and because of the often far-reaching implications of the inventions to be examined; whereas these considerations do not, however, change the nature of patent law as a primarily technical body of law and are no substitute for the other legal checks which biotechnological inventions are required to undergo from the start of their development or at the marketing stage, particularly with regard to safety.
Directive	(39) Whereas ordre public and **morality** correspond in particular to ethical or moral principles recognised in a Member State, respect for which is particularly important in the field of biotechnology in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention.
Proposal 1988	-
Common Position	-
Proposal 1995	-
Directive	(44) Whereas the Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology; whereas it should be pointed out in this connection that the Group may be consulted only where biotechnology is to be evaluated at the level of basic ethical principles, including where it is consulted on patent law.

Proposal 1988	-
Common Position	(15) Whereas processes for modifying the generic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal and the products of such processes must likewise be excluded from patentability in so far as the suffering or physical handicaps inflicted on the animals concerned are out of proportion to the objective pursued.
Proposal 1995	(25) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and also animals resulting from such processes must be excluded from patentability insofar as the suffering or physical handicaps inflicted on the animals concerned are out of proportion to the objective pursued.
Directive	(45) Whereas processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit in terms of research, prevention, diagnosis or therapy to man or animals, and also animals resulting from such processes, must be excluded from patentability.
Proposal 1988	-
Common Position	-
Proposal 1995	-
Directive	(47) Whereas it is necessary to provide for a first derogation from the rights of the holder of the patent when the propagating material incorporating the protected invention is sold to a farmer for farming purposes by the holder of the patent or with his consent; whereas that initial derogation must authorise the farmer to use the product of his harvest for further multiplication or propagation of his own farm; whereas the extent and the conditions of that derogation must be limited in accordance with the extent and conditions set out in Council Regulation (EC) No. 2100/94 of 27 July 1994 on Community plant variety rights.*

*1 September 1994, *OJ.* No. L 227, p.1 Regulation as amended by Regulation (EC) No. 2506/95 (28 October 1995 *OJ.* L 258, p..3)

Proposal 1988	Article 3 (1) Micro-organisms, biological classifications other than plant or animal varieties as well as parts of plant and animal varieties other than propagating material thereof of the kind protectable under plant variety protection law shall be considered patentable subject matter. Claims for classifications higher than varieties shall not be affected by any rights granted in respect of plant and animal varieties.
Common Position	Article 2 (2) 'Biological material' within the meaning of this Directive means any material containing genetic information and capable of self-reproducing or capable of being reproduced in a biological system.
Proposal 1995	Article 3 (1) "Biological material" means any material containing genetic information and capable of self-reproduction or of being reproduced in a biological system
Directive	Article 2 (2) For the purposes of this Directive, (a) "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.
Proposal 1988	Article 3 (2) Notwithstanding the provisions of paragraph 1 plants and plant material shall be considered patentable subject matter unless such material is produced by the non-patentable use of a previously know biotechnological process.
Common Position	-
Proposal 1995	Article 2 (2) "Microbiological process" means any process involving or performed upon or resulting in microbiological material; a process consisting of a succession of steps shall be treated as a microbiological process if at least one essential step of the process is microbiological.
Directive	Article 2 (1) For the purposes of this Directive, (b) "Microbiological process" means any process involving or performed upon or resulting in microbiological material.

Proposal 1988	Article 19 For the purpose of this Directive: (a) the word 'micro-organism', where used, shall be interpreted in its broadest sense as including all microbiological entities capable of replication, e.g. as comprising, *inter alia*, bacteria, fungi, viruses, mycoplasmae, rickettsia, algae, protozoa, and cells; and (b) the words 'self-replicable matter', where used, shall be interpreted to comprise also matter possessing the genetic material necessary to direct its own replication via a host organism or in any other indirect way, e.g. as comprising, *inter alia*, seeds, plasmids, DNA sequences, protoplasts, replicons and tissue cultures.
Common Position	-
Proposal 1995	Article 2 (3) "Essentially biological process for the production of plants or animals" means any process which, taken as a whole, exists in nature or is not more than a natural plant-breeding or animal-breeding process.
Directive	Article 2 (2) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.
Proposal 1988	-
Common Position	-
Proposal 1995	-
Directive	Article 2 (3) The concept of "plant variety" is defined by Article 5 of Regulation (EC) NO 2100/94.
Proposal 1988	Article 4 Uses of plant or animal varieties and processes for the production thereof shall be considered patentable subject matter.
Common Position	Article 3 Biological material, including plants and animals, as well as parts of plants and animals, except plant and animal varieties as such, shall be patentable.
Proposal 1995	Article 7 Uses of plant or animal varieties and processes for their production, other than essentially biological processes for the production of plants or animals, shall be patentable.
Directive	Article 4 (1) The following shall not be patentable: (a) plant and animal varieties.

Proposal 1988	-
Common Position	Article 4 Uses of plant or animal varieties and processes for their production, other than essentially biological processes for the production of plants or animals, shall be patentable. Article 6 Essentially biological processes for the production of plants or animals shall not be considered patentable. In determining this exclusion, human intervention and its effects on the result obtained shall be taken into account. A process which, taken as a whole, does not exist in nature and is more than a traditional breeding process shall be considered patentable.
Proposal 1995	Article 6 Essentially biological processes for the production of plants or animals shall not be patentable.
Directive	Article 4 (1)The following shall not be patentable: (b) essentially biological processes for the production of plants or animals.
Proposal 1988	-
Common Position	-
Proposal 1995	-
Directive	Article 4 (2) Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

Proposal 1988	Article 5 Microbiological process shall be considered patentable subject matter. For purposes of this Directive, this term shall be taken to mean and to include a process (or processes) carried out with the use of or performed upon or resulting in a micro-organism. Article 6 A process consisting of a succession of steps shall be regarded as a microbiological process, if the essence of the invention is incorporated in one or more microbiological steps of the process.
Common Position	Article 5 (1) Microbiological processes shall be patentable. For the purposes of this Directive 'microbiological process' means a process involving or performed upon or resulting in microbiological material. (2) A process consisting of a succession of steps shall be treated as a microbiological process if a t least one essential step of the process is microbiological.
Proposal 1995	Article 5 Microbiological process and products obtained by means of such process shall be patentable.
Directive	Article 4 (3) Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.
Proposal 1988	-
Common Position	Article 2 (3) Inventions shall be considered unpatentable where publication or exploitation would be contrary to public policy or **morality**, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Member States.
Proposal 1995	Article 9 (1) Inventions shall be considered unpatentable where exploitation would be contrary to public policy or **morality**; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
Directive	Article 6 (1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

Proposal 1988	-
Common Position	Article 2 (2) On this basis, the following *inter alia* shall be unpatentable: Processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animal, and animals resulting from such processes.
Proposal 1995	Article 9 (3) On the basis of paragraph 1, the following shall be considered unpatentable: Processes for modifying the genetic identity of animals which are likely to cause them suffering or physical handicaps without any substantial benefit to man or animals, and also animals resulting from such processes, whenever the suffering or physical handicaps inflicted on the animals concerned are disproportionate to the objective pursued.
Directive	Article 6 (2) On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.
Proposal 1988	-
Common Position	-
Proposal 1995	-
Directive	Article 7 The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

APPENDIX Chapter 2

2.2 International Conventions and Treaties

1. Paris Convention for the Protection of Industrial Property
   Signed 20 March 1883.* Relating to the fundamental principles for the protection of inventions.[α]

2. The European Convention for the Protection of Human Rights and Fundamental Freedoms[β]
   Signed 4 November 1950 entered into force 3 September 1953.

3. Treaty of Rome.
   Treaty establishing the European Economic Community signed in Rome 25 March 1957

4. The International Union for the Protection of New Varieties of Plants (The UPOV Convention).
   Signed in 1961 and revised in 1972, 1978 and the latest revision in March 1991. Provided the first International Convention of plant breeders rights to act as a forum for the discussion and agreement on issues relating to plant varieties.[χ]

5. Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (Strasbourg Convention)
   Signed 27 November 1963. Unifying substantive patent law between contracting member states.

6. The Patent Co-operation Treaty (PCT)
   Signed on 19 June 1970 and entered into force in 1978. It is governed by the Word Intellectual Property Organisation (WIPO) provides for an international filing and search phase thereafter passing into the national phase of designated states. European patents may be obtained by the PCT route.[δ] Aim to facilitate filing search, and examination procedural system to expedite the acquisition of patents.

7. **The European Patent Convention** signed 5 October 1973

8. Community Patent Convention (CPC)
   Signed on 15 December 1975 in Luxembourg. The basic text of the CPC has still not been ratified by all EU Member States. A community patent will be enforceable in every EU Member State through any EU national court. Whilst having its own Basic Agreement and Legal Texts it will be complementary to the EPC.

9. The United Nations Convention on Biodiversity (Biodiversity Treaty)
   Signed 1992 and entered into force 29 December 1993. Dealing with the conservation of biodiversity, and the sustainable use, access, sharing and transfer of related technology. Aim to ensure fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

10. Council Regulation (EC) No 2100/94 of 27 July 1994[ε] on Community Plant Variety Rights.[♦]

11. Agreement on Trade Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (TRIPs Agreement) 1995
    The Uruguay Round of the General Agreement on Tariffs and Trade (GATT- first signed in 1947)

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* Subsequently amended 1900,1911, 1925, 1934 and 1958.

[α] F.K. Beier 100 years of International Co-operation - The Role of the Paris Convention in the past, present and future (1984) 15 *IIC*, p. 1.

[β] For an account see P. van Dijk G.J.J. Van Hoof *Theory and Practice of the European Convention on Human Rights* (Kluwer Law International April 1998) 3rd Edition; for text as amended by Protocol 11 see http://conventions.coe.int/Treaty/EN/CadreListeTraites.htm (last visited 24/8/01).

[χ] For account see N. Byrne *Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties* (Centre for Commercial Studies, Queen Mary and Westfield College, University of London 1996).

[δ] For an account see I. Muir, M. Brandi-Dohrn and S. Gruber *European Patent Law and Procedure under the EPC and PCT* (Oxford University Press 1999).

[ε] (11 September 1994) *OJ.* No L227 p. 1.

[♦] For account see P.A.C.E. van der Kooij *Introduction to the EC Regulation on Plant Variety Protection* (Kluwer Law International 1997).

terminated with the conclusion in Marrakech in Morocco on 15 April 1994 of the TRIPs Agreement which came into effect on 1 January 1995. Agreement provides a global system for the protection of intellectual property rights which provides for national rights being recognised by all signatories.[7] The Agreement is administered by the World Trade Organisation (WTO) which was established by WTO Agreement in 1994 (including Final Act) and which incorporated GATT Uruguay Round.

12. Council Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions, (The Biotech Directive). To be implemented by E.U. Member States by 30 July 2000.

[7] For detailed analysis see C.M. Correa and A.A. Yusuf (Eds) *Intellectual Property and International Trade The TRIPS Agreement* (Kluwer Law International 1998); GATT TRIPS Agreement: Supplement (1994) 11 *EIPR* p.1.

APPENDIX Chapter 2

2.3 Patentable subject matter proposed by various countries during discussions leading to the TRIPs Agreement

Proposals submitted by various Countries during Multilateral TRIPs Negotiations (Uruguay Round)	
United States	Patents should be available for inventions in any technological field provided the invention is a new, useful, and unobvious product or process. It shall not discriminate against inventions in particular fields of technology.*
	Article 23 - Patentable Subject Matter. Patents shall be granted for all products and processes, which are new, useful, and unobvious.α
Japan	Annex (2) Equal and non-discriminatory treatment shall be guaranteed in the requirements for application for a patent, and obtaining, maintenance and exercise of patent. (3) Participants may exclude such inventions as are contrary to public safety on health, or to the maintenance of public order or morality from what patents are give for.β
European Community	D.3.a (ii) Patents shall be granted for any inventions, whether products or processes, which are susceptible of Industrial application, which are new and which involve an inventive step. Patents shall be available for inventions in all fields of technology, except for: – Inventions the publication or exploitation of which would be contrary to "ordre public" or morality; – Plant or animal varieties or essentially biological processes for the production of plants or animals; this does not apply to microbiological processes or the products thereof.χ

* MTN.GNG/NG/NG11/W/14 - 20 October 1987
α MTN.GNG/NG11/W/70 - 11 May 1990
β MTN.GNG/NG11/W/17 - 23 November 1987
χ MTN.GNG/NG11/W/26 - 7 July 1988

India	A patent shall be granted for an invention. However, some subject matter may be regarded as unpatentable; for example: a. the mere presentation of information; b. mere discoveries; c. schemes, rules or methods of performing a mental act, playing a game or doing business; and inventions the use of which would be contrary to public order or **morality.**[δ]
Canada	Patents should be available for all products and processes in all fields of technology. National laws, however, may provide that the following are not patentable: i. multicellular life-forms or processes for producing new multicellular life-forms; ii. methods of medical treatment for humans or animals; iii. mere scientific principles; iv. schemes, plans or systems for doing business, accounting, playing games and the like; v. printed or design material having intellectual connotations only; and algorithms and computer programs per se.[ε]
Korea	1.1 Patents should be granted for products and processes which are new, progressive and capable of industrial application. They include chemical and pharmaceutical products and micro-organisms. The following inventions, however, should not be patentable: i. inventions liable to contravene public order or **morality** or to injure public health; ii. inventions of substances manufactured by nuclear atomic transformation process. 19 Patents should be granted to those inventions which satisfy the criteria of patentability, exception made to inventions that are contrary to **morality**, religion, public order, public health and bearing in mind public interest and technological and economic development considerations.[♦]

[δ] MTN.GNG/NG11/W/40 - 5 September 1989
[ε] MTN.GNG/NG11/W/47 - 25 October 1989
[♦] MTN.GNG/NG11/W/48 - 26 October 1989

Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay and Pakistan	Article 4 1 Patent protection shall be available for inventions in all fields of technology which are new, which involve an inventive step and which are industrially applicable, except for: i. inventions whose use would be contrary to public order, law or morality or injurious to public health; ii. plant or animal varieties or essentially biological processes for the production of plants or animals; iii. discoveries and materials or substances already existing in nature; iv. methods of medical treatment for humans or animals; nuclear and fissionable material. 2 Parties may exclude from patentability, on grounds of public interest, national security, public health or nutrition, certain kinds of products or processes for the manufacture of those products, provided that such exclusion applies equally to inventions by nationals and foreigners.[7]
Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1994)	Article 27 2 Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. 3 Members may also exclude from patentability: (a) Diagnostic, therapeutic and surgical methods for the treatment of humans or animals (b) Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

[7] MTN.GNG/NG11/W/71 - 14 May 1990

APPENDIX Chapter 4

4.1 Claims of U.S. Patent Application 'Transgenic Non-human Mammals' No 4,736,866 filed at USPTO by Harvard on 22 June 1984

Other Embodiments:

Other embodiments are within the following claims. For example, any species of transgenic animal can be employed. In some circumstances, for instance, it may be desirable to use a species e.g. a primate such as the rhesus monkey, which is evolutionarily closer to humans than mice.

Claims:

1. A transgenic non-human eukaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said animal, at an embryonic stage.

2. The animal of claim 1, a chromosome of said mammal including an endogenous coding sequence substantially the same as a coding sequence of said oncogene sequence.

3. The animal of claim 2, said oncogene sequence being integrated into a chromosome of said animal at a site different from the location of said endogenous coding sequence.

4. The animal of claim 2 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.

5. The animal of claim 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible.

6. The animal of claim 1 wherein said oncogene sequence comprises a coding sequence of a c-myc gene.

7. The animal of claim 1 wherein transcription of said oncogene sequence is under the control of a viral promoter sequence.

8. The animal of claim 7 wherein said viral promoter sequence comprises a sequence of an MMTV promoter.

9. The animal of claim 7 wherein said viral promoter sequence comprises a sequence of an RSV promoter.

10. The animal of claim 1 wherein transcription of said oncogene sequence is under the control of a synthetic promoter sequence.

11. The animal of claim 1, said animal being a rodent.

12. The animal of claim 11, said rodent being a mouse.

13. A method of testing material suspected of being a carcinogen comprising exposing the animal of claim 1 to said material and detecting neoplasms as an indication of carcinogenicity.

14. A method of providing a cell culture comprising culturing said somatic cells of the animal of claim 1.

15. A method of producing a transgenic eukaryotic animal having an increased probability of developing neoplasms, said method comprising introducing into an animal embryo an activated oncogene sequence.

16. The method of claim 15 wherein said activated oncogene sequence comprises a fused gene comprising an oncogene sequence fused to an activating viral or synthetic promoter sequence.

17. The method of claim 15 wherein said activated oncogene sequence comprises a DNA sequence selected from the oncogenes src, yes, fps, abl, ros, fgr, erbB, fms, mos, raf, Ha-ras-1, Ki-ras 2, Ki-ras 1, myc, myb, fos, ski, rel, sis, N-myc, N-ras, Blym, mam, neu, erbAl, ra-ras, mht-myc, myc, myb-ets, raf-2, raf-1, Ha-ras-2 or erbB.

18. A method of testing material suspected of conferring protection against the development of neoplasms, said method comprising treating an animal of claim 1 with said material and detecting a reduced incidence of development of neoplasms, compared to an untreated animal of claim 1, as an indication of said protection.

19. The method of claim18, further comprising exposing said treated and untreated animals to a carcinogen prior to, after, or simultaneously with treating said animal with said material.

20. Plasmid having ATCC Accession No. _____.

21. Plasmid having ATCC Accession No. _____.

22 Plasmid having ATCC Accession No. _____.

23. Plasmid having ATCC Accession No. _____.

24. Plasmid having ATCC Accession No. _____.

APPENDIX Chapter 4

4.2 Claims of Canadian Patent Application 'Transgenic Animals' No 484723 filed at CIPO by Harvard on 21 June 1985

1. A transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.

2. The mammal of claim 1, a chromosome of said mammal including an endogenous coding sequence substantially the same as a coding sequence of said oncogene sequence.

3. The mammal of claim 2, said oncogene sequence being integrated into a chromosome of said mammal at a site different from the location of said endogenous coding sequence.

4. The mammal of claim 2 wherein transcription of said oncogene sequence is under the control of promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.

5. The mammal of claim 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible.

6. The mammal of claim 1 wherein said oncogene sequence comprises a coding sequence of a c-myc gene.

7. The mammal of claim 1 wherein transcription of said oncogene sequence is under the control of a viral promoter sequence.

8. The mammal of claim 7 wherein said viral promoter sequence comprises a sequence of an MMTV promoter.

9. The mammal of claim 7 wherein said viral promoter sequence comprises a sequence of an RSV promoter.

10. The mammal of claim 1 wherein transcription of said oncogene sequence is under the control of a synthetic promoter sequence.

11. The mammal of claim 1, said mammal being a rodent.

12. The mammal of claim1, said mammal being a mouse.

13. A method of testing a material suspected of being a carcinogen comprising exposing the mammal of claim 1 to said material and detecting neoplasms as an indication of carcinogenicity.

14. A method of producing a transgenic cell culture comprising: a) introducing an activated oncogene sequence into pluripotent cells of a mammalian embryo; b) allowing said embryo to develop into an adult animal; and, c) culturing somatic cells of said animal.

15. A method of producing a transgenic mammal having an increased probability of developing neoplasms, said method comprising introducing into a mammal embryo an activated oncogene sequence.

16. The method of claim 15 wherein an activated oncogene sequence comprises a fused gene comprising an oncogene sequence fused to an activating viral or synthetic promoter sequence.

17. The method of claim 15 wherein an activated oncogene sequence comprises a DNA sequence from one of the oncogene sequences src, yes, fps, abl, ros, fgr, erbB, fms, mos, raf, Ha-ras-1, Ki-ras 2, Ki-ras 1, myc, myb, fos, ski, rel, sis, N-myc, N-ras, Blym, mam, neu, erbAl, ra-ras, mht-myc, myc, myb-ets, raf-2, raf-1, Ha-ras-2 or erbB.

18. Use of the transgenic mammal of claim 1 in a method of testing a material suspected of altering neoplastic development, said method comprising treating said mammal with said material and detecting a reduced or increased incidence of development of neoplasms, compared to an untreated mammal of claim 1, as an indication of said alteration.

19. The use of claim 18, further comprising exposing said treated and untreated mammals to a carcinogen prior to, after, or simultaneously with treating said mammal with said material.

20. Plasmid having ATCC Accession No. 39745.

21. Plasmid having ATCC Accession No. 39746.

22. Plasmid having ATCC Accession No. 39747.

23. Plasmid having ATCC Accession No. 39748.

24. Plasmid having ATCC Accession No. 39749.

25. A somatic cell culture derived from a transgenic mammal wherein the cells of said cell culture contain an activated oncogene sequence integrated into a chromosome.

26. Use of a transgenic mammal according to any one of claims 1 to 12 to test a material suspected of altering neoplastic development in a mammal.

APPENDIX Chapter 4

4.3 Claims of European Patent Application 'Method for Producing Transgenic Animals' No 85304490.7 for Oncomouse filed by Harvard at EPO on 24 June1985

Claims

1. A method for producing a transgenic eucaryotic animal having an increased probability of developing neoplasms, said method comprising introducing into an animal embyo an activated oncogene sequence.

2. A method as claimed in claim 1 wherein the chromosome of the animal includes an endogenous coding sequence substantially the same as the coding sequence of the oncogene.

3. A method as claimed in claim 2 wherein said oncogene sequence is integrated into a chromosome of said animal at a site different from the location of said endogenous coding sequence.

4. A method as claimed in claim 2 or claim 3 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.

5. A method as claimed in any one of claims 2 to 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible.

6. A method as claimed in any one of claims 1 to 4 wherein said activated oncogene sequence comprises a fused gene comprising an oncogene sequence fused to an activating viral or synthetic promoter sequence.

7. A method as claimed in claim 6 wherein said viral promoter sequence comprises a sequence selected either from an MMTV or an RSV promoter.

8. A method as claimed in any one of claims 1 to 7 wherein said oncogene sequence comprises a coding sequence of a c-myc gene.

9. A method as claimed in any one of claims 1 to 7 wherein said activated oncogene sequence comprises a DNA sequence selected from the oncogenes src, yes, fps, abl, ros, fgr, erbB, fms, mos, raf, Ha-ras-1, Ki-ras 2, Ki-ras 1, myc, myb, fos, ski, rel, sis, N-myc, N-ras, Blym, mam, neu, erbAl, ra-ras, mht-myc, myc, myb-ets, raf-2, raf-1, Ha-ras-2, or erbB.

10. A method as claimed in any one of claims 1 to 8 wherein said activated oncogene is provided in the form of a plasmid.

11. A plasmid selected from the group comprising plasmids ATCC 39745, 39746, 39747, 39748, 39749.

12. A method as claimed in claim 1 wherein the activated oncogene sequence is derived from a plasmid as defined in claim 11.

13 A method as claimed in claim 1 which comprises injecting into the male pronucleus of a fertilized one-cell mouse egg a linearized plasmid as defined in claim 11.

14 A method of testing a material suspected of being a carcinogen which comprises exposing an animal produced according to the method of any one of claims 1 to 13 to said material and detecting neoplasms as an indication of carcinogenicity.

15 A method of testing a material suspected of conferring protection against the development of neoplasms, said method comprising treating an animal produced according to the methods of any one of claims 1 to 13 with said material and detecting a reduced incidence of development of neoplasms, compared to an untreated animal, as an indication of said protection.

16 A method as claimed in claim 15, further comprising exposing said treated and untreated animals to a carcinogen prior to, after or simultaneously with treating said animals with said material.

17 A transgenic non-human eucaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at an embryonic stage, said oncogene optionally being further defined according to any one of claims 3 to 10, said animal preferably being a rodent.

18 A chromosome of an animal as claimed in claim 17, which comprises an oncogene as defined in any one of claims 3 to 10.

APPENDIX Chapter 4

4.4 Chronological summary of progress of US, Canadian and European Patent Applications for the Harvard Oncomouse.

1984	22 June Patent Application for Oncomouse filed at USPTO.
1985	21 June Patent Application for Oncomouse filed at CIPO (No. 484723 – Transgenic Animals).
	24 June Oncomouse patent application filed by Harvard at EPO.
1987	April USPTO confirms non-naturally occurring non-human animals patentable.
1988	12 April US patent granted by USPTO for Harvard Oncomouse.
1989	14 July Examining Division of EPO issues notice of refusal of Harvard Oncomouse patent.
1992	13 May EPO grants provisional patent for Harvard Oncomouse.
1993	24 March CIPO Examiners Final Action.
1995	4 August Canadian Patent Review Appeal Board.
1996	2 Febraury Notice of Appeal filed by Harvard.
1998	21 April Canadian Federal Court Trial Division.
1999	September Canadian Biotechnology Advisory Committee set up.
2000	3 August decision of Canadian Federal Court of Appeal.
	2 October Leave to appeal to Canadian Supreme Court.

4.5 Claims of US Patent No 4,736,866 Filed on 22 June 1984 and dated 12 April 1988 'Transgenic Non-Human Mammals'

Other Embodiments:

Other embodiments are within the following claims. For example, any species of transgenic animal can be employed. In some circumstances, for instance, it may be desirable to use a species e.g. a primate such as the rhesus monkey, which is evolutionarily closer to humans than mice.

Claims:

1. A transgenic non-human-mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.

2. The mammal of claim 1, a chromosome of said mammal including an endogenous coding sequence substantially the same as a coding sequence of said oncogene sequence.

3. The mammal of claim 2, said oncogene sequence being integrated into a chromosome of said mammal at a site different from the location of said endogenous coding sequence.

4. The mammal of claim 2 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.

5. The mammal of claim 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible.

6. The mammal of claim 1 wherein said oncogene sequence comprises a coding sequence of a c-myc gene.

7. The mammal of claim 1 wherein transcription of said oncogene sequence is under the control of a viral promoter sequence.

8. The mammal of claim 7 wherein said viral promoter sequence comprises a sequence of an MMTV promoter.

9. The mammal of claim 7 wherein said viral promoter sequence comprises a sequence of an RSV promoter.

10. The mammal of claim 1 wherein transcription of said oncogene sequence is under the control of a synthetic promoter sequence.

11. The mammal of claim 1, said mammal being a rodent.

12. The mammal of claim 11, said rodent being a mouse.

APPENDIX Chapter 4

4.6 Details of the stages in the prosecution of European Patent Application No. 85304490 for the Harvard Oncomouse

1. 24 June 1985 Application filed at EPO No 85304490.7 by President and Fellows of Harvard College claiming priority from US Patent Application No 623,774 (Patent No 4,736,866).
2. 29 January 1986 Application published.
3. 20 April 1988 Communication from Examining Division pursuant to Article 96(2) and Rule 51(2) EPC advising Harvard that application does not meet requirements.
4. Various requests for extension of time to file response made by Harvard. Total extensions of time amounted to 9 months.
5. 22 December 1988 Harvard files written response.
6. 28 March 1989 Examining Division responds to Harvard.
7. 13 June 1989 Harvard sends further documents to Examining Division.
8. 26 June 1989 Oral proceedings. Harvard's representative in attendance.
9. 14 July 1989 EPO notifies Harvard of refusal. Examining Division presents written summary of facts and submissions.
10. 13 November 1989 Notice of Appeal under Article 106 (1) EPC filed by Harvard including Grounds of Appeal and Amendments.
11. Observations filed by third parties under Article 115 (1) EPC.
12. 3 October 1990 Decision of Technical Board of Appeal T19/90.
13. 22 October 1990 correction issued by EPO.
14. 11 December 1990 Communication of EPO pursuant to Article 96 (2) and Rule 51 (2) EPC. Application to be re- examined by the Examining Division. Harvard invited to comment.
15. 16 April 1991 Harvard responds.
16. 14 October 1991 Notification of intention to grant under Rule 51(4) EPC and Annex to Form 2035.3/2004 – Comments of Examining Division issued.
17. 3 April 1992 Decision to grant European patent pursuant to Article 97 (2) EPC.
18. 13 May 1992 EPO grants provisional patent. Opposition period starts to run.
19. 19 May 1992 transmission of Certificate pursuant to rule 54(1) EPC.
20. 17 Oppositions filed within 9 month Opposition period.
21. 15 February 1993 Opposition period ends.
21. 17 June 1994 Observations of Harvard filed in relation to 17 purported Oppositions against European Patent No 0169672 .
22. October 1994 Comments submitted with letter dated 17 October 1994 by Opponent I on the observations of the Harvard on Oppositions lodged against EP No 0169672.
23. February 1995 Scientific comments submitted by Opponent I with letter dated I March 1995.
24. 26 September 1995 Provisional observations of Opposition Division on Harvard's observations of 17 June 1994.
25. 20 October 1995 Harvard comments on provisional opinion of Opposition Division.
24. 13 November 1995 Opponent I comments on the letter of Harvard dated 20 October 1995

25. 21 November - 24 November 1995 Oral Proceedings before Opposition Division of EPO. Auxiliary Claim Requests submitted by Harvard.
26. Observations continue in writing.
27. 28 November 1995 7 Auxiliary Claim Requests filed by Harvard.
28. 25 March 1996 Further observations on Article 53(b) EPC filed by Opponent I.
29. 15 April 1996 Annex to Form 2323 issued by Opposition Division seeking observations on Auxiliary requests and on the Decision of the Enlarged Board in G3/95.
30. Observations filed by Opponents I, II, III, VII, VIII – XV, XVI and XVII.
31. 9 August 1996 Observations of Opponent I on Auxiliary Claim Requests submitted by Harvard on 28 November 1995.
32. 23 August 1996 Transcription of extract of Oral Proceedings filed by Harvard
33. 24 April 1997 Observations filed by Harvard and withdrew 3rd, 4th and 6th Auxiliary Claim Requests.
34. 24 August 1999 Letter Harvard to Opposition Division.
35. 6 September 1999 Letter Harvard to Opposition Division.
36. 14 April 2000 Opponent IV withdraws from proceedings.
37. 20 September 2000 Notice issued by Opposition Division to all parties inviting comments on changes to Implementing Regulations in the light of the Biotech Directive and Decision G1/(8 (Novartis) of the Enlarged Board of Appeal.
38. 29 September 2000 Harvard sends letter to EPO.
39. 30 October 2000 Notice of replacement of Legal Member on Opposition Board. New Member appointed, R. Moufang.
40. 11 January 2001 Observations filed by Opponent I.
41. May 2001 Notice of further Oral Proceedings to be held 6th to 8th November 2001.
42. 28 August 2001 Annex to Summons issued by Opposition Division.
43. 6 September 2001 Written submissions filed by Harvard commenting on Annex to summonsissued by Opposition Division.

APPENDIX Chapter 4

4.7 Articles of EPC Considered by EPO during Prosecution of Harvard Oncomouse Patent Application

Article 54 – Novelty

1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the pubic by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, of which the dates of filing are prior to the date referred to in paragraph 2 and which were published under Article 93 on or after that date, shall be considered as comprised in the state of the art.

(4) Paragraph 3 shall be applied only in so far as a Contracting State designated in respect of the later application, was also designated in respect of the earlier application as published.

(5) The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.

Article 52 – Patentability

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c)schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

(4)Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall no apply to products, in particular substances or compositions, for use in any of these methods.

Article 53 – Exceptions to Patentability

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation 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;

(b) plant or animal varieties or essentially biological processes for the production of plants or animal; this provision does not apply to microbiological processes or the products thereof;

APPENDIX Chapter 4

4.7 Articles of EPC Considered by EPO during Prosecution of Harvard Oncomouse Patent Application

Article 56 – Inventive Step	Article 83 - Disclosure of Invention
An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents are not to be considered in deciding whether there has been an inventive step	The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

APPENDIX Chapter 4

4.8 Amendments to claims of European Patent Application No 85304490.7 submitted by Harvard by letter dated 22 December 1988 in response to objections raised by Examining Division.

Method for Producing Transgenic Animals

Claims

1. A method for producing a transgenic non-human eucaryotic animal having an increased probability of developing neoplasms, said method comprising introducing into a non-human animal embryo an activated oncogene sequence.

2. A method as claimed in claim 1 wherein the chromosome of the animal includes an endogenous coding sequence substantially the same as the coding sequence of the oncogene.

3. A method as claimed in claim 2 wherein said oncogene sequence is integrated into a chromosome of said animal at a site different from the location of said endogenous coding sequence.

4. A method as claimed in claim 2 or claim 3 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.

5. A method as claimed in any one of claims 2 to 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible.

6. A method as claimed in any one of claims 1 to 4 wherein said activated oncogene sequence comprises a fused gene comprising an oncogene sequence fused to an activating viral or synthetic promoter sequence.

7. A method as claimed in claim 6 wherein said viral promoter sequence comprises a sequence selected either from an MMTV or an RSV promoter.

8. A method as claimed in any one of claims 1 to 7 wherein said oncogene sequence comprises a coding sequence of a c-myc gene.

9. A method as claimed in any one of claims 1 to 7 wherein said activated oncogene sequence comprises a DNA sequence selected from the oncogenes src, yes, fps, abl, ros, fgr, erbB, fms, mos, raf, Ha-ras-1, Ki-ras 2, Ki-ras 1, myc, myb, fos, ski, rel, sis, N-myc, N-ras, Blym, mam, neu, erbAl, ra-ras, mht-myc, myc, myb-ets, raf-2, raf-1, Ha-ras-2, or erbB.

10. A method as claimed in any one of claims 1 to 8 wherein said activated oncogene is provided in the form of a plasmid.

11. A plasmid selected from the group comprising plasmids ATCC 39745, 39746, 39747, 39748, 39749.

12. A method as claimed in claim 1 wherein the activated oncogene sequence is derived from a plasmid as defined in claim 11.

13. A method as claimed in claim 1 which comprises injecting into the male pronucleus of a fertilized one-cell mouse egg a linearized plasmid as defined in claim 11.

14. A method of testing a material suspected of being a carcinogen which comprises exposing a non-human animal produced according to the method of any one of claims 1 to 13 to said material and detecting neoplasms as an indication of carcinogenicity.

15. A method of testing a material suspected of conferring protection against the development of neoplasms, said method comprising treating a non-human animal produced according to the methods of any one of claims 1 to 13 with said material and detecting a reduced incidence of development of neoplasms, compared to an untreated animal, as an indication of said protection.

16. A method as claimed in claim 15, further comprising exposing said treated and untreated animals to a carcinogen prior to, after or simultaneously with treating said animals with said material.

17. A transgenic non-human eucaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at an embryonic stage, said oncogene optionally being further defined according to any one of claims 3 to 10.

18. An animal as claimed in claim 17 which is a rodent.

19. A chromosome of an animal as claimed in claim 17, which comprises an oncogene as defined in any one of claims 3 to 10.

APPENDIX Chapter 4

4.9 Amendments to Claims of European Patent Application No 85304490.7 submitted by Harvard at Oral proceedings on 26 June 1989.

Method for producing Transgenic Animals
Application No 85304490.7

Claims

1. A method for producing a transgenic non-human eucaryotic animal having an increased probability of developing neoplasms, said method comprising introducing an activated oncogene sequence into a non-human animal at a stage no later than the 8-cell stage.

2. A method as claimed in claim 1 wherein the chromosome of the animal includes an endogenous coding sequence substantially the same as the coding sequence of the oncogene.

3. A method as claimed in claim 2 wherein said oncogene sequence is integrated into a chromosome of said animal at a site different from the location of said endogenous coding sequence.

4. A method as claimed in claim 2 or claim 3 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.

5. A method as claimed in any one of claims 2 to 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible.

6. A method as claimed in any one of claims 1 to 4 wherein said activated oncogene sequence comprises a fused gene comprising an oncogene sequence fused to an activating viral or synthetic promoter sequence.

7. A method as claimed in claim 6 wherein said viral promoter sequence comprises a sequence selected either from an MMTV or an RSV promoter.

8. A method as claimed in any one of claims 1 to 7 wherein said oncogene sequence comprises a coding sequence of a c-myc gene.

9. A method as claimed in any one of claims 1 to 7 wherein said activated oncogene sequence comprises a DNA sequence selected from the oncogenes src, yes, fps, abl, ros, fgr, erbB, fms, mos, raf, Ha-ras-1, Ki-ras 2, Ki-ras 1, myc, myb, fos, ski, rel, sis, N-myc, N-ras, Blym, mam, neu, erbAl, ra-ras, mht-myc, myc, myb-ets, raf-2, raf-1, Ha-ras-2, or erbB.

10. A method as claimed in any one of claims 1 to 8 wherein said activated oncogene is provided in the form of a plasmid.

11. A plasmid selected from the group comprising plasmids ATCC 39745, 39746, 39747, 39748,39749.

12. A method as claimed in claim 1 wherein the activated oncogene sequence is derived from a plasmid as defined in claim 11.

13. A method as claimed in claim 1 which comprises injecting into the male pronucleus of a fertilized one-cell mouse egg a linearized plasmid as defined in claim 11.

14. A method of testing a material suspected of being a carcinogen which comprises exposing an animal produced according to the method of any one of claims 1 to 13 to said material and detecting neoplasms as an indication of carcinogenicity.

15. A method of testing a material suspected of conferring protection against the development of neoplasms, said method comprising treating an animal produced according to the methods of any one of claims 1 to 13 with said material and detecting a reduced incidence of development of neoplasms, compared to an untreated animal, as an indication of said protection.

16. A method as claimed in claim 15, further comprising exposing said treated and untreated animals to a carcinogen prior to, after or simultaneously with treating said animals with said material.

17. A transgenic non-human eucaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at a stage no later than the 8-cell stage, said oncogene optionally being further defined according to any one of claims 3 to 10.

18. An animal as claimed in claim 17 which is a rodent.

19 A chromosome of an animal as claimed in claim 17, which comprises an oncogene as defined in any one of claims 3 to 10.

Additional subsidiary request filed by Harvard seeking to amend claims 1 and 17 to refer to 1-cell stage

APPENDIX Chapter 4

4.10 Auxiliary claim requests (Sets A, B, C and D) to European Patent Application No. 85304490.7 filed by Harvard with Notice of Appeal 13 November 1989.

Method for producing Transgenic Animals
Application No 85304490.7

Amended Claims SET A

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal.

13. A method as claimed in any one of claims 1 to 12 wherein said chromosomal incorporation is at a stage no later than the 8-cell stage.

14. A method as claimed in any one of claims 1 to 12 wherein said chromosomal incorporation is at a stage no later than the 1-cell stage.

15. A method as claimed in claim 1 which comprises injecting into the male pronucleus of a fertilized one-cell mouse egg a linearized plasmid as defined in claim 11.

16. A method of testing a material suspected of being a carcinogen which comprises exposing an animal produced according to the method of any one of claims 1 to 15 to said material and detecting neoplasms as an indication of carcinogenicity.

17. A method of testing a material suspected of conferring protection against the development of neoplasms, said method comprising treating an animal produced according to the methods of any one of claims 1 to 15 with said material and detecting a reduced incidence of development of neoplasms, compared to an untreated animal, as an indication of said protection.

18. A method as claimed in claim 17, further comprising exposing said treated and untreated animals to a carcinogen prior to, after or simultaneously with treating said animals with said material.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

20. An animal as claimed in claim 19 which is a rodent.

21. An animal as claimed in claim 19 or claim 20 wherein said chromosomal incorporation is at a stage no later than the 8-cell stage.

22. An animal as claimed in claim 19 or claim 20 wherein said chromosomal incorporation is at a stage no later than the 1-cell stage.

23. A chromosome of an animal as claimed in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

Method for producing Transgenic Animals
Application No 85304490.7 Amended Claims SET B

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally introducing an activated oncogene sequence into a non-human mammalian animal at an embryonic stage.

13. A method as claimed in any one of claims 1 to 12 wherein said chromosomal incorporation is at a stage no later than the 8-cell stage.

19 A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at an embryonic stage, said oncogene optionally being further defined according to any one of claims 3 to 10.

20. An animal as claimed in claim 19 which is a rodent.

21. An animal as claimed in claim 19 or claim 20 wherein said introduction is at a stage no later than the 8-cell stage.

22. An animal as claimed in claim 19 or claim 20 wherein said introduction is at a stage no later than the 1-cell stage.

23 A chromosome of an animal as claimed in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

Method for producing Transgenic Animals
Application No 85304490.7 Amended Claims SET C

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing-an activated oncogene sequence into a non-human mammalian animal at a stage no later than the 8-cell stage.

13. A method as claimed in claim 1 which comprises injecting into the male pronucleus of a fertilized one-cell mouse egg a linearized plasmid as defined in claim 11.

14. A method of testing a material suspected of being a carcinogen which comprises exposing an animal produced according to the method of any one of claims 1 to 13 to said material and detecting neoplasms as an indication of carcinogenicity.

15. A method of testing a material suspected of conferring protection against the development of neoplasms, said method comprising treating an animal produced according to the methods of any one of claims 1 to 13 with said material and detecting a reduced incidence of development of neoplasms, compared to an untreated animal, as an indication of said protection.

16. A method as claimed in claim 15, further comprising exposing said treated and untreated animals to a carcinogen prior to, after or simultaneously with treating said animals with said material.

17. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at a stage no later than the 8-cell stage, said oncogene optionally being further defined according to any one of claims 3 to 10.

18. An animal as claimed in claim 17 which is a rodent.

19. A chromosome of an animal as claimed in claim 17, which comprises an oncogene as defined in any one of claims 3 to 10.

Method for producing Transgenic Animals
Application No 85304490.7

Amended Claims SET D

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising introducing an activated oncogene sequence into a non-human mammalian animal at a stage no later than the 1-cell stage.

13. A method as claimed in claim 1 which comprises injecting into the male pronucleus of a fertilized one-cell mouse egg a linearized plasmid as defined in claim 11.

14. A method of testing a material suspected of being a carcinogen which comprises exposing an animal produced according to the method of any one of claims 1 to 13 to said material and detecting neoplasms as an indication of carcinogenicity.

15. A method of testing a material suspected of conferring protection against the development of neoplasms, said method comprising treating an animal produced according to the methods of any one of claims 1 to 13 with said material and detecting a reduced incidence of development of neoplasms, compared to an untreated animal, as an indication of said protection.

16. A method as claimed in claim 15, further comprising exposing said treated and untreated animals to a carcinogen prior to, after or simultaneously with treating said animals with said material.

17. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said animal, or an ancestor of said animal, at a stage no later than the 1-cell stage said oncogene optionally being further defined according to any one of claims 3 to 10.

18. An animal as claimed in claim 17 which is a rodent.

20. A chromosome of an animal as claimed in claim 17, which comprises an oncogene as defined in any one of claims 3 to 10.

APPENDIX Chapter 4

4.11 Claims of European Patent No 0 169 672 granted by EPO for the Harvard Oncomouse

Claims

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal.

2. A method as claimed in claim 1 wherein the chromosome of the animal includes an endogenous coding sequence substantially the same as the coding sequence of the oncogene.

3. A method as claimed in claim 2 wherein said oncogene sequence is integrated into a chromosome of said animal at a site different from the location of said endogenous coding sequence.

4. A method as claimed in claim 2 or claim 3 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.

5. A method as claimed in any one of claims 2 to 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible.

6. A method as claimed in any one of claims 1 to 4 wherein said activated oncogene sequence comprises a fused gene comprising an oncogene sequence fused to an activating viral or synthetic promoter sequence.

7. A method as claimed in claim 6 wherein said viral promoter sequence comprises a sequence selected either from an MMTV or an RSV promoter.

8. A method as claimed in any one of claims 1 to 7 wherein said oncogene sequence comprises a coding sequence of a c-myc gene.

9. A method as claimed in any one of claims 1 to 7 wherein said activated oncogene sequence comprises a DNA sequence selected from the oncogenes src, yes, fps, abl, ros, fgr, erbB, fms, mos, raf, Ha-ras-1, Ki-ras 2, Ki-ras 1, myc, myb, fos, ski, rel, sis, N-myc, N-ras, Blym, mam, neu, erbAl, ra-ras, mht-myc, myc, myb-ets, raf-2, raf-1, Ha-ras-2, or erbB.

10. A method as claimed in any one of claims 1 to 8 wherein said activated oncogene is derived from a plasmid.

11. A plasmid selected from the group comprising plasmids ATCC 39745, 39746, 39747, 39748, 39749.

12. A method as claimed in claim 1 wherein the activated oncogene sequence is derived from a plasmid as defined in claim 11.

13. A method as claimed in any one of claims 1 to 12 wherein said chromosomal incorporation is at a stage no later than the 8-cell stage.

14. A method as claimed in any one of claims 1 to 12 wherein said chromosomal incorporation is at a stage no later than the 1-cell stage.

15. A method as claimed in claim 1 which comprises injecting into the male pronucleus of a fertilized one-cell mouse egg a linearized plasmid as defined in claim 11.

16. A method of testing a material suspected of being a carcinogen which comprises exposing an animal produced according to the method of any one of claims 1 to 15 to said material and detecting neoplasms as an indication of carcinogenicity.

17. A method of testing a material suspected of conferring protection against the development of neoplasms, said method comprising treating an animal produced according to the methods of any one of claims 1 to 15 with said material and detecting a reduced incidence of development of neoplasms, compared to an untreated animal, as an indication of said protection.

18. A method as claimed in claim 17, further comprising exposing said treated and untreated animals to a carcinogen prior to, after or simultaneously with treating said animals with said material.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

20. An animal as claimed in claim 19 which is a rodent.

21. An animal as claimed in claim 19 or claim 20 wherein said chromosomal incorporation is at a stage no later than the 8-cell stage.

22. An animal as claimed in claim 19 or claim 20 wherein said chromosomal incorporation is at a stage no later than the 1-cell stage.

23. A chromosome of an animal as claimed in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 22.

APPENDIX Chapter 4

4.12 Comparison of Claims of US (No 4,736,866) and European (No 0169642) Patents for the Harvard Oncomouse

US Claim Number	EP Claim Number	US Patent No: 41736,866 Transgenic Non-Human Mammals	EP Patent No: 0169672 Method for producing Transgenic Animals
1	1	Transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage	A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal.
2	2	The mammal of claim 1, a chromosome of said mammal including an endogenous coding sequence substantially the same as a coding sequence of said oncogene sequence.	A method as claimed in claim 1 wherein the chromosome of the animal includes an endogenous coding sequence substantially the same as the coding sequence of the oncogene.
3	3	The mammal of claim 2, said oncogene sequence being integrated into a chromosome of said mammal at a site different from the location of said endogenous coding sequence.	A method as claimed in claim 2 wherein said oncogene sequence is integrated into a chromosome of said animal at a site different from the location of said endogenous coding sequence.
4	4	The mammal of claim 2 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.	A method as claimed in claim 2 or claim 3 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence.
5	5	The mammal of claim 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible	A method as claimed in any one of claims 2 to 4 wherein said promoter sequence controlling transcription of said oncogene sequence is inducible.

Appendix Chapter 4
Comparison of Claims of US (No 4,736,866) and European (No 0169642) Patents for the Harvard Oncomouse

US Claim Number	EP Claim Number	US Patent No: 41736,866 Transgenic Non-Human Mammals	EP Patent No: 0169672 Method for producing Transgenic Animals
7 & 10	6	The mammal of claim 1 wherein transcription of said oncogene sequence is under the control of a viral promoter sequence. The mammal of claim 1 wherein transcription of said oncogene sequence is under the control of a synthetic promoter sequence	A method as claimed in any one of claims 1 to 4 wherein said activated oncogene sequence comprises a fused gene comprising an oncogene sequence fused to an activating viral or synthetic promoter sequence.
8 & 9	7	The mammal of claim 7 wherein said viral promoter sequence comprises a sequence of an MMTV promoter. The mammal of claim 7 wherein said viral promoter sequence comprises a sequence of an RSV promoter.	A method as claimed in claim 6 wherein said viral promoter sequence comprises a sequence selected either from an MMTV or an RSV promoter.
6	8	The mammal of claim 1 wherein said oncogene sequence comprises a coding sequence of a c-myc gene	A method as claimed in any one of claims 1 to 7 wherein said oncogene sequence comprises a coding sequence of a c-myc gene.
	9		A method as claimed in any one of claims 1 to 7 wherein said activated oncogene sequence comprises a DNA sequence selected from the oncogenes src, yes, fps,abl, ros, fgr, erbB, fms, mos, raf, Ha-ras-1, Ki-ras 2, Ki-ras 1, myc, myb, fos, ski, rel, sis, N-myc, N-ras, Blym, mam, neu, erbAl, ra-ras, mht-myc, myc, myb-ets, raf-2, raf-1, Ha-ras-2, or erbB.
	10		A method as claimed in any one of claims 1 to 8 wherein said activated oncogene is derived from a plasmid.
	11		A plasmid selected from the group comprising plasmids ATCC 39745, 39746, 39747, 39748, 39749.
	12		A method as claimed in claim 1 wherein the activated oncogene sequence is derived from a plasmid as defined in claim 11.

Appendix Chapter 4
4.12 Comparison of Claims of US (No 4,736,866) and European (No 0169642) Patents for the Harvard Oncomouse

US Claim Number	EP Claim Number	US Patent No: 41736,866 Transgenic Non-Human Mammals	EP Patent No: 0169672 Method for producing Transgenic Animals
	13		A method as claimed in any one of claims 1 to 12 wherein said chromosomal incorporation is at a stage no later than the 8-cell stage.
	14		A method as claimed in any one of claims 1 to 12 wherein said chromosomal incorporation is at a stage no later than the 1-cell stage.
	15		A method as claimed in claim 1 which comprises injecting into the male pronucleus of a fertilized one-cell mouse egg a linearized plasmid as defined in claim 11.
	16		A method of testing a material suspected of being a carcinogen which comprises exposing an animal produced according to the method of any one of claims 1 to 15 to said material and detecting neoplams as an indication of carcinogenicity.
	17		A method of testing a material suspected of conferring protection against the development of neoplasms, said method comprising treating an animal produced according to the methods of any one of claims 1 to 15 with said material and detecting a reduced incidence of development of neoplasms, compared to an untreated animal, as an indication of said protection.
	18		A method as claimed in claim 17, further comprising exposing said treated and untreated animals to a carcinogen prior to, after or simultaneously with treating said animals with said material.
	19		A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.
11	20	The mammal of claim 1, said mammal being a rodent.	An animal as claimed in claim 19 which is a rodent.
	21		An animal as claimed in claim 19 or claim 20 wherein said chromosomal incorporation is at a stage no later than the 8-cell stage.
	22		An animal as claimed in claim 19 or claim 20 wherein said chromosomal incorporation is at a stage no later than the 1-cell stage.

Appendix Chapter 4

4.12 Comparison of Claims of US (No 4,736,866) and European (No 0169642) Patents for the Harvard Oncomouse

US Claim Number	EP Claim Number	US Patent No: 41736,866 Transgenic Non-Human Mammals	EP Patent No: 0169672 Method for producing Transgenic Animals
	23		A chromosome of an animal as claimed in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.
	24		A method of providing a cell culture comprising providing a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 and culturing a somatic cell thereof.
	25		A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 22.
12		The mammal of claim 11, said rodent being a mouse.	

APPENDIX Chapter 5

5.1 Opponents to European Patent No .EP 0169672

Opponent	Name
I	Compassion in World Farming Supporters (CWF); British Union for the Abolition of Vivisection; et al.* [Represented by D.S. Alexander (Barrister)]
II	Bundesverband Der Tierversuchsgegner Menschen für Tierrechte e.V. et al.α [Represented by W. Schindler (Patent Agent)]
III	Ökologisch-Demokratische Partei (ÖDP) [represented by R. Zahn (Patent Attorney)]
IV	R. Büchner et alβ
V	A. Meinel et al; Fraktion Bündnis 90
VI	U.Fuchs et al.χ
VII	R.Paulig et al; Die Grünen im Bayerischen Landtag.
VIII+	Evangelischer Stadtkirchenverband Köln. (+Opponents represented by R.Wilhelms (Patent Agent)
IX+	Bundesland Hessen vertr. Durch das Hessische Ministerium für Jugend. Familie und Gesundheit.
X+	F. Koechlin, P. Schenkelaars et al; European Co-ordination 'No Patents on life!'δ (Belgium)
XI+	J. Voggenhuber et al.Grüner Klub im Parlament (Nationalratsabgeordnete des Osterreichischen Parlaments)
XII+	Verein "Keine Patente auf Leben" ε
XIII+	Sylvia Hamberger et al; Deutsche Koordination "Kein Patent auf Leben"
XIV+	Bundeszentrale der Tierversuchsgegner Österreichs
XV+	Wiener Tierschutzverein und Zentralverband Tierschutzvereine Österreichs
XVI	H.Helletsberge [represented by W. Kern (Patent Agent)]
XVII	Deutsches Tierhilfswerk e.V. [Represented by Grußdorf (Patent Agent)]

* Including 40 animal welfare support groups throughout Europe and the world.

α Including Tierschututzverein Müchen e.V.; Ärzte gegen Tierversuche e.V.; Animal 2000, Tierversuchsgegner Bayern e.V.; Animal Peace e.V.; PAKT Politischer Arbeitskreis füTierrechte in Europa e.V.

β plus 16 named supporters.

χ 1265 individual names and address were recorded by the EPO supporting this opposition

δ Representing associated organisations worldwide including Friends of the Earth Germany, Dutch Society for the Protection of animals and including organisations for the protection of animal rights in Belgium, Denmark,Greece, GB, Ireland, Italy, Luxembourg, Netherlands,Norway, Austria, Sweden, Spain, Brazil, India and the US.

ε Supported by 80 other groups including EcoSolidar Zurich, Fondation Franz Weber Montraux, Greenpeace Schweiz, WWF Schweiz and other Human and Animal Welfare Groups and Religious groups.

Appendix Chapter 5

5.2 Summary of Grounds of Opposition of Opponents to European Patent No. 0169672

ART EPC	OPPONENT	TOTAL
52	II, VI, VII, IX to XVI incl.	11
53 (a)	I, II, IV to XVI incl.	15
53 (b)	II to XVI incl.	16
54	VIII to XV incl.	8
56	XVI	1
83	III, IV, VI, VII to XV incl.	11

APPENDIX Chapter 5

5.3 European Patent No 0 169 672 Auxiliary Claim Requests 1 - 7 submitted to Opposition Division of EPO by Harvard by letter dated 28 November 1995 (Amended claims only shown)

1st Auxiliary Claim Request

Claims

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal; said animal being for experimental or testing purposes.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said animal being for experimental or testing purposes, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22, and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

European Patent No 0 169 672
2nd Auxiliary Claim Request

Claims

1 A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal; said animal being for experimental or testing purposes.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said animal being for experimental or testing purposes, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal defined in any one of claims 19 to 22 and culturing a somatic cell hereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

Proposed Amendment to the Description in Respect of Auxiliary Claim Requests 3, 4 and 6;

By "experimental" we mean herein permissible for use in animal experimentation or testing purposes under prevailing legislation in at least one contracting State or so permissible in supranational legislation applying to any such state.

European Patent No 0 169 672
3rd Auxiliary Claim Request

Claims

1. A method for producing a transgenic experimental non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal.

19. A transgenic non-human experimental mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of an animal as defined in claim 19 but whether or not experimental, which comprises an oncogene as defined in any one of claims 3 to 10.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 but whether or not experimental,and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 but whether or not experimental.

European Patent No 0 169 672
4th Auxiliary Claim Request

Claims

1. A method for producing a transgenic experimental non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal.

19. A transgenic non-human experimental mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of an animal as defined in claim 19 but whether or not experimental, which comprises an oncogene as defined in any one of claims 3 to 10.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 but whether or not experimental.

European Patent No 0 169 672
5th Auxiliary Claim Request

Claims

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal; said animal being for experimental or testing purposes.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said animal being for experimental or testing purposes, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of an animal as claimed in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 22.

European Patent No 0 169 672
6th Auxiliary Claim Request

Claims

1. A method for producing a transgenic experimental non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal.

19. A transgenic non-human experimental mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of an animal as claimed in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 22.

European Patent No 0 169 672
7th Auxiliary Claim Request

Claims

1. A method for producing a transgenic rodent having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a rodent.

19. A transgenic rodent whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor or said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

22. A chromosome of an animal as claimed in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

23. A method of providing a cell culture comprising providing a transgenic animal as defined in any one of claims 19 to 21 and culturing a somatic cell thereof.

24. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 21.

APPENDIX Chapter 5

5.4 Analysis of Auxiliary Claims Requests 1-7 submitted to Opposition Division of EPO by Harvard by letter dated 28 November 1995

TN-HM= Transgenic non-human mammal	Claim 1 – Method for making the animal			Claim 19 – The animal			Claim 23 – The chromosome of a….				
	Transgenic non-human mammal for exper'tl or testing purposes	Transgenic exper'tl non-human mammal	Transgenic rodent	TN-HM for exper'tl or testing purposes	TN-H exper'tl mammal	Transgenic rodent	Transgenic non-human mammal	TN-HM whether or not exper'tl	TN-HM for exper'tl or testing purposes	TN-H exper'tl mammal	Transgenic rodent
1st Auxiliary Claim Request	●			●					●		
2nd Auxiliary Claim Request	●			●					●		
3rd Auxiliary Claim Request		●			●			●			
4th Auxiliary Claim Request		●			●			●			
5th Auxiliary Claim Request	●			●					●		
6th Auxiliary Claim Request		●			●					●	
7th Auxiliary Claim Request			●			●					●

5.4 Analysis of Auxiliary Claims Requests 1-7 submitted to Opposition Division of EPO by Harvard by letter dated 28 November 1995

TN-HM= Transgenic non-human mammal	Claim 24 – Method for a cull culture from a….					Claim 25 – A cell for making a cell culture from a…..				
	Transgenic non-human mammal	TN-HM for exper'tl or testing purposes	TN-HM whether or not exper'tl	TN-H exper'tl mammal	Transgenic rodent	Transgenic non-human mammal	TN-HM whether or not exper'tl	TN-HM for exper'tl or testing purposes	TN-H exper'tl mammal	Transgenic rodent
1st Auxiliary Claim Request	●					●				
2nd Auxiliary Claim Request		●						●		
3rd Auxiliary Claim Request			●				●			
4th Auxiliary Claim Request				●					●	
5th Auxiliary Claim Request		●						●		
6th Auxiliary Claim Request				●					●	
7th Auxiliary Claim Request					●					●

5.5 Auxiliary claim requests submitted to Opposition Division of EPO by Harvard by letter dated 24 April 1997. (Amended claims only shown)

1st Auxiliary Claim Request

Claims

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal; said animal being for experimental or testing purposes.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said animal being for experimental or testing purposes, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22, and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

Auxiliary Claim Request No 1A

Claims

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal; said animal being for testing purposes.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence a as result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said animal being for testing purposes, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22, and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into

the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

European Patent No 0 169 672
2nd Auxiliary Claim Request

Claims

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal; said animal being for experimental or testing purposes.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said animal being for experimental or testing purposes, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 20-22.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal defined in any one of claims 19 to 22 and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

European Patent No 0 169 672
Auxiliary Claim Request No 2A

Claims

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal; said animal being for testing purposes.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said animal being for testing purposes, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claims 20-22.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animals defined in any one of claims 19 to 22 and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said oncogene optionally being further defined according to any one of claim 3 to 10, and said animal optionally further defined by the feature of any one of claims 20 to 22.

European Patent No 0 169 672
3rd Auxiliary Claim Request

Claims

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal; said animal being for experimental or testing purposes.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said animal being for experimental or testing purposes, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of an animal as defined in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 22.

European Patent No 0 169 672
Auxiliary Claim Request 3A

Claims

1. A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal; said animal being for testing purposes.

19. A transgenic non-human mammalian animal whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor of said animal, said animal being for testing purposes, said oncogene optionally being further defined according to any one of claims 3 to 10.

23. A chromosome of an animal as defined in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

24. A method of providing a cell culture comprising providing a transgenic non-human mammalian animal as defined in any one of claims 19 to 22 and culturing a somatic cell thereof.

25. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 22.

European Patent No 0 169 672
4th Auxiliary Claim Request

Claims

1. A method for producing a transgenic rodent having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a rodent.

19. A transgenic rodent whose germ cells and somatic cells contain an activated oncogene sequence as a result of chromosomal incorporation into the animal genome, or into the genome of an ancestor or said animal, said oncogene optionally being further defined according to any one of claims 3 to 10.

22. A chromosome of an animal as defined in claim 19, which comprises an oncogene as defined in any one of claims 3 to 10.

23. A method of providing a cell culture comprising providing a transgenic animal as defined in any one of claims 19 to 21 and culturing a somatic cell thereof.

24. A cell derived from a somatic cell obtained from a transgenic non-human mammalian animal as defined in any one of claims 19 to 21.

APPENDIX Chapter 5

5.6 Analysis of Amendments to Auxiliary Claim Requests submitted to Opposition Division of EPO by Harvard by letter dated 24 April 1997

	Claim 1 – Method for making the animal				Claim 19 – The animal				Claim 23 – The chromosome of a....					
TN-HM= Transgenic non-human mammal	Transgenic non-human mammal for exper'tl or testing purposes	Transgenic exper'tl non-human mammal	TN-HM for testing purposes	Transgenic rodent	TN-HM for exper'tl or testing purposes	TN-HM for testing purposes	TN-H exper'tl mammal	Transgic rodent	Transgenic non-human mammal	TN-HM whether or not exper'tl	TN-HM for exper'tl or testing purposes	TN-H exper'tl mammal	TN-HM for testing purposes	Transgic rodent
1st Auxiliary Claim Request	●				●						●			
1A Auxiliary Claim Request			●			●							●	
2nd Auxiliary Claim Request	●				●						●			
2A Auxiliary Claim Request			●			●							●	
3rd Auxiliary Claim Request	●				●						●			
3A Auxiliary Claim Request			●			●							●	
4th Auxiliary Claim Request				●	(Claim 22)			●						●

5.6 Analysis of Amendments to Auxiliary Claim Requests submitted to Opposition Division of EPO by Harvard by letter dated 24 April 1997

	Claim 24 – Method for a cull culture from a….						Claim 25 – A cell for making a cell culture from a…..					
TN-HM= Transgenic non-human mammal	Transgenic non-human mammal	TN-HM for testing purposes	TN-HM for exper'tl or testing purposes	TN-HM whether or not exper'tl	TN-H exper'tl mammal	Transgenic rodent	Transgenic non-human mammal	TN-HM whether or not exper'tl	TN-HM for exper'tl or testing purposes	TN-H exper'tl mammal	TN-HM for testing purposes	Transgenic rodent
1st Auxiliary Claim Request			●						●			
1A Auxiliary Claim Request		●									●	
2nd Auxiliary Claim Request			●						●			
2A Auxiliary Claim Request		●									●	
3rd Auxiliary Claim Request			●						●			
3A Auxiliary Claim Request		●									●	
4th Auxiliary Claim Request						●						●

GLOSSARY*

AAT (Alpha-1-Antitrypsin)	A protein made in the liver which regulates the amount of the enzyme in the lung wall. Used as a drug to treat emphysema and cystic fibrosis.
Bacteria	Single celled organisms (prokaryotes) and characterized by their comparatively simple cell structure and by having their essential genetic DNA in the form of a single closed-loop molecule.
Bacteriophage	A natural virus of bacteria.
Blastocyst	Cleavage stage embryo.
Cell line	Cells which grow permanently in tissue culture.
Chimaera	An organism where individual cells do not have the same genetic composition as each other i.e. being a mixture of cells derived from two or more separate embryos from the same or different species.
Chromosome	A structure in the cell nucleus containing DNA which carries the inheritable characteristics of the cell. Self-replicating at nuclear division so that one copy passes into each daughter nucleus. The number of chromosomes in somatic cells is constant for a species.
Clone	A population of organisms, cells or molecules all having the same genetic information derived from a single progenitor.
Cloning	A process of asexual reproduction of an organism that creates multiple genetically identical copies (a clone) of the original. This is achieved experimentally by nuclear transfer from a somatic cell into an enucleated oocyte.
Cloning of DNA	The selective replication of a particular piece of DNA by dealing (ligating) it into the autonomously replicating DNA of a bacterial plasmid or virus and introducing the vector molecule into a suitable host molecule (usually a bacterium).
Cytoplasm	The region of eukaryotic cells lying outside the nucleus.
DNA (Deoxyribonucleic Acid)	A large molecule consisting of long chains of nucleotides, each nucleotide comprising a base linked to a special sugar (deoxyribose) linked to a phosphate molecule. The DNA chain is held together by phosphate-sugar-phosphate bonds and the bases project laterally from the main chain. Native DNA is predominantly double-stranded, with paired chains held together by complementary pairing of bases.
DNA (gene) sequencing	Methods for obtaining the base sequence of one strand of DNA.
Endogenous	Originating inside an organism.
Enucleated	Removal of a nucleus from cell e.g. an oocyte

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* Sources include: D. Bruce and A. Bruce, Society (Eds) *Engineering Genesis* Religion & Technology Project (Earthscan Publications Limited, 1998); P. Wheale and Ruth McNally (Eds) *Animal Genetic Engineering* (Pluto Press 1995); Dr. Mae-Wan Ho *Genetic Engineering Dream or Nightmare* (Gateway Books UK 1998); *New Developments in Biotechnology, 5, Patenting Life*, April 1989 Office of Technology Assessment, Congressional Board of the 101st Congress; J.M. Walker and M. Cox *The Language of Biotechnology, a Dictionary of Terms* (American Chemical Society 1995) Second Edition.

GLOSSARY

Eukaryote (Eucaryote)	Organisms having the major part of their DNA divided between a number of chromosomes in their cell nuclei. Include most animals except bacteria and blue green algae.
Gene	A segment of DNA that is transcribed into an RNA molecule to serve some particular function in the organism - often to encode a polypeptide chain of an enzyme or some other kind of protein.
Gene Therapy	The treatment of inherited genetic disease by replacing the defective gene with a functional copy of the gene which has been isolated by a gene cloning procedure
Genetic Engineering	The construction of DNA molecules, containing novel combinations of genes, by in vitro molecular biology techniques.
Genome	The complete set of genetic information of an individual.
Germ cells	Reproductive cells.
GMO	Genetically modified organism. An organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
Integration of DNA	The sealing of DNA fragments into the genomic DNA of the organism.
Ligases	Enzymes which join pieces of DNA or RNA together.
Morphological	A taxonomic description of an organism i.e. a detailed analysis of its form and structure.
Neoplasm	A new growth of tissue serving no physiological function (e.g. a tumour).
Nucleotide	The base-sugar-phosphate (nucleoside-phosphate) unit found in nucleic acids. Nucleotides can exist with one, two or three phosphate groups.
Nucleus	'Command centre' of the cell which containing the majority of the DNA.
Oncogene	A type of gene, originally found in cancer-inducing viruses, that is conducive to malignancy. Oncogenes are often mutant derivations of normal genes that, properly regulated, play essential roles in the cell.
Oncogenesis	The induction or formation of tumours.
(An) oncomouse	A mouse whose genotype has been modified to include an oncogene..
Oocyte	Single celled 'egg'.
Phenotype	All the observable physical characteristics of an organism that can be determined without genetic tests and are the result of the interaction between the genetic characteristics (genotype) of an organism and its environment.
Plasmid	An extrachromosomal piece of DNA found in the cytoplasm and capable of replicating and segregating independently of the host chromosome. They may contain genes of occasional use to their host organisms, e.g. by determining antibiotic resistance in bacteria.
Pluripotent (Pleuripotent)	Capacity to differentiate into different things e.g. stem cells which can differentiate into various different types of cells.

GLOSSARY

Prokaryote (Procaryote)	Organism having no cell nuclei, but with a single DNA loop in each cell (i.e. bacteria).
Promoter	A special DNA sequence upstream of the coding sequence of a gene which acts as a signal for the start of transcription of the gene into RNA.
Pronucleus	Nucleus of mature egg cell or sperm cell.
Protein	Large molecule, consisting of polypeptide chains in turn composed of amino acid units (sometimes with the addition of a sugar component - glycoproteins), that makes up much of the bulk of the cell and is responsible for most cell functions. Enzymes, the catalysts of metabolism, and antibodies are all specific kinds of protein.
Recombinant DNA	A DNA molecule containing a new combination of sequences e.g. recombinant plasmid.
Replication (of DNA)	New synthesis by copying from pre-existing DNA. The two mutually complementary strands of double-stranded DNA are separated and a new complementary strand is synthesised alongside each one. according to the rules of base complementarity.
Retrovirus	Viruses which encode their hereditary information in the nucleic acid RNA. They can be engineered to be used as vectors in human gene therapy.
RNA (Ribonucleic Acid)	A nucleic acid polymer similar to DNA but comprises ribonucleotides which consist of a ribose sugar, a phosphate group and the base uracil instead of thymine.
Sequence	The precise order of bases in a nucleic acid molecule or of amino acids in a polypeptide.
Sequencing	Determination of the order of nucleotides in a DNA or RNA molecule or the order of amino acids in a protein.
Somatic cells	All cells of an organism other than the germ (reproductive) cells.
Somatic Gene Therapy	Introduction of genes into somatic cells for treatment of hereditary diseases.
Stem Cells	Progenitor cells which have the capacity to differentiate into a diverse range of somatic tissues. Derived from the inner cell mass of the pre-emplanted embryo.
Sui generis system	System devised for its own special purpose.
Targeting	The integration of a gene, supplied to the cell as a DNA fragment, into a desired place in the genome, usually the site at which it naturally resides.
Taxon	General term for a taxonomic group whatever its rank.
Transcription	The enzyme-catalysed synthesis of a strand of RNA using a strand of DNA as a template, according to the base-complementarity rules.
Transformation	Change in type of a cell or organism brought about by artificial introduction of DNA.
Transgenic	In genetic engineering, term used to describe an organism carrying a foreign gene as the result of transformation.

GLOSSARY

Translation	The synthesis of a polypeptide chain of a specific amino acid sequence determined by the base sequence in the corresponding messenger RNA.
Vector	A carrier or transmission agent in the context of genetic engineering. Used to introduce the foreign DNA molecule into the host cells. Recombinant DNA vectors include plasmids, bacteriphages and other forms of DNA.
Virus	An infectious agent, consisting of a DNA or RNA genome wrapped in a protein coat, that can get itself replicated in host cells (either animal, plant or bacterial), but with no cellular structure of its own, relying on the host cell for most of the metabolic functions needed for its own propagation.
Xenotransplantation	Transplantation of an organ between different species.
Zygote	Fertilised oocyte before it undergoes cleavage.

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