The Patenting of Biological Materials In The Context of TRIPS

Luigi Palombi, Australian National University
The Patenting of Biological Materials In The Context of The Agreement on Trade-Related Aspects of Intellectual Property Rights

Luigi Palombi

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Law School
The University of New South Wales
Sydney, New South Wales
Australia
ABSTRACT

In January 1995, the World Trade Agreement (WTA) became operative and the World Trade Organisation (WTO) was formed. Today the WTO has one hundred and forty seven countries as members. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of a number of associated Agreements of the WTA. This Thesis provides a definition for the word ‘invention’ by reference to the judicial authorities in the United States, the United Kingdom and Australia and the relevant patent statutes that apply in those countries and in Europe through the European Patent Convention (EPC) and argues that the ‘invention’ parameter of patentability is fundamental to patent law throughout the world. It suggests that its inclusion in art. 27.1 TRIPS confirms this. However, since the mid to late 1980s the ‘invention’ parameter has been the subject of a severe distortion through which the proponents of biotechnological patents have manipulated the ‘international’ patent regime to facilitate the granting of thousands of patents that concern ‘isolated’ or ‘purified’ biological materials or those produced by technical means. In most instances these patents claim a twenty year monopoly over biological material that is materially identical to their natural counterparts which include human genes and proteins. This Thesis argues that the European Biotechnology Directive passed by the European Parliament in 1998 (Directive) is the first legislative measure to incorporate, what this Thesis calls, the ‘isolation contrivance.’

The problem which this Thesis has identified is that the Directive violates TRIPS because the word ‘invention’ in TRIPS is inconsistent with the Directive’s objective which requires European Community (EC) countries to amend their patent laws so that recombinantly produced proteins that are indistinguishable to natural proteins are deemed to be ‘inventions’ within art. 52(1) EPC. Moreover, the Directive positively discriminates in favour of Directive technologies contrary to the express requirement in TRIPS that the patent parameters contained in art. 27.1 TRIPS apply ‘without discrimination’ to any technology. This Thesis suggests however, that there is a solution in the form of a sui generis intellectual right which it calls the Genetic Sequence Right (GSR). The proposed GSR assists the biotechnology industry in that it does away with the parameters of patentability as a prerequisite to registration, but equally its removes the right of the GSR owner to control the uses that others can make of the genetic sequence which comes within the ambit of GSR. Clearly, there is a need to reward those that can identify new genetic sequences that code for specific proteins especially when the properties and characteristics of those proteins can serve a useful purpose. This objective can be achieved through the payment of a reasonable royalty to the GSR owner by the user of that information, rather than through the exclusionary rights granted to patent owners. Therefore, in much the same way as the copyright system gives the owner of copyrighted works the right to receive a royalty for the use of their work, the GSR rewards the scientific work that has led to the identification of a new and useful genetic sequence.
DECLARATION

I hereby declare that this submission is my own work and to the best of my knowledge it contains no materials previously published or written by another person, nor material which to a substantial extent has been accepted for the award of any other degree or diploma at UNSW or any other educational institution, except where due acknowledgement is made in the thesis. Any contribution made to the research by others, with whom I have worked at UNSW or anywhere, is explicitly acknowledged in the thesis.

I also declare that the intellectual content of this thesis is the product of my own work, except to the extent that assistance from others in the project’s design and content or in style, presentation and linguistic expression is acknowledged.

Luigi Palombi
September, 2004
I would like to acknowledge the invaluable support given to me by my wife, Vanessa, through this time of intense and unprecedented effort. Without her love, support, encouragement and ear, I doubt that I would have been able to complete my work at all let alone in three years. To our friends and family that have understood and forgiven me for my periods of intense social hibernation. To Mr. Stephen Robb QC and Dr. Lynn Dalgarno who supported my application. Finally, to Professor Jill McKeough, who as my supervisor provided me with many helpful comments, corrections and advice.

It is important also for me to recognise that this Thesis would never have materialised had it not been for my clients and colleagues in the legal profession and science who provided me with the opportunity to learn and practice intellectual property law. There are many but those I particularly wish to thank are Mr. Des Ryan, Ms. Katrina Howard, Mr. David Catterns QC, Justice Dr. Annabelle Bennett, Dr. Stephen Locarnini, Dr. Lynn Dalgarno, Dr. Gregory Reyes, Professor David Kemp, Professor Baruch Blumberg, Dr. Daniel Bradley, Mr. Ken Sharples, Ms. Sylvia Tassos, Dr. Ian Ernst, Mr. Gary Cox and the late Mr. Michael Warren QC and his wife, Patricia.

Sydney, NSW, Australia
September, 2004
DEDICATION

For my dear friend and mentor

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This Thesis is about the meaning of the word ‘invention’ in art. 27.1 of *The Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) and its relationship to the kind of technology described in art. 3 and art. 5 (Directive technologies) of the European Biotechnology Directive (Directive). Directive technologies come under the umbrella of ‘biotechnology’ because expressly included are ‘biological materials’ derived from any natural source including ‘elements’ derived from the human body that are either ‘isolated’ or ‘produced by means of a technical process’ irrespective of their identity to the ‘natural’ counterpart. Essentially, ‘biological materials’ as defined by the Directive include, but are not limited to, such things as viral, animal and human proteins and their corresponding genetic materials.

As part of this analysis, two case studies are conducted. The first in Chapter 4 concerns human *Erythropoietin* (Epo). The second in Chapter 5 concerns *Hepatitis C virus* (HCV). Patents that have been granted with respect to each of these biological materials are examples of patented Directive technologies. This Thesis critically evaluates these patents in the context of the litigation that has been conducted in the United States of America, the United Kingdom and Australia and the patent opposition process that has been conducted through the European Patent Office (EPO).

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1 Art. 27.1 “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.” (Emphasis added)


3 Article 3.1 “… a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.”

4 Article 3.2. “Biological material which is isolated from its natural environment or produced by means of a technical process … even if it previously occurred in nature.”


6 Art. 2.1. Directive defines ‘biological material’ to mean “any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.”

7 This word ‘isolated’ in this context means that the biological material or human element has been separated or removed from its natural environment and has been purified to some degree.

8 A technical process includes the process for the recombinant production of a protein.
Generally though, a consideration of the relationship between the word ‘invention’ in art. 27.1 TRIPS and Directive technologies is important given the debate that has raged throughout the world about the suitability of patents that claim, within the scope of their monopolies, the processes and methods of production of proteins and their products. This debate commenced long before the Directive was passed by the European Parliament in 1998. It was originally limited by the territorial and jurisdictional limits of the word ‘invention’ in the context of the applicable national patent law, but with the advent of the World Trade Agreement (WTA) in January 1995 and its associated agreements, such as TRIPS, the debate has developed a multilateral significance.

Today, the implications of the debate go beyond the jurisdictional limits of the patent law of any one WTO member or two WTO members that are parties to a bilateral Free Trade Agreement or even the EC, which is a WTO member separate to the nations that are members of the EC. Consequently this jurisdictional overlap applies to each of the one hundred and forty seven nations that are WTO members because each are bound by the WTA which stipulates that “[e]ach Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements,” with TRIPS being one of these. Relevantly, TRIPS contains a detailed set of minimum international legislative and regulatory standards that are designed to “promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.” Clearly, these standards must be uniformly adhered to if the WTO is to function fairly and efficiently and if the stated objectives of TRIPS are to be met.

9 Since May 1, 2004 the European Communities is made up of twenty five nations.
10 The 147 members of the WTO as at April 23, 2004 are: Albania, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Bahrain, Bangladesh, Barbados, Belgium, Belize, Benin, Bolivia, Botswana, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso, Burundi, Cameroon, Canada, Central African Republic, Chad, Chile, China, Colombia, Congo, Costa Rica, Côte d’Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Democratic Republic of the Congo, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Estonia, European Communities, Fiji, Finland, Former Yugoslav Republic of Macedonia (FYROM), France, Gabon, The Gambia, Georgia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea, Guinea Bissau, Guyana, Haiti, Honduras, Hong Kong, China, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kenya, Korea, Kuwait, Kyrgyz Republic, Latvia, Lesotho, Liechtenstein, Lithuania, Luxembourg, Macao-China, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Mauritania, Mauritius, Mexico, Moldova, Mongolia, Morocco, Mozambique, Myanmar, Nepal, Netherlands and the Netherlands Antilles, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Pakistan, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Romania, Rwanda, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Senegal, Sierra Leone, Singapore, Slovak Republic, Slovenia, Solomon Islands, South Africa, Spain, Sri Lanka, Suriname, Swaziland, Sweden, Switzerland, Chinese Taipei, Tanzania, Thailand, Togo, Trinidad and Tobago, Tunisia, Turkey, Uganda, United Arab Emirates, United Kingdom, United States of America, Uruguay, Venezuela, Zambia and Zimbabwe.
11 Article. XVI.4 WTA.
12 First recital to TRIPS. (Emphasis added).
Daniel Gervais in his authoritative work on the drafting history of TRIPS described this Agreement as one of the “most significant milestones in the development of intellectual property in the twentieth century,” giving “new life” to the Berne and Paris Conventions of the nineteenth century. This breath of life, he explained, came in the form of the enforcement of intellectual property rights, which “for the first time” enables WTO members to seek economic redress against each other for violations of the WTA. Accordingly, if these minimum standards are violated, the WTO is able to levy economic penalties against the guilty party, but the consequences of a violation may not end with the WTO. For example, already some EC members have argued that the Directive is invalid because it violated art. 27.3 TRIPS, and although the Court of Justice of the European Community (Court of Justice) held in that case that there was no inconsistency with TRIPS and that the Directive was valid, it foreshadowed that a violation of an obligation (such as contained in art. 27.1 TRIPS) could render the Directive invalid.

Accordingly, TRIPS is a pivotal document toward the global standardisation and enforcement of intellectual property rights.

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13 Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis, 2nd Ed., London, Sweet & Maxwell, 2003. See also: Nuno Pires de Carvalho, The TRIPS Regime of Patent Rights, Kluwer Law International, 2002 in which the author describes TRIPS as “the most comprehensive international agreement on intellectual property protection ever established”; 24, 1 and he explains that TRIPS is distinguishable from both the Berne and Paris Conventions of the 19th century because first, TRIPS contains provisions which concern both copyright (Berne Convention, 1866) and industrial property (Paris Convention, 1883) and second, TRIPS contains provisions related to the enforcement of intellectual property rights, 24-25; Markus Nolff, TRIPS, PCT and Global Patent Procurement, Kluwer Law International, 2001, in which the author explains that “TRIPS is the most far-reaching intellectual property agreement yet enacted on a global level,” and that it “will for the first time set coherent standards regarding the availability, scope and duration of patent rights and their exceptions on a global scale.”, 39; and Susan K. Sell, Private Power, Public Law: The Globalization of Intellectual Property Rights, Cambridge University Press, 2003 in which the author explains that “TRIPS is a dramatic expansion of the rights of IP owners” which is “far-reaching” with “important implications for innovation, research and development, economic development, the future location of industry, and the global division of labor”, 7-9.

14 Ibid, 3, 1.01.

15 Ibid.

16 See The Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission) [2002] All ER (EC) 97.

17 Ibid. The Court of Justice held that “… the legality of a Community instrument can be called in to question on grounds of breach of international agreements to which the Community is a party only if the provisions of those agreements have direct effect.” [para 51] (Emphasis added) There is no question about the status of the WTA and TRIPS. They are both international agreements to which the EC is a separate party and that have direct effect, particularly art. 27.1 TRIPS, which does not contain any discretionary language compared to art. 27.3 TRIPS which does. It was principally because of the discretionary language of art. 27.3 TRIPS that the Court of Justice held that there was no violation of TRIPS.

Article 27.1 TRIPS\textsuperscript{19} concerns patents. It stipulates that there are four parameters of patentability. The first is the \textit{invention}. The second is the \textit{novelty} of the ‘invention’. The third is the \textit{inventive step} of the ‘invention’. The fourth is the \textit{industrial applicability} of the ‘invention’. This means that each of these parameters must be satisfied before any WTO member may grant a patent, or enable one to ‘be available’ under its national patent laws. It also requires the administrative and regulatory patent regimes of WTO members to be applied and interpreted consistently with these parameters. A granted patent that does not satisfy these parameters violates TRIPS and, as a consequence, the patent law and regime from which it derives its legal status violates art. XVI.4 WTA.\textsuperscript{20}

In this context, it is relevant to contrast art. 27.1 TRIPS with art. 3.1\textsuperscript{21} Directive (as an example of \textit{Directive} technologies) because the \textit{Directive} mandates all EC members to amend their own patent laws so as to be consistent with it.\textsuperscript{22}

Art. 3.1 \textit{Directive} mimics art. 27.1 TRIPS with respect to the four parameters of patentability. It confirms that each are the parameters of patentability which is consistent with art. 52(1) of the European Patent Convention (\textit{EPC}) and the corresponding national patent laws of EC members.\textsuperscript{23} However, it departs from art. 27.1 TRIPS in one very important respect, namely, it mandates that “a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used”\textsuperscript{24} be deemed an ‘invention’ within the terms of the \textit{EPC} and the national patent laws of EC members. This departure, which “shall be” undertaken by all EC members is, however, questionable because a product consisting of biological material which has been ‘isolated’ or ‘produced by means of a technical process’ that is \textit{identical} to a natural biological material arguably is not an ‘invention’ within the meaning of the word in art. 27.1 TRIPS. It is questionable because such biological material, although it is \textit{per se} artificial or is in an artificial stasis, is indistinguishable from the natural counterpart.

\textsuperscript{19} Art. 27.1 TRIPS provides “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application ….”.

\textsuperscript{20} “Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements”.

\textsuperscript{21} Art. 3.1 \textit{Directive} provides “For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.”

\textsuperscript{22} Art. 15.1 \textit{Directive} “Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 July 2000. They shall forthwith inform the Commission thereof.”

\textsuperscript{23} See for example s.1(1) Patents Act, 1977 (UK).

\textsuperscript{24} These words are found in art. 3.1 \textit{Directive}. 4
This Thesis disagrees with the generally held view\(^\text{25}\) that the artificiality of isolated biological materials produced as a result of \textit{some} human intervention makes them ‘inventions’ and argues that it is contrary to clear and persuasive authority.\(^\text{26}\) The principle authority is \textit{Diamond, The Commissioner of Patents v Chakrabarty (Chakrabarty)} which requires not only that the human intervention be \textit{significant}, but that the resulting artificial biological material displays \textit{markedly different characteristics to any found in nature} and which \textit{new} characteristics possess the potential for \textit{significant utility}.\(^\text{27}\) Support for this position is derived from an analysis of the ‘invention’ parameter contained in U.S.C. 35 s.101 (\textit{US Act}), art. 52.1 EPC, s.1(1) Patents Act, 1977 (UK) (\textit{UK Act}) and s.18(1) Patents Act, 1990 (Cwth) (\textit{AU Act}) and the interpretation of that parameter by the these authorities.

Chapter 2 demonstrates that in each of the four jurisdictions of the United States, the European Communities, the United Kingdom and Australia, the ‘invention’ parameter is an essential parameter of patentability within these patent regimes. Moreover, each jurisdiction has in place a regime that has complied with the \textit{Paris Convention for the Protection of Industrial Property of 1883} (as amended at various times) and one that predates TRIPS. The Chapter examines the drafting history of art. 27.1 TRIPS and proposes that common principles\(^\text{28}\) link the invention parameter in each of the above mentioned jurisdictions so that, even though each patent law uses its own unique language to describe this parameter, that language more or less defines the same thing, and the word ‘invention’ in art. 27.1 TRIPS is consistent with these common principles.\(^\text{29}\) It

\(^{25}\) For example, \textit{The Guidelines for Examination in the European Patent Office}, C:IV 2.3, Revision of July 1999, which states, “... if a substance found in nature has first [been] isolated from its surroundings and a process for obtaining it ... developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which it is obtained or by other parameters ... and it is “new” in the absolute sense of having no previously recognised existence, then the substance per se may be patentable. ...” See also G. Kamstra et al, \textit{Patents on Biotechnological Inventions: The E.C. Directive}, 1st Ed, 2002, London, Sweet & Maxwell, 25-26.; Li Westerlund, \textit{Equivalence and Exclusions under European and U.S. Patent Law}, 1st Ed., 2002, New York, Kluwer Law International, 23-58.


\(^{27}\) “... the patentee has produced a \textit{new} bacterium with \textit{markedly different characteristics from any found in nature} and one having the potential for \textit{significant utility},” \textit{Diamond, The Commissioner of Patents v Chakrabarty} (1980) 447 U.S. 303 (US Supreme Court) per Justice Berger, 305.

\(^{28}\) The common principles are: 1) That there is a distinction between an ‘invention’ and a ‘patentable invention’; 2) That an ‘invention’ \textit{per se} must be new and useful; 3) That an ‘invention’ which is not novel, which lacks an ‘inventive step and which is not industrially applicable is not a ‘patentable invention’, and 4) That laws of nature, physical phenomena, and abstract ideas \textit{per se} are prohibited as ‘inventions’.

\(^{29}\) “This is not to suggest that \textit{101} has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable,” per Justice Berger, \textit{Diamond, The Commissioner of Patents v Chakrabarty} (1980) 447 U.S. 303, 309; It is a “fundamental requirement which must be satisfied before a patent can properly be granted, namely that the applicant has made an ‘invention,’ per Mustill LJ, \textit{Genentech Inc’s Patent} [1989] RPC 147, 262 lines 36-37;
follows that the meaning of the word ‘invention’ in art. 27.1 TRIPS is a restatement of these common principles, which include that a product of nature or something substantially identical to a product of nature is not an ‘invention’, nor is it ‘patentable subject matter’, nor is it the ‘proper subject of letters patent within s.6 of the Statute of Monopolies’.

Chapter 3 continues this theme explaining how a device, which this Thesis describes as the ‘isolation contrivance’, has been developed by the ‘patent community’ to facilitate the categorisation of ‘isolated’ biological materials or biological materials produced by technical means as ‘inventions’. This device has been successfully employed by the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the Japanese Patent Office (JPO) since 1988 to justify the grant of patents concerning ‘Directive’ technologies. The patent community argues that isolated biological materials or those produced by technical means are chemical compounds and since chemical compounds have been long recognised as being suitable subject matter for patents, that it follows that ‘Directive’ technologies are ‘inventions’. However, this argument is seriously flawed and Chapter 3 explains the nature of the flaws. The case studies in Chapters 4 and 5 then provide anecdotal evidence supporting the critique of this device.

“[H]owever advantageously man may alter the conditions of growth, the fruit is still not produced by his action,” National Research Development Corporation v. Commissioner of Patents (1959) 102 CLR 252, 279. (By analogy, the production of ‘proteins’ by recombinant processes - the ‘protein’ is the fruit of the gene or genome from which it is inextricably linked.)

See art. 52(1) EPC and s.1(1) UK Act and Genentech Inc’s Patent [1989] RPC 147 (UK Court of Appeal).


Peter Drahos defines the ‘patent community’ to include “patent attorneys and lawyers, patent administrators, and other specialists who play a part in the exploitation, administration and enforcement of the patent system. They form a community by virtue of their technical expertise and general pro-patent values. Regular users of the patent system (like the pharmaceutical companies) might also be said to be part of this community.” P. Drahos, Biotechnology Patents, Markets And Morality, (1999) 21(9) EIPR 441-444, 442.

A key proponent of this contrivance is Stephen Crespi and in his paper Biotechnology Patenting: The Wicked Animal Must Defend Itself (1995) 17(9) EIPR, 431-441, he writes a passionate defence of its application in patent law.

In 1988 the USPTO, the EPO and the JPO issued a joint communique explaining their position regarding the patentability of ‘Directive’ technologies. The communique provides: ‘Purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds.’ The source of the text is footnote 9, Nuffield Council of Bioethics Discussion Paper, 2002, The Ethics of Patenting DNA, 26, para 3.14.

It is a central theme of this Thesis that the ‘isolation contrivance,’ which has now been written into the EPC by effect of the Directive, has seriously distorted what can loosely be described as the ‘international’ patent system. Of course, there is no single legislatively created and administered international patent system, but the impact of various treaties and agreements such as the Paris Convention, 1893, the Patent Cooperation Treaty, 1971 and the Patent Law Treaty, 2000 together with TRIPS means that today, more than at any time in the past, the national patent regimes that operate throughout the world are more or less linked to each other.

Since the mid to late 1980s, patent regimes around the world have been the subject of this distortion, resulting in the granting of patents concerning technologies that are not ‘inventions’ within art. 27.1 TRIPS.

This Thesis examines the ‘invention’ parameter in the context of biotechnology, and demonstrates, through the two case studies in Chapters 4 and 5, precisely how the patent offices, courts and legislatures of the United States, the European Community, the United Kingdom and Australia have distorted their patent systems and concludes that the Directive, as an example of a legislative intervention, is a violation of TRIPS.

However, the Directive remains controversial, and although the European Parliament has attempted to settle this debate in Europe, eight of the original fifteen EC members have refused to transform the Directive into their national patent laws. Therefore, until the Directive is repealed...

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37 J. Pila, Inherent Patentability in Australia, United Kingdom and EPC Law: A History, PhD thesis, July 2003, University of Melbourne, explains the history of the patentable invention in three jurisdictions. She concludes that “restrictions to inherent patentability” have been whittled down in the patent systems of Australia, the United Kingdom and the European Community suggesting that “[w]hilst the rise and fall of those restrictions have hinged largely on the terms ‘manufacture’ and ‘technical’, underlying the courts’ construction of those terms has run the deeper question of the reason and basis for the need to show an ‘invention’ at all.”, 235.

38 Both HCV and Epo are the subject of patents granted throughout the world. The patent owner of the HCV patents is Chiron Corporation (Chiron), a US corporation. The patent owner of the Epo patents is Kirin-Amgen, Inc. (Amgen) also a US corporation. Both Chiron and Amgen have been involved in global litigation concerning the original patents granted respectively to them. They have also been the subject of Oppositions in the EPO that have concluded before a Technical Board of Appeal of the EPO. An appeal concerning the original Epo patent, which will expire in December 2004, was heard by the UK House of Lords in July 2004. Their Lordships reserved their decision which is expected to be delivered before end of 2004.

39 Those failing to comply with the Directive as at July 2002 were Germany, Austria, Belgium, France, Italy, Luxembourg, the Netherlands and Sweden. However, in March 2004 the German government introduced the Directive-style amendments to its patent laws for debate before its national Parliament.

40 On May 1, 2004 the European Community extended its membership to a further ten countries bringing the total membership to twenty-five. It is not clear as at the date of writing which of these additional members will comply with the Directive.
or held by the Court of Justice to be invalid, *Directive* technologies will be deemed by the EPO to be an ‘invention’ within article 52(1) *EPC*.

The HCV and Epo case studies demonstrate the impact that these patents have had on the development of patent law in the United States, the European Communities, the United Kingdom and Australia and on research into human health. One impact has been the creation of research bottlenecks.\footnote{See M.A. Heller and R.S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, The American Association for the Advancement of Science, Volume 280, Number 5364, 1 May 1998, pp. 698-701, and R.P. Merges and R.R. Nelson, *On The Complex Economics Of Patent Scope*, (1990) 90 Colum. L. Rev. 839.} These research bottlenecks are hindering medical and scientific research because ownership claims to biological materials in an isolated form, have restricted the medical and scientific research opportunities of independent laboratories and universities.\footnote{“Contemporary biologists are privileged to work at a time of unprecedented excitement. But overly enthusiastic protection of intellectual property, too early in the process of product development, can impede the delivery of public health benefits from discoveries in many important fields, including genomics.” Testimony of Professor Harold Varmus, former Director of the National Institutes of Health, before the US House of Representatives Judiciary Subcommittee On Courts And Intellectual Property, Washington D.C., July 13, 2000.}

In Chapter 6, this Thesis concludes that the distortion to the ‘international’ patent system manifested by the ‘isolation contrivance’ can only be removed through the creation of a new *sui generis* intellectual property right. The threads of the argument put forward in this Thesis are brought together in support of the case for a *sui generis* intellectual property right, called the *Genetic Sequence Right* or GSR. The proposed GSR provides intellectual property protection for the identification of biological materials and their function, without bestowing on the holder of the GSR the ability to control the down-stream use or application of biological materials. It is proposed that in this way, the owner of the GSR will be economically and legally rewarded without being able to exert an influence on subsequent use of the biological materials whether that use be for research or otherwise.

Professor Baruch S. Blumberg was awarded the *Nobel Prize for Physiology or Medicine* in 1976 in recognition of his research concerning mechanisms involved in the origin and spread of infectious diseases and, specifically, for the discovery of the hepatitis B virus and for the development of methods for detection of HBV and the vaccine for HBV. He testified in the Federal Court of Australia in proceedings concerning an Australian patent granted over Hepatitis C proteins. He explained in that case that,

> I have reviewed Chiron’s Australian Patent No. 624105 for the purposes of these proceedings. In my opinion, the claims in this patent are very broad. These claims represent a view in scientific thought, i.e., that knowledge of the nucleotide sequence of the virus genome, let
alone part of it, tells one all that needs to be known about the functions of the proteins produced by the virus and hence all that needs to be known about the virus. I do not subscribe to this view. Such a view infers that all other information about the proteins and their effects, including post-translational changes in the gene-produced proteins, interactions of viral proteins with each other, interactions of the viral gene products with the host, the biology of the virus and its host, demonstration of effectiveness, etc. is redundant. It states in effect: “Anything that is done with the HCV virus is covered by this patent and all research and development on the virus is subservient to it.” … Based on the unusually broad nature of the patent, if I were a research director for anti-virals and had the option of working on several viruses, the existence of this patent would weigh against my deciding to undertake HCV research. A company, or even an academic laboratory, might well be deterred from conducting research on HCV because the patent is, in effect, intimidating.\(^{43}\)

The concerns which Professor Blumberg expressed in 1995 have more recently been repeated with respect to the patenting of SARS\(^{44}\) viral proteins by the Centers for Disease Control and Prevention (CDC)\(^{45}\) and British Columbia Cancer Agency. Both of these organisations are publicly funded and their work, leading to the isolation and sequencing of the viral genome of the SARS virus, has also led to the application for worldwide patents. Dr. Richard Gold from the Centre for Intellectual Property Policy at McGill University in Quebec, Canada observed in response to this action that,

The goal of the patent system is to serve the public good, here by not only encouraging biomedical research but also providing access to the results of that research. Giving exclusive rights to inventors is simply the means through which the system reaches this goal but is not the goal itself. Thus, if we keep our eye on the target of our efforts, we soon realise that the system as currently constructed fails to meet its own objectives. As the CDC’s and BCCA’s efforts illustrate, researchers are concerned that patents held in private hands will decrease research, particularly for the development of clinical applications such as genetic tests. Whilst empirical data are not yet conclusive, researchers are feeling threatened by the current system. Health-care administrators have also voiced concern that the patent system limits access to biomedical advances. Whatever the empirical data eventually demonstrate, there is an emerging crisis of confidence in the patent system that is in itself serious.\(^{46}\)

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\(^{43}\) The affidavit of Prof. Baruch S. Blumberg filed in the Federal Court of Australia in *Murex Diagnostics Australia Pty Ltd v Chiron Corporation* Action No: NG 106 of 1994.

\(^{44}\) The term SARS means ‘Severe Acute Respiratory Syndrome’.

\(^{45}\) The Centers for Disease Control and Prevention is a US Government organisation that is charged with the responsibility to research assess and react to the spread of infectious diseases in the United States. Its headquarters and laboratories are in Atlanta, Georgia, U.S.A.

In his presentation speech at the 1962 award ceremony of the *Nobel Prize in Physiology or Medicine* to Drs. Crick, Watson and Wilkins, Professor A. Engström of the Royal Caroline Institute said,

Today no one can really ascertain the consequences of this new exact knowledge of the mechanisms of heredity. We can foresee new possibilities to conquer disease and to gain better knowledge of the interaction of heredity and environment and a greater understanding for the mechanisms of the origin of life. In whatever direction we look we see new vistas. We can, through the discovery by Crick, Watson and Wilkins, to quote John Kendrew, see ‘the first glimpses of a new world’.
CHAPTER 2
THE FIRST PARAMETER OF PATENTABILITY:
THE INVENTION PER SE

There is no express universal definition of the word ‘invention,’ 1 and the absence of an express definition of the word in art. 27.1 TRIPS gives rise to an implication that the word is meaningless or boundless in scope – that literally, anything can come within the meaning of the word ‘invention’ so long as the thing that is the subject of the patent is novel, contains an inventive step and is industrially applicable. 2 For example, Li Westerlund 3 suggests that the absence of an express definition of the word in TRIPS means that “in principle it does not prevent the exclusion of naturally occurring substances, such as genes and cells, from patent protection.” 4 Daniel Gervais explains that “the three usual criteria, i.e., novelty, industrial applicability and involving an inventive step” 5 for patentability are the only parameters contained within art. 27.1 TRIPS. Yet Nuno Pires de Carvalho explains that although “[a]rt. 27 lists three conditions of patentability,” 6 he poses the question “[c]an there be more?” arguing that art. 27.1 TRIPS “leaves many questions unanswered.” Unlike Daniel Gervais, he explores the topics of ‘inventions and discoveries’ and ‘patentable subject matter’ and suggests that ‘inventions’ are “artificial creations that stem from the need to solve technical problems” 7 whereas ‘discoveries’ are “not the result of creation – even if creativity has been needed to reveal information concealed in nature.” 8

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1 Ann Monotti and Sam Ricketson explain that, “…it is impossible to find a form of language that will adequately cover, at any time, the multifarious and diverse forms in which human inventiveness may manifest itself” and suggest that “[h]istorically, courts in each of the national systems … [have been] unable to cope with this by a process of progressive interpretation.” See A. Monotti with S. Ricketson, Universities and Intellectual Property: Ownership and Exploitation, 1st Ed., 2003, Oxford University Press, 61, 3.22. This Thesis disagrees and challenges this assertion for the reasons explained in this Chapter.

2 For example Markus Nolff in his discussion of art. 27.1 TRIPS does not refer to an invention as being a parameter of patentability, rather he explains that “TRIPS requires (‘shall’) as a general proposition the availability of patents if the required patentability requirements of novelty, non-obviousness and industrial applicability are met.” In TRIPS, PCT and Global Patent Procurement, Kluwer Law International, 2001, 12. Although, in Biogen, Inc v Medeva plc (1997) RPC 1 Lord Hoffmann held in the context of s.1(1) UK Act which mirrors art. 52(1) EPC that, “[I]n the absence of a definition one cannot say with certainty that one might not come across something which satisfied all the conditions but could not be described as an invention” – Section 9 of his speech.


7 Ibid, 146, 27.8

8 Ibid.
Chapter 2: The First Parameter of Patentability: The Invention per se

This Thesis accepts Nuno Pires de Carvalho’s scepticism and argues that art. 27.1 TRIPS contains an additional parameter of patentability, that is, the ‘invention’. What Li Westerlund and Daniel Gervais fail to explain in their analyses of art. 27.1 TRIPS is why the word ‘invention’ is part of its language if the only parameters of patentability are novelty, inventive step and industrial applicability. Art. 27.1 TRIPS provides that “patents shall be available for any inventions” and uses the word “provided” to emphasise that the remaining conditions of patentability are subsidiary. It is the ‘invention’ per se that must be “new, involve an inventive step and capable of industrial application”. Clearly, the article requires that the subject matter of the patent be an ‘invention’ first and foremost. Thereafter it is the ‘invention’ per se which must satisfy the three residual parameters of patentability if it is to be a ‘patentable invention’.

This interpretation is not only consistent with the language of art. 27.1 TRIPS, but is consistent with the judicial interpretation of s.1(1) UK Act which uses similar language to art. 52(1) EPC. In the 1989 UK Court of Appeal decision in Genentech Inc’s Patent (Genentech), Mustill LJ explained that the word ‘invention’ in s.1(1) UK Act and art. 52(1) EPC is one of the “four conditions” that “turns an invention into a patentable invention”. This interpretation, he held, was “fortified” by the Guidelines for Examination in the EPO which stated:

First, in paragraph 1.1 of Chapter IV that:

1. There must be an ‘invention’.
2. The invention must be ‘susceptible of industrial application’.
3. The invention must be ‘new’.
4. The invention must involve an ‘inventive step’.

Secondly, in paragraph 2.2 of Chapter IV that:

It must also be borne in mind that the basic test of whether there is an invention within the meaning of Article 52(1) is separate and distinct from the questions whether the subject-matter is susceptible of industrial application, is new and involves an inventive step.

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9 “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

10 “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; ….”

11 “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. …”


13 Ibid, per Mustill LJ, 262, line 45.

The reasoning of Mustill LJ on this issue is undoubtedly correct. Not only is his reasoning consistent with the distinction between ‘invention’ and ‘patentable invention’ contained within art. 52(1) EPC and s.1(1) UK Act, but it is consistent with the same distinction contained in s.101 US Act and s.18(1) AU Act. It is not surprising therefore that the original draft of TRIPS, tabled by the EC with the TRIPS Negotiating Group on March 29, 1990 also contained this distinction. According to Daniel Gervais the tabling of this draft (“Brussels Draft”) was “the spark which ignited the work towards the TRIPS Agreement” and that “subject to a few changes, would serve as the basis for the emerging Agreement.”

A comparison of the drafting documents reveals that the word ‘invention’ in art. 27.1 TRIPS was not subject to any amendment following the tabling of the ‘Brussels Draft’. It was present in the ‘Brussels Draft’ and in the subsequent working document, the ‘Draft of July 23, 1990 (W/76)’. Furthermore, Daniel Gervais suggests that the language of art. 27.1 TRIPS was also “inspired in part by Art. 10 of an early draft of the World Intellectual Property Organisation, Patent Law Treaty”.

Clearly, although TRIPS does not expressly define the word ‘invention’ it is incorrect to interpret art 27.1 TRIPS to limit the parameters of patentability to “the three usual criteria.” Rather, as the language of art. 27.1 TRIPS has both an EC precedence in the form of art. 52(1) EPC and a draft of art. 10 of the Patent Law Treaty, it would seem that the probable nexus to the word ‘invention’

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15 P.G. Ducor, *Patenting the Recombinant Products of Biotechnology and Other Molecules*, Kluwer Law International, 1998 confirms that “[f]irst, the invention must constitute patentable subject matter, as defined by s.101 of the Patent Act. This requirement can be considered as a ‘precondition’ for patentability, anterior to any other legal evaluation.” Also the High Court of Australia in *NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited* (1995) 183 CLR 65 where the Court held that the answer of whether something was an ‘invention’ was not based upon a consideration of the parameters of patentability of ‘novelty’ or ‘inventive step’ in s.18(1)(b) AU Act because the “more specific requirements of novelty and inventive step” are only to be considered after the prerequisite parameter of ‘invention’ is satisfied.

16 The TRIPS Negotiating Group was formed as part of the Uruguay Round of GATT. The chairman was Ambassador Lars E.R. Anell of Sweden. For a detailed history see D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 2nd Ed., London, Sweet & Maxwell, 2003, 3-26.


18 Ibid.

19 Ibid.

20 This is the terminology of Daniel Gervais.

21 This is the terminology of Daniel Gervais.

22 Ibid, 220, 2.257.

23 Ibid.
is the EPC. In this regard, it is to be noted that there is no express definition of the word ‘invention’ in the EPC nor in the corresponding national patent laws of EC members.\textsuperscript{24}

However, the TRIPS negotiations were not all Eurocentric. Daniel Gervais explained that the United States, which did have a definition of the word ‘invention’\textsuperscript{25} in the \textit{US Act} also tabled a draft TRIPS Agreement with the TRIPS Negotiating Group on May 11, 1990.\textsuperscript{26} The ‘US Draft’ was in similar terms to the ‘Brussels Draft’ and their “common structure”\textsuperscript{27} became the basis of all subsequent negotiations with respect to TRIPS.\textsuperscript{28} In these circumstances, it is fair to infer that the absence of an express meaning of the word ‘invention’ was not due to a lack of consensus with respect to its meaning, but rather that the principles behind the word were common to both jurisdictions.\textsuperscript{29} Furthermore, the lack of disagreement or comment by the other participating countries in the negotiating process supports the inference, which this Thesis invites, that there was a common understanding concerning the meaning of the word ‘invention’ generally and consequently it was included in the final text of the Agreement without amendment. What this suggests is the following:

Firstly, that the absence of an express definition of the word ‘invention’ does not support the notion of endless scope, because the case law of the United States, the United Kingdom and Australia recognise an implicit prohibition regarding the patentability of natural phenomena, laws of nature and abstract information. This prohibition applies equally to patent laws that do not define the word ‘invention’, such as the EPC and UK Act, as they do to patent laws that do, such as the US Act and the AU Act.

\textsuperscript{24} For example the UK Patents Act, 1977 does not contain an express meaning of the word ‘invention’.

\textsuperscript{25} Section 100 \textit{US Act} states “The term ‘invention’ means invention or discovery.” Section 101 states “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.” Sections 100 and 101 must be read together, for it is s.101 that provides the criteria of patentable subject matter or ‘invention’.


\textsuperscript{27} \textit{Ibid}. 

\textsuperscript{28} Daniel Gervais speculates that the similarity in structure and language between the ‘Brussels Draft’ and the ‘US Draft’ was a result of “transatlantic consultations” conducted before the tabling of the two documents. \textit{Ibid}, 16, 1.18.

\textsuperscript{29} P.G. Ducor, \textit{Patenting the Recombinant Products of Biotechnology and Other Molecules}, Kluwer Law International, 1998, confirms “[i]f the invention must constitute patentable subject matter, as defined by s.101 of the Patent Act. This requirement can be considered as a ‘precondition’ for patentability, anterior to any other legal evaluation.”. 6. This requirement is also consistent with paragraph 2.2 of the \textit{Guidelines for Examination in the EPO (1988)} and the interpretation of those \textit{Guidelines} by Mustill LJ in \textit{Genentech} in respect of art 52(1) EPC and s.1(1) UK Act.
Secondly, the notion that the residual parameters of novelty, inventive step and industrial application “contain every element of the concept of an invention in ordinary speech” was considered by UK House of Lords in *Biogen Inc, v Medeva plc* (Biogen) and not applied “because in the absence of a definition one cannot say with certainty that one might not come across something which satisfied all the conditions but could not be described as an invention.”

Their Lordships in *Biogen* acknowledged that neither the EPC nor the UK Act contained an express definition of the word and that the UK Act should be consistent with the EPC as “nearly as practicable”. Nevertheless, they were not prepared to conclusively rule in favour of an interpretation that would render the word ‘invention’ completely subservient to “the four conditions” in s.1(1) UK Act. To the contrary, their Lordships were of the view that the word ‘invention’ had a meaning beyond “the four conditions,” suggesting that there were categories of subject matter that would satisfy “the four conditions” and yet not be ‘inventions’ within the meaning of s.1(1) UK Act. Indeed, Lord Mustill in a separate speech reinforced the reasoning of Lord Hoffmann who delivered the leading speech for the Appellate Committee. Lord Mustill emphasised the necessity “for a valid patent to concern an invention, as well as satisfying the conditions expressed in paragraphs (a) to (d) of section 1(1) of the Act.”

The Appellate Committee’s rationale is significant because even though s.1(2) UK Act expressly excludes certain subject matter from being an ‘invention’, the ruling implies that the subject matter exclusions are not exhaustive, suggesting that it is possible for something to be novel, contain an

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30 *Biogen, Inc. v Medeva plc* [1997] RPC 1 per Lord Hoffmann, 55 (UK House of Lords)
31 Ibid.
32 Ibid.
33 Section 130 UK Act.
34 Section 1(1) UK Act requires the ‘invention’ to (a) be new, (b) involve an inventive step, (c) be capable of industrial application and (d) be not expressly excluded in s.1(2) UK Act. Section 1(2) UK Act provides, “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.”
35 Cf. It may be said by some commentators that Lord Hoffmann’s statement that “the draftsmen of the Convention and the Act, as well as counsel at the bar, were unable to think of any examples” of technologies that “satisfied all the conditions but could not be described as an invention” suggest that his Lordship was critical of Lord Mustill’s position. However, this sentence has to be read in the context of his later reservation that “there may one day be a case in which it is necessary to decide whether something which satisfies the conditions can be called an invention, but that question can wait until it arises.” If Lord Hoffmann had wanted to dismiss Lord Mustill’s position out of hand he could easily have made that reservation.
36 *Genentech Inc’s Patent* [1989] RPC 147 per Mustill LJ, 262-263.
Chapter 2: The First Parameter of Patentability: The Invention per se

inventive step, be industrially applicable and not be a ‘discovery’,\(^{37}\) and yet not be an ‘invention’ within s.1(1) UK Act. The Committee’s reasoning supports the notion that the ‘invention’ parameter cannot be satisfied by just anything. Whatever the it may be, unless it is an ‘invention’ it is not eligible for patent protection.

Thirdly, as can been seen from the following table, the language of art. 52(1) EPC, s.1(1) UK Act and art. 27.1 TRIPS is strikingly similar.

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<th>Art. 27.1 TRIPS</th>
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<td>“… patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application …”</td>
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<th>S.1(1) 1977 UK Act</th>
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<tr>
<td>“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; ….“</td>
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This comparison demonstrates that there are four conditions of patentability. There must be:

(a) an ‘invention’;

(b) which invention is new;

(c) which invention involves an inventive step; and

(d) which invention has an industrial application.

The point of distinction between the EPC and the UK Act on one hand and TRIPS on the other is that both the EPC and the UK Act specifically exclude certain subject matter as ‘inventions’, whereas TRIPS does not. However, the absence of such an exclusion in TRIPS does not mean that every kind of subject matter excluded in art. 52(2) EPC and s.1(2) UK Act, is by default an ‘invention’ within TRIPS.

Although paradoxical, the case law of the United States, the United Kingdom, and Australia demonstrate how the presence or the absence of a list of excluded subject matter in the context of ‘invention’ neither adds nor detracts from the meaning of the word ‘invention’. Whether something that is a ‘discovery’ is capable or is incapable of being an ‘invention’ depends on the

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\(^{37}\) Section 1(2)(a) UK Act.
kind of discovery that it is and its application. This point has been well recognised by the courts in each of these jurisdictions.

In the United Kingdom, the specific exclusion of ‘discoveries’ from patentable subject matter has been interpreted to mean a pure form of discovery as Whitford J in Genentech Inc’s Patent explained:

> It is trite law that you cannot patent a discovery, but if based on that discovery you can tell people how it can be usefully employed, then a patentable invention may result.

In the United States, the US Supreme Court in Chakrabarty has held that even though the express definition of ‘invention’ in s.100 US Act is “invention or discovery”, not every form of discovery is patentable subject matter or an ‘invention’. The Court explained,

> This is not to suggest that ß 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. See Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); O’Reilly v. Morse, 15 How. 62, 112-121 (1854); Le Roy v. Tatham, 14 How. 156, 175 (1853). Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are ‘manifestations of ... nature, free to all men and reserved exclusively to none.’ Funk, supra, at 130.

In Australia, the AU Act requires an invention to be a “manner of manufacture within the meaning of section 6 of the Statute of Monopolies”. The Act defines ‘invention’ to mean “any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute

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41 s.18(1) AU Act: “an invention is a patentable invention … if the invention, …: (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and (b) when compared with the prior art base as it existed before the priority date of that claim: (i) is novel; and (ii) involves an inventive step; and (c) is useful; …”

Section 6 of the Statute of Monopolies of 1623 states: “That any Declaration before-mentioned shall not extend to any Letters Patents and Grants of Privilege for the Term of Fourteen Years or under, hereafter to be made, of the sole Working or Making of any Manner of new Manufactures within this Realm, to the true and first Inventor and Inventors of such Manufactures, which others at the Time of Making such Letters Patents and Grants shall not use, so as also they be not contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient: The said Fourteen Years to be accounted from the Date of the first Letters Patents, or Grant of such Privilege hereafter to be made, but that the same shall be of such Force as they should be, if this Act had never been made, and of none other.”
Chapter 2: The First Parameter of Patentability: The Invention per se

of Monopolies, and includes an alleged invention.”\(^{42}\) In 1959 the High Court of Australia in *National Research Development Corporation v. Commissioner of Patents (‘NRDC’)\(^{43}\)* explained that,

> There may indeed be a discovery without invention - either because the discovery is of some piece of abstract information without any suggestion of a practical application of it to a useful end, or because its application lies outside the realm of ‘manufacture.’\(^{44}\)

*Genentech, Chakrabarty and NRDC* are seminal cases that explain that a ‘discovery’ is not mutually exclusive\(^{45}\) to an ‘invention’ despite the express inclusion or exclusion of a ‘discovery’ as an ‘invention’ in the relevant patent legislation. In fact, in *NRDC* the High Court of Australia went so far as to suggest that “the truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion.”\(^{46}\)

These three authorities confirm that an ‘invention’ is more than a discovery about a natural phenomenon or a law of nature. It is more than an abstract piece of information. Rather it is the *end result* of an intellectual process that may involve, in part, a discovery or an abstract piece of information, but which ultimately involves the utilisation of other components, whether they be biological, electrical, mechanical or chemical that together are manifested in a product, process or method. The focus on the complete *end result* is why the High Court of Australia asserted that “the fallacy lies in dividing up the process that [an inventor] puts forward as his invention”.\(^{47}\) If the invention involves a number of components, which includes the discovery of a natural phenomenon, it is a mistake to focus on its discovery *per se* and define the end result by that element alone and in isolation to the totality of the components that make up the end result. It is the end result, whether it be a product, process or method which must be an ‘invention’ in order to satisfy the ‘invention’ parameter. Furthermore the artificiality of the end result is but one of a number of indicia of ‘invention’. They suggest that to overcome the long standing prohibition on the patenting of natural phenomena, the level of human intervention necessary to bring the end

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\(^{42}\) Schedule 1 *AU Act*.

\(^{43}\) *National Research Development Corporation v. Commissioner of Patents* (1959) 102 CLR 252 (High Court of Australia).

\(^{44}\) *Ibid*, 264.

\(^{45}\) In other words these concepts are not necessarily separate and incompatible with each other. It is possible for an innovation to be both a discovery and an invention. The point is made here because some commentators suggest that an innovation is either one or the other and cite the prohibition of ‘discoveries’ in art. 52(2)(a) *EPC* in support of the mutual exclusivity of the two concepts. However, s.100 of the US Act defines an invention to be “invention or discovery” and the UK and Australian case law tends to support the idea that a discovery can form the “substratum of invention [when] applied in a technique or process or incorporated in a product”. (*Genentech Inc’s Patent* [1989] RPC 147, per Purchas LJ, 209 lines 7-8, 12.09 (UK Court of Appeal)).

\(^{46}\) *National Research Development Corporation v. Commissioner of Patents* (1959) 102 CLR 252, 264 (High Court of Australia).
result into the realm of invention must be significant. As will be further explained in Chapter 3, they suggest that the mere ‘isolation’, ‘purification’ or ‘production by technical process’ of artificial biological materials (which are materially identical to natural phenomena) is unlikely to meet the threshold of invention.

The relevance of the totality of the end result is emphasised in section 101 US Act which provides that “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 thereof, subject to the conditions and requirements of this title”\(^\text{48}\) is entitled to a patent. Moreover, the words “whoever invents or discovers” emphasise that to the extent that there is a distinction between the concepts of ‘invention’ and ‘discovery’, it is the totality of the end result that determines the patentability of the subject matter.

According to s.101 US Act for the end result to be an ‘invention’ it must be a new and useful:\(^\text{49}\)

a) process;

b) machine;

c) manufacture; or

d) composition of matter.

These four things are the indicia of ‘invention’, provided that they are new and useful, because each define an end result, something tangible which is not “a law of nature, a physical phenomena, and an abstract idea.”\(^\text{50}\)

What is also important to note about s.101 US Act, is its function. It defines ‘invention’ only, so that satisfying its criteria does not result in a ‘patentable invention’. It merely defines the technology that is an ‘invention’. To reach the status of a ‘patentable invention’, the other parameters of patentability, including s.102 US Act (novelty) and s.103 US Act (inventive step), must be satisfied. Therefore, the US Act distinguishes between the words ‘new’ and ‘novelty/inventive step’ just as it does between an ‘invention’ and a ‘patentable invention’. So an ‘invention’ must be new, whereas a ‘patentable invention’ must be novel and contain an inventive step.

\(^{47}\) Ibid.

\(^{48}\) The main “other requirements” are found in ss. 102 (novelty), 103(inventive step) and 112US Act (utility-enablement).

\(^{49}\) It is important to note that the words “new and useful” are not a reference to either s.102 US Act (novelty) or s.103 US Act (inventive step).

\(^{50}\) Diamond, the Commissioner of Patents v Chakrabarty (1980) 447 U.S. 303, 309 (US Supreme Court).
Therefore, s.101 US Act applies the prerequisite of new to the four indicia of ‘invention’ separately and distinctly from the other parameters of patentability. The word new, although alluding to the parameters of patentability of ‘novelty and inventive step’ in ss.102 and 103 US Act, does not mean the same thing. It would be absurd for the US Act to define an ‘invention’ by the same criteria that defines a ‘patentable invention’. Not only would this be a duplication but also it would blur the boundary between what is an ‘invention’ and what is a ‘patentable invention’.

The US Act’s emphasis on the end result is also contained in the AU Act. Even though the AU Act defines ‘invention’ by reference to an antiquated statute which was long ago repealed by the Parliament that enacted it, the word ‘invention’ is associated with the word ‘exploit’, which is a defined, “in relation to an invention … to include (a) where the invention is a product… and (b) where the invention is a method or process ....”

The definition expressly and exhaustively refers to three indicia of invention, namely a ‘product’, a ‘process’ and a ‘method’, suggesting that an ‘invention’ must be one of these three things because the right of the patent owner to exploit the ‘invention’ and the invention per se are indivisible in the sense that there is no economic reward in respect of a technology that is not exploitable within the meaning of the AU Act.

Moreover, section 6 of the Statute of Monopolies of 1623 links the prerequisite of new as in “any Manner of new Manufactures” to s.18(1)(a) AU Act which is separate and distinct from the parameters of novelty and inventive step which are provided for by s.18(1)(b) AU Act.

Therefore, the AU Act is similar to the US Act and in terms of s.18(1)(a) AU Act, an ‘invention’ must be new. In bringing together the definitions of ‘invention’ and ‘exploit’ this means that an ‘invention,’ for the purposes of the AU Act, is a new product, process or method, but to be a patentable invention, the ‘invention’ must also satisfy the more specific parameters that include novelty and inventive step in s.18(1)(b) AU Act.

This very issue was the subject of the High Court of Australia in NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited (Philips). In this decision the High Court considered the word new as in ‘manner of new manufacture’ in s.6 of the Statute of Monopolies of 1623 together with the parameters of novelty and inventive step in s.18(1)(b) AU Act and specifically whether they were the same. The Court held that the word ‘new’ in the definition of ‘invention’ had a

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51 Schedule 1 AU Act.
52 NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited (1995) 183 CLR 655 (High Court of Australia).
different purpose and meaning to the parameters of novelty and inventive step. The Court explained,

In the light of what has been said above about what is involved in an alleged manner of new manufacture, that threshold requirement of ‘an alleged invention’ will, notwithstanding an assertion of ‘newness’, remain unsatisfied if it is apparent on the face of the relevant specification that the subject matter of the claim is, by reason of absence of the necessary quality of inventiveness, not a manner of new manufacture for the purposes of the Statute of Monopolies. That does not mean that the threshold requirement of ‘an alleged invention’ corresponds with or renders otiose the more specific requirements of novelty and inventive step (when compared with the prior art base) contained in s 18(1)(b). It simply means that, if it is apparent on the face of the specification that the quality of inventiveness necessary for there to be a proper subject of letters patent under the Statute of Monopolies is absent, one need go no further.

The words “need go no further” mean that the ‘invention’ parameter is a prerequisite which must be satisfied anterior to “the more specific requirements” of novelty and inventive step in s.18(1)(b) AU Act. Furthermore, the Court held that the invention parameter was to be assessed by “the quality of inventiveness” as defined by the word new. It thereby reinforced the distinction between an ‘invention’ and a ‘patentable invention’ making it crystal clear that “[t]he effect of those opening words of s.18(1) is that the primary or threshold requirement of a ‘patentable invention’ is that it be an ‘invention’.”

Therefore what appears to be a significant difference between Australian, UK, European and US patent law in terms of ‘invention,’ is in truth insignificant, because the proviso in s.101 US Act has the effect of restricting the ambit of a ‘discovery’ in s.100 US Act to a form that is consistent with the ‘invention’ within art. 52(1) EPC, s.1(1) UK Act and s.18(1)(a) AU Act. What unifies these separate provisions is the sharing of common principles of patent law, one of which is, that the end result must not violate the prohibition concerning “[t]he laws of nature, physical phenomena, and abstract ideas”.

This Thesis concludes that the ‘invention’ parameter contained in the patent regimes of the EPC and the UK Act which do not define the word ‘invention’ is the same as the ‘invention’ parameter contained in the US and Australian patent regimes which do. Accordingly, the definition of ‘invention’ in art. 27.1 TRIPS, art. 52(1) EPC, s.1(1) UK Act, s.100 and 101 US Act or s.18 AU Act, means that ‘discovery’ and ‘invention’ are not mutually exclusive and it is possible to have a

53 Ibid, 663-4 (emphasis added).
54 Ibid, 663.
discovery that is an invention provided that the end result is a new and useful composition of matter, product, process, method, machine or manufacture.

However, before the discussion can be brought to a conclusion it remains necessary to address some of the obiter dicta of Lord Hoffmann in Biogen. Lord Hoffmann accepted that the UK Act “lays down various conditions, both positive (in paragraphs (a) to (c)) and negative (in paragraph (d)) which an invention must satisfy in order to be a ‘patentable invention’”. This pronouncement confirms the presence in the UK Act of a distinction between an ‘invention’ and a ‘patentable invention’ and is consistent with TRIPS, the EPC, the US Act and the AU Act. However, he cautioned against “the practice [of] first decid[ing] whether the claimed invention can properly be described as an invention at all [because] in most cases [this would] be a mistake and cause unnecessary difficulty”. An interpretation of this cautionary note is that the ‘invention’ issue is not to be determined in isolation to the other parameters of patentability, inferring that the criteria for assessing ‘invention’ is not dissimilar to the criteria for assessing ‘patentability’. If this interpretation were to be correct it may be thought that UK patent law had taken a divergent path to that of the US and Australia. However, this Thesis proposes that this is not what his Lordship meant because such an interpretation would be at odds with the intention of s.1(1) UK Act that there be a distinction between an ‘invention’ and a ‘patentable invention.’ Clearly, if the parameters for assessing ‘patentability’ and ‘invention’ were the same or near enough to be indistinguishable, the distinction would cease to be relevant.

This rationale may explain why Daniel Gervais and Markus Nolff have expressed the view that patentability per se is decided by the satisfaction of only three parameters of patentability, namely novelty, inventive step and industrial application. The argument is an attractive one for the reason expressed by Lord Hoffmann in Biogen that the ‘various conditions’ in s.1(1) UK Act “probably also contain every element of the concept of an invention in ordinary speech.” But its attractiveness is superficial for Lord Hoffmann went on to explain, “I say probably, because in the absence of a definition one cannot say with certainty that one might not come across something

56 Biogen, Inc. v Medeva plc [1997] RPC 1, per Hoffmann LJ, 41 (House of Lords).
57 See Li Westerlund, Biotech Patents: Equivalence and Exclusions under European and U.S. Patent Law, Kluwer Law International, 2002. He maintains, that “[I]n most patent laws the object of the exclusive right lacks a positive definition. … This lack of explicit definition does not mean that there is no clear notion of the concepts’ content. On the contrary, the concept of invention in Sweden’s patent laws and those of other countries has been concisely and coherently developed through the case law.”, 6, 1.3.
58 Ibid. (Emphasis added)
61 Biogen, Inc. v Medeva plc [1997] RPC 1, per Hoffmann LJ, 55 (House of Lords)
which satisfied all the conditions but could not be described as an invention.”62 This reservation is particularly pertinent because ‘condition (d)’ in s.1(1) UK Act is a direct reference to the common principle of patent law that prohibits the grant of a patent monopoly over “[t]he laws of nature, physical phenomena, and abstract ideas.”63

The problem with the reasoning employed by Daniel Gervais and Mark Nolff is that ‘industrial applicability,’ or utility as it is also called, has been the key parameter through which the proponents of the ‘isolation contrivance’ have neutralised the prohibition against the patenting of natural phenomena. As will be seen in Chapter 3, the ‘technical contribution’ test has been liberally applied so as to create an artificiality conduit between prohibited things, such as natural phenomena on the one hand, and ‘inventions’ on the other. The proponents of this view argue that the prohibition is not violated because the ‘technical contribution’ made by the application of a ‘discovery,’ such as a human gene, in a ‘product’, ‘process’ or ‘method’ makes the human gene different to its natural equivalent.

This Thesis disagrees with Daniel Gervais and Mark Nolff and prefers the views expressed by Mustill LJ in Genentech and later reinforced in his separate speech in Biogen. Lord Mustill explained,

Certainly, in the great majority of cases, there will be no need to complicate the enquiry by looking outside the four conditions. The traditional law of patents is, however, in the course of adapting itself to new technologies, beyond contemplation when the foundations of that law were established. This process is not without strain, and I believe that in some instances a close conceptual analysis of the nature of patentability will not be a waste of time. Such a case was Genentech Inc's Patent where the claim was for a product already existing in nature, a subject far distant from the mechanical and chemical inventions to which so much of traditional patent law relates. There may well be others in the future.64

The point of Lord Mustill’s and Lord Hoffmann’s *obiter dicta* is that in the majority of patent cases the technologies in issue are of the kind that traditionally have been regarded as ‘inventions,’ such as new and useful machines. In these cases, patentability can usually be decided by reference to the parameters of novelty, inventive step and industrial application. However, not all cases are so simple and into this category fall patents that concern biological materials, such as proteins and the processes of their production. In these cases, it will be necessary to undertake an ‘invention’ inquiry.

62 Ibid.
64 *Biogen, Inc. v Medeva plc* [1997] RPC 1, per Mustill LJ, 31, line 36 – 32, line 2 (House of Lords).
Lord Mustill clearly rejected the Gervais-Nolff rationale and this is apparent from his reasoning in *Genentech* while Lord Hoffmann’s qualification, made by his use of the word ‘probably,’ suggests that while he also rejected it he was not as definite as Lord Mustill. Nevertheless, there are two good reasons for rejecting it.

First, implicit in *Chakrabarty* is the distinction between subject matter that is appropriate for a patent and subject matter that is not. In this respect, the Supreme Court did not assess ‘novelty’ under s.102 *US Act* nor involved an ‘inventive step’ under s. 103 *US Act* in order to resolve whether the artificial bacterium was an ‘invention’ within s.101 *US Act*. To the contrary it looked only at the words of s.101 *US Act* and held that the genetically modified bacterium was a new composition of matter because it displayed “markedly different characteristics from any found in nature.” The word *new* was not a reference to s.102 nor 103 *US Act*. This identical approach was followed by the High Court of Australia in *Philips* where the Court held that the threshold for a ‘manner of *new* manufacture’ is reached “if it is apparent on the face of the specification that the *quality of inventiveness* necessary for there to be a proper subject of letters patent under the Statute of Monopolies [is present]”. Furthermore, so as to reinforce the distinction between the ‘invention’ parameter from the other parameters the Court held that if this *quality of inventiveness* was “absent, one need go no further,” meaning that unless there was an ‘invention’ it would be unnecessary to consider whether the subject matter of the patent was novel, involved an inventive step or was capable of industrial application. This reinforced the relevance of the distinction between an ‘invention’ and a ‘patentable invention’ implying that the criteria of invention was not the same as the criteria applicable to patentability.

Secondly, the idea that the parameters of novelty, inventive step and industrial application which correspond with s.1(1)(a)-(c) *UK Act*, arts. 54, 56 and 57 *EPC*, s.18(1)(b), and s.18(1)(c) *AU Act* and s.102, 103 and s.112 *US Act* “probably also contain every element of the concept of an

65 “I say probably, because in the absence of a definition one cannot say with certainty that one might not come across something which satisfied all the conditions but could not be described as an invention,” per Lord Hoffmann in *Biogen Inc v Medeva plc* [1997] RPC 1.


68 Ibid.

69 Although utility parameter appears to be contained within s.101, s.112 (whether specification provides enabling disclosure) completes the parameter as the two sections are closely related. If patent claim fails to meet utility requirement (35 USCS § 101) because it is not useful or operative, then it also fails to meet how-to-use aspect of enablement requirement (35 USCS § 112). *Process Control Corp. v HydReclaim Corp.* (1999) 190 F3d 1350, 52 USPQ2d 1029 (CAFC), reh den (1999) 1999 US App LEXIS 31878 (CAFC) and cert den (2000) 146 L Ed 2d 346, 120 S Ct 1531, (US Supreme Court).
invention in ordinary speech”, if correct, renders the distinction between an ‘invention’ and a ‘patentable invention’ otiose, which is contrary to the intention of s.1(1) UK Act.

In fairness to Lord Hoffmann, his assessment probably does no more than reflect the concerns expressed by the High Court of Australia back in 1959 in which it held that the invention parameter should be considered with the totality of the claimed invention because “[t]he fallacy lies in dividing up the process that he puts forward as his invention,” but to go beyond this, as he well recognised, is an error.

What this analysis suggests is that each of the patent regimes considered in this Chapter do have an ‘invention’ threshold that must be satisfied as part of the assessment of patentability. While the distinction between discovery and invention, as a mutually exclusive concept, is not decisive, this does not mean that the word ‘invention’ is meaningless or boundless in scope so that anything can be patentable if it satisfies the other parameters of novelty, inventive step and industrial application. One thing is clear: not everything under the sun that is made by man is an invention.

In conclusion, it is fair to suggest that the word ‘invention’ in art. 27.1 TRIPS is not meaningless nor boundless in scope, but has a specific meaning and one that is referable to the patent laws of the United States, the United Kingdom and Australia and from the EPC and their interpretation by the seminal cases of Chakrabarty, Genentech and NRDC.

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70 Biogen, Inc. v Medeva plc [1997] RPC 1, per Lord Hoffmann, 55 (House of Lords).

71 National Research Development Corporation v. Commissioner of Patents (1959) 102 CLR 252, 264 (High Court of Australia)

72 Cf: P. J. Federico, a principal draftsman of the 1952 US Patents Act, in his testimony regarding that legislation: “[U]nder section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man...” (emphasis added). Hearings on H. R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951) from n.6 Diamond, Commissioner Of Patents And Trademarks v. Chakrabarty 447 U.S. 303, 309.
Testifying before the United States Congress in 1951 P. J. Federico, a principal draftsman of the US Act swore that, “… under section 101 [of the Bill that became the US Patents Act, 1952] a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man”.¹

Thirty years later in Chakrabarty, the Supreme Court cited Mr. Federico’s evidence in a footnote,² and with that his words³ became the foundation stone of the ‘modern biotechnology industry.’⁴ Indeed some commentators such as Philippe Ducor⁵ have gone further, confidently asserting that “as a result [of Chakrabarty] eligibility issues no longer play a significant role in developing [patent] case law.”⁶

The importance of Chakrabarty in patent law jurisprudence goes well beyond the United States. This is evident from the opinion of the Advocate General to the Court of Justice in The

¹ Hearings on H. R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951). Throughout this Thesis the phrase ‘made by man’ is used, however, this phrase is not a reference to gender, but is a reference to artificiality. Although in modern western society such a phrase is not considered politically correct, the use of the phrase in the context herein described is appropriate simply because of its historical relevance and its use by the US Supreme Court in 1980.


³ The Supreme Court explained that “The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’” Diamond, the Commissioner of Patents v Chakrabarty (1980) 447 U.S. 303, 309.

⁴ M. Andrea Ryan president elect of the American Intellectual Property Lawyers Association gave evidence before the Oversight Hearing on Gene Patents And Other Genomic Inventions before the Subcommittee on Courts and Intellectual Property Committee on the Judiciary U.S. House Of Representatives, Washington, D.C., July 13, 2000. She testified that “… patent protection should be made available to anything ‘under the sun that is made by man’. Those words and that court decision [Diamond v Chakrabarty] were instrumental in launching the modern biotechnology industry.” Also see the opinion of the Advocate General in The Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission) (Case C-377/98) [2002] All ER (EC) 97 (Court of Justice of the European Communities), para 37, “[t]hat ruling prompted the establishment of a number of commercial firms that manufacture quantities of gene-engineered substances for a variety of mostly medical and ecological uses.”


⁶ Ibid, 6.
Chapter 3: The Invention per se and Biotechnology

Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission)\(^7\) who explained that,

The biotechnological industry began to develop seriously after a decision by the US Supreme Court in 1980 that ‘a live, human-made micro-organism is patentable subject matter’ (Diamond v Chakrabarty 447 US 303 (1980)).\(^8\)

This Thesis agrees that Chakrabarty was seminal, but argues that the decision has been largely misunderstood and misrepresented. For example, Philippe Ducor\(^9\) maintains that,

Generally, ‘products of nature’ are patentable when some human intervention has been necessary to make them available. The intervention generally resides in the isolation or purification of the naturally-occurring product, and translates in claim language as ‘essentially pure’, ‘biologically pure’, or ‘isolated’. The current situation is well summarized by the Court in Diamond v Chakrabarty: patentable subject matter includes ‘anything under the sun that is made by man’.\(^10\)

The impression that his explanation leaves is that all that is necessary to transform a ‘product of nature’ into an ‘invention’ in accordance with Chakrabarty is some level of human intervention, implying that the slightest amount of human intervention is sufficient. It also suggests that so long as the ‘product of nature’ is artificial in some degree that the transformation is complete. However, as simple and attractive as his explanation may appear, it is wrong.

First, as will be demonstrated in this Chapter, the Supreme Court did not hold that all that was necessary to transform a ‘product of nature’, such as a natural bacterium, into a ‘product of man’ was merely ‘some human intervention’. Rather, it required a significant level of human intervention. Secondly, nowhere in its decision did the Court hold, either impliedly or expressly, that the mere ‘isolation’ or ‘purification’ of a product of nature or its production in a technical process, was the type of ‘human intervention’ which it contemplated coming within the words ‘anything under the sun made by man’. Undoubtedly, the words made by man contemplated that an ‘invention’ be artificial, but the degree of artificiality required to bring something intrinsically natural within the meaning of those words was not some but significant.

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\(^7\) The Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission) [2002] All ER (EC) 97 (Court of Justice of the European Communities)

\(^8\) Ibid, para 36.


\(^10\) Ibid, 6 (Emphasis added).
Nuno Pires de Carvalho explained that “[i]t is artificiality, not inventiveness, that distinguishes inventions from discoveries,”¹¹ and that “[w]hen Justice Berger noted in Diamond v Chakrabarty that Congress intended statutory subject matter to ‘include anything under the sun made by man;’ he was actually stressing the element of artificiality that presides over human intervention.”¹² However, even his explanation underestimated the degree of artificiality required by Chakrabarty. This Thesis argues that too much emphasis has been placed on the words of P. J. Federico and as a consequence that their true meaning has been lost.

The United States of America

Chakrabarty

The ‘invention’ in the Chakrabarty patent was a genetically modified bacterium.¹³ It was considered to be ‘genetically modified’ because the natural bacterium from the genus Pseudomonas did not contain “two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway”. So it was the addition of these two plasmids, the human intervention, which was responsible in 1972 of transforming a natural bacterium into an artificial bacterium.

The central question for the Supreme Court was whether this artificial bacterium, was an ‘invention’ within s.101 US Act, that is, was it a new and useful manufacture or composition of matter? The Court decided by a narrow majority of 5 to 4 that it was. However, it was not its artificiality per se that was decisive. The Court held,

… the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under ß 101.

¹³ It was “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.”
The Court considered three characteristics about the artificial bacterium to be crucial. First was the genetic modification or human intervention. Second was the end result, the function that “no naturally occurring bacteria”\textsuperscript{15} could perform, namely, the degradation of crude oil. Third was the potential of the new function to provide significant utility.

Firstly, the artificial bacterium was significantly modified when compared to any natural microorganism or cell, not just the bacterium in issue. The human intervention involved the genetic modification of a natural bacterium through the insertion of two plasmids that were not found in any naturally occurring microorganism or cell. The artificial bacterium was not simply ‘isolated’ from its natural environment.

Secondly, the artificial bacterium displayed markedly different characteristics from any found in nature, namely it degraded crude oil. The words from any found in nature meant precisely that. There was no naturally occurring microorganism or cell that degraded crude oil. It is important to appreciate that the Court’s emphasis was not on the artificial bacterium performing a new function in comparison to the natural bacterium, but rather on the artificial bacterium performing a function different from any found in nature. It did more than simply replicate or reproduce an identical substance or thing already produced in nature, such as insulin, human growth factor, hepatitis C virus, erythropoietin or human tissue plasminogen activator.

Thirdly, the markedly different characteristics not found in nature had the potential for significant utility. The significant utility was directly attributable to the new characteristics of the artificial bacterium. In other words, the utility was not a product of the replication of the function of the natural bacterium or bacteria or any micro-organism or cell in general, it was a characteristic of the end result that was not found in nature. The utility displayed by the artificial bacterium, that is, the degradation of crude oil, was foreign to nature nor derived from nature.

In satisfying all three criteria, the Supreme Court ruled that the artificial bacterium was a ‘new and useful’ composition of matter, not in the context of novelty or inventive step, but in the context of ‘invention’.\textsuperscript{16}

The Court made it clear that ‘artificiality’ in the sense of some human intervention was not enough. More was required and unless the genetic modification performed on the natural bacterium resulted in an artificial bacterium displaying “markedly different characteristics to any

\textsuperscript{15} Diamond, the Commissioner of Patents v Chakrabarty (1980) 447 U.S. 303, 305 (US Supreme Court).

\textsuperscript{16} “This case does not involve the other ‘conditions and requirements’ of the patent laws, such as novelty and nonobviousness. 35 U. S. C. ß ß 102, 103.” Ibid, 307, footnote 5.
found in nature” and whose new characteristics were useful, there was no ‘invention’. It is important to note at this juncture that the decision emphasised that it was the new characteristics per se which possessed the potential for significant utility, not the artificiality of the bacterium per se. It was the former and not the latter which persuaded the Court to hold that there was an ‘invention,’ that it was not ‘nature’s handiwork.’ Therefore, what was crucial was the significant degree of artificiality that the genetically modified bacterium displayed and this requirement was emphasised by the Court’s use of the word “markedly” before the word “different.” The word “markedly” in this context implied that any minor or insignificant differences between the characteristics of the artificial bacterium compared to anything natural were to be disregarded.

For Directive technologies the reasoning implies that isolated or purified biological materials or those produced through a technical process are not ‘inventions’ unless they have been significantly modified by human intervention, thus resulting in biological materials per se that are significantly different to ‘any found in nature’ and which have the ‘potential for significant utility’ beyond anything found in nature. Note, that the emphasis is on the end result, not on the components or the processes used in achieving the end result. This is important to understand, because the vast majority of protein patents contain claims not only to the recombinantly produced protein, but also to the components and process of their production, such as genetically modified host cells or ‘isolated’ DNA sequences that have been made ‘suitable for’ recombinant production.

The Court used the word ‘characteristic’ as a reference to a “distinguishing trait, quality, or property.”17 This means that the relevant difference for the Court was not merely the genetic modification performed on the natural bacterium, but how this genetic modification produced a result different from any found in nature and to what degree. On the facts in Chakrabarty, the distinguishing trait, quality, or property was not simply the insertion of the plasmids, but how their insertion into the genetic structure of the natural bacterium made the artificial bacterium function differently to any found in nature.18

Arguably, if the genetic modification in Chakrabarty achieved nothing more than to enable the artificial bacterium to produce an end result already found in nature, the human intervention would not have resulted in an ‘invention’ within s.101 US Act because the artificial bacterium would not have been either new or useful. This is precisely the problem facing Directive technologies, because generally the isolation of a gene sequence that codes for a protein which is then modified

17 Merriam-Webster Medical Dictionary, 2002 Merriam-Webster, Inc.
18 The Court held, “Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty’s invention is believed to have significant value for the treatment of oil spills.” Diamond, the Commissioner of Patents v Chakrabarty (1980) 447 U.S. 303, 305 (US Supreme Court). (Emphasis added)
so as to be suitable for use in some process of recombinant production results in the replication of a protein that already exists in nature and is indistinguishable from it. True, there may have been human intervention, perhaps even a significant level of human intervention in terms of the cloning of the gene (i.e., its isolation) and then in modifying the genetic information of that gene so as to be suitable for the process of recombinant production of the protein for which it codes for, but the inescapable reality is that the end result of such examples is a protein which is indistinguishable from a natural protein. Accordingly, the end result is neither a distinguishing trait, quality, nor property when compared to the natural protein, and it lacks the potential for significant utility beyond that already possessed by the natural protein. Moreover, the processes and their component parts, such as DNA fragments, vectors and host cells contain or use the very same genetic material that is contained in the gene that codes for the natural protein. What distinguishes the processes and the component parts are the very DNA fragments that code for the protein of choice. The modifications that have been performed on the components of the recombinant processes result in components that are themselves artificial in that they are not found in nature, for example, a hamster cell that expresses human insulin, but this is not the point. The point is first, that these components are merely replicating nature by enabling the expression of a protein that is indistinguishable from the protein made by the human body. They are merely surrogates. Secondly, they are part of a complete process. As individual components they are intrinsically useless. It is the insertion of the DNA fragment into the vector, which is then used to infect the host cell and take over the normal functioning of the host cell so that the host cell produces the protein coded for by the DNA fragment, that is relevant to the achievement of the end result.

The utility of the process is in the amount of protein that is produced and the purity of that protein, not in the protein per se. This distinction is the reason why the Supreme Court cited and distinguished Funk Brothers Seed Co. v. Kalo Inoculant Co on its facts. In Funk Brothers the issue was whether a certain mixed culture of root-nodule bacteria that were capable of inoculating the seeds of leguminous plants belonging to several cross-inoculation groups was an ‘invention’. The Court held that the subject matter of the patent was not an

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19 “…the overwhelming evidence, including Amgen’s own admissions, establishes that uEPO and rEPO are the same product. The EPO gene used to produce rEPO is the same EPO gene as the human body uses to produce uEPO. The amino acid sequences of human uEPO and rEPO are identical.” See Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc (1989) 13 U.S.P.Q.2D 1737 (US District Court) (Emphasis added).

20 Funk Brothers Seed Co. v. Kalo Inoculant Co (1948) 333 U.S. 127 (US Supreme Court).

21 The Court held “The point is underscored dramatically by comparison of the invention here with that in Funk.” Diamond, the Commissioner of Patents v Chakrabarty (1980) 447 U.S. 303, 309-10. (US Supreme Court).
‘invention’. It held despite the fact that by mixing six root-nodule bacterial strains from the species *Rhizobium*, the process of inoculating leguminous plants was made more efficient as a farmer could perform the inoculation in one single operation. This saved the farmer time and reduced costs, so it is fair to conclude that the combination was *useful*. However this was not enough to make the subject matter of the patent an ‘invention’. The Court held,

> There is, of course, an advantage in the combination. The farmer need not buy six different packages for six different crops. He can buy one package and use it for any or all of his crops of leguminous plants. And, as respondent says, the packages of mixed inoculants also hold advantages for the dealers and manufacturers by reducing inventory problems and the like. *But a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery.*

In satisfying the requirements of ‘invention or discovery’ the Court focused its attention on how the inoculants, which individually were products of nature, performed in a combined state compared to individually and concluded that there was no difference. The combined inoculants did not display markedly different characteristics to any found in nature. The utility of the product was merely in the combination. The Court held,

> The application of this newly-discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance. But once nature’s secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. *Even though it may have been the product of skill, it certainly was not the product of invention.* There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself. That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough.

The point which the Court made in *Funk Brothers* about the human intervention involved in the combination of the inoculants is analogous to the human intervention involved in cloning a gene or genome and the elucidation of its genetic sequence. Although the cloning of a gene and the

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modification of its DNA sequence may be a product of skill and labour, it certainly is not the product of invention.

There is no doubt that the human intervention combining the six bacterial strains involved skill and labour. There is also no doubt that their removal from their natural and independent environments placed them in an artificial environment. It was an artificial product. However, the artificiality of the product did not transcend the threshold of 'invention'. What was needed was an end result that was significantly different to anything found in nature. The Court held in Funk Brothers, that the degree of artificiality demonstrated on the facts of that case did not meet the threshold of 'invention' because, even when combined the end result of the product was no different to what was achieved by the natural bacteria, albeit independently.

The fact that in Funk Brothers there was no human manipulation in the genetic structure of the six bacteria was irrelevant unless that intervention so varied the bacteria that they produced a result not producable in nature. That was why the Court in Chakrabarty distinguished but approved of Funk Brothers. The Court held,

Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.

The Court held that the distinction between the subject matter in Funk Brothers and the subject matter in Chakrabarty was “underscored dramatically” by the “new bacterium with markedly different characteristics from any found in nature”.

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24 “I have already acknowledged, and am glad to repeat, that to this layman at least Genentech appear to have performed an excellent piece of work. But the excellence resided in a combination of tenacity, skill and managerial efficiency. As to tenacity, it is impossible to read Dr Pennica’s affidavit without admiration for the way in which she worked literally day and night for months in the most adverse physical conditions. But others worked hard too. When Dr Ny told Dr Pennica about his work, he said that it had nearly killed him. Should one not also credit the skilled worker with diligence and determination? As to skill, one sees it in abundance. But this is not the same as inventiveness.” Per Mustill LJ in Genentech Inc’s Patent [1989] RPC 147, 286 lines 28-36 (UK Court of Appeal).


27 Ibid.

Barbara Looney has argued, and this thesis agrees, that the words “markedly different” in *Chakrabarty* were synonymous with the word “significant”\(^{29}\) in the context of human intervention. She maintained that,

> “The judiciary has interpreted this requirement to mean that an invention in the biotechnological realm must have a significant ‘human innovation’ component, to move the invention from an ‘object of nature’ to ‘patentable subject matter’ status.”\(^{30}\)

The “sufficient human innovation” which Barbara Looney referred to was not however, a reference to the mere manipulation of the genetic structure of the bacterium alone - rather it was a reference to the totality of the human intervention, namely, the genetic manipulation of the bacterium and the product of that manipulation - its new and useful\(^{31}\) ability to degrade crude oil.

If it were the case that the Court in *Chakrabarty* was of the view that genetic manipulation of the bacterium alone was ‘sufficient’ to enable there to be an ‘invention’ it would be difficult to understand why the Court used the word “damatically” in its distinction of *Funk Brothers*. Arguably, the Court was so motivated because of the emphasis that it wished to place on the need for the human intervention (whether be the genetic manipulation of a bacterium as in *Chakrabarty* or the physical combination of bacteria that were otherwise separate as in *Funk Brothers*) was the causal nexus in the achievement of not only a “nonnaturally occurring manufacture or composition of matter”\(^{32}\) but one that also displayed “markedly different characteristics from any found in nature”\(^{33}\).

If all the Court in *Chakrabarty* required for there to be an ‘invention’ was human intervention resulting in a “nonnaturally occurring manufacture or composition of matter” it would not only have distinguished *Funk Brothers*, but it would have overruled it because the combining of six bacteria into one environment was most definitely a “nonnatural composition of matter”. However, the fact that it did not overrule it reinforced the point of the Court’s distinction of *Funk Brothers*, which was that human intervention alone in the production of a “nonnatural composition of matter” was not enough to transcend the threshold of ‘invention’.

\(^{29}\) Op cit 25.

\(^{30}\) Ibid.

\(^{31}\) These words appear in s.101 US Act. The word ‘new’ therefore is not a reference to novelty and inventive step which are both specifically and separately addressed by ss. 102 and 103 US Act.


\(^{33}\) Ibid, 310.
In this regard the mere isolation, purification and production of biological materials by human intervention may very well result in a “nonnatural composition of matter” because there is direct human intervention of the biological material per se, but this alone does not satisfy the complete test of ‘invention’ as stipulated in Chakrabarty.  

This point appears to have been marginalised by some legal commentators.  

For instance, Rebecca Eisenberg opined ten years after Chakrabarty that Funk Brothers “seem[ed] to represent the high-water mark in the ‘products of nature’ doctrine,” arguing that “[u]nder Chakrabarty, the relevant inquiry for distinguishing between patentable subject matter and unpatentable products of nature is whether the claimed invention is the result of human intervention.” In the context of the human genome she pointed out that, “even if the claimed DNA sequence is identical to a sequence that exists in nature, it may still fall within the categories of patentable subject matter if the patent applicant has made the sequence available in an isolated or purified form that does not exist in nature.” She cited Merck & Co. v. Olin Mathieson Chemical Corp as one of the decisions that made up a “substantial body of case law that newly isolated or purified materials may be patented even though those materials exist in nature in an impure state….”

The problem with her summary of the law is that first, Merck was the decision of the 4th Federal Circuit of Appeals, not the Supreme Court; second, Merck was decided in 1958, some twenty two years before Chakrabarty and was neither cited nor referred to in Chakrabarty; third, the other cases which made up the ‘substantial body’ of case law which she cited were In re Bergstrom and In re Bergy, both the decisions of Bergstrom and Bergy were decisions of the US Court of Customs and Patent Appeals in 1970 and 1977 respectively, predating Chakrabarty. Furthermore, in Chakrabarty, the Supreme Court cited Bergy merely to point out that it had been appealed to the Supreme Court but was “dismissed as moot” in favour

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34 This point was reinforced by the House of Lords in its decision in Kirin-Amgen v TKT [2004] UKHL 46 which was delivered on October 21, 2005, some three weeks after this thesis was submitted. For more analysis of the decision see the postscript to Chapter 4.


36 Ibid (Emphasis added).

37 Ibid, 724 (Emphasis added).

38 Merck & Co. v. Olin Mathieson Chemical Corp (1958) 253 F.2d 156 (4th Cir.).


41 In re Bergy (1977) 563 F.2d 1031 (CCPA).

of the decision in *Chakrabarty*. Bergstrom was neither cited nor referred to in *Chakrabarty*. As for the decision of *Chakrabarty*, her description of that case in a footnote\(^{36}\) in support of the proposition that the “biologically pure culture of the microorganism *streptomyces vellosus* [is] patentable since it did not exist in nature in a pure form and could be produced only under carefully controlled laboratory conditions” was wrong. That quote came from the decision of US Court of Customs and Patent Appeals in *Bergy*.

Her summary was a misdescription of *Chakrabarty* because nowhere did the Court refer to the ‘isolation’ or ‘purification’ of the artificial bacterium nor to its production in a carefully controlled laboratory as being indicia of ‘invention.’ Rather, the *ratio decidendi* stipulated that unless the human intervention was the causal nexus to something that: (a) was a “nonnatural composition of matter or manufacture” and (b) displayed “markedly different characteristics to any found in nature” and (c) which “markedly different characteristics” had the “potential for significant utility,” there was no ‘invention’ within s.101 *US Act*.

Therefore, her thesis that a mere isolated or purified DNA sequence *per se* that is identical to a sequence that exists in nature is patentable subject matter within s.101 *US Act* is inconsistent with *Chakrabarty* because such a sequence satisfies only one of the three compotents of the test of biological ‘invention’, namely, that it is a nonnatural composition of matter. Furthermore, her attempt to relegate *Funk Brothers* into the history books by suggesting that it represented the “high-water mark” of the “product of nature doctrine”, failed to explain why the Court in *Chakrabarty* did not overrule nor criticise it. To the contrary, the Court cited it with approval. The Court’s approval emphasised her error because if *Chakrabarty* supported her thesis, then *Funk Brothers* was not only “the high water mark” but it was wrongly decided.

It is important to recognise that there is a real difference between the human intervention involved in merely replicating the function of a naturally occurring biological material through some technical process, method or product and the human intervention involved in modifying biological material so that it displays “markedly different characteristics to any found in nature” and which has the “potential for significant utility”. The former is simply a replication of a naturally occurring biological material. The latter, however, is not and provided that the modification results in a biological material that is an enhancement of its natural counterpart then the test of biological ‘invention’ is satisfied.

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For example, in Chapter 4 the thesis examines in detail the litigation concerning the patenting of a human devised process for the production of a nonnatural form of a protein called ‘erythropoietin’. The end product of the process that was the subject of patent litigation in the United Kingdom was a nonnatural form of this protein, so it was definitely the product of human intervention. In fact, the evidence showed that without human intervention it was not possible to produce this protein outside of the human body. The evidence also showed that this protein had been extracted from human urine before the date of the ‘invention’, but in such small quantities that it was not readily available in commercial quantities and moreover that even then it did not have the efficacy in humans which the nonnatural form of the protein displayed (although the nonnatural form was bioequivalent to the protein produced by the human body). Therefore there is no doubt that the production of the nonnatural form of the protein had “potential for significant utility”. Despite this, the House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* decided in October 2004 (some one month after the thesis was submitted for examination) that the protein claim to the end product of a process which provided for the production of an isolated and purified form of this protein by the use of a technical process which utilised an isolated segment of the human gene responsible for its production in humans, was invalid because the end product of the process was not ‘new’. In other words, the isolated and purified protein was indistinguishable from the natural counterpart and therefore was not new. On that basis, if one accepts that a process and its product are inextricably linked, if the product claim is invalid what does that mean for the process claim?

The oft quoted phrase of P.J. Federico that “anything under the sun that is made by man” is, in the context of biotechnology, nothing but misleading unless the *ratio decidendi* of *Chakrabarty* is understood because as this analysis demonstrates, the fact that the subject matter of a patent is isolated and purified is simply not enough to make it an ‘invention’. While it was appropriate for the US Supreme Court to take into account the Congressional Committee Reports concerning the *US Act*, for commentators like Philippe Ducor and Rebecca Eisenberg to suggest that *Chakrabarty* is authority for the proposition that mere isolated biological materials *per se* are ‘inventions’ is giving those words a meaning which the Supreme Court never intended.

However, while this Thesis agrees that *Chakrabarty* requires a ‘significant level of human intervention component,’ Barbara Looney’s assertion that the identification of gene sequences does not involve the alteration of natural biological material is also misleading. Of course, there are some alterations inevitably caused by the process involved in the cloning or identification

44  *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2004] All ER (D) 286 (House of Lords).
45  *Ibid*, per Lord Hoffmann, para 132.
process. So while the identification and elucidation of a gene sequence is a discovery of fact, the processes used to achieve that knowledge do involve human intervention which consequently produce an artificial result. This the point of Chakrabarty. It is neither the human intervention alone nor the artificiality of the biological material alone which is decisive. Clearly, an isolated DNA sequence derived from a gene that has been made suitable for use in the recombinant production of the protein that it naturally codes for, does not satisfy the ‘invention’ threshold in Chakrabarty even though the DNA sequence in that form does not exist in nature.

No doubt those that subscribe to the contrary view will argue that such an interpretation, if correct, spells the end of the modern biotechnology industry and the scientific research which it supports, but the response to such a scenario can be found in the unemotive words of Justice Berger in Chakrabarty. He explained thus,

The grant or denial of patents on microorganisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent’s claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.47

In his opinion the proper forum for the resolution of this debate is not through the courts, but through the political process because the courts are “without competence to entertain these arguments -- either to brush them aside as fantasies generated by fear of the unknown, or to act on them.”48 On this occasion his comments were directed towards those that argued against ‘extending’ patentability to a ‘live’ bacterium. The patenting of something ‘alive’ was very controversial in 1980 and it is in this respect that the decision was a difficult one. It must be appreciated that it was a very close decision of 5 to 4, and even then, the majority imposed some very clear and stringent criteria so that the implicit prohibition against the patenting of natural phenomena contained within s.101 US Act was not rendered otiose.

48 Ibid., 317. Justice Berger also held that “Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted.”

The Supreme Court revisited Chakrabarty in 2001 in JEM Ag Supply, Inc., DBA Farm Advantage, Inc. v. Pioneer Hi-Bred International, Inc. (Pioneer). This case, however, did not concern microorganisms, but concerned “seeds and plants of the inbred line and the hybrids produced by crossing the protected inbred line with another corn line”. The ‘seeds and plants’ while undoubtedly natural, had been “developed by crossing corn plants with desirable characteristics and then inbreeding the resulting plants for several generations until the resulting plant line is homogenous”.50 The Court noted that while “[i]nbred plants are often weak and have a low yield … [h]ybrid seeds are produced by crossing two inbred corn plants and are especially valuable because they produce strong and vibrant hybrid plants with … ‘superior yield for maturity, excellent seedling vigor, very good roots and stalks, and exceptional stay green.’”51

The argument against the validity of the patent was that sexually reproducing plants did not come within US Act because the Plant Variety Protection Act and the Plant Patent Act were “the exclusive means of obtaining a federal statutory right to exclude others from reproducing, selling, or using plants or plant varieties.”52 But the Court disagreed holding that there was no Congressional intention of exclusivity established in the two Plant Acts.

Although the Court did not expand upon Chakrabarty it approved of its reasoning and reinforced its importance in US patent law jurisprudence. In terms of the facts in Pioneer, the modifications which the patent owner performed upon unmodified natural corn seeds in order to develop and produce the artificial modified corn seeds and plants were significant, even with the use of sexual reproduction, an age old technology. More importantly however, the modifications that were made to the unmodified corn seeds were specifically designed to enhance the characteristics or properties of the corn plants that would grow once the modified seeds were cultivated. It is important to note that it did not matter that the methodology employed to create the artificial corn seeds was well known and practised. What mattered was the end result. The significance of this distinction is important because as will be seen in the case studies in Chapters 4 and 5, much has been made on the facts of these cases that the technology employed in the process of cloning or identification of the Epo gene or hepatitis C virus were themselves ‘novel’ or ‘inventive.’ The emphasis in those cases, as in the majority of the patents that concern biological materials, is on

50 Ibid, per Justice Thomas, 596.
51 Ibid.
52 Ibid.
the identification process of the gene or genomes and the subsequent elucidation of the genetic sequence. But *Pioneer* made it clear that it was not the process used to derive the ‘new and useful’ artificial corn seeds that was important so much as how the artificial corn seeds, when cultivated in the earth, produced corn plants that displayed *markedly different characteristics to any found in nature*53 and the significant potential utility of these *new* characteristics.

The decision in *Pioneer* is somewhat analogous to the Australian High Court decision in *NRDC* (discussed later in this Chapter) which decided that the use of a known herbicide in a process that eradicated certain types of weeds from certain crop pastures without harming the crops was an ‘invention’ even though the herbicide was known. Although the invention was a process using a known chemical in a herbicide in a new way, so that both the process and the active ingredient were intrinsically artificial, the human intervention lay in its *new* use which the Court held produced an ‘artificial state of affairs’ and one which displayed “a remarkable advantage, indeed to the lay mind a sensational advantage” and “[t]he method cannot be classed as a variant of ancient procedures” as “[i]t is additional to the cultivation” in that “[i]t achieves a separate result, and the result possesses its *own economic utility* consisting in an important improvement in the conditions in which the crop is to grow, whereby it is afforded a better opportunity to flourish and yield a good harvest.”54

Similarly, in *Pioneer* the unmodified corn seeds being intrinsically natural were subjected to human intervention, not by way of genetic engineering but through the use of an old and well known technology, that of sexual reproduction. This human intervention produced a modified corn seed, which, although sexually reproduced was ‘artificial’ in the sense that, but for the human intervention, the artificial corn seed would never have existed in that form. The artificial corn seed when cultivated produced a corn plant that obviously existed in nature, yet the artificial corn plant was *significantly* different. This significant difference was in the characteristics that it displayed, which were *markedly different to any found in nature*. Furthermore, and most importantly, the new characteristics which the artificial corn plant possessed had the potential for significant utility, and like the end result of the invention in *NRDC* was a *separate result* possessing its *own economic utility* affording the farmer a better opportunity to yield a better harvest. The artificial corn plants that grew from the artificial corn seeds were themselves *new* in that they displayed a *remarkable advantage* over the corn plants produced by other corn seeds and they had their own economic utility in addition to and separate from *any* found in nature. The relevant distinction


54 National Research Development Corporation v. Commissioner of Patents (1959) 102 CLR 252, 277 (High Court of Australia).
here is that end result was not something identical to nature – true it was a corn plant, but critically
it was a superior corn plant. This is not the case with recombinant protein production because the
end result is a protein that is indistinguishable from the natural protein in every conceivable way.55

As this discussion has explained, the emphasis in Chakrabarty, NRDC and Pioneer is on the end
result not on the marvels of genetic engineering or the laborious search for a gene or a genome or
the magic of recombinant technology. Irrespective of how a biological material is produced
(including the intermediate products of that process) what is crucial to the ‘invention’ parameter is
whether the end result is a new and useful biological material. So unless the artificial biological
material possesses markedly different characteristics from any found in nature and which new
characteristics have the potential for significant utility, then it is not an ‘invention’ and neither are
the components used in nor the process of its production.

Clearly, what has facilitated the biotechnology industry’s objective to patent proteins produced by
recombinant means has been a fundamental misunderstanding of Chakrabarty. The industry has
focused on producing the identical protein, albeit artificial, through the use of genetic engineering.
Of course, it was obvious to patent attorneys even before Chakrabarty that the production of a
protein that possessed the same qualities or properties as a natural protein would come within the
prohibition implicit in s.101 US Act. Therefore the solution which patent attorneys devised,
focused on the components used in and the processes for the recombinant production of proteins,
such as ‘isolated’ and ‘purified’ DNA sequences and genetically engineered host cells containing
these sequences. Their rationales relied on the components used in the recombinant process being
‘products of man’ and in crafting the scope of the monopoly so as to capture the product of the
process. Therefore, the solution was not to claim the recombinant products per se as ‘inventions,’
although some did (e.g., Genentech and t-PA; Chiron and HCV) but the processes of their
production or the component parts of those processes (e.g., Amgen and Epo; Chiron and HCV;
Genentech and t-PA). The patent attorneys believed (and most still do) that they had found a
loophole in the prohibition against the patenting of natural phenomena and went about exploiting
that loophole.

The problem with this solution, however, is this: If the product which is produced as a result of
the recombinant process is indistinguishable from a natural phenomenon not only is the product
not an ‘invention,’ but neither is the process or the components of that process. This is because the

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55 “…the overwhelming evidence, including Amgen’s own admissions, establishes that uEPO and rEPO
are the same product. The EPO gene used to produce rEPO is the same EPO gene as the human body
uses to produce uEPO. The amino acid sequences of human uEPO and rEPO are identical.” See Amgen,
Court).
process and the product are inextricably linked\textsuperscript{56} and it would render the prohibition implicit in s.101 US Act meaningless if a product that would otherwise be prohibited as an ‘invention’ is brought within the scope of patent protection merely because it is produced recombinantly.\textsuperscript{57} Moreover, the components or intermediate products are individually useless. They have no independent utility outside of the recombinant process. For example, an isolated DNA sequence that has been modified so as to be suitable for recombinant production has no utility outside of the process for which it has been designed to function. It is useless by itself. It merely holds biological information, which just so happens to be exactly the same as the protein coding region of the natural gene.

The fallacy of the biotechnology industry’s approach is due principally to the erroneous analogy to chemical patents, that is, that a patent that claims a newly synthesised chemical or the process for the production of a synthesised chemical as an ‘invention’ must not only protect the chemical in issue but the production of variants. The weakness with this analogy is that even though genes are chemicals, firstly that is not their only role and secondly, although related to the proteins that they code for, they are different to them. The gene and the protein are not the same thing.

Firstly, DNA sequences are equivalent to the information recorded on recordable medium, such as a DVD. The cell and the organism within which that cell exists is equivalent to the DVD player and a television. As the DVD is read by the DVD player, the information contained on the DVD is translated into a signal which is interpreted by the internal components of the DVD player and then expressed as sound and vision through a television. The expressed sound and vision can be measured and has its own formula which a television translates into a form that we can see and hear. This formula which the television translates is not, however the same as the information on the DVD; it is quite different, though related, through the medium of the DVD player. In much the same way, a substance, such as insulin, has a chemical formula (amino acid sequence). The chemical formula for insulin though related to the DNA sequence contained in the insulin gene, is different to it.\textsuperscript{58} The insulin gene stores information in a form that when incorporated into a cell


\textsuperscript{57} See also Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2004] All ER (D) 286 (House of Lords).

\textsuperscript{58} This difference has been acknowledged because of the degeneracy of the genetic code. Therefore, although there is a relationship between the nucleotide sequence contained in a gene and the amino acid sequence of the protein for which it codes, it is possible for amino acids to be substituted. See In re Bell (1993) 991 F.2d 781 (CAFC) where the Court rejected the argument that knowledge of the amino
Robert Blackburn, Chief Patent Counsel for Chiron,\(^6^0\) has acknowledged that there are significant differences between chemistry and biotechnology.\(^5^1\) He has explained that traditional chemistry “focus[es] on the basic structures of small chemical compounds that ha[s] pharmaceutical activity” and that the “chemist’s real expertise [i]s in making many derivatives … in the hope of finding one that w[ill] have sufficient activity, minimal side effects, and an economical method of manufacture.”\(^6^2\) Whereas, “the first-generation bio-technologist finds a disease or medical problem in which the cause or cure is a large, naturally occurring biochemical called a protein. Once that protein is isolated, the bio-technologist searches for the gene that encodes it. Then she uses the gene to manufacture large quantities of the protein by a process using recombinant DNA technology. This is what people classically think of as biotechnology--a natural protein, artificially-made, which has a pharmaceutical utility.”\(^6^3\) It is of note that he concedes that the end result of recombinant DNA technology is ‘a natural protein’.

Therefore a chemist is interested in the formula for a protein, not the information contained within the gene that codes for it.\(^6^4\) Whereas, for a molecular biologist, this work is unnecessary once the acid sequence of human insulin-like growth factor (hIGF) rendered the nucleotide sequence of the hIGF gene obvious i.e., lacking an inventive step within s. 103 US Act. The Court held, “It may be true that, knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene. However, because of the degeneracy of the genetic code, there are a vast number of nucleotide sequences that might code for a specific protein.”, 784. See also In re Deuel, (1995) 51 F.3d 1552 (CAFC) “A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein.”, 1558.

\(^5^9\) “Unlike the majority of chemical compounds … the main technological significance of DNA is wrapped up in its central role in mediating cell physiology. … [I]t is the mediation of cell physiology, through directed expression of proteins, which is currently the most commercially important function of DNA.” See A. Varma and D. Abraham, DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market, 9 Harv. J. Law & Tec 53.

\(^6^0\) Chiron Corporation is the owner of worldwide patents that claim the hepatitis C virus and the recombinant production of HCV proteins. Some of these patents will be discussed in Chapter 5.

\(^6^1\) “There is a significant difference between biotechnology and traditional pharmaceutical chemistry.” R. Blackburn, Evolving Patent Law in the New Age of Biomedical Science, 4 Tex. Rev. Law & Pol. 85 – 96, 87.

\(^6^2\) Ibid, 88.

\(^6^3\) Ibid. Also R. Blackburn provides examples of what he terms “first generation biotechnology products” including “factor VIII (the blood-clotting factor for hemophiliacs), interleukin-2 (a cancer drug with promise in treating AIDS), erythropoietin (a treatment for anemia in cancer and kidney dialysis patients), the Hepatitis-B vaccine (a vaccine that avoids infectious contamination of the original vaccine), insulin (human rather than the older porcine sequence), and growth hormone (a treatment for dwarfism),” 88. Interestingly, he failed to mention Hepatitis C virus proteins.

\(^6^4\) “Therefore, the relationship between the DNA and the protein(s) it codes for, rather than the actual DNA sequence, creates value. The biotechnologist patent applicant is usually not interested in the DNA
gene sequence has been elucidated, because by using this information an exact copy of the protein can be produced, rapidly and inexpensively using standard and routine recombinant technology. Biotechnology therefore uses the relational nexus between the gene and the protein to mass produce the protein, whereas traditional chemistry cannot.

Secondly, it is the protein encoded by the genetic sequence of a gene which is of commercial interest to the biotechnology industry but as Anita Varma and David Abraham explain, “[m]inor changes in the DNA sequence … may produce major changes in the function of DNA,” so that “[a] minor change in the DNA’s chemical structure (e.g. a pinpoint mutation) may completely eliminate the DNA’s ability to direct expression of a desired protein. The DNA sequence alone is thus subjectively useless.”

In terms of the mass production of a human protein by recombinant technology, the object is to produce a protein which has the identical in vivo biological properties of the natural protein. This relationship between the gene and the protein must be identical and even a minor variation in the DNA sequence can result in the expression of a protein that does not have the same biological properties as the natural protein. A protein’s efficacy is dependent on its shape. It is important to understand that the shape of a protein and the way it folds determines how the protein reacts inside the human body. This is very different to how a synthesised pharmaceutical works. The relevance of the three dimensional shape of a protein in terms of an antibody-antigen reaction was explained in the case of Murex Diagnostics Australia v Chiron Corporation.

as a product in its own right, as was the case in traditional chemistry and chemical patent law. Rather, the biotechnologist is interested in the DNA as an apparatus or tool to obtain the desired product: the coded for protein.” See A. Varma and D. Abraham, DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market, 9 Harv. J. Law & Tec 53.


66 Ibid.

67 “A polypeptide only becomes a protein once it is folded into the correct shape, often with cross linking between cysteine amino acids known as disulphide bridges. If a protein loses its correct shape, it ceases to be effective as a protein: it is denatured. A protein also has some internal sequences -known as active sites - which are more important for its biological functions than other such sequences.” (emphasis added) per Neuberger J [2001] All ER 150 appealed to the Court of Appeal and referred to with approval by that Court in Kirin Amgen Inc and others v Hoechst Marion Roussel Ltd and others (UK Court of Appeal) [2002] All ER 491 at para. 12.45. This appeal concerned the European patent equivalent of US 4,703,008.

68 Murex Diagnostics Australia Pty Ltd v Chiron Corporation NG 106 of 1994 [Federal Court of Australia, N.S.W. District Registry]. This case settled out of court on August 28, 1996 and accordingly there is no judgment. This evidence was given by by Dr. Peter Coleman who in 1995 was Chief of the CSIRO Division of Biomolecular Engineering and Director of the Biomolecular Research Institute. He was an independent expert in the field of protein crystallography and had used this technology to conduct research on many proteins. In 1995 his work was focused on the antigen-antibody interactions of human influenza viruses.

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The shape of the combining site of an antigen or an antibody is dictated by the underlying structures of the two proteins and the amino acids from which they are formed. When an antibody and an antigen combine, the shape and chemical character of one molecule must complement that found on the other molecule. Since protein structures are dynamic entities, the shape of each molecule is capable of partial change. If part of the antibody structure overlaps part of the antigen structure repulsive forces resist the molecules coming together. The relative strength of these forces when balanced against the attractive forces (namely, hydrogen bonds, electrostatic, Van der Waals and hydrophobic) play a vital role in determining the binding affinity and specificity of an antibody for an antigen. Thus the ability of an antibody to recognise an antigen epitope of slightly different shape will be dependent on the strengths and weaknesses of the attractive and repulsive forces that are involved in the interaction. If the attractive forces out weigh the repulsive forces then binding would take place. The specificity of that binding will however be dependent on the relative strengths of the intermolecular forces involved.  

It follows that a protein produced by recombinant methods and derived from a natural phenomenon such as a gene must be identical or substantially identical to that protein produced naturally, otherwise the recombinant protein will not react in the same way in the human body as will the naturally produced protein. There is a fundamental relationship between the genetic sequence and the three dimensional shape of the protein and it is the close adherence to this natural relationship that makes recombinantly produced proteins commercially valuable.

The point is that product-by-process claims simply do not work when it comes to recombinant processes for the production of products that are indistinguishable from natural products and this is especially so if the decision of Newman J in Scripps Clinic & Research Foundation v. Genentech, Inc (Scripps) remains the law. In Scripps the CAFC held “product-by-process claims ... are not limited to product prepared by the process set forth in the claims” meaning that the scope of the monopoly of such claims can extend to products that are not strictly produced by the defined process. Although Scripps was challenged by another CAFC decision in Atlantic Thermoplastics Co. v. Faytex Corp (Atlantic) in which Rader J held “process terms in product-by-process claims serve as limitations in determining infringement,” this apparent conflict has not been resolved. Recently, in Trustees of Columbia University v. Roche Diagnostics GmbH (Columbia), the

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69 Affidavit of Dr. Peter Colman filed in Murex v Chiron NG 106 of 1994 [Federal Court of Australia, N.S.W., District Registry], 1.18.
71 Ibid, 1583.
United States District Court for the District of Massachusetts followed *Scripps* in preference to *Atlantic* and although this decision is now on appeal to the CAFC, irrespective of which direction the appellate court resolves the issue, the fact remains that even if the narrower approach is preferred, a claim that captures a protein that is indistinguishable from a natural protein *ipso facto* captures the natural protein.

### The European Community and the United Kingdom

In a report to the European Parliament and the European Council entitled, *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering*, the European Commission explained,

> As set out in recital 21 [of the Directive], the reasoning is that, to qualify for patentability, an element from the human body, including a sequence or partial sequence of a gene, must, for instance, be the result of technical processes which have identified, purified, characterised and multiplied it outside of the human body. Such techniques cannot be found in nature. Taken out of their natural context, elements isolated from the human body cannot be exploited on an industrial basis. They would show only natural properties which man alone, through genetic engineering, is capable of exploiting and inserting into a technical process.

The difficulty with this rationale is this: even if such techniques cannot be found in nature, an element from the human body, including a sequence or partial sequence of a gene that is substantially identical to that element’s natural counterpart, remains what it is: the sequence of a human gene or a protein. A human gene that codes for a particular protein remains substantially the same, even if it is isolated using techniques that are not found in nature and even if the protein that it codes for is produced by such techniques.

The rationale presupposes that it is the method that is applied to the isolation of the human element, or the method used to produce the human element, which distinguishes the human element from its natural counterpart, and therefore makes the human element somehow artificial by which it becomes exploitable as a man-made technology. Despite conceding that “[t]aken out

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75 Ibid, 17, 4.

76 See for example Mustill LJ in *Genentech* “… there is no difference between recombinant t-PA and any other kind of t-PA” at [1989] RPC 147, 270 line 24 (Court of Appeal); Michel J in *Amgen Inc v Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc.*, “… the district court concluded that the patent failed to identify a single standard by which the ‘difference’ could be measured” between
of their natural context, elements isolated from the human body cannot be exploited on an industrial basis,” the European Commission justifies the Directive and the exploitation of human elements by focusing on the artificiality of the techniques used to separate those elements from the human body or to produce them outside of the human body. This is consistent with the approach taken by the ‘patent community’ in the United States. But the argument is specious because if the ‘invention’ is an ‘isolated’ human element, or the production of an ‘isolated’ human element, which is identical to the natural human element (using artificial methods or techniques) the artificiality of the ‘isolated’ human element is negated by its identity to the natural human element. The reason being that the ‘isolated’ human element, irrespective of its method of production, cannot be distinguished from its natural counterpart.  

It follows that if the ‘isolated’ human element is identical to its natural counterpart, then the grant of a patent right over the ‘isolated’ human element is tantamount to the grant of a patent right over the natural human element per se. This is the dilemma that confronts the biotechnology industry.

This dilemma was exposed in 1989 by Mustill LJ in Genentech where he explained that,

… It may be that the explosively new technology with which we are concerned has exposed some deep flaws even in the current regime; but if this is so, any necessary repairs must be effected by the legislation, not by the courts. I approach the present appeal on the footing that our task is to understand the Act, and apply it.  

His reference to the ‘deep flaws’ in the EPC and UK patent regimes is a reference to the tension between the desire of the patentee to gain a commercially useful statutory monopoly on the one hand, and the long standing prohibition on the patenting of products of nature on the other.

He recognised that the schemes of patentability provided by the EPC and the UK Act as they were in 1988 required legislative amendment if a solution to this dilemma was to be found, but in the absence of such an amendment, he was of the view that his duty was to enforce the law as it was then written, and this meant that the patent in Genentech was not the subject of an ‘invention’.


This problem has been well recognised by the biotechnology industry. Stephen Crespi argues, that “[t]o grant a patent only for a particular method of isolation of the gene ... would in practice often be of little commercial value. This has long been recognised in the field of natural products, where the original method used in the research laboratory rarely survives in the development stage and is superseded by methods more suitable for commercial scale operation.” See S. Crespi, Biotechnology Patenting: The Wicked Animal Must Defend Itself, (1995) 17(9) EIPR, 431-441, 433.

The Directive and the corresponding amendments to the EPC and the UK Act are perhaps the type of ‘repairs’ which Mustill LJ foreshadowed as necessary in order to give the biotechnology industry the type of patent protection that it demanded, but if this is so, this ‘repair’ has not been successfully effected because the Directive and its objective, as this Thesis asserts, is in violation of art. 27.1 TRIPS.

In this regard, an examination of the decision in Genentech is important because the language of art. 27.1 TRIPS is a derivative of art. 52(1) EPC as it was at the time. Accordingly, the judicial views expressed in Genentech by the Court of Appeal in 1988 provide support for the hypothesis of this Thesis, which is that, the word ‘invention’ in art. 27.1 TRIPS has a meaning that excludes Directive technologies as ‘inventions’.

**Genentech Inc’s Patent**

In Genentech the UK Court of Appeal decided two to one that an isolated form of the protein, human tissue plasminogen activator (t-PA), produced by recombinant technology was not an ‘invention’ within the meaning of the word in s.1(1) UK Act. This decision was not only relevant in the United Kingdom, but was also relevant to the EPC because s.130 UK Act provides that the UK Act be consistent with the EPC as “nearly as practicable” and the EPC equivalent of s.1(1) UK Act is art. 52(1) EPC.

The technical advance which was the subject of the patent was the mass production of t-PA, a protein produced and used by the human body in the process of dissolving blood clots. In large quantities, t-PA became available as a therapeutic agent and this was a useful development for human health. However, before t-PA could be produced by recombinant technology, it was first necessary to identify the human gene that coded for t-PA. It was generally known that all proteins consisted of amino acids, but the complete amino acid sequence of t-PA was not known. The patent disclosed the DNA sequence of the t-PA gene and the complete amino acid sequence of t-PA.

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79 See sections 76A and 125A UK Act which came into force on July 28, 2000.

80 Act revising the Convention on the grant of European patents (European Patent Convention) of 5 October 1973, last revised at 17 December 1991, JO EPO Special Edition 4/2001 as approved by the Administrative Council of 28 June 2001. “Article 52(1) EPC has been brought into line with Article 27.1, first sentence, of the TRIPs Agreement with a view to enshrining ‘technology’ in the basic provision of substantive European patent law, clearly defining the scope of the EPC, and making it plain that patent protection is available to technical inventions of all kinds.” As per the explanatory remarks in the Basic Proposal For The Revision of the European Patent Convention MR/2/00 prepared by the Administrative Council in Munich on 13 October 2000, 43.
Claim 1, the primary claim of the patent, defined the scope of the monopoly as recombinant human tissue plasminogen activator essentially free of other protein of human origin. Claim 3 defined the scope of the monopoly as human tissue plasminogen activator as produced by recombinant DNA technology. Both of these claims were product claims to an isolated form of t-PA, meaning that the product claims were not directed to the form in which t-PA was produced in the human body but to t-PA produced recombinantly.

Both at first instance and on appeal the patent was held to be invalid.

**Dillon LJ**

Contrary to Mustill and Purchas LJJ, Dillon LJ held that claims 1 and 3 were to ‘inventions’ within s.1(1) UK Act because they were not ‘discoveries’ within s.1(2)(a) UK Act. In his opinion, the products defined in the claims were “to the practical application of the discovery in the production of human t-PA (defined on page 9 of the specification as ‘corresponding to t-PA otherwise native to human tissue’) by recombinant DNA technology”.

In coming to this conclusion he referred to the decision of Falconer J in Merrill Lynch’s Application and disapproved of his reasoning. Although he noted that the technology in issue in Merrill Lynch was a ‘computer program’ within s.1(2)(c) UK Act and that he was concerned with ‘isolated’ t-PA within s.1(2)(a) UK Act, this distinction in technology did not appear to concern him.

In Merrill Lynch Falconer J held that “in so far as the invention resides in the computer program itself” it is not an ‘invention’. His reasoning was ultimately upheld by the Court of Appeal with the result the patent was declared invalid. However, at the time that the Court of Appeal heard the appeal in Genentech, the Court of Appeal in Merrill Lynch had not delivered its decision and so Dillon LJ was postulating on the possible consequences of Falconer J’s reasoning in terms of s.1(2) UK Act generally. He held,

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81 s.1(2) UK Act provides “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 …”.
83 Merrill Lynch’s Application [1988] RPC 1 (Patents Court).
84 s.1(2) UK Act provides “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 (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;”
85 Merrill Lynch’s Application [1988] RPC 1 (UK Patents Court).
Such a conclusion [i.e. Falconer J’s conclusion], when applied to a discovery, would seem to mean that the application of the discovery is only patentable if the application is itself novel and not obvious, altogether apart from the novelty of the discovery. That would have a very drastic effect on the patenting of new drugs and medicinal or microbiological processes.\(^87\)

However, the issue for Dillon LJ in *Genentech* was different to the issue for Falconer J and the Court of Appeal in *Merrill Lynch*. Dillon LJ had to decide whether the elucidation of something intrinsically natural and its mass production by some technical means was a ‘discovery’, whereas Falconer J and the Court of Appeal in *Merrill Lynch* had to decide how something intrinsically artificial and used in combination with a computer was a ‘computer program’. In *Merrill Lynch*, the ‘invention’ was a piece of computer code that formed part of a computer or machine that provided an “improved data processing apparatus for making an automated market for one or more securities.”\(^88\) There the issue was *the extent to which* the relevant code contributed to the ‘improved’ capabilities of a computer or machine as part of a business scheme.

In this regard, the relationship of the technology defined as the ‘invention’ to the end product, process or method is relevant. What the mass production of biological material by technical means achieves is a *replication* of the biological material, albeit in a purified form. This end result although artificially produced, and therefore itself artificial, is nonetheless identical to the very thing that is produced by the human body. There is absolutely no difference between the two.

This protein identity was irrelevant to Dillon LJ. As far as he was concerned the artificiality of the end result was all that mattered and the fact that t-PA was produced by means of a technical process was enough to distinguish it from a natural phenomenon.\(^89\)

However, despite his ruling that it was an ‘invention’ he held that it was not a ‘patentable invention’ because the methodology employed in arriving at the discovery was obvious to a person of ordinary skill and therefore the invention lacked an inventive step as required by s.1(1)(b) *UK Act*.\(^90\)

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88 Patent specification in *Merrill Lynch*.

89 This reasoning is consistent with present EPO practice but is absurd because if the recombinant protein is identical to the natural protein it is impossible for the process employed in the production of the recombinant protein to be the point of distinction. To produce one is to produce both.

Chapter 3: The Invention per se and Biotechnology

**Purchas LJ**

Purchas LJ held that the genetic sequence of t-PA in ‘figure 5’ of the patent was the ‘underlying discovery’ of Genentech’s alleged invention. However, from this ‘underlying discovery’ came two possible classes of products neither of which were available before this discovery. One class was genetic sequence probes, which no claim was made to by the patentee because they “would be of little or no commercial value now that the full molecular structures are known”. The other class was “expression vectors, including the DNA gene coding for t-PA”, that is, components or intermediate products used in the recombinant process.

In terms of the production of the latter class of products he held on the facts in *Genentech* that the “method embracing [the] discovery of the full molecular structure of DNA coding for t-PA and the full amino acid sequences of the latter” was a ‘discovery’ within s.1(2)(a) *UK Act*. In his opinion, the “plasmids or vectors described in the patent” and “the plasmids or vectors readily available within the state of the art or their immediate derivations or variations and incorporating genes resulting from minor adjustments to the molecular structure of the t-PA gene” were not ‘inventions’ because they were not “clearly identified and defined” in such a way so as to “exclude any speculative element.” He held that the plasmid and vector claims were claims “for protection of the discovery as such” and therefore were not ‘inventions’ within s.1(1) *UK Act* because such claims “protected against any use of this information, howsoever this may be achieved in the future”.

He also concluded that claims 1 to 6, the primary product claims to t-PA, a substance which was available prior to the discovery of the t-PA gene were also ‘discoveries’ within s.1(2)(a) *UK Act*

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91 Purchas LJ considered whether ‘the other claims can be brought under the umbrella of a claim to an invention which incorporates the figure 5 data as its underlying discovery, in contrast to a claim to the figure 5 data as such’. *Genentech Inc’s Patent* [1989] RPC147, 226 lines 47-48, 14.06.
92 Ibid, per Purchas LJ, 226 line 51 - 227 line 1, 14.06.
93 Ibid, per Purchas LJ, 226 lines 47-48, 14.06.
94 Ibid.
96 *Genentech Inc’s Patent* [1989] RPC147, per Purchas LJ, 228 lines 5-10, 14.10 (UK Court of Appeal).
97 Ibid, 228 lines 50-51, 14.13.
98 Ibid, 228 line 52, 14.13.
100 Ibid, 228 lines 14-15, 14.10.
because they were claims to t-PA per se, “in one form or another and prepared by one method or another”.

Purchas LJ accepted that s.1(1) UK Act contained a prerequisite that the patent disclose an ‘invention’. However, as to what constituted an ‘invention’ he deferred to s.1(2) UK Act. In his opinion, the list of prohibited subject matter was exhaustive in relation to the meaning of the word ‘invention’ in s.1(1) UK Act. Therefore, unless the subject matter of the claim was expressly prohibited it was an ‘invention’.

In this respect he was of the view that it was theoretically possible for components of recombinant production, such as plasmids or vectors that incorporated the ‘discovery’ of a DNA sequence, to be ‘inventions’. But despite the theory, he found in actuality that the components and process claims to the production of t-PA were also claims to the ‘discovery as such’. He held,

I have come to the conclusion, whilst recognising the near-esoteric distinctions involved, that claims 16 and 17, as presently drafted (even in their expanded form), cannot be said to be claims to be a method embracing a discovery rather than claims to the discovery as such. They cannot, by virtue of section 1(2), be claims to inventions for the purpose of the Act.

In explaining his conclusion he suggested that the lack of well defined components was relevant, but beyond this he did not illuminate.

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102 s.1(2) UK Act provides “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.

103 Ibid, 208, 12.09.
104 Claims: 16. A process which comprises expressing DNA encoding human tissue plasminogen activator in a recombinant host cell.; 17. A process for producing human t-PA, which process comprises: a. preparing a replicable expression vector capable of expressing the DNA sequence encoding human t-PA in a host cell; b. transforming a host cell culture to obtain a recombinant host cell; c. culturing said recombinant host cells under conditions permitting expression of said t-PA encoding DNA sequence to produce human t-PA; d. recovering said human t-PA; 18. A process according to claim 16 or claim 17 wherein the host cell is a mammalian cell line; 19. A process for producing human tissue plasminogen activator, substantially as described herein; 20. Human tissue plasminogen activator produced by a process according to any one of claims 16 to 19.

106 “Claim 17 fails to define the method in the sense that the nature of the vector is wholly at large.” Ibid, 234 lines 9-10, 14.17.
This aspect of his decision is difficult to fathom because assuming the component claims had specifically defined plasmids and vectors, how would a specific limitation to a specific plasmid or vector have made the process ‘clearly identified and defined’ so as to ‘exclude any speculative element’? More to the point however, is the fact that if the process claims had been narrowed to the use of specific plasmids or vectors, the value of the patent protection afforded to Genentech would have been virtually worthless because the use of different plasmids or vectors would have avoided infringing the patent. In such a situation anyone could have recombinantly produced t-PA.

Despite his comment that he “would have probably taken a different view if claims 16 and 17 had been more specifically drafted,” it is difficult to imagine a drafting scenario that would have satisfied his requirements and at the same time provided Genentech with what it perceived to be a fair monopoly, that is to t-PA howsoever produced. This is because if the primary product claims to t-PA were invalid, then the only way that Genentech believed it could achieve a monopoly over t-PA would be to capture any use of the DNA sequence as a component for use in a recombinant process.

It is arguable that what Purchas LJ meant is that while a process or method that incorporates an isolated DNA sequence can potentially be the subject of ‘invention’, whether it meets the threshold depends on the end result being distinguishable from a ‘product of nature’. The implication being, that if the end result is indistinguishable from a ‘product of nature,’ the claim to the process that captures the product cannot ipso facto be a ‘well defined method’ because the process claim “protects against any use of this information, howsoever this may be achieved in the future.”

This is so because irrespective of the vectors used as components in a process, fundamental to all recombinant protein production is the DNA sequence that codes for the desired protein. This is central to all recombinant production of proteins and explains why he was prepared, in theory, to extend patent protection to the components of recombinant production, individually or as part of a process, but not if the that process “protected against any use of this information, howsoever this may be achieved in the future”.

To have done otherwise would have been inconsistent because the product of a process is defined by the process of its manufacture. Therefore to uphold the process claims but strike down the product claims or visa versa in the context of the recombinant production of proteins that are identical to natural proteins is absurd.

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It seems plausible that what Purchas LJ was trying to avoid was a blanket policy that would effectively ban patent protection for the ‘practical’ application of a newly discovered technology in a general sense and it is for this reason that he was critical of Falconer J in Merrill Lynch. In his view it was theoretically possible for a ‘discovery’ to form the “substratum of invention” when “applied in a technique or process or incorporated in a product”. To this extent he concurred with the EPO in T208/84 Vicom/Computer Related Invention (Vicom), which he interpreted as being consistent with English patent law. However, in approving of the reasoning in Vicom, he did not mean to apply the ‘technical contribution’ test to a biological ‘discovery’, in the same way that it applied to a ‘computer program’ and this is evident both from his decision to invalidate the patent and the decision of Dillon LJ, who in applying the same test, came to the opposite conclusion.

On the reasoning of Dillon LJ in Genentech and the TBA in Vicom it was irrelevant that the end result be identical to a natural product and indeed that is how the Opposition Division of the EPO decided Howard Florey. The emphasis of their combined reasoning was on the process employed in producing the end result and this suggested that in their views an old product could be new (i.e., distinguishable from a natural product) if the process of its manufacture was also new. In this regard, the distinguishing element in the process (i.e., that distinguished it from existing and known process) was the isolated and purified sequence of the relevant gene used in the process and which was unknown at the date of the patent. By virtue of the use of the unknown sequence the process was rendered new. What followed from this was that the end result was also new.

In Genentech the primary claims defined a product. The product was recombinantly produced t-PA. It was artificial in that it was produced by means of the application of biological material, the discovery, in a technical process. Despite this and the reasoning of Dillon LJ in Genentech and the TBA in Vicom, Purchas LJ held the primary claims to be “for the protection of the discovery as

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110 Ibid, 207, 12.08-09.
111 Ibid, 209 lines 7-8, 12.09.
112 T208/84 Vicom/Computer Related Invention [1987] 2 EPOR 74.
115 “… if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. … The proprietor has developed a process for obtaining H2-relaxin and the DNA encoding it, has characterised these products by their chemical structure and has found a use for the protein. The products are therefore patentable under Article 52(2) EPC.” Ibid, para 5.1 and 5.2 (Emphasis added).
116 Ibid.
such” and invalid because the end result, the isolated and purified t-PA was identical to and indistinguishable from the ‘discovery’, natural t-PA. He held,

[A] claim in the form: ‘I claim this discovery harnessed to make useful artefacts’, in which case it amounts to a claim to the discovery ‘as such’ and, therefore, is not an ‘invention for the purposes of this Act’.\footnote{117}

The fact that t-PA was known to exist and that its properties were also known prior to the discovery of the amino acid sequence of t-PA (which was not known) was clearly relevant. But, it was not so much the availability of the natural protein before the priority date of the patent that was relevant, as much as the non availability of its genetic sequence. His reasoning made it clear that he understood the relevant scientific advance to be the elucidation of the t-PA amino acid sequence which was previously unknown. This was new information.

According to the Opposition Division’s reasoning in \emph{Howard Florey}, t-PA would have had “no previously recognised existence”\footnote{118} because until its amino acid sequence was known it was not possible for it to be “properly characterised by its structure”.\footnote{119} Therefore, for the Opposition Division, new information about a natural protein, if applied in a process, made the both the process and end product new. That is precisely what Dillon LJ decided. However, Purchas LJ disagreed and held that the use of that information in a process, did not transform recombinant t-PA into an ‘invention’ because it was indistinguishable from natural t-PA.

In \emph{Kirin-Amgen} the House of Lords held a patent for the recombinant production of erythropoietin invalid because the end result of the process was not ‘new’\footnote{120}. In other words, the isolated and purified erythropoietin was indistinguishable from its natural counterpart and so a claim to the process for its manufacture could not be valid.

In his speech Lord Hoffmann explained that under the 1949 \emph{UK Patents Act} a practice developed that permitted identical products to be distinguished by their processes of manufacture so that a new process for the manufacture of an existing product could be the subject of a valid patent (i.e., product-by-process claims). He found, however, the practice “not particularly logical because the history of how a product was made is not an attribute which it carries around and makes it something new. It was still the same product, even if made in a different way.”\footnote{121}

\footnotesize{\begin{itemize}
  \item 117 \emph{Genentech Inc’s Patent} [1989] RPC 147, per Purchas LJ, 14.02.
  \item 118 V 00008/1994 \emph{Howard Florey Institute of Experimental Physiology and Medicine v. Fraktion der Gronen im europCischen Parlament, Paul Lannoye – Relaxin}. (Opposition Division – EPO), para 5.1.
  \item 119 \emph{Ibid}.
  \item 120 \emph{Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others} [2004] All ER (D) 286 (House of Lords), per Lord Hoffmann, para 132.
  \item 121 \emph{Ibid}, per Lord Hoffman para 88.
\end{itemize}}
His Lordship then explained that s.60(1)(c) 1977 UK Patents Act (which incidentally was the law that applied in *Genentech*) “removes the practical argument for allowing product-by-process claims” 123 because it provides that a patented process brings the resulting product of that process within the scope of its monopoly. In his opinion, this means “that a new process is not enough to make the product new.” 124

It is arguable that Lord Hoffmann’s speech suggests that reasoning of Purchas LJ in *Genentech* is to be preferred to that of Dillon LJ and so even though the issue of invention was not strictly before the Appellate Committee, it would seem that an isolated or purified biological material that is identical to a natural biological material is not an ‘invention’ even if it is produced by technical means. His reasoning also suggests that the Opposition Division decision in *Howard Florey* is not reliable.

**Mustill LJ**

Mustill LJ held that patentability could not be decided by reference only to the three patentability conditions contained in s.1(1)(a)-(c) UK Act. In his opinion, such an argument tended “to mask a more fundamental requirement that must be satisfied before a patent can properly be granted, namely that the applicant has made an ‘invention’”. 125 He argued that this parameter was made clear by s.1(1) UK Act and “fortified” 126 by the Guidelines for Examination in the EPO which guided the interpretation of art. 52(1) EPC. According to Mustill LJ the four parameters of patentability are:

1. There must be an ‘invention’.
2. The invention must be ‘susceptible of industrial application’.
3. The invention must be ‘new’.
4. The invention must involve an ‘inventive step’. 127

In his opinion, it was possible for the subject matter of a patent not to be a ‘discovery’ within s.1(2)(a) UK Act and also not be an ‘invention’ within s.1(1) UK Act. His approach diverged in degree to that of Purchas LJ because he was not prepared to define ‘invention’ by reference only to

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122 “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.” Art. 64(2) EPC upon which s.60(1)(c) UK Act is derived.
123 *Ibid*, per Lord Hoffman para 90.
124 *Ibid*.
126 *Ibid*, 262 line 5.
the excluded subject matter in s.1(2) UK Act. In other words, Mustill LJ believed that the list of excluded subject matter was not exhaustive.\textsuperscript{128}

Furthermore, his consideration of the t-PA patent included an appreciation of the meaning of the word ‘recombinant’, which in his opinion, did not describe “the product itself, but its history.”\textsuperscript{129} He held that the use of this word ‘recombinant’ to describe t-PA produced by recombinant means was misleading because it suggested that the “protein molecules with the amino acid sequences shown in figure 5 and the functional characteristics set out in the specification” were new when in fact “[they] have existed since far into the distant past.”\textsuperscript{130} In his opinion the technical process used to mass produce t-PA, did not in the end, result in a product that was any different to the t-PA produced by the human body. He explained,

\begin{quote}
We are here concerned with a process for synthesising a substance identical to that which occurs in nature. The t-PA produced by the process is not ‘artificial’ t-PA or ‘synthetic’ t-PA, in the sense of artificial silk or synthetic rubber: ie in the sense of something which resembles the natural substance, or can perform a similar function, or act as a substitute. It is not ersatz. The t-PA which Genentech made is neither more nor less than t-PA\textsuperscript{131}
\end{quote}

He compared the product defined in the primary claim by reference to naturally produced t-PA. The fact that it was recombinantly produced did not alter his opinion that it was no different to its natural counterpart. Genentech’s ability to control the production of t-PA by recombinant technology suggested to him that it was of “more than academic interest”\textsuperscript{132} to understand precisely what the claimed invention was, as well as whether “the applicant has made an ‘invention’”\textsuperscript{133} because s. 1(1) UK Act contained, in his opinion, a “fundamental requirement”\textsuperscript{134} of ‘invention’ which must be satisfied prior to and independently of “the three conditions precedent to the grant of a patent set out in paragraphs (a) to (c) of section 1(1)”.\textsuperscript{135}

\begin{flushright}
\textsuperscript{128} \textit{Re Gale’s Application} [1990] RPC 305, per Nicholls LJ, 324, lines 27-31 where he agrees that s.1(2) UK Act does not contain an exhaustive list.
\textsuperscript{129} \textit{Genentech Inc’s Patent} [1989] RPC 147, per Mustill LJ, 262 line 10.
\textsuperscript{130} \textit{Ibid}, 262 lines 13-16.
\textsuperscript{131} \textit{Ibid}, 262 lines 1-6 (Emphasis added).
\textsuperscript{132} \textit{Ibid}, 262 line 21.
\textsuperscript{133} \textit{Ibid}, 262 line 36.
\textsuperscript{134} \textit{Ibid}, 262 line 35.
\textsuperscript{135} \textit{Ibid}, 262 lines 33-34. This interpretation is consistent with s.101 US Act (see P.G. Ducor, \textit{Patenting the Recombinant Products of Biotechnology and Other Molecules}, Kluwer Law International, 1998, confirms “[f]irst, the invention must constitute patentable subject matter, as defined by s.101 of the Patent Act. This requirement can be considered as a ‘precondition’ for patentability, anterior to any other legal evaluation.”; 6.) and s.18(1) AU Act (see High Court of Australia in \textit{Philips} as explained in Chapter 2).
\end{flushright}
He concluded that the products defined by claims 2136 and 4137 were not ‘inventions’ and “should fall at the very first hurdle”.138 Similarly, he concluded that the inventions defined in claims 1139 and 3140 were equally invalid because “there is no difference between recombinant t-PA and any other kind of t-PA. If so, claim 3 must, like claims 2 and 4, be unsound. Genentech did not invent t-PA. At most, they invented a new way of making it. The same objection is, in my view, fatal to claim 1.”141

The component and process claims were also unacceptable to Mustill LJ but not because they were incapable of being ‘inventions’. Like Purchas LJ, his reasoning permitted in theory at least, such claims to components or processes in the recombinant production of t-PA. However, with the exception of claims 9 and 19, he held them to be invalid because they were “so wide as to embrace products which Genentech have not invented, and which others may invent in the future”.142 Even so, despite distinguishing claims 9 and 19 because the former was to a specific plasmid and the latter to a process that could use that plasmid, he nevertheless held these to be invalid because they lacked an inventive step. In the end he concluded that “Genentech are not entitled to any reward through the medium of a patent monopoly.”143

Despite the distinction that he made between the product claims to t-PA, which he held not to be ‘inventions’ and the component and process claims to t-PA which he held to be ‘inventions’ but not patentable inventions, what is clear is that he was of the opinion that Genentech was not entitled to a patent monopoly over t-PA howsoever produced. Moreover, for Genentech to have narrowed the component and process claims so that they were valid would have meant reducing the scope of protection to the point of being practically worthless because it would have left the door open for others to produce t-PA recombinantly.

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136 Human tissue plasminogen activator unaccompanied by associated native glycosylation.
137 Biologically active human tissue plasminogen activator in essentially pure form, unaccompanied by protein with which it is ordinarily associated.
139 Recombinant human tissue plasminogen activator essentially free of other protein of human origin.
140 Human tissue plasminogen activator as produced by recombinant DNA technology.
143 Ibid, 287 lines 11-12.
Chapter 3: The Invention per se and Biotechnology

Mustill and Purchas LJJ

It is important to appreciate at this juncture that both Purchas and Mustill LJ came to the same conclusion about the ‘invention’ issue. They both held that there was no invention. Where they diverged is with respect to this question: Does s.1(1) UK Act required an examination of the word ‘invention’ separately to the excluded subject matter in s.1(2) UK Act? In this regard, Purchas LJ was of the view that the word ‘invention’ was inextricably linked to s.1(2) UK Act and therefore the categorisation of subject matter as an ‘invention’ in s.1(1) UK Act depended upon whether it was or was not included in the list of excluded subject matter contained in s.1(2) UK Act. This implied that the list was exhaustive. Whereas for Mustill LJ, although s.1(1) and s.1(2) UK Act were related, the word ‘invention’ in s.1(1) UK Act required an inquiry in an appropriate case, separate to s.1(2) UK Act. In his opinion, it was possible for something not to come within s.1(2) UK Act and also not be an ‘invention’ with s.1(1) UK Act. Therefore, the list of excluded subject matter was not exhaustive and it was possible for something not to be, for example, a ‘discovery’ within s.1(2)(a) UK Act and also not be an ‘invention’ within s.1(1) UK Act.

Despite the fact that Genentech was decided in 1989, this debate has not been resolved. However, there is some indication from the Court of Appeal that Mustill LJ is to be preferred on the issue. For example, Nicholls LJ in Gale held,

The language of section 1(2), and of the corresponding article, Article 52(2) and (3), of the European Patent Convention, is apt as an embodiment of this principle of United Kingdom patent law. Section 1(2) comprises a non-exhaustive catalogue of matters or things, starting with ‘a discovery’, which as such are declared not to be inventions.144

Moreover, in Biogen the House of Lords impliedly endorsed Mustill LJ’s approach, although with some caution. While not making any specific reference to s.1(2) UK Act, the House advised that it is possible for something not to be an ‘invention’ and yet satisfy the conditions of novelty, inventive step, industrial application and come within one of the excluded subject matter. Lord Hoffmann held that,

One can of course imagine cases in which the alleged subject-matter is so obviously not an invention that it is tempting to take an axe to the problem by dismissing the claim without inquiring too closely into which of the conditions has not been satisfied”[, for example,] “it

144 Re Gale’s Application [1991] RPC 305, per Nicholls LJ, 324, lines 27-31 (Emphasis added) (UK Court of Appeal)
may seem pedantic to say that water fails the condition in paragraph (a) of section 1(1) because it is not new.¹⁴⁵

Although he cautioned judges not to be tempted to decide the issue of ‘invention’ without first considering the conditions in s.1(1)(a)-(d) UK Act, clearly he did not rule out the possibility that even if some technology came within those conditions, it may still fail to be an ‘invention’. Furthermore, Mustill LJ, who gave the only other speech in Biogen held,

My reason for referring to [the debate about invention] is simply to make clear that in concurring with all your Lordships in the reasons for dismissing the appeal I should not be taken to accept, without full argument, that the need for an invention would always be academic, or that no such need is expressed by the words of section 1(1): nor indeed do I understand my noble and learned friend [Lord Hoffmann] as advancing any conclusion to that effect.¹⁴⁶

The flawed association of Dillon LJ to Purchas LJ

The headnote in Genentech reads:

(9) (per Purchas and Dillon LJJ: Mustill LJ dubitante) A patent which claimed the practical application of a discovery did not relate to the discovery as such and patentability was not excluded by section 1(2) even if the practical application might be obvious once the discovery had been made (pp 208, 239).

Unfortunately, for the reasons already explained, it is wrong.

However, this association first made by the author of the headnote was also made by Fox LJ in Merrill Lynch and by Nicholls LJ in Gale’s Application. Nicholls LJ, citing Merrill Lynch with approval held that

Thus a discovery as such is not patentable as an invention under the Act. But when applied to a product or process which, in the language of the 1977 Act, is capable of industrial application, the matter stands differently. This was so held in Genentech Inc’s Patent, [1989] RPC 147. There, this court by a majority decision held that section 1(2) did not depart from the established principle mentioned above.¹⁴⁷

¹⁴⁵ Biogen Inc v Meleva plc [1997] RPC 1, per Hoffmann LJ, 42 lines 16-26 (House of Lords).
¹⁴⁶ Ibid, per Mustill LJ, 31 lines 41-46.
¹⁴⁷ In Gale’s Application [1991] RPC 305, per Nicholls LJ, 324, lines 31-36 (Emphasis added) (UK Court of Appeal).
Even though it is literally correct that Purchas LJ held that a discovery “is capable of forming the substratum of invention so that if it is applied in a technique or process or incorporated in a product it is patentable,” this summary when cited out of context is misleading because he qualified this statement by explaining the conditions necessary to transform that ‘substratum of invention’ concerning biological materials from a ‘discovery’ to an ‘invention’. As explained earlier, he held that it was not enough that the substratum of invention be merely incorporated into a product. More was required. However, for Dillon LJ, nothing more was required.  

Summary

The association first made judicially by the UK Court of Appeal in Merrill Lynch is a watershed because it marks the infiltration of the Vicom ‘technical contribution’ test of ‘invention’ as understood by Dillon LJ into UK patent law jurisprudence. The first UK judicial decision which saw the application of this test in the context of biotechnology was Dillon LJ in Genentech, but he was in the minority on the issue. However, it was Aldous J. in Chiron Corporation v Murex Diagnostics Limited (No 3) and the Court of Appeal in Chiron Corporation v Murex Diagnostics Limited(No 12) that entrenched it in terms of biotechnology. Both of the Chiron decisions are the subject of Chapter 5 and so will not be considered here, but before leaving this discussion, it is necessary to have an understanding of Vicom.

Vicom – Technical Board of Appeal, EPO

Vicom was not about biotechnology. It was about the operation of a mathematical algorithm as an electrical signal and how the algorithm enhanced the performance of a computer’s processing speed. Accordingly, the technology was intrinsically artificial, as was the technology with which it related, namely a computer. Both of these technologies existed only because of human intervention.

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149 Genentech Inc’s Patent [1989] RPC 147, per Dillon LJ, 240 lines 21-31. “In so far as a patent does not, in my judgment, relate only to the discovery as such, even if the practical application may be obvious once the discovery has been made, even though unachievable in the absence of the discovery. When I look at the claims of the patent in the present case other than claims 2 and 4, they are not claims for the discovery of the sequences as such, but claims in relation to the practical application of the discovery in the production of human t-PA (defined on page 9 of the specification -- as "corresponding to t-PA otherwise native to human tissue") by recombinant DNA technology. In my judgment, therefore, this patent does not fall foul of subsection (2) of section 1 of the 1977 Act.”
151 Chiron Corporation and Others v Murex Diagnostics Ltd and Others (No 12) [1996] RPC 535 (UK Court of Appeal).
The Board decided on the facts of that case that the algorithm per se was not an ‘invention’ because an “algorithm being only an abstract concept describing how to operate on the numbers [there is] [n]o direct technical result … produced by the method as such”.\textsuperscript{152} So the issue was the extent to which an algorithm, something which is excluded from being an ‘invention’, can form part of a technology, such as a computer component, that is capable of being an invention and therefore become part of an ‘invention’.

Given the nature of the technology in \textit{Vicom} it was understandable that the Board would consider the issue in terms of the ‘technical contribution’ which the algorithm made to the overall performance of a computer. The Board held,

\begin{quote}
...if a mathematical method is used in a technical process, the process is carried out on a physical entity (which may be a material object but equally an image stored as an electric signal) by some technical means implementing the method and provides as its result \textit{a certain change} in that entity.\textsuperscript{153}
\end{quote}

It concluded that,

\begin{quote}
The Board is of the opinion that a claim directed to a technical process which process is carried out under the control of program (be this implemented in hardware or in software) cannot be regarded as relating to a computer program as such within the meaning of Article 52(3) EPC, as it is \textit{the application of the program for determining the sequence of steps in the process for which in effect protection is sought}. Consequently, such a claim is allowable under Article 52(2)(c) and (3) EPC.\textsuperscript{154}
\end{quote}

So, because the patent claim concerned \textit{the application} of something excluded per se in something not excluded, the technology that was the subject of the claim (that is, the application) was not excluded by art. 52(2)(c) EPC. This reasoning means, that the \textit{mere} application of the algorithm in a computer was enough to side step the prohibition.

Dillon LJ applied the reasoning in \textit{Vicom} literally and without amendment to the technology in \textit{Genentech}, whereas Purchas LJ did not. Purchas LJ understood that the technology in issue was a human protein not an algorithm. He also understood that the nature of the prohibition was a ‘discovery’ not a ‘computer program’. Accordingly, Purchas LJ understood that the literal application of \textit{Vicom} to the facts of \textit{Genentech} was not satisfactory because it would have enabled

\textsuperscript{152} \textit{T208/84 Vicom/Computer Related Invention} [1987] 2 EPOR 74, para 5.

\textsuperscript{153} \textit{Ibid}. (Emphasis added)

\textsuperscript{154} \textit{Ibid}, para 12.
Genentech to “be protected against any use of this [genetic sequence] information, howsoever this may be achieved in the future”\(^{155}\) and this was not consistent with his understanding of patent law.

Mustill LJ in \textit{Genentech} also referred to \textit{Vicom}, but with scepticism. Firstly, he found the decision “so compressed” as to be “almost incomprehensible”.\(^{156}\) Secondly, he found that the “controversy raise[d] a puzzling question” in the respect of the contention that the discovery of the genetic sequence of t-PA was a “step towards or even preceded by the creation of the expression vectors” which, in his opinion, was not unequivocally supported by the evidence. This raised the possibility that “the factual assumptions of the argument on section 1(2)(a) …[and] the close attention focussed on the discovery may have been misplaced.”\(^{157}\) Although, in the end nothing turned on the latter point, it was clearly germane because so much of the \textit{Vicom} decision assumed a direct causal connection between the technical contribution and the enhanced performance of the computer and if this causal connection was lacking on the facts in \textit{Genentech}, then \textit{Vicom} was strictly irrelevant.

Interestingly, the Board explained that the ‘technical process’ had to produce a ‘certain change’ in the entity within which it was applied. The physical entity being a computer, the technical process in this case produced a change in the form of a faster processing speed. Therefore, the change which the Board referred to, manifested itself as an enhancement to the physical entity. This suggests that for something to be a ‘technical contribution’ not only must it be of a technical nature but also it must produce a noticeable change.

In the case of a DNA sequence made suitable for recombinant production, not only is the DNA sequence identical to the natural source and arguably is not ‘technical,’ but importantly it does not result in any change in the protein (the physical entity) because the DNA sequence codes for a protein and it is the very same protein that is produced by the process in which it is applied. The point is that if the modified DNA sequence were to code for an enhanced protein and one distinguishable to the natural produced then perhaps it would be a relevant ‘technical’ contribution because firstly the DNA sequence would be significantly different to the natural protein coding region of the human gene, but importantly the resulting protein would be distinguishable to the natural protein.


\(^{156}\) \textit{Ibid}, per Mustill LJ, 269 line 31.

\(^{157}\) \textit{Ibid}, 269 lines 33-42.
The High Court of Australia’s decision in *NRDC* was not about biotechnology. The subject matter of the patent in *NRDC* concerned chemicals that existed and which were known to exist at the priority date of the patent. The chemicals (O-(2:4-dichlorophenoxy) -butyric and -caproic acids, their salts, esters, nitriles and amides) were essential to the ‘invention’ but were not new. However, the use of these chemicals in a herbicide was new. The three patent claims in issue were directed to a method to eradicate or control weeds in leguminous fodder crops of the genera *Trifolium* and *Medicago*, celery and parsnip, lucerne (alfalfa) and clover. The use of a herbicide containing these chemicals resulted in the eradication or control of weeds without effecting the specified crops. The advantage of this herbicide to farmers was that they could apply the herbicide to crop paddocks generally with a significant reduction in cost.

The invention was not the chemicals that were used in the herbicide, nor was it the herbicide that contained these chemicals. Rather, the invention was the method of using the herbicide containing these chemicals to achieve a specific result, namely, *to eradicate or control weeds in leguminous fodder crops of the genera* *Trifolium* and *Medicago*, celery and parsnip, lucerne (alfalfa) and clover. So the scope of the monopoly of the subject patent did not extend to either the chemicals or the herbicide. Anyone was able to make either of these products without infringing the patent.

Central to the ‘invention’ was the discovery that these chemicals (when contained in a herbicide and sprayed in paddocks which were growing certain crops) would eradicate certain types of weeds without harming the crops. The issue was whether this ‘discovery’ could also be the subject of an ‘invention’?

Although decided in 1959, the High Court of Australia was aware of the consequences that a narrow decision could have had on the scope of patentable subject matter generally. Specifically though, it was concerned to address the argument that was raised by the Commissioner of Patents that “agricultural or horticultural processes are, by reason of their nature, outside the limits of patentable inventions.”\(^{158}\) It is because of this aspect of the case that *NRDC* is considered relevant to biotechnology in Australia because the Commissioner’s objection implied that there were other technologies that were also “outside the limits of patentable inventions”.

\(^{158}\) *National Research Development Corporation v. Commissioner of Patents* (1959) 102 CLR 252, 279 (High Court of Australia).
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The Court answered that although not all agricultural or horticultural processes were suitable subject matter for a patent because “if there were nothing that could properly be called a ‘product’ of the process, even an ingenious new departure would be outside the limits of patentability,”\textsuperscript{159} it found that there was a ‘product’ in the form of the effect achieved by the herbicide.\textsuperscript{160} It was this effect which it held was a new and vendible and useful\textsuperscript{161} product. According to the Court a process was a patentable invention, even if it was agricultural or horticultural in nature, because the end result of the process was the achievement of an effect on the production of crops that was unprecedented.

The Court, as did Dillon LJ in Genentech, focused on the end result - the ‘product,’ to decide the issue of ‘invention’. The ‘product’ was the nexus between the ‘discovery’ of the new use of the known chemicals and the ‘invention’,\textsuperscript{162} the process. The fact that in issue were not product claims but were process claims was irrelevant because the end result of the process was ‘a product’ the form of a new, vendible and useful effect on crop production.\textsuperscript{163} Using this rationale, it was irrelevant that the claims did not claim a ‘product’ because a claim to the ‘process’ by definition captured the resulting ‘product’ of that process.

It is important to appreciate this distinction because, as will be seen in postscript to Chapter 4, it was the nexus between the process and the product in Kirin-Amgen which would have resulted in the revocation of the Amgen erythropoietin patent had the process claim been challenged. Unfortunately it was not, but there the House of Lords accepted “the logical argument that a new

\textsuperscript{159} Ibid.

\textsuperscript{160} “We are here concerned with a process producing its effect by means of a chemical reaction, and the ultimate weed-free, or comparatively weed-free condition of the crop-bearing land is properly described as produced by the process.” \textit{Ibid}, 277.

\textsuperscript{161} “The effect produced by the appellant’s method exhibits the two essential qualities upon which ‘product’ and ‘vendible’ seem designed to insist. … It achieves a separate result, and the result possesses its own economic utility consisting in an important improvement in the conditions in which the crop is to grow, whereby it is afforded a better opportunity to flourish and yield a good harvest.” \textit{Ibid}, 277.

\textsuperscript{162} “… the view which we think is correct in the present case is that the method the subject of the relevant claims has as its end result an artificial effect falling squarely within the true concept of what must be produced by a process if it is to be held patentable.” \textit{Ibid}, 278.

\textsuperscript{163} “The effect produced by the appellant’s method exhibits the two essential qualities upon which ‘product’ and ‘vendible’ seem designed to insist. It is a ‘product’ because it consists in an artificially created state of affairs, discernible by observing over a period the growth of weeds and crops respectively on sown land on which the method has been put into practice. And the significance of the product is economic; for it provides a remarkable advantage, indeed to the lay mind a sensational advantage, for one of the most elemental activities by which man has served his material needs, the cultivation of the soil for the production of its fruits.” \textit{Ibid}, 277.
process is not enough to make the product new”\textsuperscript{164} and accordingly if the product of the process was not “new”\textsuperscript{165} then the process is of questionable validity.

If that was the end of the matter, then it might be argued that the decision in \textit{NRDC} supported the approach of Dillon LJ in \textit{Genentech}. However, relevant to Dillon LJ’s approach was an important distinction which he failed to make, but one which Purchas and Mustill LJ in \textit{Genentech} and the High Court of Australia in \textit{NRDC} made.

In \textit{NRDC} the end result or ‘product’ produced by the process was completely man-made with no natural counterpart. Whereas, in \textit{Genentech} while the isolated t-PA produced by recombinant technology was artificial, neither the human t-PA gene nor human produced t-PA were. They were both natural. What was artificial about isolated t-PA was its purity, but this merely reflected that isolated t-PA was “essentially free of other protein of human origin,”\textsuperscript{166} which made absolutely no difference to its \textit{in vivo} biological performance within a human body.

This distinction is significant because it goes to the heart of problem facing patents that claim isolated biological materials that are indistinguishable to their natural counterparts.\textsuperscript{167} The artificiality of the end result is neutralised by its close identity to the natural phenomenon. Clearly, to describe these ‘products’ as artificial, while literally true, is nothing more than semantics.\textsuperscript{168}

While in \textit{NRDC} the High Court of Australia was concerned to ensure that the scope of patentable subject matter was not restricted by “the new use of an old substance” in terms of its application to horticultural processes, its comments about the need for flexibility in respect to patentable technology\textsuperscript{169} were directed to ‘products of man’, not ‘products of nature’. The Court’s rationale

\begin{footnotes}
\item[164] “The first requirement is that the product must be new and that a difference in the method of manufacturing an identical product does not make it new.” On the facts in the case the trial judge had held that there was no difference between natural erythropoietin and recombinantly produced erythropoietin. \textit{Ibid}, per Lord Hoffmann, para 98. See also para 90.
\item[165] \textit{Ibid}, per Lord Hoffmann, para 132.
\item[166] Claim 1 of the Genentech patent.
\item[168] “It is true that the word ‘recombinant tissue plasminogen activator’ may be a useful turn of phrase, but this should not be allowed to disguise the fact that ‘recombinant’ describes, not the product itself, but its history.” Per Mustill LJ, 262 lines 8-10 in \textit{Genentech Inc’s Patent} [1989] RPC 147 (UK Court of Appeal).
\item[169] “The purpose of s. 6, it must be remembered, was to allow the use of the prerogative to encourage national development in a field which already, in 1623, was seen to be excitingly unpredictable. To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the
\end{footnotes}
was that the scope of patentable subject matter within the meaning of s. 6 of the Statute of Monopolies of 1623 should not be constrained so as to exclude a new and useful application of something intrinsically artificial even if it did involve agricultural or horticultural processes. Furthermore, the Court’s examination and explanation of old English authorities concerning the distinction between an ‘invention’ and a ‘discovery’ was predicated on this basis. It did not consider the possibility of patenting a genetically modified ‘life’ form as did the US Supreme Court in Chakrabarty nor did it consider the possibility of patenting an isolated protein of human origin produced by recombinant technology as the UK Court of Appeal did in Genentech. Rather it focused its attention on resolving the controversy about whether the ‘discovery’ of a new and useful application of known chemicals could be part of an ‘invention’ which manifested an effect that eradicated weeds. The Court used the 1892 decision of Lindley LJ in Lane Fox v. Kensington and Knightsbridge Electric Lighting Co as a starting point, but was not content to stop there. The Court explained that,

… a man who discovers that a known machine (his Lordship might equally have said a known substance) can produce effects which no one before him knew could be produced by it has made a discovery, but has not made a patentable invention unless he so uses his knowledge and ingenuity as to produce either a new and useful thing or result, or a new and useful method of producing an old thing or result.

At the time when NRDC was decided, the production of genetically modified ‘life’ forms or the recombinant production of human proteins were not contemplated outside of the realm of science fiction. Consequently, it maybe argued that in describing any attempt to precisely define the word ‘manufacture’ as “folly” because “science has made such advances that the concrete applications more obvious, not to say the more primitive, illustrations of the broad sweep of the concept.” National Research Development Corporation v. Commissioner of Patents (1959) 102 CLR 252, 271 (High Court of Australia). This statement must, however be understood in the context of the issue before the High Court and that was whether “agricultural or horticultural processes are, by reason of their nature, outside the limits of patentable inventions”. The Court held that “agricultural or horticultural processes” could be if the end result of those processes was a ‘product’ that was vendible and useful. But by ‘useful’ it meant firstly, that the ‘product’ had to display a ‘remarkable advantage’ over the existing technology and secondly, that it did not extend to the ‘fruit’ of the crop. The Court held that, “[h]owever advantageously man may alter the conditions of growth, the fruit is still not produced by his action.” This statement, by analogy, applies to the production of ‘proteins’ by recombinant processes because the ‘protein’ is the fruit of the gene or genome from which it is inextricably linked.

170 “We are here concerned with a process producing its effect by means of a chemical reaction, and the ultimate weed-free, or comparatively weed-free condition of the crop-bearing land is properly described as produced by the process. The fact that the relevance of the process is to agricultural or horticultural enterprises does not in itself supply or suggest any consideration not already covered which should weigh against the conclusion that the process is a patentable invention.” Ibid, 279

171 Lane Fox v. Kensington and Knightsbridge Electric Lighting Co (1892) 3 Ch 424, 428 - 429; (1892) 9 RPC 413, 416 (Emphasis added) (UK Court of Appeal).

172 National Research Development Corporation v. Commissioner of Patents (1959) 102 CLR 252, 264 (High Court of Australia).

173 Ibid.
of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say
the more primitive, illustrations of the broad sweep of the concept,"174 the Court was reaching out
into the future and beyond the facts of the case. In this sense, the Court extended the concept of a
‘product’ to include an *end result* that produced *an effect*, which on the facts of the case, it found
to provide a “remarkable advantage”175 and one that achieved “a separate result … possess[ing] its
own economic utility consisting in an important improvement in the conditions in which the crop
is to grow, whereby it is afforded a better opportunity to flourish and yield a good harvest.”176

Certainly, the Australian Patent Office (APO) has interpreted *NRDC* as authority supporting the
patenting of ‘life’ forms.177 However, this interpretation by the APO has yet to be the subject of a
decision of the Australian courts178 and the Court’s own objection in *NRDC* to the patenting of
fruits and vegetables because “however advantageously man may alter the conditions of growth,
the fruit is still not produced by his action”179 suggests that the Court did not mean to extend the
boundary of patentable subject matter to include ‘isolated’, ‘purified’ biological materials or those
produced by technical processes that are identical or practically identical to their natural
counterparts. This is because this statement, by analogy, applies to the production of ‘proteins’ by
recombinant processes for the ‘protein’ is the *fruit* of the gene or genome from which it is
inextricably linked.

Nevertheless, the APO has ignored this limitation and continues to grant patents in Australia on all
manner of isolated materials adopting a philosophy akin to that adopted by the EPO, the USPTO
and the JPO in 1988.

Support for the APO view, however, has recently come from the *Australia Law Reform
Commission* (ALRC) which released its Final Report entitled *Gene Patents and Human Health*
in August 2004. In its *Report* the ALRC noted that some commentators including,

178 There has been only one case before an Australian court which challenged the validity of a patent that
claimed a genetic sequence and proteins as patentable subject matter - *Murex Diagnostics Australia Pty
Ltd v Chiron Corporation* NG 106 of 1994 Federal Court of Australia. The trial commenced in June
1996 and ended after a ten week hearing. There was no judgement handed down as the case settled
prior to the completion of the trial. The patent in issue was AU 624,105 entitled “Non-A Non-B
Hepatitis Virus Diagnostics and Vaccines”.
179 *National Research Development Corporation v. Commissioner of Patents* (1959) 102 CLR 252, 279
(High Court of Australia).
Dr Dianne Nicol has suggested that inventions involving genetic materials and technologies appear to satisfy the NRDC requirements because genetic research and treatments are commercial in nature and have value in an economic sense, both directly through the activities of the Australian biotechnology industry and indirectly through the ability of such technology to alleviate disease.\(^{180}\)

But this interpretation of NRDC ignores the fact that nowhere did the High Court suggest that ‘the commercial nature’ of such technology alone made it patentable subject matter. There was much more to it than that. Furthermore, the argument that “the isolation of naturally occurring materials” makes them ‘inventions’ because of the “skill and labour [involved] in their isolation”\(^{181}\) ignores the fact that the threshold of ‘invention’ is not decided by this criterion. If this were true, then just about anything involving human intervention would be an ‘invention’.

Dianne Nicol has argued that “generally process patents will more readily satisfy the requirement of s.18(1)(a) than product patents”\(^{182}\) because “[p]roduct patents … give stronger form of protection [as] they protect the product itself irrespective of its method of manufacture”\(^{183}\) concluding that “… although the identification of a naturally occurring gene may be a discovery, the isolation and characterisation of the gene and gene products will be patentable inventions.”\(^{184}\)

In support the Australian Patent Office Examiners Manual was cited. Further support was derived from the US Supreme Court decision in *Chakrabarty* that Dianne Nicol interpreted as follows:

> The *only* requirement to bring material that has been isolated and purified under the umbrella of patentable subject matter would seem to be that it offers *some material advantage* in utility over the naturally occurring material.\(^{185}\)

Unfortunately, Dianne Nicol and thus the ALRC have misunderstood NRDC and *Chakrabarty*.

Firstly, the distinction between a ‘discovery’ and “the isolation of naturally occurring materials that have involved skill and labour in their isolation” fails to take into account that the human intervention involved in the isolation isolation and characterisation of the gene and gene products

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\(^{182}\) Ibid, 238, footnote 52.

\(^{183}\) Ibid.

\(^{184}\) Ibid (Emphasis added).

\(^{185}\) Ibid.
per se does not materially alter the end result. The isolation of a natural biological material means no more than removing the biological material from its natural environment. The material maybe ‘purified’ but even so it remains what it is and retains the same properties. This situation is in complete contrast to the facts in Chakrabarty where the artificial bacterium was so significantly modified that it degraded crude oil, something that it could never have done naturally and which had no natural precedence. What was relevant was the significant change to the function of the natural bacterium produced by that modification. The relevant skill and labour was not in its isolation, but in the end result: the degradation of crude oil.

Secondly, the suggestion that ‘product’ claims provide stronger protection because such claims “protect the product itself irrespective of its method of manufacture” is the very complaint which both Mustill and Purchas LJJ in Genentech raised against the primary claims to t-PA. As Purchas LJJ explained, once the patent owner claimed a human gene as a ‘product’, the particular method of production of that product has to be “clearly identified and defined”\(^\text{186}\) so as to “exclude any speculative element”\(^\text{187}\) for otherwise the process claim is no more than “a claim for protection of the discovery as such.”\(^\text{188}\) In other words, a process claim to a mass produced biological material that is identical to the corresponding natural biological material is no more than a claim to a ‘mere discovery’. More to the point, so must be the components used in that process.

Furthermore, although the proposition that “generally process patents will more readily satisfy the requirement of s.18(1)(a) than product patents”\(^\text{189}\) is supported by the Australian Patent Office practice of permitting ‘product-by-process’ claims\(^\text{190}\), it is not certain that that practice is correct in law. The House of Lords in Kirin-Amgen had cause to refer to product-by-process claims. In his speech Lord Hoffmann explained that the practice under the 1949 UK Patents Act (which modern Australian patent law is related to) was “not particularly logical because the history of how a product was made is not an attribute which it carries around and makes it something new. It was still the same product, even if made in a different way.”\(^\text{191}\) Moreover, his Lordship was of the opinion that a process to the manufacture of a product that was not new could not be valid. His conclusion therefore tends to contradict Dianne Nicol because he suggests that an existing product (such as a natural protein) that is produced by a new process cannot be distinguished by that

\(^{186}\) Genentech Inc’s Patent [1989] RPC 147, per Purchas LJ, 228 lines 50-51, 14.13 (UK Court of Appeal).

\(^{187}\) Ibid, per Purchas LJ, 228 line 52, 14.13.

\(^{188}\) Ibid, per Purchas LJ, 228 lines 15-16, 14.10.


\(^{190}\) Product-by-process claims permit the distinction of an identical product on the basis of the process by which it is made.

\(^{191}\) Ibid, per Lord Hoffman, para 88.
process and therefore cannot be the subject of patent protection. His Lordship suggested that the claim for the recombinant production of isolated and purified erythropoietin was of questionable validity because the claim to the product of that process was identical to natural erythropoietin and therefore invalid on that basis.\(^{192}\)

Finally, in *Chakrabarty* the artificial bacterium displayed *markedly different characteristics from any found in nature*. This is vastly different to offering “some material advantage in utility over the naturally occurring material”. The threshold was not *some*, but *substantial*. Even so, this was not the ‘only requirement’, but one of three necessary to bring an artificial biological material within s.101 *US Act*.

**The European Patent Office**

At this point it is necessary to look to the decisions of the EPO which have considered art. 52(2)(a) *EPC* in the context of proteins in order to better appreciate the EPO’s position on the patentability of this type of subject matter. In this regard, it must be noted that the decisions of the EPO are strictly the decisions of a patent office and are not judicial decisions. Therefore they are not truly independent decisions, but are decisions of review within the EPO itself.

Even so, the House of Lords made it clear in *Biogen* that “[d]ecisions of the EPO on questions of law are … of considerable persuasive authority”\(^{193}\) and therefore are relevant to the discussion in this Chapter. Moreover, s. 91(1)(c) *UK Act* requires that UK courts take “judicial notice” of “any decisions, or expression of opinion by” the EPO\(^{194}\) “on any question” concerning the *EPC*. No doubt the reason for this policy is based on the need for the harmonisation of patent law between the EPO and EC national courts.

Nevertheless, the *EPC* and the *UK Act* do not give EPO decisions any binding authority over the courts and the words “judicial notice” in s. 91(1)(c) *UK Act* do not mandate the UK courts to follow EPO decisions, let alone do as the House of Lords suggests in *Biogen*.\(^{195}\) To give the decisions of the EPO the status of “considerable persuasive authority” elevates the meaning of the words “judicial notice” to a much higher level than intended and one, which arguably, is not justifiable as a general rule. Clearly, the law requires that EPO decisions be taken into account, but in this regard it must also be noted that the EPO appellate process is not independent of the

\(^{192}\) *Ibid*, per Lord Hoffman, para 132.

\(^{193}\) *Biogen Inc v Medeva plc* [1997] RPC 1.

\(^{194}\) The EPO is designated by s.130(1) *UK Act*.

\(^{195}\) For example Mustill LJ in *Genentech* thought the TBA decision in *Vicom* was “so compressed” as to be “almost incomprehensible”.

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organisation that is charged with the specific task of ‘granting’ patents under the EPC and therefore, a degree of scepticism by EC national courts would not be altogether unwarranted. In this way, at least, there maybe some semblance of a ‘check and balance’ in the development of EC patent law, but without it, the EPO has practically a free hand in persuading national courts to adopt its internal policies with respect to the EPC. This scenario is in complete contrast to the position that existed in the UK prior to the UK Act and to the current situation in the United States and Australia where the courts have a specific role of reviewing the decisions made by the USPTO and the APO both prior to and after the grant of a patent.

This Thesis argues that the lack of a proper ‘check and balance’ on the EPO has facilitated the implementation of EPO policy, under the guise of ‘harmonisation.’ This has enabled the EPO, as Peter Drahos argues, in being “singularly successful in giving a narrow reading to the limits on invention and patentability contained in Articles 52 and 53 EPC” based upon a “foundational interpretive assumption for European patent law…[t]he effect of [which] is to make the restrictions on patentability function weakly, if at all.”

The impact of the EPO’s muscle is exemplified in the July 2002 Report prepared by the Nuffield Council on Bioethics entitled, The Ethics of Patenting DNA: A Discussion Paper. There the Council noted:

... the important point is that patent offices maintain that the DNA sequences claimed in patents are not natural phenomena. Instead, they ... take the view that extracting the genetic information encoded by a DNA sequence is not just a matter of gaining scientific knowledge about a natural phenomenon: it involves the use of cloning techniques to create an artificial molecule in such a way that it includes much the same genetic information as is to be found in the natural phenomenon. And what is held to be important here is that the scientific knowledge concerning the genetic information has been discovered through the creation of the artificial molecule. That is to say, without isolating and cloning a gene, it is not possible to identify the sequence of bases of which it is comprised. Hence, patent offices have concluded, the genetic information is essentially part of an ‘invention’, a molecule which is human handiwork, and can be patented as such.

The Council confirmed that in 1988 the EPO, the USPTO and the Japanese Patent Office (JPO) issued a joint communiqué that:

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Purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds.  

Despite the fact that the Council suggested that “[t]he assumption … that the isolation and cloning involved does produce genuinely new molecules of a kind which do not occur naturally, can be questioned” it was not prepared to review the “patents awarded in th[e] early days” because “the procedures involved in the early days of cloning genes were certainly inventive and arduous.” The Council saw the problem as one of ‘stringency’ in the application of existing patent law. This it argued, however, was a consequence of the administration of patent law in Europe, rather than as a deficiency in existing patent law itself. In its opinion, if the ‘patent community’ would only properly apply the existing patent law, the “number of patents that assert rights over DNA sequences would be … reduce[d] substantially.”

Of course, the ‘patent community’ in Europe argues that it does ‘stringently’ apply existing patent law and commentators such as Stephen Crespi and Melanie Howlett and Andrew Christie support their argument. Unfortunately, the solution to the problem that was the subject of the Council’s Report cannot be solved so simply, especially in light of the Directive.

In the following analysis of the only biotechnology decision of the EPO concerning art. 52(2)(a) EPC directly, the ‘analytically weak’ argument, as Peter Drahos describes it, is examined.

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199 Ibid, 3.22.
200 Ibid.
201 Ibid.
203 M.J. Howlett and A.F. Christie, An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequence (ESTS), International Review of Industrial Property and Copyright, Vol. 34, pp. 581-602, 2003. The authors argue that their research demonstrates that the parameters of novelty, inventive step and utility are sufficiently stringent. They conclude that “Given the few hypothetical claims found valid in the comparative study, it seems that the practice of the patent offices is such that not many ESTs will pass the stringent requirements for patentability. Accordingly, it seems that the fear of numerous EST patents inhibiting later research is also unfounded.”
204 Cf: See the Danish Council of Ethics Report, Patenting Human Genes and Stem Cells, 2004 where it described the language of the Directive as being “a creatively worded ploy to avoid the criticism leveled at patents on human material”; 13.
In this Opposition, art. 52(2)(a) EPC was considered in the context of a patent that claimed “[a] DNA fragment encoding human H2-preprorelaxin, said H2-preprorelaxin having the amino acid sequence set out in Figure 2” as the ‘invention’. The patent had its genesis in Australian patent application AU 7247/82 filed with the Australian Patent Office on December 13, 1982 and was based upon a European patent application filed on December 12, 1983.

The Opponents alleged that the patent should have been refused on the ground that Relaxin, as defined by claim 1, was a ‘discovery’ and therefore not an ‘invention’ within art. 52(1) EPC. The Examining and Opposition Division of the EPO rejected this argument for the following reasons.

Firstly, the ‘long standing’ practice of the EPO was to allow such claims. The EPO examiners guidelines ‘C-IV, 2.3’, stated:

A substance freely occurring in nature is mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if this substance can be properly characterised by its structure and it is new in the absolute sense of having no previously recognised existence, then the substance per se may be patentable.

Secondly, human Relaxin had no previously recognised existence. The inventors had “developed a process for obtaining Relaxin and the DNA encoding it”, that is, had “characterised [Relaxin by its] chemical structure and … found a use for [it].”

Thirdly, the breadth of the scope of the monopoly granted by the primary claim that “prevented anyone else from making … a selection invention on H2-relaxin [including] the possibility of further inventions, for example improved derivatives of the protein” was “perfectly justified because “H2-relaxin has been made available to the public for the first time”.

205 V 00008/1994 Howard Florey Institute of Experimental Physiology and Medicine v. Fraktion der Gronen im europäischen Parlament, Paul Lannoye - Relaxin

206 Ibid, para 5.2.

207 Ibid, para 5.3.

208 Ibid.

209 Ibid.
Finally, even though “the mere finding of something freely occurring in nature is not an invention [but Relaxin] had a technical character, i.e. it constituted an industrially applicable technical solution to a technical problem [that could be] reproducibly obtainable without undue burden”\textsuperscript{210} and it is therefore a product which is also novel “in the sense of having had no previously recognised existence.”\textsuperscript{211}

There are a number of problems with the EPO’s reasoning.

Firstly, what is immediately apparent is that nowhere in the decision did the Opposition Division refer to any EC national court decision that either supported or undermined its reasoning. It contained no discussion about what constituted an ‘invention’ within the meaning of art. 52(1) EPC beyond the \textit{EPO Examination Guidelines} which basically confirmed “the long-standing practice of the European Patent Office concerning the patentability of natural substances”. Clearly, the ‘invention’ was directed to the same product as produced in humans and displayed precisely the same \textit{in vivo} biological properties, but these facts were not germane to the EPO because its focus was adhering to the ‘party’ line officially adopted by the EPO in 1988.

In \textit{Gale}, Nicholls LJ acknowledged the policy of the \textit{UK Act} requiring UK courts to take ‘judicial notice’ of decisions of the EPO. In this context he suggested that it would be reasonable for the EPO to reciprocate. He explained,

\begin{quote}
Of course, this should be a two-way flow. No doubt, in appropriate cases, the European Patent Office has regard to, and takes into account, decisions of the courts of this country as well as decisions of the courts of other contracting states, and will continue to do so.\textsuperscript{212}
\end{quote}

\textit{Howard Florey} is an appropriate example of how the EPO ignored the decisions of the UK courts and highlights a bias in favour of the implementation of the 1988 policy.

Secondly, even though \textit{Chakrabarty} was not binding on the EPO it was a decision that would have been known to the EPO. Clearly, had the EPO considered \textit{Chakrabarty} it would have discovered that the technology defined by the primary claim would not have satisfied the criteria of ‘invention’ established in that case. Firstly, the DNA fragment encoding human Relaxin did not involve a substantial modification to the DNA sequence of human Relaxin gene. Secondly, the Relaxin produced by means of the use of the DNA fragment was identical to human Relaxin

\begin{footnotesize}
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\item \textsuperscript{210} \textit{Ibid}, para 5.4.
\item \textsuperscript{211} \textit{Ibid}.
\item \textsuperscript{212} \textit{Re Gales’s Application} [1991] RPC 305 per Nicholls LJ, 323 lines 23-26 (UK Court of Appeal).
\end{itemize}
\end{footnotesize}
produced by the human body and did not display any characteristics different from human Relaxin. The human Relaxin produced by use of the DNA fragment did not possess any utility above and beyond human Relaxin produced by the human body.

Thirdly, even though Genentech was not binding on the EPO it was a decision of the UK Court of Appeal and it dealt with a claim to human protein within the context of s.1(1) UK Act and art. 52(2)(a) EPC. The decisions of both Purchas and Mustill LJJ were clearly relevant and the effect of their decisions would have given the EPO cause to question the basis of its ‘long-standing policy’. Certainly, on the reasoning of Mustill and Purchas LJJ the claim was not an ‘invention’ within art. 52(1) EPC.

Fourthly, the EPO found that it was “perfectly justified to grant broad protection in view of the fact that H2-relaxin has been made available to the public for the first time”\(^\text{213}\). While it may have been true that the ‘H-2’ human gene was first identified and its genetic sequence elucidated by the ‘inventors’, the purpose and functional properties of human Relaxin had been known to the skilled person and part of the scientific literature since 1926.\(^\text{214}\) Moreover, non-human Relaxin had been expressed in the late 1970s using recombinant means.\(^\text{215}\) Accordingly, the facts in this case were analogous to the facts in Genentech with the only material difference being the protein described in the primary claim. In Genentech the primary claim was for ‘recombinant human tissue plasminogen activator essentially free of other protein of human origin’, whereas in Howard Florey the primary claim was for ‘a DNA fragment encoding human H2-preprorelaxin, said H2-preprorelaxin having the amino acid sequence set out in Figure 2.’ Apart from the difference in claim language, the gist of the two claims was clear. The Genentech claim was getting at recombinantly produced t-PA and the Howard Florey claim was getting at recombinantly produced human Relaxin. On the reasoning adopted by Purchas LJJ the Howard Florey claim was nothing more than “a claim for the protection of the discovery as such” and therefore was a claim to a ‘discovery’ within art. 52(2)(a) EPC.

Interestingly, the House of Lords in Kirin-Amgen recently drew doubt upon the validity of a claim to a process for the manufacture of erythropoietin because the end result of that process was

\(^{213}\) V 0008/94 Relaxin – EPO Opposition Division, 5.3. (Emphasis added).

\(^{214}\) As confirmed by the patent specification: “Pioneering work by Hisaw (1926) suggested an important role for the peptide hormone relaxin in mammals through its effects in dilating the pubic symphysis, thus facilitating the birth process. Relaxin is synthesized and stored in the corpora lutea of ovaries during pregnancy and is released into the blood stream prior to parturition.” EP 0,112,149, granted April 10, 1991.

\(^{215}\) As confirmed by the patent specification: “[t]he availability of ovaries has enabled the isolation and amino acid sequence determination of relaxin from pig (James et al, 1977; Schwabe et al, 1977) rat (John et al, 1981) and shark (Schwabe et al, 1982).” EP 0,112,149, granted April 10, 1991.
isolated erythropoietin which was not “new”.\(^\text{216}\) Lord Hoffmann’s reasoning seemed arguably consistent with that of Purchas LJ in *Genentech*, even though the issue of ‘invention’ was not directly before their Lordships in *Kirin-Amgen* as it was before the Court of Appeal in *Genentech*. Just as in *Genentech*, what was *new* was the genetic sequence of erythropoietin and the gene which coded for it. But that was, neither to Purchas LJ in *Genentech* nor to Lord Hoffmann in *Kirin-Amgen*, to the point. What was to the point was the evidence which established that it was not possible to distinguish between natural erythropoietin which was known and recombinantly produced erythropoietin which was the end result of the patented process.

With respect to Relaxin it is difficult to understand how the EPO could justify its decision given the fact that Relaxin had been known since 1926.

Finally, the decision used the logic of the 1988 EPO, USPTO and JPO joint communiqué to distinguish between a ‘discovery’ and an ‘invention’ using the ‘technical contribution’ approach:

> As already pointed out, the mere finding of something freely occurring in nature is not an invention. An invention must have a technical character, ie should constitute an industrially applicable technical solution to a technical problem, and must be reproducibly obtainable without undue burden.\(^\text{217}\)

Apart from confusing ‘insufficiency’ (art. 83-84 *EPC*) with ‘invention’ (art. 52(1) *EPC*) by referring to “undue burden”, the ‘invention’ defined in the primary claim was to something intrinsically natural. It therefore did not possess a ‘technical character’. The solution to the ‘problem’ of mass producing human Relaxin using recombinant means was not ‘technical’, but natural. It was the biological material defined by the sequence in “Figure 2”.\(^\text{218}\) The fact that this material was incorporated into “a DNA fragment,” was not part of the solution because by the late 1970s this step was nothing more than standard routine science. The solution was the ‘discovery’ and elucidation of the genetic sequence of the H-2 Relaxin human gene. Of course, the relevant

\(^{216}\) *Ibid*, per Lord Hoffmann, para 132 “Standing back from the detail, it is clear that Amgen have got themselves into difficulties because, having invented a perfectly good and ground-breaking process for making EPO and its analogues, they were determined to try to patent the protein itself, notwithstanding that, even when isolated, it was not new.”

\(^{217}\) *V 0008/94 Relaxin – EPO Opposition Division*, para 5.4.

\(^{218}\) “Figure 2 : compares the amino acid and mRNA sequence of human preprorelaxin H2 (upper) with the corresponding H1 (lower) sequence. The sequences have been aligned to maximize homology with nucleotide identities being indicated by asterisks and amino acid homologues by boxed-in areas. Amino acids are numbered from the start of the B-chain (H2 gene sequence starting at -1 and H1 sequence at +1) although this position represents only the hypothetical start of the B chain sequence and has been deduced simply from the homology to the related porcine and rat preprorelaxin structures. The asterisk beneath Ala 45 in the C peptide denotes the position of an intron in the G/CA codon in both genes.” *EP0,112,419*, granted April 10, 1991.
biological material was housed in “a DNA fragment” because the skilled molecular biologist knew by this time, that to recombinantly produce a protein, such as Relaxin or t-PA or Epo, meant that “the cloned genes are expressed by the host cell when fused with a host-expressable prokaryotic or eukaryotic gene.”

**Harmonisation**

Both Anthony McInerney and Peter Drahos have identified the patent ‘harmonisation process’ as one of the principle reasons for the adoption of the ‘isolation contrivance’ in Europe. Anthony McInerney suggests,

> The reliance by the biotechnology industry on the patent system and the internationalisation of patent law put pressure on current patent law to grant a monopoly for the “skilful exertion of time and resources”. This view is supported by critics of the patent system who argue that the system is out of step with modern research methods and no longer provides sufficient incentive for invention owing to the enormous cost associated with it. Proponents of these views favour an approach where patent protection is accorded at an earlier stage of the research for an invention.

In the context of Howard Florey, Peter Drahos reminds us that the EPO cannot perform the function of prosecutor, judge and jury because it is not independent of the ‘patent community’. He explains,

**Notes**

219 “More specifically, this invention relates to an isolated and purified (i.e., ‘cloned’) human gene coding for prorelaxin, preprorelaxin, and the A and/or B and/or C peptide chains of human relaxin, methods for isolating and purifying the genes and a method for transferring the genes to and replicating the genes in a host cell. The cloned genes are expressed by the host cell when fused with a host-expressable prokaryotic or eukaryotic gene. The genes are thus useful in the production of human relaxin for therapeutic purposes.” EP0,112,149, granted April 10, 1991. (Emphasis added)

220 A. McInerney, *Biotechnology: Biogen v Medeva in the House of Lords*, (1998) 20(1) EIPR 14-21. He argues, “The biotechnology industry provides a practical example of the interaction between the efforts to harmonise European patent law and the acceptance of internationalisation--the theory of national economic growth through the capture of economic benefits from this technology. In particular, “[p]atents are abnormally attractive to the biotechnology industry” because the industry requires patent protection of its key discoveries both as an “incentive mechanism” and to “maintain the creation of the benefits flowing from biotechnological research.”, 16 (Emphasis added).

221 P. Drahos, *Biotechnology Patents, Markets And Morality*, (1999) 21(9) EIPR 441-44. He argues, that “The patent system has undergone a process of regulatory globalisation and harmonisation. This simply means that more and more countries have adopted patent systems and that those patent systems have progressively become more like each other. Patent systems are not harmonised at the level of rules, but they share common principles. The degree of patent harmonisation is increasing rather than decreasing. … A crucial aspect to the expansion of the patenting in biotechnology has been the development of juridical arguments and theories that have enabled applicants for biotech patents to overcome existing bars.”, 442-3.


223 Peter Drahos defines the ‘patent community’ to include “patent attorneys and lawyers, patent administrators, and other specialists who play a part in the exploitation, administration and enforcement of the patent system. They form a community by virtue of their technical expertise and general pro-
[The] European Patent Office (‘EPO’) [is a] hybrid creature, business bureaucracy which makes [its] living from granting more rather than less patent registrations, from ensuring the repeat custom of their transnational clientele and from going on proselytising missions in those developing states or new market economies which are in the middle of acquiring patent systems. … [In the case of the EPO, [it has] exercised a profound harmonising influence on national systems and] has been singularly successful in giving a narrow reading to the limits on invention and patentability contained in Articles 52 and 53 of the EPC. \( ^{224} \)

*Howard Florey* is not an isolated example of the reasoning that Peter Drahos refers to. There are others. However, what distinguishes this case from other Oppositions concerning proteins is the fact that art. 52(2)(a) *EPC* was actually a ground of objection in the Opposition in the first place. In other Oppositions concerning proteins, the Opponents, mainly biotechnology or pharmaceutical companies, have not raised the ‘invention’ objection, but instead have chosen to challenge the grant of the patent on grounds of ‘arts. 54 (novelty), 56 (inventive step), 57 *EPC* (utility) and 83-84 *EPC* (insufficiency). The reason for this is obvious. The vast majority of Opponents are competitors in the field of biotechnology and either have their own protein patents or have filed patent applications as such and it is simply against their own interests to raise an objection that could be raised against their own patents or patent applications. Accordingly, Oppositions in general have operated under the assumption that the subject matter of the patent already satisfies art. 52(1) *EPC*. *Howard Florey* is an exception because the Opponents in this case were not members of the ‘patent community,’ but consisted of a person and a public interest group with a membership of between six and twenty-five persons which had no disincentive to raise an objection under art. 52 *EPC*. Rather, the precise purpose of the public interest group was to challenge, on moral and social grounds, the rationale for the expansion of the European patent system to include patents over human proteins. \( ^{225} \)

The lack of directly relevant EPO authority on the issue of art. 52(2)(a) *EPC* specifically dealing with the issue of ‘invention’ in the context of biotechnology is a significant deficiency in the European patent regime.

\( ^{224} \) *Ibid.*

\( ^{225} \) In regard to these arguments the Opposition Division held, “Turning now to the opponents’ specific allegations relating to the present human H2-relaxin DNA, the patenting of the DNA would indeed be abhorrent to the overwhelming majority of the public if it were true that the invention involved the patenting of human life, an abuse of pregnant women, a return to slavery and the piecemeal sale of women to industry. However, the opposition division emphatically rejects these arguments,” 6.3.
In these circumstances, it is understandable that EPO case law has developed the ‘technical contribution’ approach to ‘invention’ in the context of art. 52(2)(c) EPC, [the exclusion of ‘computer programs’ as ‘inventions’]. In fact, the principle authority for this approach, as cited in Merrill Lynch, Gale, Chiron, Fujitsu, Biogen and Amgen is Vicom, an EPO Opposition that had nothing to do with biotechnology nor discovery.

This issue of ‘invention’ has yet to be adequately dealt with by the EPO and given the Directive and the consequential amendments to the EPC that have followed on from the Directive, it is unlikely to.

Interestingly, even though the EPO has assessed compliance with art. 52(1) EPC in the context of the parameters of patentability of novelty, inventive step and utility, meaning that something that satisfies these parameters is by definition an ‘invention’ and patentable, the Nuffield Council of Bioethics has recommended that the existing parameters of patentability, “particularly the criterion of [inventive step], be stringently applied to applications for product patents which assert, inter alia, rights over DNA sequences for use in diagnosis”226 because firstly, “[w]e take the view that the description of an association between a gene and a disease amounts to little more than a discovery”227 and secondly, “… that allowing property rights to be asserted over all uses, or even all diagnostic uses, of DNA sequences in relation to diagnostic tests gives inventors too great a monopoly in the light of the contribution and inventiveness of their product, may hamper innovation and may not, in fact, satisfy the legal criteria for patenting.”228

The Nuffield Council of Bioethics Report was written after the Directive and the consequential amendments to the UK Act. Accordingly, the Report did not challenge the premise upon which the Directive stands, rather it assessed the patenting of DNA in the context of the residual parameters of patentability, namely, novelty, inventive step and utility. So its findings and recommendations must be understood in the context of this caveat. Even so, the Report explained that a principal concern was the ability of a patent owner to assert its monopoly over all “subsequent uses” of a DNA sequence and not merely the use identified in the patent. It recommended that patents that

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226 Nuffield Council on Bioethics, The Ethics of Patenting DNA: A Discussion Paper, July 2002, 70, 6.7. Cf: M.J. Howlett and A.F. Christie, An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequence (ESTS), International Review of Industrial Property and Copyright, Vol. 34, pp. 581-602, 2003. The authors argue that their research demonstrates that the parameters of novelty, inventive step and utility are sufficiently stringent. They conclude that “Given the few hypothetical claims found valid in the comparative study, it seems that the practice of the patent offices is such that not many ESTs will pass the stringent requirements for patentability. Accordingly, it seems that the fear of numerous EST patents inhibiting later research is also unfounded.”

227 Ibid.

228 Ibid.
claim DNA sequences and their use in diagnostic tests be limited so that “the owner of the patent is entitled to rights only to the use of the DNA sequence for his specific diagnostic test for a particular disease, and not all diagnostic tests for that disease involving the use of the sequence.”

By way of contrast, in its 2004 Report entitled *Patenting Human Genes and Stem Cells*, the Danish Council of Ethics described the language of the Directive as “a creatively worded ploy to avoid the criticism leveled at patents on human material” and stated that its “principal objection to the wording of the Directive was precisely that in reality it rubber-stamps the practice that has gradually evolved in the USA, Japan and Europe whereby, under certain conditions—which it turns out to be very hard to get a grasp on in practice—parts of the human body can nevertheless be patented.”

Clearly, without any deliberate attempt to criticise the Nuffield Council, the Danish Council identified the very issue which the Nuffield Council completely ignored – namely, the semantics introduced into European patent law by the passage of the Directive. In this regard, the Danish Council noted:

> In the members’ view, it cannot be said with any reasonableness that a sequence or partial sequence of a gene ceases to be part of the human body merely because an identical copy of the sequence is isolated from or produced outside of the human body.

**The Defence of Gene Patents**

One of the most prominent European pro-gene patent commentators, Stephen Crespi, has argued that once a gene has been cloned, by which he means ‘isolated,’ the methodology employed to isolate that gene “is of historical interest only” because “[n]o licensee of a recombinant DNA patent of the usual kind would expect to have to duplicate the highly laborious method used by the initial inventor; he would expect to be handed the clone,” so a patent for the isolation methodology “would in practice often be of little commercial value”. The real commercial value, he has argued, is in the mass production of the recombinant protein, which should be patentable subject matter.

His point is a fair one for finding and cloning and isolating a gene or genome may not be straightforward. Certainly, this was the case in the mid-seventies and early eighties, when

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231 *Ibid*.
molecular biological techniques were rudimentary. As such the scientists involved in the search for genes (e.g., t-PA, Epo) and genomes (e.g., HCV) used novel techniques in their search. The problem, argues Stephen Crespi, is that the route taken to isolate genes and genomes becomes irrelevant once the discovery is made, because the economic reward is not in the route taken to find the specific biological material, but in the mass production of the biological material that the gene or genome codes for.

He argues that it is only fair that the biotechnology industry be permitted to patent the recombinant methods for their mass production and capture proteins within their scope. This approach, although initially resisted by patent offices, was pursued by the biotechnology industry and eventually the disputes between patent applicants and the patent offices made it to the courts. The arguments which the biotechnology industry raised in defence of these patents eventually found favour with the CAFC. In this regard, it is important to note that the cases that came before the CAFC did not challenge the patents in issue on the ground that there was no invention within s.101 US Act, as was the case with Chakrabarty, but on other grounds related to the parameters of patentability of novelty, inventive step and industrial applicability or utility. These challenges, though attacking the validity of the patents, nevertheless conceded that the subject matter of the patent was an ‘invention’. Therefore, the decisions created the impression that the subject matter was patentable and that the real controversy was with respect to novelty, inventive step and industrial application, when in fact, the issue of invention was far from settled.

In response to the proliferation of patent applications from the United States into Europe concerning isolated genes and gene sequences, the EPO acted by adopting this standard through

234 R. Blackburn provides examples of what he terms “first generation biotechnology products” including “factor VIII (the blood-clotting factor for hemophiliacs), interleukin-2 (a cancer drug with promise in treating AIDS), erythropoietin (a treatment for anemia in cancer and kidney dialysis patients), the Hepatitis-B vaccine (a vaccine that avoids infectious contamination of the original vaccine), insulin (human rather than the older porcine sequence), and growth hormone (a treatment for dwarfism),” See R. Blackburn, Evolving Patent Law in the New Age of Biomedical Science, 4 Tex. Rev. Law & Pol. 85 – 96, 88.

235 There are literally hundreds of examples of such patents, but one worth examining is AU 624,105 entitled, Non-A Non –B hepatitis C Virus Diagnostics and Vaccines granted to Chiron Corporation by the Australia Patent Office in 1992. Equivalent patents are: GB 2,212,511 entitled Hepatitis C Virus; EP 0,318,216 entitled Non-A Non –B hepatitis C Virus Diagnostics and Vaccines and US 6,027,729 entitled Non-A Non –B hepatitis C Virus Diagnostics and Vaccines.


237 For example in the case of In re Bell, the US Patent Office had rejected the patent application on the ground that the claimed invention was not patentable because there was no inventive step. The appeal therefore concerned s.103 US Act and whether the USPTO Board of Appeal had erred in concluding that the claimed nucleic acid molecules would have been obvious in light of the prior art.
the concept of ‘technical contribution’ or ‘practical application’. Stephen Crespi justifies the adoption of this standard thus:

The distinction between discovery and invention is difficult to define in any of the sciences of nature because the act of discovery so closely underpins the resultant practical application which constitutes the invention. As one of the contributors to the above-mentioned Heidelberg Workshop (ethicist W. Ch. Zimmerli) put it “every scientific discovery, if made technologically applicable, becomes an invention”. Suppose, for example, that the scientist discovers and formulates a certain mathematical relationship between the molecular weight of a protein and the viscosity of its aqueous solution. In itself this is the discovery of a relationship. But if it leads to practical application as a method of determining molecular weight by measurement of the viscosity of the solution, such a method can be reasonably categorised as an invention (presiding from the level of actual inventiveness it entails). These two things are but different sides of the same coin.

There is no justification for writing this sort of technological achievement out of the ambit of patent protection on the basis of an arbitrary judgment that genes are to be categorised as mere discoveries. Genetic engineering is a sophisticated form of technical intervention to adapt natural mechanisms and materials to a predesigned end. The resulting processes and products should be accorded their proper status as inventions rather than discoveries. This conclusion is well established in patent law.\(^{238}\)

However, do the ends justify the means? Stephen Crespi and those that share his views argue that they do. However, is he correct to assert that his conclusion is well established in patent law?

Firstly, the UK Courts until Chiron had resisted this argument as is evident from the UK Court of Appeal decision in Genentech and the House of Lords decision in Biogen. In this regard it is important to note that when the Court of Appeal handed down its decision in Chiron, the House of Lords had not made their speeches in Biogen. Therefore, the Court of Appeal in Chiron did not have the benefit of the Houses’ reasoning.

Secondly, Anthony McInerney\(^{239}\) has argued that Biogen was “a well-reasoned decision” which sought “to reach a just result having regard to the internal efficacy of the patent system, and implicitly rejects the fashionable winds of internationalisation which howl around it”.\(^{240}\) In his opinion, the EPO has been driven by an expansionist policy directed to international trade,


\(^{240}\) Ibid, 20.
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whereas the House of Lords has tried to hold to existing principles of patent law. He maintains that EPO policy has overridden the balanced development of patent law in Europe.

Accordingly, within the UK courts there has been some considerable tension between those judges who have displayed a more traditional approach to patent law, such as Mustill LJ and Purchas LJJ in Genentech and the House of Lords in Biogen, and those that have been persuaded that consistency with the EPO approach is paramount, such as Dillon LJ in Genentech, Aldous J and the Court of Appeal in Chiron (No 3) and Neuberger J in Amgen. This judicial tension, as Anthony McInerney has exposed is based on a ‘policy’ debate and one which Stephen Crespi maintains “ought to be tackled comprehensively and not selectively to suit the agenda of the Greens, animal rights campaigners, and their supporters”. Stephen Crespi’s condescending characterisation of those that favour a conservative approach, such as ‘animal rights campaigners’, typifies his attitude towards a “proper debate” on the subject.

Those that favour a conservative approach, like Peter Drahos, argue that law and morality are intertwined and that “like it or not, the creation, operation and interpretation of the patent system is linked to moral standards”. In his opinion, the ‘patent community’ has, through the process of the harmonisation of patent law across the globe, expanded the subject matter of patents to the point where a ‘product of nature’ and a ‘product of man’ are indistinguishable. He argues that this has been achieved by “the development of juridical arguments and theories that have enabled applicants for biotech patents to overcome existing bars to patentability. Specifically, he points to the ‘re-categorisation’ of ‘products of nature’ as ‘inventions’ through the use of the isolation contrivance. He suggests, that

[I]f Mother Nature had a patent on a particular naturally occurring gene sequence, she would almost always win a patent suit brought against the alleged inventor, since typically all that happens in nonnatural gene sequences is the removal of redundant codons. In essence the sequences are the same. To most people outside the patent community this kind of argument seems like a triumph of form over substance. How many people would think that the rock

242 Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2002] RPC 1 (UK Patents Court).
244 Ibid.
246 Ibid, 441.
247 Ibid, 443.
they pick up in the park becomes an invention of theirs after they have washed and polished it.\textsuperscript{248}

Of course, the obvious rebuttal to his argument is that it is not just any rock in the park that is important, but a particular rock and this rock may have taken much skill and labour to find. Perhaps, the fairer analogy is finding the ‘treasure in a castle’ developed in the Australian Federal Court decision in \textit{Genetics Institute, Inc v Kirin-Amgen, Inc (No 3)}\textsuperscript{249}. Heerey J explained,

\begin{quote}
The castle has many gates, each with a combination lock (this being a modern castle). The combination for each lock is the same. Anyone who knows the combination can enter the castle. Finding the treasure may require some further time and trouble but this will merely be a matter of carefully searching through every room and cupboard in the castle. The critical knowledge is the combination of the locks. Without that, it is impossible to enter the castle. Once you have that, entry can be obtained through any gate. With reasonable time and effort the treasure will be discovered. I think the protein coding sequence, the essential information contained in Table VI, is analogous to the combination of the castle locks.\textsuperscript{250}
\end{quote}

But even so, the combination to the castle gates is not information derived from a ‘product of man’, but is information derived from a ‘product of nature’. In any event, all of the discussion about combinations and locks and castles was quite irrelevant because as the House of Lords eventually found in \textit{Kirin-Amgen}, new information about an old product does not make the old product new.\textsuperscript{251} In other words, having the combination of the locks to the castle may have been new information but it did not entitle the code-breaker to ownership of the treasure in the castle. The new information simply opened the doors to the castle.

The problem with these kinds of analogies is that neither adequately deals with the issue. Just as the isolation of a gene is not as simple as finding a rock in the park and cleaning it, it is irrelevant that the combination to the lock is difficult and laborious to obtain.

The decisive rebuttal to Stephen Crespi is that no matter how much skill and labour is expended, a patent that claims \textit{an element isolated from the human body, animal or organism such as a virus or bacterium, or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element} is making a claim to something that is inextricably linked to a product of nature.

\begin{footnotes}
\item[\textsuperscript{248}]\textit{Ibid}.
\item[\textsuperscript{249}]\textit{Genetics Institute, Inc v Kirin-Amgen, Inc (No 3)} (1998) 156 ALR 30 (Federal Court of Australia).
\item[\textsuperscript{250}]\textit{Ibid}.
\end{footnotes}
Ultimately, he falls back upon the traditional EPO answer that if a discovery “… leads to [a] practical application, [such] as a method, … [that] method can be reasonably categorised as an invention.”

The problem, as he readily concedes, is that “in practice [the method will] often be of little commercial value”. The real value is in the DNA sequence encoding the protein and that, with respect, is the real issue because irrespective of the novelty of this type of information, it is not and can never be an ‘invention’. In Kirin-Amgen, Lord Hoffmann explained thus,

> It seems to me that a good deal of the argument in this case … really turns on a dispute over exactly what the invention is: whether it is the discovery of the DNA sequence which codes for EPO, or a way of making EPO, or a new artificial form of EPO. And the confusion is compounded by the fact that claims 19 and 26 are both in essence product-by-process claims, even though, in the case of claim 19, the product is distinguished from prior art by an artificial condition about molecular weight. All this creates ambiguity about the nature of the invention.

Their Lordships were in this regard quite critical of the trial judge because in their opinions he had concluded “that the invention was the discovery of the sequence of the EPO gene and the associated information” when in fact “it was not the invention. An invention is a practical product or process, not information about the natural world.”

Their Lordships did however contemplate the possibility that a patent claim to a product or process could be framed so that “in practice it will be impossible to use the information … disclosed, even to develop important improvements”, but did not elaborate further as to how this could be achieved. Why they did this is a matter of speculation, but it seems relevant that on the facts of the appeal before them, that even though Amgen had tried to frame claim 1 to claim rEpo howsoever produced, their Lordships objected to it because the end result, recombinant Epo, was identical to natural Epo. This begs the question – how is it possible to frame a product or process claim so that

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251 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2004] All ER (D) 286 (House of Lords) per Lord Hoffmann, paras 95-96, 132.

252 *Ibid*.


254 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2004] All ER (D) 286 (House of Lords) per Lord Hoffmann, para 104.

255 *Ibid*, para 76.

256 *Ibid*, para 68.


258 *Ibid*, para 77.
it is impossible to use the genetic information of a natural product and not be making a claim to a product of nature?

**Summary**

Much of the discussion in this Chapter has centred on the distinction between ‘discovery’ and ‘invention’ not because the relationship between these two concepts is mutually exclusive, so that if something is one it cannot be the other, but because historically the courts and the legislatures have expressed an intention to ensure that the concept of ‘invention’ should not trespass into the domain of nature and the dichotomy between ‘invention’ and ‘discovery’ has been a product of this intention. This dichotomy although not a legislative feature of the US Act,\(^{259}\) is part of US patent law jurisprudence as the Supreme Court in *Funk Brothers* and *Chakrabarty* have clearly held: not all ‘discoveries’ are ‘inventions’. In the UK this dichotomy has a legislative recognition\(^ {260}\) and is present in the *EPC*.\(^ {261}\) In Australia, it has not been legislatively recognised, but it is present in the common law and statutory interpretation of the three hundred and eighty year old concept of ‘manner of new manufacture’.\(^ {262}\)

However, no matter how this dichotomy is expressed, it is today a fundamental principle to patent law throughout the world. The concept of ‘invention’ has been enshrined in TRIPS through art. 27.1.

Although TRIPS does not contain a definition of ‘invention’, as explained in Chapter 2, it is not a meaningless or boundless word. Moreover, as Philippe Ducor has explained, the invention parameter is “a ‘precondition’ for patentability, anterior to any other legal evaluation.”\(^ {263}\) In truth it has been long recognised that the concept of ‘invention’ does not permit a trespass into the domain of nature for as the US Supreme Court held in *Chakrabarty*, “[t]he laws of nature, physical phenomena, and abstract ideas have been held not patentable.”\(^ {264}\)

Throughout this Chapter the discussion has focused on the concept of ‘invention’ and its relationship to *Directive* technologies. It has explained that some commentators argue that

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259 Section 100 *US Act* defined invention to mean invention or discovery.

260 Section 1(2)(a) *UK Act*.

261 Article 52(2)(a) *EPC*.

262 Definition of ‘invention’ in Schedule 1 *AU Act*.


“ownership of the information derived from a gene and the commercial exploitation of that information” that include “isolated gene sequences, the method for synthetically producing the gene, diagnostics tests associated with that gene, and potentially, components of the therapeutic treatment regime” come within the concept of ‘invention’. But, the problem with this argument is that:

Firstly, ownership of the ‘information derived from a gene’ is tantamount to ownership of the gene if the patent defines the scope of the monopoly to include any method or technology for the production of that gene or its corresponding protein and this point was recognised by the UK Court of Appeal in Genentech and the House of Lords in Kirin-Amgen; and

Secondly, the ‘isolation’, ‘purification’ or production by technical means of biological material *per se* does not result in something that displays *markedly different characteristics from any found in nature* as required by Chakrabarty.

The analysis of the decisions of the UK Court of Appeal in Genentech and the High Court of Australia in NRDC demonstrate the existence of common jurisprudential principles with Chakrabarty.

**The Following Case Studies**

In Chapters 4 and 5, this Thesis presents two case studies. The first considers the human hormone, *Erythropoietin*. The second considers the virus causative of a human disease called hepatitis C. The abbreviation for this virus is HCV. Both are the subject of patents that have been granted all over the world. The process that led to the grant of these worldwide patents was facilitated by various international conventions, but the country of origin was the United States and the owners of these patents are also US corporations.

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The case studies continue the theme commenced in this Chapter but discuss the issues raised in the context of these specific biological materials. The purpose is to demonstrate how the ‘international’ patent system has been and is being used by the biotechnology industry to control the mass production of biological materials by various technical means and the further downstream research that is facilitated by their discovery. These artificially produced biological materials are identical in every material respect to the corresponding naturally produced biological materials.

The patent litigation that has engulfed these patents provides an excellent basis to examine these patents and the issues pertinent to this Thesis because the written decisions produced as a consequence distil the primary expert scientific evidence into a form that enables analyses that would simply not have been possible without the cooperation of the patent owners, and the expenditure of millions of dollars in research and legal fees.
The scientific work performed\(^1\) by Dr. Fu-Kuen Lin, led in October 1983, to the isolation of the human gene that codes for the protein \textit{Erythropoietin} (Epo). Dr. Lin was then an employee of Amgen, Inc (Amgen) a Californian biotechnology company.

Amgen filed its first patent application with the USPTO concerning this achievement in December 1983 and was eventually granted a US patent in October 1987. The patent, US 4,703,008 was entitled, \textit{DNA Sequences Encoding Erythropoietin} and as its title suggests, it claimed the genetic materials of the Epo gene and the host cells used in the recombinant production of Epo (rEpo) as ‘inventions’.

In addition to being granted this patent, Amgen was successful in being granted corresponding patents throughout the world. In this Chapter, some of these patents will be considered together with the associated patent litigation in the United States of America, the United Kingdom, the European Patent Office (EPO) and Australia.

At the earliest priority date\(^2\) Epo was known to exist. Being a hormone\(^3\) produced by humans, it was known that its function was to regulate the level of red blood cells and that its production source was the kidneys. It was also known that humans that suffered from kidney failure would benefit from therapeutic treatment with Epo. In this regard, small amounts of Epo had been obtained from human urine (uEpo). Furthermore, in October 1980 Dr. Rodney Hewick,\(^4\) then of the California Institute of Technology had been able to sequence twenty six of the amino acids that made up Epo and this information was published at a scientific meeting held in the United States in December 1981 and in the scientific literature in June 1983.

\(\text{\footnotesize\textsuperscript{1}}\) “Dr. Fu-Kuen Lin obtained the amino acid sequence for Epo and designed two sets of probes to isolate the Epo gene from a ‘genomic library,’ a mixture containing most, if not all, of the human genes.” See \textit{Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc} (1989) 13 U.S.P.Q.2D (BNA) 1737 (US District Court for the District of Massachusetts).

\(\text{\footnotesize\textsuperscript{2}}\) December 13, 1983. This is the filing date of the first US patent application.

\(\text{\footnotesize\textsuperscript{3}}\) A hormone is a protein. A protein is also known as a polypeptide.

\(\text{\footnotesize\textsuperscript{4}}\) Dr. Hewick subsequently commenced employment with Genetics Institute, Inc. in September 1981.
What was unknown was the nucleotide sequence of the human Epo gene and the complete amino acid sequence of Epo.

To obtain this sequence information Dr. Lin and his team at Amgen first had to clone the Epo gene. To this end, molecular biological experiments were conducted in August 1983 using tryptic Epo fragments which had been obtained from Dr. Eugene Goldwasser, a consultant retained by Amgen to work with Dr. Lin’s team. By September 1983, Dr. Lin’s team had designed two sets of oligonucleotide probes known as EpY and EpO which were then used to screen a library made from the tryptic Epo fragments that hopefully contained the Epo gene. The molecular biology which was then carried out by Dr. Lin’s team followed the teachings of Dr. Maniatis, which were already considered routine, although it is possible that the oligonucleotide probes that were designed by Dr. Lin and used to screen the library were more complex than had been published in the scientific literature and may have signified an advance in the state of the art. In any event, by October 1983 using this methodology with the EpY and EpO set of probes, Dr. Lin’s team successfully identified positive Epo gene clones that had hybridised to the oligonucleotide probes. Of course, the next immediate step was to pull out as much of the Epo gene from the library so that the complete nucleotide sequence of the Epo gene would be known and confirmed. This work was quite routine and was carried out by others employed by Amgen. By early December 1983 Dr. Lin had hybridised the human Epo gene to monkey cDNA and on December 13, 1983 he filed his first patent application.

The next phase of their work was directed to producing rEpo, which is human rEpo expressed from cells that were not in their natural environments. These cells, either prokaryotic (bacterial...
cells such as E. Coli) or eukaryotic (mammalian cells can be either human or animal, such as Chinese hamster ovary cell [CHO] or a monkey cell [COS]) were transfected with a vector that contained Epo genetic material.\textsuperscript{13} Part of this work involved the use of a gene amplification process that was considered routine,\textsuperscript{14} the purpose of which was to amplify the Epo genetic material so as to obtain a very high level of expression of rEpo. By mid-January 1984 this had been achieved using a mammalian expression system. By February 1984, Dr. Lin’s team conducted experiments that confirmed that the rEpo produced in monkey cells was biologically active, or in other words, that it had therapeutic properties. At this point, Dr. Lin filed a second patent application with the USPTO. By mid-March 1984, the complete human Epo gene cDNA had been confirmed. After this time, experiments were conducted to enable the production of rEpo in other types of cells including yeast cells. This subsequent work led to a third\textsuperscript{15} and then a fourth\textsuperscript{16} patent application being filed with the USPTO.

The methodology and experiments performed during this time and described in these four US patent applications formed the basis of the first Epo patent applications filed throughout the world in December 1984. Moreover, the first patent application, filed in December 1983, remains the foundation stone of US 4,703,008 and all other Epo patents because it established the earliest priority date, being the date by which the then existing prior art is assessed against the technological advances described in the numerous Epo patents. It is this technological gap by which the thresholds of the parameters of patentability of novelty\textsuperscript{17} and inventive step\textsuperscript{18} are assessed.

Although these other parameters are relevant to the validity of the subject patents and were considered in the cases that make up the series, they will not be considered in this Chapter. This is

\textsuperscript{13} This is where the analogy to a factory can be made. These expression cells are biological factories that are genetically modified by the insertion of foreign DNA to express the protein of interest.


\textsuperscript{15} Filed with USPTO on September 28, 1984.

\textsuperscript{16} Filed with the USPTO on November 30, 1984.

\textsuperscript{17} For example, s. 102 US Act provides, “A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, …”

\textsuperscript{18} For example, s.103(a) US Act provides, “A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.”
because this Thesis is concerned only with the invention parameter. Accordingly, the following discussion will be confined to the ‘invention’ parameter, but it should be understood that this is not the only contentious issue concerning these patents.

From the moment that Amgen filed the first patent application with the USPTO the subject matter was controversial. It remains so today. In both the United States and in the United Kingdom, litigation concerning one or more of these patents continues. Specifically, the House of Lords heard an appeal in July 2004 concerning the very first European Epo patent\(^\text{19}\) even though the patent expires in December 2004.

In terms of defining the ‘invention’ that is the subject of these patents, the decision of the Technical Appeal Board of the European Patent Office (“TBA”) in \textit{T421/93 Kirin-Amgen, Inc v Genzyme Corporation & Others}\(^\text{20}\) is useful. The TBA explained\(^\text{21}\) that the mass production of rEpo was made possible by the provision of \textit{the sequence information provided by Table VI}. This sequence information was “the \textit{most important} bit of essential new information that the person skilled in the art needed” to make rEpo because “[t]he other steps involved applying known methods.”\(^\text{22}\)

In other words, the TBA explained that crucial to the mass production of rEpo by recombinant means was the ‘discovery’ of the Epo gene and the elucidation of its genetic sequence. But, it is important to appreciate that \textit{the sequence information provided by Table VI} is not merely a reference to the ‘sequence information’ in the abstract, but is also a reference to the corresponding protein, for as the TBA acknowledged in \textit{T923/92 Genentech Inc v The Wellcome Foundation Limited & Others}\(^\text{23}\) “the skilled person would consider the reference to the chemical formula, that is, to the amino acid sequence, of a protein as having not merely an informational character, but as being \textit{a primary technical feature linked to the character and nature of the product}.”\(^\text{24}\) Therefore,
it must be understood that the amino acid sequence is nothing more than a biological description of Epo per se.

**Erythropoietin in the United States**

*Amgen, Inc. v Chugai Pharmaceutical Co. Ltd. and Genetics Institute, Inc – 1989 to 1991*

This series of cases was essentially a fight over who was the first true inventor. Both Amgen and Genetics Institute had filed patent applications that claimed essentially the same technology. Both had been granted US patents. Consequently, neither party was interested in attacking the validity of each other’s patent on the ground that the subject matter of the patents did not come within s.101 US Act. However, this mutual concession did not mean that the issue of ‘invention’ was decided by default; rather it meant that this issue of ‘invention’ was not the subject of judicial review.

Unfortunately this important fact has been lost on most legal commentators and so what developed was the perception that ‘isolated’ or ‘purified’ Epo was patentable subject matter in the United States. However, this mutual *inter partes* concession has benefited this analysis for the evidence was prepared with the issues of inventorship and infringement in mind and not with the ‘invention’ issue in mind. Consequently, the litigation presents an opportunity to use the findings without fear that the evidence upon which they are based was tainted with an ‘invention’ bias.


26 See for example B. Looney, *Should Genes Be Patented? The Gene Patent Controversy: Legal, Ethical, And Olicy Foundations Of An International Agreement*, (1994) 26 Law & Policy in International Business 231-272, 254 argues that “[u]nder Amgen, genes and gene sequences are likely patentable”; also J. Murray, *Owning Genes: Disputes Involving DNA Sequence Patents*, (1999) 75 Chi.-Kent. L. Rev. 231, footnote 86 which states “Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) (stating that ‘[a] gene is a chemical compound, albeit a complex one’), cert. denied, 502 U.S. 856 (1991)” in the context of this sentence: “A patent may be obtained for certain classes of invention, including chemical compounds like DNA molecules, only when particular statutory requirements are met; also R.S. Eisenberg, *Re-Examining The Role Of Patents In Appropriating The Value Of DNA Sequences*, (2000) 49 Emory L.J. 783, footnote 16 which states, “Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1959 (D. Mass. 1990) (‘The invention claimed in the ‘008 patent is not as plaintiff argues the DNA sequence encoding human EPO since that is a nonpatentable natural phenomenon ‘free to all men and reserved exclusively to none.’ ... Rather, the invention as claimed in claim 2 of the patent is the ‘purified and isolated’ DNA sequence encoding erythropoietin.’) (quoting Chakrabarty, 447 U.S. at 309).’” In the context of this sentence she explains, “[p]atents have thus issued on ‘isolated and purified’ DNA sequences, separate from the chromosomes in which they occur in nature, or on DNA sequences that have been spliced into recombinant vectors or introduced into recombinant cells of a sort that do not exist in nature”.
**Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc (The District Court)**

The first in the series was decided by the US District Court for the District of Massachusetts in December 1989.27

Amgen had alleged that both Chugai and Genetics Institute had infringed its patent. So prior to the trial an issue for Chugai, another party, was whether the rEpo it produced in Japan and exported to the United States infringed any of the Amgen patent claims, given that the patent contained no claims that arguably caught Chugai’s activities in the United States concerning rEpo.

**Motion for Summary Dismissal – Young J**

Young J, who heard the motion for summary dismissal brought by Chugai28 described the scope of the patent claims thus:

> There are 31 claims contained in the ’008 patent, and those claims, in essence, encompass the following inventions: 1) purified and isolated DNA sequences encoding erythropoietin; 2) DNA vectors for transporting such DNA sequences into host cells; and 3) host cells transformed or transfected with such DNA sequences.29

There were no claims to rEpo per se. This was relevant because in United States v. Studiengesellschaft Kohle30 it was held,

> A product patent gives the patentee the right to restrict the use and sale of the product regardless of how and by whom it was manufactured. A process patentee’s power extends only to those products made by the patented process. A process patent thus ‘leaves the field open to ingenious men to invent and to employ other processes.’ … A sale of a product made by a patented process does not itself infringe the patent; it is the unauthorized use of the process that infringes the patent.31

So there was apparently no claim to rEpo howsoever produced, only to rEpo produced using the claimed product components. It is worth noting at this juncture that this distinction was meaningless in 1984 for the simple reason that any recombinant technology producing rEpo at the

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29 Ibid, 106.
31 Ibid (Emphasis added).
time required the use of ‘host cells transformed or transfected with DNA sequences’ encoding Epo, that is claim 4.

Amgen’s response to this motion, although directed to other issues is very relevant to this Thesis. It countered Chugai’s argument by referring to claims 4 and 23 which were claims to the host cells transformed or transfected with a DNA sequence encoding Epo allowing the host cell to express Epo. According to Young J these claims were ambiguous because it was not clear whether what was covered was a ‘product’, namely the host cells or a ‘process’, namely the manner of transforming or transfecting the host cell allowing for the production of Epo. However, due to the application of ‘prosecution history estoppel’,\(^\text{32}\) he ruled that the claims did not permit a “process interpretation.”\(^\text{33}\) So what was covered by the patent were the host cells, as products, which naturally enough expressed rEpo having been transformed or transfected with a DNA sequence encoding Epo.

Chugai, however, did not use any host cells transformed or transfected with a DNA sequence encoding Epo within the United States. These cells were used in Japan but because there were insufficient facts “presently before the Court to permit a decision whether Chugai has infringed the product claims contained in the ’008 patent,”\(^\text{34}\) Young J could not conclusively rule on Chugai’s motion. Nevertheless, he was prepared to venture an opinion “that if” production of Epo was conducted by it using those cells in the United States, “such use would constitute an infringement of the ’008 patent.”\(^\text{35}\) The implication of this opinion was clear. If Chugai manufactured rEpo in the United States using host cells coming within claims 4 and 23, then it would infringe those claims. As far as the importation and sale in the United States of Chugai Japanese produced rEpo went, Young J was not in a position to decide the issue, although he did refer to Section 337 of the Tariff Act of 1930 suggesting that it was arguable that Chugai’s activities in the United States could violate this law if a product manufactured in a foreign country using a US patented ‘process’ was imported into the United States.

In other words, Amgen did not need a product claim to rEpo nor a process claim to the manufacture of rEpo in order to monopolise the production of rEpo in the United States. All it

\(^{32}\) Under the doctrine of prosecution history estoppel, a patentee is precluded from obtaining a claim construction in an infringement action where such an interpretation would ‘resurrect subject matter surrendered during prosecution of his patent application.’ Thomas & Betts Corp. v. Litton Systems, Inc., 720 F.2d 1572, 1579, 220 U.S.P.Q. (BNA) 1 (Fed. Cir. 1983).

\(^{33}\) “[T]his Court rules that the ’008 patent does not contain any process claims; specifically, the ’008 patent does not contain a process claim covering the process of manufacturing recombinant erythropoietin,” per Young J, Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc (1989) 706 F. Supp. 94, 110.

\(^{34}\) Ibid.

\(^{35}\) Ibid.
needed was a claim to an essential component, namely the host cells defined in claim 4 and 23. The preliminary skirmish revealed that Amgen constructed the claims in such a way deliberately to avoid an argument that it was claiming uEpo or rEpo \textit{per se}, with the knowledge that given the state of recombinant technology at the time, that a claim to the components of Epo or Epo recombinant production was tantamount to capturing within the ambit of the patent’s monopoly rEpo howsoever made.

\textit{Trial – District Court}

Once the case went to trial other facts emerged, the most relevant for the purposes of this Thesis is the similarity between rEpo and uEpo. The Court found that they were identical ‘products’. It held,

\ldots the overwhelming evidence, including Amgen’s own admissions, establishes that uEPO and rEPO are the same product. The EPO gene used to produce rEPO is the same EPO gene as the human body uses to produce uEPO. (Tr. 25, 14). The amino acid sequences of human uEPO and rEPO are identical. (Chugai’s Req. Adm. to Amgen No. 436; Egrie Dep. Tr. 2-165). There are no known differences between the secondary structure of rEPO produced in a CHO cell and EPO produced in a human kidney. (Chugai’s Req. Adm. to Amgen No. 437)…. Amgen’s own scientists have concluded that by all criteria examined, rEPO is the ‘equivalent to the natural hormone.’ In particular, they noted that the uEPO preparation had an equivalent biological activity in the RIA and bioassays. (DX 323, pp. 217-218). Amgen’s Product License Application to the FDA states that all ‘physical tests performed on both r-HuEPO and u-HuEPO . . . show these proteins to be indistinguishable’; that r-HuEPO and u-HuEPO are ‘indistinguishable in their biological and immunological properties’; and that testing ‘confirms the similarity of the secondary and tertiary protein structures of r-HuEPO and u-HuEPO as predicted by the equivalence of their immunological and biological activities.’ (DX 328, pp. 762, 782, 789).\textsuperscript{36}

This finding is not particularly surprising given that the objective was to produce rEpo with the same \textit{in vivo} biological activity as uEpo. Naturally, it followed that if the DNA sequence coding for uEpo, as derived from the natural gene, is first isolated and purified and then inserted into a host cell, that the end result would be rEpo identical to uEpo. Of course, in the context of an inventorship and infringement battle, Amgen never disputed the finding in the subsequent appeal to the CAFC. But in the context of this analysis, this finding is particularly significant because it

Chapter 4: Case Study 1 – The Patenting of Erythropoietin

confirms that neither rEpo nor the isolated Epo gene displayed “markedly different characteristics” to uEpo nor the corresponding natural Epo gene.

Given that Chakrabarty made it crystal clear that a natural phenomenon was not an ‘invention’ and that to be a new and useful manufacture or composition of matter for the purposes of s.101 US Act the natural phenomenon had to be subjected to human intervention so that it displayed markedly different characteristics from any found in nature, the findings that “overwhelming evidence … establishes that uEpo and rEpo are the same product” and that “rEpo is the ‘equivalent to the natural hormone’” would have been fatal to this patent had s.101 US Act been in contention.

True enough, the claims were not to rEpo per se, but were to isolated and purified DNA sequences encoding Epo and other components, such as host cells transformed or transfected with a DNA sequence derived from the Epo gene, but given firstly, that the end result of the use of these components in any recombinant process as understood in 1984 was rEpo; secondly, that the components were independently useless outside of the recombinant process itself and thirdly, that rEpo was the real subject of the “battle over turf,” it is absurd to consider these components separately from the process to which they belong.

In any event, even if considered independently, the host cells of claim 4 and 24 did not meet the criteria of Chakrabarty. True it is that the host cells were modified by the insertion of a vector containing isolated DNA encoding Epo, something foreign to them. True it is that as so modified they were artificial. True it is that as artificial host cells they expressed a protein, rEpo, being a substance that they would never produce in nature. Even so, the protein which was expressed by the host cell was a substance that was identical in every material particular to a substance already existing in nature. More to the point, the expressed protein did not possess any characteristics or properties that distinguished it from uEpo. It did not behave within the human body in a way that distinguished it from uEpo. It did not perform a function that distinguished it from uEpo. Rather, the host cells acted as surrogates through which a naturally occurring substance could be

37 “… the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.” Diamond, The Commissioner of Patents v Chakrabarty (1980) 447 U.S. 303, 310 (Emphasis added).
replicated identically\(^{40}\) using isolated DNA that, although artificial, was identical to that produced by the human gene.\(^{41}\)

It is this aspect of the technology in issue that distinguishes the facts in this case from those in *Chakrabarty*. In *Chakrabarty* the artificial bacterium performed a completely new and unknown natural function in degrading crude oil. Not only was this characteristic foreign to the natural bacterium but it was foreign to nature.\(^{42}\) There was no microorganism or cell known to nature that had the capacity to perform the function that the artificial bacterium could perform. That was not the case with respect to Epo. Not only was Epo a known substance with known properties, but it was known that the human body contained cells that housed the blueprint for Epo. Therefore, the capability of cellular components to produce Epo was not foreign to nature as was the capability of bacteria to degrade crude oil. Therefore, like the seeds in *Pioneer* that produced corn plants that displayed enhanced characteristics, for the Epo recombinant process to be patentable subject matter it was necessary that rEpo be superior in its *in vivo* performance to some significant degree as compared to uEpo.

This distinction is absolutely critical and it is not insignificant. It goes to the very heart of the reasoning in *Chakrabarty* because there the Supreme Court explained that natural phenomena are prohibited from being considered as ‘inventions’ within the *US Act* and Epo, no matter how it is produced, is a natural phenomenon.

*Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc (The CAFC) – 1991*

On appeal, ‘invention’ was not in issue, but Lourie J, who wrote the CAFC’s decision held that “… neither Fritsch nor Lin invented Epo or the Epo gene.”\(^{43}\) Obviously, the CAFC was not concerned with who was the ‘inventor’ as much as it was concerned with who was the first ‘discoverer’. It is to be remembered that under s.100 *US Act* there is no distinction between ‘invention’ and ‘discovery’ in terms of the process leading to patentable subject matter or ‘invention’ within s.101 *US Act*. This is why, s.100 *US Act* defines ‘invention’ to mean ‘invention or discovery’. Therefore, it was irrelevant to the inventorship issue whether of these two scientists had actually ‘invented’ either Epo or the Epo gene. What was relevant, however, was the process

\(^{40}\) “… that uEPO and rEPO are the same product. … The amino acid sequences of human uEPO and rEPO are identical.” *Ibid.*

\(^{41}\) “The EPO gene used to produce rEPO is the same EPO gene as the human body uses to produce uEPO.” *Ibid.*

\(^{42}\) “A microbiologist filed a patent application relating to his invention of human-made, genetically engineered bacteria capable of breaking down multiple components of crude oil, *a capability possessed by no naturally occurring bacteria.*” (Emphasis added) as per the Summary of Diamond, the Commissioner of Patents v Chakrabarty (1980) 447 U.S. 303 (US Supreme Court).

\(^{43}\) *Ibid*, 1206.
that led them to the discovery of the Epo gene and the elucidation of its genetic sequence. The issue for the CAFC was who got there first, Dr. Fritsch or Dr. Lin?  

In resolving the issue of inventorship, Lourie J focused on the experimental route that was devised and adopted by the two competing scientists in the early eighties to clone and sequence the Epo gene, as it was this work that was identified by the Court as being the crucial step to the formation of “a complete mental conception of a purified and isolated DNA sequence encoding EPO.” The Court was compelled to answer the question using the traditional thresholds of “conception” and “reduction to practice” even though neither had ‘invented Epo or the Epo gene’. Of course, it undertook this examination without first considering whether the subject matter was in fact ‘an invention’ within the meaning of s. 101 US Act.

However, resolving this issue using these traditional concepts was not straightforward given the nature of the technology in issue. The solution which the CAFC applied was the ‘simultaneous conception and reduction to practice’ concept. In this regard, the legal maxim “hard cases make

44 That issue, of course, had to be considered in terms of s. 101 US Act so that the discovery process could be assessed in terms of the end result, namely a new and useful composition of matter. But, because s. 101 was not in issue it was assumed that this part of the ‘invention’ equation had been satisfied.

45 Under U.S. patent law the right to claim Epo, assuming it was patentable subject matter, depended on which scientist was the first to conceive and reduce to practice “the invention”.

46 It followed that once EPO or a fragment of it had been cloned, that the genetic sequence of EPO would be obtained. Lourie J. explained the significance of this step. “As Dr. Sadler, an expert for GI, testified in his deposition, ‘[y]ou have to clone it first to get the sequence.’ In order to design a set of degenerate probes, one of which will hybridize with a particular gene, the amino acid sequence, or a portion thereof, of the protein of interest must be known. Prior to 1983, the amino acid sequence for EPO was uncertain, and in some positions the sequence envisioned was incorrect.” [927 F.2d 1200 at 1206 [2] line 15-26.]

47 As neither scientist had actually invented Epo or the Epo gene, Lourie J. explained that to be able to make a claim to the Epo gene the inventor had to have, “a complete mental conception of a purified and isolated DNA sequence encoding Epo and a method for its preparation, in which the precise identity of the sequence is envisioned, or in terms of other characteristics sufficient to distinguish it from other genes”. [927 F.2d 1200 at 1206 [2] line 27-31.]

48 “Conception is the ‘formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.’ Hybritech, 802 F.2d at 1376, 231 U.S.P.Q. at 87 (citing 1 Robinson on Patents 532 (1890)); Coleman v. Dines, 754 F.2d 353, 359, 224 U.S.P.Q. (BNA) 857, 862 (Fed. Cir. 1985) (citing Gunter v. Stream, 573 F.2d 77, 80, 197 U.S.P.Q. (BNA) 482, 484 (CCPA 1978)). Conception requires both the idea of the invention's structure and possession of an operative method of making it. Oka v. Youssefieh, 849 F.2d 581, 583, 7 U.S.P.Q.2d (BNA) 1169, 1171 (Fed. Cir. 1988)” per Lourie J, Ibid, 1206.

49 “Reduction to use within meaning of patent law need not necessarily be commercial use; process is reduced to practice within meaning of patent law when it is successfully performed; and composition of matter when it is completely composed.” See Corona Cord Tire Co. v Dovan Chemical Corp. (1928) 276 US 358, 72 L Ed 610, 48 S Ct 380.

50 Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc (1991) 927 F.2d 1200, 1206 (CAFC). “In some instances, an inventor is unable to establish a conception until he has reduced the invention to practice through a successful experiment. This situation results in a simultaneous conception and reduction to practice. See 3 D. Chisum, Patents § 10.04[5] (1990). We agree with the district court that that is what occurred in this case.”
bad law” applies to this case.\textsuperscript{51} The problem for the Court was the fact that even if the act of isolating the Epo gene provided a pathway to the nucleotide sequence of the Epo gene, because “[y]ou have to clone it first to get the sequence,”\textsuperscript{52} once the Epo gene had been cloned the sequencing work was not only routine, but the DNA sequence encoding the Epo gene \textit{per se} was intrinsically natural.

Nevertheless, the CAFC had to resolve the inventorship dispute one way or another. It was not able to decide that neither scientist was entitled to be the ‘inventor’ and so it was compelled to apply precedential law which concerned patents that related more to the realm of traditional manufacture rather than to molecular biology in order to justify its election.

One of the earliest cases that explains the threshold requirement for “invention” is \textit{Agawam Co. v Jordan}.\textsuperscript{53} This case was decided in 1869 and stands for the proposition that “[h]e who first perfected [the] thing is [the] inventor although others might have experimented with [the] idea”.\textsuperscript{54} Another important case is \textit{Corona Cord Tire Co. v Dovan Chemical Corp}.\textsuperscript{55} This case was decided in 1928 and stands for the proposition that “[r]eduction to use within [the] meaning of patent law need not necessarily be commercial use; process is reduced to practice within meaning of patent law when it is successfully performed; and composition of matter when it is completely composed.”\textsuperscript{56} Yet another is \textit{Toner v Sobelman}\textsuperscript{57} decided in 1949. This case stands for the proposition that “[i]nvention involves mental conception or idea and its embodiment in physical form reduced to practice, actually or constructively; it is intangible existing independently of law and tangible form which embodies it.”\textsuperscript{58} Finally, but not exhaustively, there is the case of \textit{Popeil Bros., Inc. v Schick Electric, Inc.}\textsuperscript{59} decided in 1972. This case stands for the proposition that “[i]nvention is not completed until there has been reduction to practice, either actual reduction to practice by embodying invention into practical form as by building working model or by actually

\textsuperscript{51} “It may, of course, be objected that the adoption of a hard-and-fast rule to be applied to all cases will sometimes produce what appears to be some hardship but, if so, it should also be recalled that hard cases make bad law.” \textit{McHale v Watson} 115 CLR 199 per Menzies J (High Court of Australia).
\textsuperscript{52} \textit{Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc} (1991) 927 F.2d 1200, 1206. Here the Court cited the evidence of one of the expert witnesses called by Genetics Institute, Dr. Saddler.
\textsuperscript{53} \textit{Agawam Co. v Jordan} (1869) 74 US 583, 7 Wall 583, 19 L Ed 177.
\textsuperscript{54} LexisNexis US Patent Law s.101 para 124.
\textsuperscript{55} \textit{Corona Cord Tire Co. v Dovan Chemical Corp.} (1928) 276 US 358, 72 L Ed 610, 48 S Ct 380.
\textsuperscript{56} LexisNexis US Patent Law s.101 para 125.
\textsuperscript{57} \textit{Toner v Sobelman} (1949, DC Pa) 86 F Supp 369, 81 USPQ 304.
\textsuperscript{58} LexisNexis US Patent Law s.101 para 126.
\textsuperscript{59} \textit{Popeil Bros., Inc. v Schick Electric, Inc.} (1972, ND Ill) 356 F Supp 240, 176 USPQ 101, affd (1974, CA7 Ill) 494 F2d 162, 181 USPQ 482.
practising process of invention is directed to method or process, or constructive reduction to practice by filing patent application thereon.”

It was not until the late 1970s that US courts had to apply the concept of invention to something that was the result of ‘molecular biology’. In 1980 Chakrabarty made it clear that ‘invention’ of a live but artificial bacterium that was significantly different to its natural counterpart in that it performed a function foreign to nature was an ‘invention’ within s.101 US Act. However, in this appeal the CAFC had no cause to consider the legality of the subject matter of the competing patents in terms of resolving the inventorship dispute. It was therefore assumed that the subject matter was within s.101 US Act. Of course, whether it was or was not was another issue entirely. The point is, that the CAFC never decided the issue in this appeal.

In these circumstances it is understandable that the CAFC looked to what it perceived to be an analogous technology in explaining which of the two inventors took precedence. The Court opined, “[a] gene is a chemical compound, albeit a complex one”. The CAFC accordingly reached for the traditional chemistry “hook” on which to hang the biotechnology “hat”. Therefore, whoever ‘formulated’ the chemical formula of the Epo gene was the first true inventor.

This Thesis argues that the CAFC was wrong in using the chemistry analogy because it was not then, nor is it today, appropriate for the reasons discussed in Chapter 3.

Despite these differences between chemistry and biotechnology, the CAFC ignored them and decided the inventorship dispute with these two sentences:

The invention recited in claim 2 is a ‘purified and isolated DNA sequence’ encoding human EPO. The structure of this DNA sequence was unknown until 1983, when the gene was cloned by Lin; Fritsch was unaware of it until 1984.

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61 Ibid, 1206.

62 See R.S. Eisenberg, Re-Examining The Role Of Patents In Appropriating The Value Of DNA Sequences 49 Emory L.J. 783, 784-785. She explains, “The patent system, which inevitably requires years to resolve even routine matters, has so far focused primarily on the discoveries of the 1980s. DNA sequences that were the subject of patent claims in that era typically consisted of cloned genes that enabled the production of proteins through recombinant DNA technology. Patents on the genes encoding these proteins promised exclusivity in the market for the protein itself, equivalent to the protection that a pharmaceutical firm obtains by patenting a new chemical compound that can be used as a drug. From this perspective, patents on DNA sequences seemed analogous to patents on new chemical entities. The Court of Appeals for the Federal Circuit accordingly turned to prior cases considering patents on chemicals in resolving disputed issues about how patent law should apply to DNA sequences.”

Accordingly, the Court considered that knowledge of the DNA sequence of the Epo gene was the ‘mental conception and reduction to practice’ of the ‘invention’ and it used this ‘knowledge’ of the ‘DNA sequence’ to distinguish Dr. Lin’s work from Dr. Fritsch’s work. The Court elaborated,

... until Fritsch had a complete mental conception of a purified and isolated DNA sequence encoding EPO and a method for its preparation, in which the precise identity of the sequence is envisioned, or in terms of other characteristics sufficient to distinguish it from other genes, all he had was an objective to make an invention which he could not then adequately describe or define. ... Fritsch’s conception of a process had to be sufficiently specific that one skilled in the relevant art would succeed in cloning the EPO gene. See Coleman, 754 F.2d at 359, 224 U.S.P.Q. at 862. Clearly, he did not have that conception because he did not know the structure of EPO or the EPO gene. 64

The Court equated the ‘isolation’ of the Epo gene with the ‘conception’ of the invention because it was this step that in the Court’s opinion, led to the “purified and isolated DNA sequence encoding EPO”. 65 The Court considered that having the general idea of cloning the Epo gene was insufficient to establish invention or to establish a claim to priority over the invention and concluded,

Based on the uncertainties of the method and lack of information concerning the amino acid sequence of the EPO protein, the trial court was correct in concluding that neither party had an adequate conception of the DNA sequence until reduction to practice had been achieved; Lin was first to accomplish that goal. 66

According to the Court, if the cloning of the Epo gene was the conception then its sequencing was the reduction to practice. 67

In the final analysis, the CAFC resolved the contest in favour of Dr. Lin and invalidated the patent granted to Genetics Institute in its entirety. However, whilst this decision may have resolved the issue inter parties, the litigation itself did nothing to resolve the question of whether the invention of either patent was patentable subject matter within s.101 US Act. Of course, if the District Court and the CAFC had been free to consider the patentability of the subject inventions, they would have been able to question the inventors claims to the conception and reduction to practice of the invention. In this regard, the courts would have been able to deduce that the claimed invention

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64 Ibid, 1206-1207.
65 “As Dr. Sadler, an expert for GI, testified in his deposition: ‘You have to clone it first to get the sequence.’” Ibid, 1206.
was no more than a claim to information which was stored biologically, as opposed to
electronically, and that a comparison between the “isolated and purified” information and the
“natural” information would have revealed that the information was identical. In this situation,
even if Dr. Lin was the first to know the DNA sequence of the gene encoding human Epo, that
knowledge could arguably never amount to or contribute to an act of ‘invention’ within s.101 US
Act because the DNA sequence and rEpo were not new and useful compositions of matter within
the meaning of Chakrabarty but were identical to their natural equivalents. It follows that one
cannot in the context of s.100 US Act invent nor discover something that is not patentable subject
matter within s.101 US Act.

Sir Isaac Newton explained the force of gravity using mathematics, but this did not mean that he
had conceived and reduced to practice the ‘invention’ of gravity. Gravity was always there. What
he did, and it was certainly meritorious scientific work, was to explain this force in a way that it
could be measured. The same can be said for the work of Dr. Lin. The DNA sequence encoding
human Epo was not his creation. It was always there, but the genetic sequence was unknown. Dr.
Lin’s work was meritorious, and as a result, the genetic sequence of the Epo gene was elucidated
providing a better understanding of Epo, but the Epo gene sequence was not truly something that
he conceived and reduced to practice.

Plainly, the reason that s. 101 US Act was not in issue in this case was that both parties had been
granted patents to effectively the same invention and the issue was like a two edged sword as
neither party was prepared to raise it against the other for fear of striking down the validity of their
own patent.

_Amgen Inc., v Hoechst Marion Roussel, Inc. (now known as Aventis Pharmaceuticals Inc.) and
Transkaryotic Therapies, Inc_

_CAFC - 2003_

The latest in this series of cases is _Amgen Inc., v Hoechst Marion Roussel, Inc. (now known as
Aventis Pharmaceuticals Inc.) and Transkaryotic Therapies, Inc_. In this case the CAFC revisited
the Amgen Epo invention but not with respect to US 4,703,008, the original patent, but in respect
to US 5,547,933; 5,618,698; 5,621,080; 5,756,349 and 5,955,422. As in the earlier series of cases,
first the issue of ‘invention’ within s.101 US Act was not an _inter parties_ issue and second, the
CAFC accepted that,
The rEpo so recovered has the same or similar amino acid sequences and biological properties as naturally occurring human Epo, but differs in its “glycosylation,” i.e., in the patterns of branched carbohydrate chains that attach to the protein. 69

The proviso concerning the ‘glycosylation’ of the protein is to be noted because without further explanation, it might be thought that this difference produced a protein with markedly different characteristics to any found in nature. However, the CAFC accepted that “the specification of the ’933 patent does not direct those of ordinary skill in the art to a standard by which the appropriate comparison can be made,”70 and so concluded that uEpo represented a moving target. This was the “conundrum” which the lower District Court referred to and which the CAFC held was fatal to the validity of US 5,547,933. 71 Accordingly, the Court held that as the difference in glycosylation, between uEpo and rEpo was not measurable by any objective standard and so the term was meaningless and the claims invalid.72 What this meant was that the CAFC accepted the earlier 1989 findings of the District Court concerning the ’008 patent, that uEpo and rEpo were identical products.

The appeal involved five Amgen patents. Of these, one was held invalid. The others were held valid and two of them infringed. However, this appeal did not conclude the case. The CAFC remitted the case back to the lower District Court for further deliberation.73

Given that the case did not involve a consideration of s.101 US Act, the parties in this series of cases did not prepare their evidence with Chakrabarty in mind. Accordingly, as in the earlier series of cases, the evidence produced had a higher probative value with respect to the issue of ‘invention’ than it would otherwise have had.

The claims to these patents are important in light of Chakrabarty and provide a suitable starting point for this analysis.

First, US 5,547,933 granted on August 20, 1996.

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69 Ibid., 1321.

70 Ibid, 1341

71 Ibid, 1342. “One cannot logically determine whether an accused product comes within the bounds of a claim of unascertainable scope. Accordingly, … the finding that the ’933 patent is invalid under § 112 is affirmed.” 1342.

72 Ibid, 1343. “… a claim is indefinite under § 112 ¶ 2 if it is ‘insolubly ambiguous, and no narrowing construction can properly be adopted.’ Exxon Research & Eng’g Co. v. United States, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001); ‘It is not our function to rewrite [indefinite] claims to preserve their validity,’ Allen Eng’g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1349, 63 USPQ2d 1769, 1776 (Fed. Cir. 2002). Applying these legal maxims to the facts of this case, we agree with the district court that the claims requiring “glycosylation which differs” are invalid for indefiniteness.”

73 The District Court as at September 2004 has reserved its decision.
Claim 1:

A non-naturally occurring erythropoietin glycoprotein product having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells and having glycosylation which differs from that of human urinary erythropoietin.

Second, US 5,618,698 granted on April 8, 1997;

Claim 4:

A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps: a) growing, under suitable nutrient conditions, vertebrate cells comprising promoter DNA, other than human erythropoietin promoter DNA, operatively linked to DNA encoding the mature erythropoietin amino acid sequence of FIG. 6; and b) isolating said glycosylated erythropoietin polypeptide expressed by said cells

Third, US 5,621,080 granted on April 15, 1997;

Claim 2:

An isolated erythropoietin glycoprotein having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells, wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6 and is not isolated from human urine.

Fourth, US 5,756,349 issued on May 26, 1998;

Claim 1

Vertebrate cells which can be propagated in vitro and which are capable upon growth in culture of producing erythropoietin in the medium of their growth in excess of 100 U of erythropoietin per 10^6 cells in 48 hours as determined by radioimmunoassay, said cells comprising non-human DNA sequences that control transcription of DNA encoding human erythropoietin.

Fifth, US 5,955,422 granted on September 21, 1999;

Claim 1:

A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.

What is immediately apparent from the essential features of these claims is:
Firstly, each of these claims define rEpo or a process for its production or a component in its production with the use of the provisos ‘non-naturally occurring’, ‘isolated,’ ‘purified from mammalian cells grown in culture,’ ‘glycosylated’ and ‘not isolated from human urine.’ Clearly, their purpose is to distinguish rEpo from uEpo but the most obvious question is this: How can rEpo be distinguished from uEpo when there exists “overwhelming evidence, including Amgen’s own admissions, establishing that uEPO and rEPO are the same product”? 74

Secondly, claim 1 of the ’933 patent, claim 2 of the ’080 patent and claim 4 of the ’698 patent define rEpo by the characteristic of “causing bone marrow cells to increase production of reticulocytes and red blood cells,” but as this is the ‘key characteristic’ 75 of uEpo, how does rEpo display markedly different characteristics from uEpo? 76

Thirdly, claim 2 of the ’080 patent and claim 4 of the ’698 patent define rEpo by the criteria that it has (a) “the mature erythropoietin amino acid sequence of FIG. 6 and (b) is not isolated from human urine,” but how do these criteria enable the distinction of uEpo when “Amgen’s Product License Application to the FDA states that all ‘physical tests performed on both r-HuEPO and u-HuEPO … show these proteins to be indistinguishable’; that r-HuEPO and u-HuEPO are ‘indistinguishable in their biological and immunological properties’; and that testing ‘confirms the similarity of the secondary and tertiary protein structures of r-HuEPO and u-HuEPO as predicted by the equivalence of their immunological and biological activities’”? 77

The answer to each of these rhetorical questions is obvious. As rEpo and uEpo proteins are (a) indistinguishable, (b) display the same key characteristics by performing the same in vivo biological function, and (c) are derived from a nucleotide sequences that are substantially identical to that of the natural Epo gene, the only conclusion that can be reached is that neither rEpo nor the rEpo components are ‘inventions’ with s.101 US Act. True it may be that rEpo and its manufacturing components are artificial, but as explained in Chakrabarty that is not enough to make them ‘inventions.’ The overwhelming evidence is that the relevant isolated DNA derived from the Epo gene and rEpo are no different to the corresponding natural DNA of the Epo gene and uEpo.

75 Ibid.
76 Diamond, the Commissioner of Patents v Chakrabarty (1980) 447 US 303, 310 (US Supreme Court).
Chapter 4: Case Study 1 – The Patenting of Erythropoietin

The TKT technology

In the District Court and before the CAFC Transkaryotic Therapies Inc (TKT) argued that the rEpo produced by the use of its method did not infringe any of the patent claims because it did not use the recombinant technology described in the patents. Instead, its ‘innovative’ process used “a viral promoter and certain other DNA” that did not encode Epo. Essentially, the TKT process expressed rEpo by “switching on” the Epo gene by the use of a “targeted location upstream from the native Epo gene” or endogenous DNA not by the use of a host cell transfected with exogenous DNA of the Epo gene.

The importance of this argument in the context of this analysis lies in Amgen’s response to it. Amgen argued that none of the claims contain any reference to either exogenous or endogenous DNA. The CAFC agreed with Amgen’s interpretation. It held,

Guided by our principles of claim construction, we agree with the district court that TKT improperly seeks to import the “exogenous” limitation into the claims. The plain meaning of the claims controls here, and they plainly are not so limited. The statement that the invention is “uniquely characterized” by the expression of exogenous DNA sequences does not impel us to accept TKT’s position when the asserted claims do not contain such an express limitation. In fact, TKT’s position is undermined by the doctrine of claim differentiation, as reference to other claims clearly indicates that Amgen did not intend to limit the invention to the use of exogenous DNA.

Furthermore, TKT argued that the claims in the ’080, ’349 and ’422 patents were not claims to rEpo per se. Amgen disagreed, as did the CAFC. Relevantly, in dismissing this argument the Court held,

… we are not convinced that the source limitations in the asserted claims convert the claims into anything other than product claims. As to the ’080 patent, the “non-naturally occurring” limitation in claims 3 and 4 merely prevents Amgen from claiming the human EPO produced in the natural course. By limiting its claims in this way Amgen simply avoids claiming specific subject matter that would be unpatentable under § 101. This court has endorsed this approach, recognizing that patentees can use negative limitations such as “non-human” and “non-natural” to avoid rejection under § 101. … Similarly, the “not isolated from human urine” limitation in claims 2 and 4 of the ’080 patent simply requires that the claimed EPO, however made, be obtained from a source other than human urine. Each of these limitations

78 Ibid.
79 Ibid.
80 Ibid.
only excludes human EPO from specific sources and does not restrict the claimed EPO to that produced from any particular source or by any particular method. In sum, claims 2, 3, and 4 of the ‘080 patent remain broadly drawn to the described “erythropoietin glycoprotein” or “pharmaceutical composition” produced by any method, or obtained from any source, other than those specifically excluded. As to the ‘422 patent, the limitation “purified from mammalian cells grown in culture” in claim 1 clearly limits the source of the EPO used in the claimed “pharmaceutical composition.” The limitation only speaks to the source of the EPO and does not limit the process by which the EPO is expressed. Rather, the claim is broadly drawn to a “pharmaceutical composition” having certain elements, one of those being EPO “purified from mammalian cells in culture.”

What this obiter dictum implies is that a patentee, by merely excluding “human” versions of Epo in the claim language overcomes the prohibition in s.101 US Act directed to the patentability of natural phenomena, completely ignoring the reality that such a limitation is meaningless. This passage from the decision is extraordinary and is an excellent example of the logic which Peter Drahos describes as being “analytically weak.”

To suggest that “Amgen simply avoids claiming specific subject matter that would be unpatentable under § 101”, is not only a legal fiction but is irreconcilable with the District Court’s finding in its 1989 decision that “uEPO and rEPO are the same product.” Logically, if uEpo is unpatentable because it is a natural phenomenon then it follows that rEpo, which is identical, is also unpatentable and so must be the components and process of its production for otherwise the implicit prohibition in s. 101 US Act is meaningless. This is especially true in light of the CAFC’s own finding that “Amgen’s invention is not the location of the control sequences and Epo DNA in relation to the [host] cell, but rather the production of human Epo using those sequences.”

Arguably, unless the prohibition in s. 101 US Act captures the processes that are responsible for the production of a natural phenomena or its equivalent, the patent drafting solution advocated by the ‘patent community’ is nothing more than “a lawyer’s trick.”

82 Ibid (emphasis added).
83 P. Drahos, Biotechnology Patents, Markets And Morality, (1999) 21(9) EIPR 441-44. Drahos explains “A crucial aspect to the expansion of the patenting in biotechnology has been the development of juridical arguments and theories that have enabled applicants for biotech patents to overcome existing bars. One of the interesting things is that, while these arguments are often analytically weak, they have been readily accepted by the patent community in the name of adapting the patent system to changing circumstances of technology and innovation.”
85 Cf: R. Eisenberg explains, “This is not simply a lawyer’s trick, but a persuasive response to the intuition that patents should only issue for human inventions.” See R. S. Eisenberg, Re-Examining The Role Of Patents In Appropriating The Value Of DNA Sequences (2000) 49 Emory L.J. 783-800, 786.
Therefore, according to this CAFC decision, a human protein such as Epo can come within the scope of a patent claim so long as the DNA source is not ‘human’ DNA, but is isolated or purified, an act which it argues transforms ‘human’ DNA into ‘non-human’ DNA even though the product of the ‘non-human’ DNA is identical in all material respects to the product of the human DNA. Frankly, this logic is not only contorted but is completely inconsistent with *Chakrabarty*. The CAFC may have “endorsed this approach” but the Supreme Court has not.

Peter Drahos has explained that “[o]ne way in which the potential problems of the invention/discovery distinction have been overcome is to embark on a re-characterisation strategy” where “[g]enes that have been discovered in nature when isolated and purified can no longer be said to exist in nature and may therefore be regarded as inventions.”

Arti Rai has pointed her finger at the CAFC. She argues that the “[r]esponsibility for the biotechnology race rests squarely with the CAFC” because of its “treatment of DNA-based inventions as just another species of chemical compound.” Although she makes this allegation in the context of the ‘inventive step’ parameter and not the ‘invention’ parameter, her thesis that the CAFC has misunderstood the nature of genetic sequences and their role in the production of proteins, is relevant to the issue of ‘invention’ because there is an obvious relationship between the ‘invention’ *per se* and the inventive step of the ‘invention.’ Accordingly, if it is assumed that an isolated genetic sequence and an isolated protein is patentable subject matter, then the obvious question is this: What step did the inventor take in arriving at the ‘invention’?

The standard ‘patent community’ answer to this question is that while the inventor did not invent the natural protein and gene, the ‘invention’ is not the natural protein and gene, but is the artificial protein and gene and these are only possible because (a) the inventor cloned the gene, thereby isolating it, (b) elucidated its genetic sequence and (c) used known recombinant techniques to mass produce an isolated or pure form of the protein.

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86 “By limiting its claims in this way Amgen simply avoids claiming specific subject matter that would be unpatentable under § 101. This court has endorsed this approach, recognizing that patentees can use negative limitations such as “non-human” and “non-natural” to avoid rejection under § 101.” Part II Section A, Amgen Inc., v Hoechst Marion Roussel, Inc. (now known as Aventis Pharmaceuticals Inc.) and Transkaryotic Therapies, Inc., (2003) 314 F.3d 1313 (CAFC).


88 Ibid.


90 Ibid.

91 Ibid.

This answer is not a lie nor is it ‘a lawyer’s trick,’ comments Rebecca Eisenberg. But is it not? The fallacy in the argument lies in its failure to acknowledge that the artificial gene and protein is firstly identical or practically identical so as to be indistinguishable from the natural versions and secondly, that the utility of the artificial gene and protein is not in terms of any enhancement or improvement over the natural versions themselves, either within the human body or as part of some pharmacological substance taken in by the human body. Rather, the artificial gene and the protein have no utility beyond the natural versions. The utility lies, not in the artificial protein, that is, the ‘fruit’ of the gene, but in the in the mass production of the artificial protein by way of a standard and routine process. The real usefulness is therefore a by-product of the process employed to produce the artificial protein not a by-product of the artificial protein per se. It is at this juncture that the answer unravels because the recombinant methodology that has been employed in most, if not all cases, has been scientifically routine since the mid 1970s. The breakthrough for the biotechnology industry came in the realisation that recombinant technology had a general application in terms of the production of isolated or purified proteins. Once this breakthrough became part of scientific armoury of the microbiologist, the search for genes began in earnest.

Rebecca Eisenberg argues that the ‘patent community’s’ logic is part of a long standing practice. She explains,

It prevents the issuance of patents that take away from the public things that they were previously using (such as the DNA that resides in their cells), while allowing patents to issue on new human manipulations of nature. Those of us who simply use the DNA in our own cells, as our ancestors have been doing for generations, should not and need not worry about patent infringement liability. On the other hand, those of us who get injections of recombinant insulin or erythropoietin should in fairness expect to pay a patent premium to the inventors who made these technological interventions possible.

Her argument is predicated on the basis that these substances are ‘inventions’, when in law they arguably are not. Her thesis that it is inequitable not to reward those that have made these proteins readily available is not unreasonable as a matter of equity, but it is as a matter of patent law. She assumes that the only form of intellectual property protection is the patent right while at the same time casting doubt on its suitability. She explains that “recent advances in DNA sequencing raise

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93 R. S. Eisenberg, Re-Examining The Role Of Patents In Appropriating The Value Of DNA Sequences (2000) 49 Emory L.J. 783-800, 786.
95 R. S. Eisenberg, Re-Examining The Role Of Patents In Appropriating The Value Of DNA Sequences (2000) 49 Emory L.J. 783-800, 786.
Chapter 4: Case Study 1 – The Patenting of Erythropoietin

the question of patent eligibility in a new way that courts have yet to address,” suggesting that the time may have arrived to consider a form of intellectual property protection beyond the “‘bricks and mortar’ world” which “[t]he patent system was designed to serve.” She concludes, that “it would be foolish to assume that it can meet the changing needs of the information economy simply by expanding the categories of subject matter that are eligible for patent protection.”

Her conclusion is undoubtedly correct, but this Thesis disagrees with her timing. The point of reconsideration was reached in the late 1970s.

Arti Rai argues that the logic that supports the inventive step of the traditional chemical compounds does not apply to genetic sequences and their corresponding proteins for “[a]lthough DNA sequences represent chemical compounds, they are more fundamentally carriers of information [with the result that] the current state of scientific knowledge renders the DNA sequence for a given protein obvious once the protein’s complete or partial amino acid sequence is known.” This is because with the partial amino acid sequence comes the ability to ‘isolate’ the gene that codes for that protein, thereby rendering the step of isolation of the complete gene and its genetic sequence obvious. However she asserts that despite this argument having been put by the USPTO, “under the CAFC’s contorted logic, a DNA sequence can be non-obvious even though the information necessary for isolating the sequence is publicly available.” In these circumstances the step of isolating a gene becomes perfunctory. This Thesis agrees with Arti Rai and suggests that her reasoning is consistent with that of Mustill and Dillon LJJ in Genentech on the issue of inventive step.

Nevertheless, her argument implies that if the amino acid sequence of a protein is unknown at the priority date then the isolation of the gene maybe an ‘inventive step’. This Thesis disagrees, because even if the amino acid sequence is unknown, the cloning of the gene that it codes for

Ibid.

Ibid.

Ibid.

Ibid. See also A. Varma and D. Abraham, DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market 9 Harv. J. Law & Tec 53.

See for example In re Bell (1993) 991 F.2d 781 and In re Deuel (1995) 51 F.3d 1552.


“[I] cannot see that there is an inventive step in the use by Genentech among the processes by which they discovered the sequences of a known process not devised by Genentech which only persons of high skill in the art -- of whom there are many -- have the ability to perform.” Per Dillon LJJ; “The whole enterprise was well run, and it is not surprising that Genentech finished first. Yet it is inventiveness which counts, and I cannot find it here in any degree which exceeds the amount of resource to be expected of a group mustering the skills, remarkable as they seem to a layman, ordinarily to be expected
cannot involve an inventive step within s.103 US Act because the cloning of a gene and the elucidation of its DNA sequence is not patentable subject matter within s.101 US Act. Unless s.101 US Act is first satisfied s. 103 US Act is irrelevant. In this regard it needs to be understood that the CAFC’s seminal cases of In re Bell and In re Deuel which establish the precedential authority of this ‘contorted logic’ in the context of ‘inventive step’ (s.103 US Act), assumed that the subject matter of the relevant patents satisfied s.101 US Act and her thesis is predicated on the basis of this assumption, one which this Thesis challenges. Nevertheless, her thesis unquestionably demonstrates the extent to which the CAFC has distorted patent law in order to ensure that biotechnology is protected by the US patent system.

**Erythropoietin in the European Patent Office**

EP 0,148,605 entitled “Production of erythropoietin” was filed by Amgen on December 12, 1984. The patent application was a Patent Cooperation Treaty (PCT) application that was filed with the USPTO and which relied upon US patent applications 561024 filed on December 13, 1983; US 582185 filed on February 21, 1984; US 655841 filed on September 28, 1984 and US 675298 filed on November 30, 1984 as priority documents. The patent’s earliest priority date is December 13, 1983.


103 P.G. Ducor, *Patenting the Recombinant Products of Biotechnology and Other Molecules*, Kluwer Law International, 1998, confirms “[f]irst, the invention must constitute patentable subject matter, as defined by s.101 of the Patent Act. This requirement can be considered as a ‘precondition’ for patentability, anterior to any other legal evaluation.”, 6.


106 Arti Rai argues, “The profusion of patent filings in the area of computer programs can also be traced (albeit somewhat less directly) to the CAFC’s disagreements with the PTO. In order to understand these disagreements, one must examine the historical development of the area. Prior to the formation of the CAFC in 1982, the patent law’s focus on applied technology—a focus embodied in the Constitutional requirement that patents are to be granted only on the ‘useful Arts’ and in the Congressional definition of patentable subject matter as a ‘useful process, machine, manufacture, or composition of matter’ was applied by the courts to exclude most mathematical algorithms, and hence most computer programs, from the domain of patentable subject matter. Algorithms and computer programs were seen as similar to abstract scientific principles or ideas—in other words as ‘basic tools’ of science and technology that all researchers should be free to use.” See A. Rai, *Judicial Issues: Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, (2000) 2 Wash. U. J.L. & Pol’y 199. It follows that she also believes that genetic sequences and their corresponding proteins are “basic tools” of science and technology.

107 These US patent applications are the same patent applications that precede and support US 4,703,008, Amgen’s original US Epo patent.
As the United Kingdom was one of the designated European States\(^\text{108}\) it became operative there as if it were a UK national patent from the moment that the EPO granted it on July 25, 1990. The grant of this patent was, however, the subject of Oppositions filed by a number of parties\(^\text{109}\) on April 24 and 25, 1991. The Oppositions were heard by the Opposition Division of the EPO on November 25 and 26, 1992. On January 20, 1993 the Opposition Division reached its decision that the patent was valid although some amendments were required. The Opponents filed appeals against this decision to the Technical Board of Appeal of the EPO (“TBA”) in May, 1993. The TBA heard the appeal on September 20 and 23, 1994. On November 21, 1994 the TBA reached its decision which referred the matter back to the Opposition Division.\(^\text{110}\) On May 26, 1997 the Opposition Division affirmed the validity of the patent but with modifications.\(^\text{111}\) The Opponents appealed this decision back to the TBA which dismissed the appeal in favour of Amgen on March 26, 1998.\(^\text{112}\) On December 23, 1998 Amgen amended the patent (EP 0,148,605 B2) to be consistent with the amendments made during the Opposition process.

\(^{T412/93 - November 21, 1994.}\)

The first point to note about this Opposition were the grounds of opposition which formed the basis of attack on the EPO decision to grant the patent. None of the nine Opponents opposed the patent on the ground that the patent did not comply with art. 52 \textit{EPC}, namely that there was no ‘invention’. Accordingly, as with the US Amgen cases, the TBA and the parties conducted the appeal assuming that the claims to rEpo satisfied the invention parameter. Nevertheless, the decision is germane for the same reasons that the US cases were, namely, that the arguments made before the TBA were focused on other aspects of patent law and so the persuasive value of the arguments and the evidentiary findings are higher in the context of the issue of ‘invention’.

Interestingly, the Opponents alleged that the genetic sequence disclosed in the patent lacked novelty because there was no difference between the sequence of rEpo and the sequence of

\(^{108}\) The designated states were: Austria, Belgium, Switzerland, Germany, France, Great Britain, Italy, Liechtenstein, Luxembourgh, Netherlands and Sweden.

\(^{109}\) The opponents were Genzyme Corporation, Elanex Pharmaceuticals Inc., Merckle GmbH Chem.-pharm. Fabrik, Boehringer Mannhein GmbH Patentabteilung, Weickmann, B. Huber Dr. H. Liska, Dr. J. Prechtel, Dr. B. Boumlhm Postfach, Hoechst AG and Akzo Pharma B. V.

\(^{110}\) See Case \textit{T412/93 Technical Board of Appeal of the European Patent Office.}\n
\(^{111}\) The modifications to EP 0,148,605 included the deletion of the second paragraph in example 10 in the specification and an amended claim 19 as approved by the TBA in as Auxiliary Request 11 in T412/93. Auxiliary request 11 read, “A recombinant polypeptide [having a similar structure to naturally occurring human EPO and with the biological properties of human EPO] and characterised by being the product of eucaryotic expression of an exogenous DNA sequence and which has higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources.”

uEpo\textsuperscript{113} and that the method used to isolate the Epo gene did not involve an inventive step. Amgen countered these allegations. With respect to novelty, it argued that rEpo differed from uEpo in the carbohydrate portion of the molecule and with respect to inventive step it argued that the use of prior art information would not have given the skilled team any reasonable expectation of isolating the Epo gene. In this regard, the technical problem was to provide rEpo that had the same \textit{in vivo} biological activity of uEpo, and this problem was solved by Dr. Lin’s invention.\textsuperscript{114}

The TBA dismissed both of these grounds of attack, but in doing so agreed with the Opponents that rEpo and uEpo were identical. The TBA held,

According to [Amgen], every study reported in the post-published literature demonstrated that r-Epo differs ‘significantly’ from u-Epo in the carbohydrate portion of the glycoprotein. These differences are supposed to be found consistently between any r-Epo produced in a variety of host cells and the u-Epo preparations of the prior art. [Amgen] pointed to the ten differences stated to exist between r-Epo and u-Epo in the recapitulative. However, study of these documents reveals that these differences can be attributed only to the particular cases under investigation and \textit{cannot be generalized to r-Epo as a class}. [Amgen] have not been able to demonstrate that any one of the above 10 distinguishing features for r-Epo is a ‘universal’ one for the whole class of r-Epo. \textit{The Board has thus to consider these differences as not reliable.}\textsuperscript{115}

Therefore, in terms of the protein that was the subject of the patent the TBA acknowledged that a claim to rEpo was a claim to uEpo. Moreover, it reinforced this finding by making it clear that it did not understand the specification to be providing an “incentive to obtain something different from u-Epo” for “as the aim is to produce biologically active Epo, a property u-Epo is known to possess, \textit{there seems to be no basis} for assuming that each and every recombinant DNA process \textit{must produce something different.”}\textsuperscript{116}

Once again, this line of reasoning establishes as a fact that an isolated gene is materially identical to the corresponding natural gene and that the protein that is produced by recombinant technology is identical to the corresponding natural protein. Moreover, it establishes that the commercial value of the ‘invention’ is inextricably linked to the identical \textit{in vivo} biological activity of the natural protein.

\textsuperscript{113} The Opponents relied upon scientific papers to support their argument, namely Miyake (P89), Sasaki (P113) Yanagawa (P150), Sue (P121) and Egrie (P343).

\textsuperscript{114} Amgen argued that “[t]he inventive step of the proteins followed from the fact that it was truly remarkable that despite the differences due to the recombinant DNA process, one got an obligate glycoprotein that has in vivo biological activity devoid of adverse immunological properties.”

\textsuperscript{115} \textit{T412/93}, 36-38 (TBA).

\textsuperscript{116} \textit{Ibid}, 39 (TBA) (Emphasis added).
This was the same Opposition that was considered by the TBA in T412/93. This second appeal arose from the second decision of the Opposition Division and its relevance to this analysis is not due to any findings of the fact but, rather, its pronouncement of a general policy justifying the allowance of broad patent claims for biotechnology patents. The Board held,

For the board it is a fundamental principle of patent law that a claim can validly cover broad subject matter, even though the description of the relevant patent does not enable every method of arriving at that subject matter to be carried out. Otherwise no dominant patent could exist, and each developer of a new method of arriving at that subject matter would be free of earlier patents. In many cases in the field of biotechnology, patent protection would then become illusory.\textsuperscript{117}

Ironically, the ‘illusory’ nature of patent protection in terms of \textit{Directive} technologies is precisely the hypothesis of this Thesis. The reality is that due to the actions of the patent community, the invention parameter has been so distorted that the legal protection afforded them truly is illusory.\textsuperscript{118} To overcome this ‘illusion’ the European Parliament passed the \textit{Directive} in an attempt to remove any doubt over the patentability of isolated biological materials and the processes of their manufacture.\textsuperscript{119}

The Board’s decision was also contrary to the House of Lords decision in \textit{Biogen} which it acknowledged “shows that the view of some EPC Contracting States national courts may not be the same as that expressed here.”\textsuperscript{120} This rather arrogant dismissal of the reasoning of the House of Lords lends further support to the views expressed by Peter Drahos that the EPO has been determined to expand the ambit of patentable subject matter. He argues that as a member of the patent community, its role\textsuperscript{121} in this process should not be underestimated and suggests that the

\textsuperscript{117} T636/97, 4.5 (TBA) (Emphasis added).
\textsuperscript{118} See \textit{Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others} [2004] All ER (D) 286 (House of Lords) were Amgen Inc’s first European erythropoietin patent upon which it built its business in Europe was held to be invalid some seven weeks before it expired. It was decided on the basis of pre-\textit{Directive} patent law.
\textsuperscript{119} Cf. The Danish Council of Ethics 2004 Report which explains that its “principal objection to the wording of the directive was precisely that in reality it rubber-stamps the practice that has gradually evolved in the USA, Japan and Europe whereby, under certain conditions—which it turns out to be very hard to get a grasp on in practice—parts of the human body can nevertheless be patented.”
\textsuperscript{120} \textit{Ibid}.
\textsuperscript{121} Peter Drahos argues that, “Patent offices are hybrid creatures, business bureaucracies which make their living from granting more rather than less patent registrations, from ensuring the repeat custom of their transnational clientele and from going on proselytising missions in those developing states or new market economies which are in the middle of acquiring patent systems. Patent offices can, through their decisions, include more things in the scope of patentability or narrow the operation of restrictions on patentability. Moreover, if they are supranational entities, as in the case of the EPO, they can exercise a profound harmonising influence on national systems. English courts, for example, have pointed out that
EPO has “been [a] key player … singularly successful in giving a narrow reading to the limits on invention and patentability contained in Articles 52 and 53 of the EPC.”

Interestingly, when the House of Lords considered the same patent in Kirin-Amgen (which will be considered in detail in the next section of this chapter) it held the patent invalid. In doing so, their Lordships’ felt that they needed to reconcile their conclusion with that of the EPO.

Their Lordships held that the process claimed in claim 1 was invalid because the end result, recombinant Epo was indistinguishable to natural Epo. They explained that under the EPC it was not possible for a patentee to make a product-by-process claim, but that this did not matter because for the purposes of infringement, a process claim covered the products of that process within the scope of the patent monopoly. Accordingly, if the product of that process was not distinguishable from what was known to exist, then the process itself could not be the subject of a valid claim. However, the EPO had come to a contrary view on the basis of Amgen’s argument that the ‘glycosylation pattern’ between the two were different. To this, Lord Hoffmann explained that he was “little puzzled by these findings”. In the end he concluded that it did not matter for the purposes of the appeal, because of different facts before the EPO.

The point is that although it may not have made a difference to the appeal, the inconsistent results between the EPO and the House of Lords in Biogen and Kirin-Amgen lends support to the suggestion that the TBA, which is part of the EPO, has and continues to pursue a deliberate policy of expanding patentable subject matter in much the same way as the CAFC has done and continues to do in the United States.

**Erythropoietin in the United Kingdom**

Although the Neuberger J's decision in Kirin-Amgen v Hoechst Marion Roussel Ltd and others was delivered after the passage of the Directive in 1998, the patent in issue, EP 0,148,605 entitled it is of the ‘utmost importance’ that the exclusions in section 1 of the U.K. Patents Act 1977 should have the same interpretation as the EPO gives to the exclusions contained in Article 52 of the EPC.” P. Drahos, Biotechnology Patents, Markets And Morality, (1999) 21(9) EIPR 441-449.

122 Ibid.
123 See Art. 64(2) EPC “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.”
124 Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2004] All ER (D) 286 (House of Lords), per Lord Hoffmann, para 95.
126 Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2002] RPC 1 (UK Patents Court)
‘Production of Erythropoietin’ (Epo) was subject to the EPC and the UK Act prior to the Directive and any amendments to the EPC and the UK Act occasioned by the Directive. His decision in the Patents Court was appealed to the Court of Appeal. The Court of Appeal decision is was heard by the House of Lords between July 5 and July 15, 2004 and their decision was delivered on October 21, 2004.

The primary claim of the Amgen Epo patent is the broadest of all the claims; however, for reasons that are not relevant to this analysis, Amgen did not allege infringement of claim 1, rather it alleged infringement of claims 19, 20, 22 and 26, which were all dependant on the primary claim.

The Patents Court – Neuberger J

In terms of identifying the ‘underlying discovery’, Neuberger J held,

Clearly, it can fairly be said that it was the ‘discovery’ of the gene sequence for EPO which effectively provides the basis for the whole 605 patent. Indeed, it could scarcely be otherwise given the way in which Amgen put their case on breadth of claim and Biogen insufficiency.

He felt bound by Gale and so adopted the term ‘practical application’ as used by Nicholls LJ in that appeal. For Neuberger J, this term was an abbreviated description of the condition necessary to transform a ‘discovery’ within s.1(2)(a) UK Act into an ‘invention’ within s.1(1) UK Act. Therefore, if the discovery as ‘applied in a product or process’ was “capable of industrial application” there would be a ‘practical application’ transforming the discovery into an invention. He considered the ‘practical application’ test to be consistent with the ‘technical contribution’ test applied by the TBA in Vicom and by the UK Court of Appeal in Fujitsu.

127 Kirin Amgen Inc v Hoechst Marion Roussel Ltd and others [2003] RPC 31 (UK Court of Appeal).
128 Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2004] All ER (D) 286 (House of Lords).
129 “A recombinant polypeptide having part or all of the primary structural conformation of human or monkey erythropoietin as set forth in Table VI or Table V or any allelic variant or derivative thereof possessing the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells to increase hemoglobin synthesis or iron uptake and characterized by being the product of eukaryotic expression of an exogenous DNA sequence and which has higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources.”
130 “A polypeptide product of the expression in a eukaryotic host cell of a DNA sequence according to any of Claims 1, 2, 3, 5, 6 and 7.”
131 Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2002] RPC 1, per Neuberger J, 142, 534 (UK Patents Court).
132 Ibid, 143, 535.
Limited’s Application,\textsuperscript{134} of which Aldous LJ was a member. However, having accepted that the ‘technical contribution’ test in Fujitsu was analogous to the ‘practical application’ test in Gale he noted that both Nicholls LJ in Gale and Aldous LJ in Fujitsu expressed “difficulty in identifying clearly the boundary line between what is and what is not a technical contribution.”\textsuperscript{135} However, having acknowledged the “difficulty” of where to draw the line, he simply assumed that the DNA sequence of the Epo gene was a technical contribution.

Neuberger J then refused to consider Genentech, particularly the approach adopted by Mustill LJ in that appeal, “that a particular DNA sequence was an ‘existing fact of nature, newly discovered.’”\textsuperscript{136} There were two reasons for his refusal. First, he interpreted Purchas and Dillon LJJ in Genentech as representing the majority on the issue of ‘invention’, rather than Purchas and Mustill LJJ. Secondly, he argued that “[i]f the principles [from Genentech] are tolerably clear, and there is no question of those principles having been altered as a result of Genentech” there is no need to “delv[e] into detailed judgments in other cases merely to see how the principles were applied to the facts of those other cases.”\textsuperscript{137} Accordingly, he concluded,

Claim 1 is to a DNA sequence which is ‘suitable for’ the claimed purposes, and I accept Mr Waugh’s submission that it is ‘plainly the application of the discovery which is capable of industrial application (whatever the origin of the DNA sequence)’.

But his failure to consider Genentech, which was compounded further by his refusal to carefully examine the “judgments in other cases”, was a mistake.

Firstly, although Nicholls LJ in Gale referred to the decision of Dillon LJ in Genentech in support of his adoption of the term ‘practical application’, what Neuberger LJ failed to appreciate was that Dillon LJ was in the minority on the issue of ‘invention’ in Genentech. The t-PA product claims in Genentech were held invalid on the decisions of both Mustill and Purchas LJJ because in their opinions there was ‘no invention’ within s.1(1) UK Act. True it is that they arrived at this conclusion in slightly different ways, but they nevertheless agreed that there was no invention because the primary claims of the patent which defined the protein t-PA in its recombinant and isolated form, did nothing more than claim a monopoly over something that was no different to a ‘product of nature’.

\textsuperscript{133} “[I]t is... a principle of patent law that mere discoveries or ideas are not patentable, but those discoveries and ideas which have technical aspect or make a technical contribution are.” Aldous LJ quoted by Neuberger J, 143, 536.
\textsuperscript{134} Fujitsu Limited’s Application [1997] RPC 608.
\textsuperscript{135} Ibid, 143, 537. Also see Fujitsu Limited’s Application [1997] RPC 608, per Aldous LJ, 616 lines 41-42.
\textsuperscript{136} Ibid, 143, 538.
\textsuperscript{137} Ibid, 143, 539.
Secondly, in refusing to delve into the decision in *Gale*, he failed to appreciate that while Nicholls LJ adopted the term ‘practical application,’ he was actually applying the reasoning of Purchas LJ in *Genentech*. Nicholls LJ, like so many others misunderstood Purchas LJ to be in the majority with Dillon LJ in *Genentech* and so felt compelled to use the term ‘practical application,’ but a closer examination of Purchas LJ’s decision reveals that it was not enough to incorporate a discovery into a ‘product,’ as an example of a ‘practical application,’ in order to transform a discovery into an ‘invention.’ Consistently with this approach, Nicholls LJ held in *Gale* that an algorithm could not be transformed into an invention because the instructions contained within the algorithm “do not embody a technical process which exists outside the computer”. Nicholls LJ’s reasoning in *Gale* was therefore consistent with Purchas LJ in *Genentech* because both considered the end result of what was being claimed, rather than merely the manner of its ‘practical application’. The end result in *Gale* was an algorithm and the end result in *Genentech* was an artificial product that was indistinguishable from a natural product. Both came within the prohibition in s.1(2) UK Act.

Thirdly, *Gale* was not a case about what constituted a ‘discovery’ for the purposes of s.1(2)(a) UK Act, it was a case about what constituted a ‘computer program’ for the purposes of s.1(2)(c) UK Act. As such, the decision of Nicholls LJ in *Gale* was not binding on Neuberger J, as were the decisions of Mustill and Purchas LJ in *Genentech*. The same was true of *Fujitsu* which also concerned s.1(2)(c) UK Act. Therefore, *Gale and Fujitsu* were about the extent to which an algorithm and a crystal structure respectively and their use in a computer or as part of a computer, brought those things within the excluded subject matter in s.1(2)(c) UK Act. The central issue in both of those cases was “the extent that a patent or an application for a patent relates to that thing as such” in the context of a ‘computer program’ and not in the context of a ‘discovery’. However, the issue for Neuberger J was whether rEpo made by recombinant technology was a ‘discovery’ within s.1(2)(a) UK Act. This was far removed from both the technology and the excluded subject matter in *Gale* and *Fujitsu*.

Furthermore, in *Gale* Nicholas LJ referred to Fox LJ in *Merrill Lynch* who in turn referred to the TBA in *Vicom*. In *Merrill Lynch* Fox LJ held,

> Something further is necessary. The nature of that addition is, I think, to be found in the *Vicom* Case where it is stated: ‘Decisive is what technical contribution the invention makes to

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139 *In Gale’s Application* [1991] RPC 305 per Nicholls LJ, 327 lines 51-52 (UK Court of Appeal).

140 s.1(2) UK Act provides “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 …; (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;”
Fox LJ made it clear that he linked the ‘technical contribution’ to a new result in the computer that applied the technical contribution. But the end result of the Amgen process was a substance identical to uEpo. There was nothing new about rEpo per se. So even assuming that the DNA sequence of the Epo gene could be a ‘technical contribution’ there was no new result obtained as a result of its ‘technical’ application. This is consistent with the Board in *Vicom* because there it required the technical contribution to “result in a certain change” in terms of a “substantial increase in process speed” of the computer.

But *Vicom* and *Merrill Lynch* concerned art. 52(2)(c) EPC and s.1(2)(c) UK Act (i.e., what is a ‘computer program’), and not art. 52(2)(a) EPC and s.1(2)(a) UK Act (i.e., what is a ‘discovery’). This distinction explains the reference of Fox LJ to ‘a substantial increase in process speed’ as an example of the ‘technical contribution’ of the ‘invention’ to the ‘known art’. Perhaps in the context of a computer program or something intrinsically artificial, a link to some ‘technical contribution’ that a computer program may make to the improved performance of a machine or computer, both themselves intrinsically artificial, is understandable, but with respect to something that is intrinsically natural, such as a human gene, such a link is extremely difficult to understand unless the end result of the ‘technical contribution’ is something significantly artificial, such as the oil degrading genetically modified bacterium which was held in *Chakrabarty* to display markedly different characteristics not found in nature. That is, something new in the sense that it is distinguishable from a ‘product of nature’.

However, the facts in *Amgen* do not meet this threshold. First, all that resulted from the process of isolation of the Epo gene was a better understanding of the gene, that is, its genetic sequence, but that step per se did not modify nor enhance the gene (as did the modifications in *Chakrabarty*) in a way that could be described as a ‘technical contribution’. Secondly, the application of the isolated DNA Epo gene sequence in a recombinant process did not produce a product that displayed characteristics not found in nature (as did the modified bacterium in *Chakrabarty*). In this regard, the modifications that were performed by Amgen to make the Epo gene “suitable for” the production of rEpo was not, as the TBA held in *T421/93-Amgen*, new or inventive, but involved

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141 *Merrill Lynch’s Application* [1989] RPC 561, 569 (UK Court of Appeal) (Emphasis added).

142 In *T421/93 Kirin-Amgen, Inc v Genzyme Corporation & Others* the TBA held, “Of the steps (a) to (h) necessary to carry out the invention of Claim 1, the main blockage which prevented those who were actually trying to make Epo by a recombinant DNA route from succeeding before the priority date of the patent was step (b), as they were unable to make a probe which could identify the gene coding for Epo. Thus the most important bit of essential new information that the person skilled in the art needed was the sequence information provided by Table VI. The other steps involved applying known methods to this particular case.” Para 92.
“the application of known methods”.\textsuperscript{143} Rather the TBA there held that “the most important bit of essential new information that the person skilled in the art needed was the sequence information provided by Table VI.”\textsuperscript{144} All that the human intervention enabled was the facilitation of the expression of rEpo, something that was identical in all material respects to uEpo using genetic material also identical to nature.

Thus, the modifications described in the patent specification and encapsulated by the words ‘made suitable for’ merely permitted the mass production of artificial rEpo, a substance that replicated natural uEpo. Importantly, the human modifications to the Epo DNA to make the sequence ‘suitable for’ production did not result in the expression of a form of rEpo which had superior or enhanced properties or characteristics of uEpo, merely an identical substance.

Moreover, according to Fox LJ in \textit{Merrill Lynch} the ‘technical contribution’ must not only produce a “new result” to the prior art but, the “end result … must not itself be an item excluded by s.1(2)”. On the facts of the case before him he held,

\begin{quote}
Now let it be supposed that claim 1 can be regarded as producing a new result in the form of a technical contribution to the prior art. That result, whatever the technical advance may be, is simply the production of a trading system. It is a data-processing system for doing a specific business, that is to say, making a trading market in securities. The end result, therefore, is simply ‘a method … of doing business’, and is excluded by section 1(2)(c). The fact that the method of doing business may be an improvement on previous methods of doing business does not seem to me to be material. The prohibition in section 1(2)(c) is generic; qualitative considerations do not enter into the matter. The section draws no distinction between the method by which the mode of doing business is achieved. \textit{If what is produced in the end is itself an item excluded from patentability by section 1(2), the matter can go no further}.\textsuperscript{145}
\end{quote}

Clearly, on the facts in \textit{Amgen}, not only was the methodology described in the patent specification not new, but the sequence information in concert with the “suitable for” methodology did not produce a new result. It merely produced rEpo, a protein identical to uEpo. Furthermore, the end result, rEpo, is “itself an item excluded from patentability by s.1(2)(a)” \textit{UK Act} because even though artificial, it is identical to uEpo, and therefore falls within the prohibition.

Fourthly, Neuberger J concluded,

\begin{quote}
… that while it is obviously the case that the essential feature of 605, and in particular of Claim 1, is a ‘discovery’, namely that of the DNA sequence of the EPO gene, or at least a
\end{quote}

\textsuperscript{143} \textit{Ibid.}\textsuperscript{144} \textit{Ibid.}
substantial part of that gene (including, crucially, the encoding regions, the introns and the
splice sites), it was a discovery which clearly made a technical contribution.\textsuperscript{146}

Having formed the opinion that the primary claim defined the gene that coded for Epo and that this
gene was a discovery, he nevertheless held that it was not a discovery that came within s.1(2)(a)
UK Act because it “clearly made a technical contribution”\textsuperscript{147} to the production of rEpo. Neuberger
J defined the technical contribution as “the disclosure of the Epo gene,”\textsuperscript{148} excluding the
recombinant methodology taught by the patent which he concluded was “relatively routine.”\textsuperscript{149}
Apart from the fact that his reasoning was contrary to Purchas and Mustill LJJ in Genentech, what
he failed to explain was how this disclosure, which was merely another way of describing a
product of nature, could amount to a ‘technical contribution’. The algorithm in Gale and the
crystal structure in Fujitsu were intrinsically artificial in that they concerned computers, but the
Epo gene in Amgen concerned something intrinsically natural. Not only was the isolated Epo gene
sequence in Table IV derived from the natural Epo gene sequence, but also rEpo and uEpo were
identical products in all material respects.

Finally, he concluded that if a third party produced rEpo using a method that owed nothing to the
method taught in the patent, that party would nevertheless infringe the primary claim of the
patent.\textsuperscript{150} This conclusion was contrary to the conclusion reached by Purchas and Mustill LJJ in
Genentech.

**Neuberger J and the scope of the monopoly of the primary claim**

Neuberger J had no difficulty with the idea that the primary claim included within its scope human
Epo.\textsuperscript{151} So the fact that the primary claim defined the production of rEpo through the use of the
genetic sequence of the human Epo gene in ‘a prokaryotic or eukaryotic host cell’ did not trouble
him as it had troubled Purchas and Mustill LJJ in Genentech.

\begin{footnotesize}
\begin{enumerate}
\item[Merrill Lynch’s Application] [1989] RPC 561.
\item[Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others] [2002] RPC 1 per Neuberger J, 143-144,
540 (Emphasis added). (UK Patents Court)
\item[Ibid, per Neuberger J, 144, 540.]
\item[Ibid, per Neuberger J, 172, 655.]
\item[Ibid, per Neuberger J, 172, 655.]
\item[Ibid, 172, 661, per Neuberger J, “It does not seem unreasonable if a new method of achieving artificial
expression of EPO, which, as a method owed nothing to the teaching of the patent, but which depended
on the disclosure of the patent to express EPO, infringed the patent albeit only to the extent that it
involved being adopted specifically to express EPO.”]
\item[Neuberger J held, “[t]he fact that there is no claim specifically to a cDNA sequence for human Epo is
not, to my mind, sufficient to indicate a contrary result.” Kirin-Amgen Inc v Hoechst Marion Roussel
Ltd and others [2002] RPC 1, 60, 204.]
\end{enumerate}
\end{footnotesize}
What did trouble him, however, was the reference to the ‘host cell’. TKT argued that these words restricted the scope of the monopoly of the primary claim to rEpo produced specifically by means of ‘exogenous DNA encoding for Epo or its analogue’ whereas Amgen argued that these words did not have this restrictive meaning because ‘host cell’ meant nothing more than “a cell which is host to some ‘DNA sequence’, which is foreign to it, but which need not have any particular characteristics, save that it is connected with the production of Epo or an analogue of Epo.”

The motivation for this controversy was obvious. A narrow ‘literal’ construction meant that TKT did not infringe the primary claim, whereas a broad ‘purposive’ construction meant that TKT did.

According to TKT, its method of producing rEpo used “DNA sequences upstream of the whole [Epo gene] sequence” disclosed in the patent to “switch on the endogenous encoding sequence” of the gene to produce rEpo. In other words, its method did not utilise a ‘host cell’ to produce rEpo. According to Amgen, it did not matter how TKT made rEpo, because the production of rEpo meant that it was making use of the Epo gene one way or another.

Having considered the arguments and the evidence Neuberger J preferred TKT’s narrow construction of the primary claim. However, he held that TKT nevertheless infringed claim 26 because even though TKT’s method did not utilise a ‘host cell’ its method made use of an ‘exogenous promoter construct’ or ‘targeting construct’, namely, a piece of DNA which was constructed outside the cell in which the Epo was to be produced. Accordingly, he was of the view that while TKT did not literally infringe, it did purposively infringe.

In coming to this conclusion Neuberger J referred to Improver Corporation v Remington Consumer Products Limited. He referred to Hoffmann J with approval and to this specific passage from that case.

The three questions which have to be asked were set out by Hoffmann J in Improver at [1990] FSR 189. Basing himself on the reasoning of the House of Lords, in Catnic [1982] RPC 183, Hoffmann J said that the proper approach is as follows: “If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim (‘a variant’) was nevertheless within its language as properly interpreted, the Court should ask itself the following three questions:

152 Ibid, 61, 212.
153 Ibid, 61, 214.
Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no -
Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes, -
Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention. If yes, the variant is outside the claim.”

Neuberger J justified his preference for a purposive construction by construing the rEpo produced by TKT’s method to be a ‘variant’ of the rEpo produced by the ‘host cell’ because in his opinion the primary claim “consistently with the whole thrust of the specification, and, indeed with commercial common sense, indicates that the patentee is getting at the production of Epo [and] the variant involved in TKT’s technology does not have a ‘material effect on the way the invention works.’”

This conclusion is material because it confirmed that the thrust of the primary claim was to rEpo howsoever made.

Furthermore, it confirmed that he was of the view that the disclosure of the genetic sequence of the Epo gene was a principle capable of general application because “[t]he obtaining of the amino acid sequence of EPO and of the sequence of nucleotides in the EPO gene is, in the context of the patent, a means to an end [so] Claim 1 does not merely identify the DNA sequences claimed, but it identifies those which are suitable for a certain purpose, namely the production of Epo.”

According to his reasoning, the application of this principle, first elucidated by the House of Lords in Biogen, demanded a broad ‘purposive’ construction of the primary claim.

The problem was that in coming to this conclusion he gave Amgen a monopoly on rEpo howsoever produced, contrary to the binding authority of Genentech.

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157 Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2002] RPC 1, per Neuberger J, 162, 615 (UK Patents Court).
158 Ibid, 163, 620 (Emphasis added).
159 Ibid.
The Court of Appeal

The Court of Appeal did not consider the issue of ‘invention’ on appeal. The appeal focused on the issues of ‘insufficiency’ and ‘infringement’. On the basis of its findings in respect of these issues, the Court of Appeal held the patent valid (reversing the finding of Neuberger J that claim 19 was invalid) and not infringed (reversing the finding of Neuberger J that claim 26 was infringed). As stated earlier the patentee did not allege infringement of the primary claim, but for the reasons that the Court of Appeal expressed in respect of claim 26, had the patentee alleged infringement of the primary claim the same result would have followed.

Nevertheless, the Court made some reference to the construction of the claims which is relevant to this analysis. In this regard, the Court’s comments were strictly obiter dicta, however, they are of concern. The Court, which included Aldous LJ, held:

It is not possible to obtain a patent for the discovery of a gene which by definition is found in the human body. Thus construction of the claims needs to be approached with that in mind. The position has now been made clear. The Directive 98/44/EC provides in Article 5.

The first point of concern is that the neither the Directive nor any amendments to the EPC or the UK Act occasioned by the Directive applied to the patent in issue. The Directive amendments to the UK Act were passed in 2000 and apply only to patents granted after July 28, 2000.

How the Court could refer to the Directive at all on the facts of the appeal is difficult to understand. While acknowledging that the Directive was irrelevant, the Court commented that “we draw comfort from the Directive which allows claims to biological elements 'isolated ... or otherwise produced by means of a technical process even if the structure of that element is identical to that of a natural element'”. The obvious question is: If the Directive is irrelevant then how can the Court draw comfort from it?

The second point of concern is that the Court accepted that pursuant to s.1 UK Act that “[i]t is not possible to obtain a patent for the discovery of a gene which by definition is found in the human body”. The Court referred to the Directive as support for this pronouncement of the law, but it

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160 The reason for this being that F. Hoffmann La Roche AG, the party that argued the invention issue before in the Patents Court had settled with the patentee by the time the appeal reached the Court of Appeal.

161 Kirin-Angen v Hoechst Marion Roussel Ltd and others [2003] RPC 31, 54, 23 (UK Court of Appeal).

162 Inserted by SI 2000/2037, regs 2, 8(2), Sch 2. Date in force: 28 July 2000 (in relation to applications for patents made on or after that date): see SI 2000/2037, regs 1(1), 9.


164 Ibid, 54, 23.
need not have done so, as this is was the effect of the decisions of Purchas and Mustill LJJ in *Genentech*.

The third point of concern is that despite the pronouncement of the law expressed in the preceding paragraph, art. 5.2 *Directive* expressly included, as an invention, an ‘isolated’ human gene ‘even if the structure of that element is identical to that of a natural’ human gene. Despite the acknowledgement that as a matter of law the *Directive* was irrelevant, throughout its decision the Court of Appeal referred to the ‘isolation’ of the Epo gene. The inference that arises is that the isolation of the gene was used by the Court as a hook onto which to hang the invention hat.165 This was made abundantly clear in the second sentence of the following passage from the decision:

> The patentee could not monopolise the gene per se as that existed in nature. The patentee therefore monopolised the DNA sequence encoding for DNA when isolated and in that respect was suitable for use to express EPO in a host cell.166

Despite its relevance, the Court referred to *Genentech* merely to advise that *DNA and the techniques of recombinant technology* were described in that decision.

The subject matter of the Amgen patent was the recombinant production of a human protein, Epo. Amgen, the patent owner, argued that the rEpo produced by TKT came within the scope of the monopoly of the primary claim thereby infringing claims 19, 20, 22 and 26. In essence, the patent owner claimed rEpo producible by any recombinant technology. Neuberger J accepted this argument and accordingly found that defendant TKT’s products infringed claim 26, however, the Court of Appeal rejected this argument finding that TKT’s method of rEpo production did not come within the primary claim and therefore, did not infringe claim 26.167

*The Court of Appeal and the scope of the monopoly of the primary claim.*

The Court of Appeal reversed Neuberger J’s finding on infringement, but not because of *Genentech*.168 The Court accepted that the narrow literal construction169 of the primary claim was correct, and rejected Neuberger J’s purposive construction, concluding that “[i]t follows that products which do not come from a process of such expression are not as a matter of language

165 Ibid, 60, 40. “In essence the sequence had to be isolated so as to be suitable for use in the host cell.”

166 Ibid, 63, 60 (Emphasis added).

167 By this stage one of the defendants, F. Hoffmann La Roche AG had settled with Amgen and withdrew from the appeal.

168 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others*[2003] RPC 31, 60, 42. “It follows that the TKT product does not fall within the words of claim 26 when literally construed.”
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within the claim. Anybody can make them.” The Court preferred the view that the ‘host cell’ was a reference to ‘exogenous DNA’ because “consistent with the disclosure in the specification when read as a whole” the patent in 1984 did not teach or even suggest the use of endogenous DNA to produce rEpo.

The Court disagreed with Neuberger J’s categorisation of TKT’s rEpo as a ‘variant’ of the rEpo that came within the primary claim because even though “[t]here can be no doubt that at the heart of the invention was the discovery and sequencing of the gene that produced Epo” in the Court’s opinion, the genetic sequence of the Epo gene was not claimed “as the invention … because a claim to the sequence per se would not be patentable” and would be tantamount to a claim of “the gene per se as that existed in nature.” The problem with this distinction is that it ignores the fact that the genetic sequence of the Epo gene is a description of the protein that it codes for. The two are inextricably linked.

Therefore, even though the Court did not refer to Genentech, it is clear from its rationale that it was concerned not to extend Amgen’s monopoly to Epo howsoever produced. It recognised the danger in permitting a broad construction of the primary claim, even though Amgen was the party that was adamant that the primary claim captured rEpo per se within the scope of the monopoly.

Interestingly, even though the Court of Appeal construed the primary claim narrowly for the purposes of infringement, it held that the disclosure of the genetic sequence of the Epo gene contained a principle capable of general application for the purposes of insufficiency, arguing that this entitled Amgen “to a claim in correspondingly general terms.” The Court of Appeal explained,

_The law contemplates that patents will not lack sufficiency even though the claims cover inventive improvements. If the law was otherwise there would be no room for patents._

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169 Ibid, 57, 32 “It follows that the literal construction is that favoured by the Protocol”.
170 Ibid, 55, 28 (Emphasis added).
171 Ibid, 57, 32.
172 “the variant is very different … When so viewed there can be only one answer to the first Protocol question which is ‘Yes’. There are real differences between an isolated DNA sequence which is suitable for use in a host cell and a DNA sequence in a cell which needs activation.” Ibid, 62, 52.
173 Ibid, 62, 52.
174 Ibid, 62, 52.
175 Ibid, 63, 60.
176 Ibid, 67, 78.
which disclosed a principle of general application unless the specification described how to carry out later inventions using the principle.\textsuperscript{177}

The problem with this reasoning is its inconsistency regarding the construction of the primary claim. The Court was of the view that a broad ‘purposive’ construction of the primary claim would have expanded the scope of the monopoly of the claim to “cover [all] inventive improvements … using the principle,”\textsuperscript{178} but surely, if the principle of general application was the DNA sequence of the gene encoding Epo, would not the rEpo produced by the TKT method (that used that sequence to some degree to enable the production of rEpo) be an inventive improvement?

According to Neuberger J, a finding that a principle of general application was disclosed in the specification demanded a purposive and not a literal construction of the primary claim for the reason “that … consistently with the whole thrust of the specification, and, indeed with commercial common sense, indicates that the patentee is getting at the production of EPO.”\textsuperscript{179}

The Court of Appeal however created a contradiction. The Court recognised that if it prevented TKT from producing rEpo it was tantamount to upholding the validity of a patent that claimed rEpo howsoever produced, something indistinguishable to uEpo, so it narrowed the claim to exclude TKT’s rEpo being an identical product to Amgen’s rEpo, creating an absurd situation.

\textit{Discussion}

Had the issue of ‘invention’ been before the Court the question would have been: Is the subject matter of the primary claim of the Amgen patent an invention within the meaning of s.1(1) UK \textit{Act}?

In answering this question on the facts of \textit{Genentech} Mustill LJ explained:

\begin{quote}
The kind of research which leads to a marketable form of t-PA is very expensive. The success rate is low. The benefits to suffering humanity are great. If a sufficient reward is not given in those instances where the research bears fruit, the industry will not attract the venture capital which it needs for survival, the research will cease, and humanity will continue to suffer.
\end{quote}

\textsuperscript{177} \textit{Ibid}, 64, 69 (Emphasis added).
\textsuperscript{178} \textit{Ibid}, 64, 69.
\textsuperscript{179} \textit{Kirin-Amgen v Hoechst Marion Roussel Ltd and others} [2002] RPC per Neuberger J, 162, 615 (UK Patents Court).
The appeal of this proposition is undeniable, and indeed it reflects the reasons why we have a patent system at all, yet the arguments are not all one way. If the criteria for patentability are pitched too low there is a risk that mere hard work or superiority of resources, or simple good luck, will entitle a researcher to a monopoly, the commercial and social justification for which is by no means clear, given the risk of stultifying the development of the industry by open competition.

... It may be that the explosively new technology with which we are concerned has exposed some deep flaws even in the current regime; but if this is so, any necessary repairs must be effected by the legislation, not by the courts. I approach the present appeal on the footing that our task is to understand the Act, and apply it.\textsuperscript{180}

The \textit{Directive} and the consequential amendments to the \textit{UK Act} are an obvious attempt to undertake the ‘necessary repairs’ to which Mustill LJ referred.\textsuperscript{181} It is arguable that the passage of the \textit{Directive} by the European Parliament reinforces the strength of and the foresight of his reasoning. It suggests that the \textit{Directive} is testament to the existence of ‘deep flaws’ in EC patent systems that existed before its passage and which, arguably, still exist.

In one sense it is understandable that the Court of Appeal in Amgen derived comfort from the \textit{Directive}, but in another it should have been a warning that the law which applied to the patent in issue was subject to the ‘deep flaws’ which Mustill LJ was alluding to and which formed the basis of his decision.

The primary claim of the Amgen patent defines the end product by reference to (a) the method of production and (b) the genetic sequence of the gene that codes for Epo which are set out in tables IV and V in the patent. The end product is recombinant Epo that is isolated.

At the priority date of the Amgen patent there was nothing new in the use of DNA recombinant technology. In fact, the passage from Amgen claim 1, "A DNA sequence for use in securing expression in a prokaryotic or eukaryotic host cell of a polypeptide product having at least part of the primary structural confirmation [sic] of that" could have been used in the primary claim with respect to any genetic sequence.

\textsuperscript{180} Genentech Inc’s Patent [1989] RPC per Mustill LJ, 259 lines 28-39; 259 line 52 – 260 line 3 (UK Court of Appeal)

\textsuperscript{181} See also the Danish Council of Ethics 2004 Report which explained that its “principal objection to the wording of the directive was precisely that in reality it rubber-stamps the practice that has gradually evolved in the USA, Japan and Europe whereby, under certain conditions—which it turns out to be very hard to get a grasp on in practice—parts of the human body can nevertheless be patented.”, 13.
The essential ingredient for the production of rEpo is the DNA sequence described in tables IV and V in the patent. This is precisely what Mustill LJ focused on in respect to the question “do the claims relate to inventions?” In his opinion, neither claims 1 to 4 related to inventions simply because “there is no difference between recombinant t-PA and any other kind of t-PA. If so, claim 3 must, like claims 2 and 4, be unsound. Genentech did not invent t-PA. At most, they invented a new way of making it. The same objection is, in my view, fatal to claim 1.”

The same can be said of the Amgen patent. There is no difference of any kind between rEpo and natural Epo. Amgen did not invent Epo, a fact that the Court of Appeal acknowledged. At most, Amgen invented a new way of making it, although the use of DNA recombinant technology was by the priority date of the patent, well known and routine.

The House of Lords

The appeal was heard between July 5 and July 15, 2004. The Appellate Committee that heard the appeal consisted of Lords Hoffmann, Hope of Craighead, Rodger of Earlsferry, Brown of Eaton-under-Heywood and Walker of Gestingthorpe. Amgen was represented by Anthony Watson QC and Andrew Waugh QC and TKT was represented by David Kitchen QC.

The issue of ‘invention’ within s.1(1) UK Act was not directly in issue in the appeal; indeed, TKT made it clear that it was cautious even in revisiting Genentech. Clearly, it was not in the commercial interests of either party that the patent be invalidated on the ground that the technology described in claim 1 was not an ‘invention’. For Amgen such a finding could invalidate the patent completely, and for TKT it could open up the possibility of a challenge to its own patent relating to the use of its methodology in the production of rEpo. Nevertheless, TKT

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182 Ibid, 260 line 27.
185 See also Lourie J holding that “… neither Fritsch nor Lin invented Epo or the Epo gene” in Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc (1991) 927 F.2d 1200 (CAFC).
186 Dillon LJ held “ … apart from the use of the sequences there is nothing new in the invention described in the patent. In particular it is agreed between the parties’ expert witnesses for the purposes of the proceedings that at the relevant time, in early May 1982, the ordinary skilled worker, once in possession of a complete cDNA sequence encoding t-PA, was capable of manipulating it so that the protein could be expressed in bacteria, yeast or mammalian cells, and it is also agreed that while most workers in the field would have tried to express t-PA in E coli, most workers would also have planned for expression in a mammalian cell line such as CHO.” Genentech Inc’s Patent [1989] RPC 147, 239 lines 3-11.
187 David Kitchen QC, Transcript of the House of Lords Appeal in Kirin-Amgen, Inc v Hoechst Marion Roussel Ltd and others, July 8, 2004, 400 lines 23-24. “Before turning to the facts, may I just, and with some trepidation, invite my Lords to dip into Genentech.” (Emphasis added)
was interested in attacking the patent on the basis that the sequence data of the Epo gene in Table VI was “itself ... not patentable,”¹¹⁸⁹ in support of its arguments on infringement and insufficiency. In this limited respect the issue of ‘invention’ was raised and is relevant to the issues in the appeal.¹¹⁹⁰

TKT’s argument was that the primary claim of the Amgen patent was a method claim to the production of rEpo, which first, it did not infringe (thereby not infringing the dependent claims) because the TKT method did not come within the proper construction of the claim; and second, that if the claim did capture TKT’s method, then the claim was insufficient because it was not possible at the date of the patent to have produced rEpo using the TKT method. Moreover, the claim would be a claim to a ‘discovery’. Essentially, the argument was described as a “silent squeeze”.¹¹⁹¹

Amgen countered by arguing that the Epo gene had a “beneficial property” in that “it records the sequence of Epo and when under the control of the expression sequences and the messenger RNA in a cell, it will make Epo”¹¹⁹² and this was the “technical contribution”¹¹⁹³ or “the inventive step”¹¹⁹⁴ or “inventive concept”¹¹⁹⁵ of the ‘invention’.

To this submission Lord Brown asked this question: “I am lost; I am sorry. Is the sequence the discovery?”¹¹⁹⁶ although his Lordship could equally have asked: Is the sequence the invention? In answer to this question, Andrew Waugh QC eventually replied “a discovery plus a technical aspect or a technical contribution is no longer [a] mere discovery,”¹¹⁹⁷ but is an ‘invention’. Therefore, according to Amgen, the discovery of the Epo gene plus the elucidation of the genetic sequence of the Epo gene, that is, the ‘technical contribution,’ made up the ‘invention’.

¹¹⁹⁰ Andrew Waugh QC, Transcript of the House of Lords Appeal in Kirin-Amgen, Inc v Hoechst Marion Roussel Ltd and others, July 13, 2004, 668 lines 2-5. “A discovery, as such, is not patentable subject matter under the act. See section s.1(2(a) in relation to which see Genentech’s Patent. This is an important issue in relation to infringement ...” (Emphasis added).
¹¹⁹¹ Ibid, 668 line 7.
¹¹⁹² Ibid, 668 lines 12-14.
¹¹⁹³ Ibid, 668 line 21.
¹¹⁹⁴ Ibid, 668 line 22.
¹¹⁹⁵ Ibid, 668 line 23.
¹¹⁹⁶ Ibid, per Lord Brown, 669 lines 2-3.
¹¹⁹⁷ Ibid, Andrew Waugh QC, 671 lines 20-22.
According to Amgen’s case the important technology in terms of ‘invention’ was not the method of production of claim 1\(^{198}\); rather, it was the “DNA sequence [encoding Epo] for use in securing expression.”\(^{199}\) Andrew Waugh QC explained,

> The DNA which is suitable for in whichever way you have made it suitable, is capable of industrial application. It is no longer a mere discovery. It has entered into the realms of technical utility. I can take that sequence. I can have that sequence. I can really turn that sequence to my advantage to make EPO. Again, whether I do it by taking the EPO DNA out or whether I do it by taking the shuttle vector to the DNA and then making new copies of the DNA is beside the point. In each case I have been able, with the knowledge of the EPO, to turn it to technical account.\(^{200}\)

The problem with this argument is that it captured within its scope, rEpo howsoever produced. As already explained in Chapter 3, the Court of Appeal invalidated the Genentech patent because it claimed isolated t-PA howsoever produced. According to Purchas LJ the t-PA claim was “a claim for protection of the discovery as such.”\(^{201}\) Without doubt, the mass production of t-PA was also achieved through some modification of the relevant genetic material, so as to be “suitable for” the recombinant production. But the end result of that process was a product that was identical in every material respect with natural t-PA.

This is precisely analogous to claim 1 of the Amgen patent, because although the claim was a claim to the use of DNA sequence in a method, rather than a product claim as in Genentech, the end result of that claim is a product and it is this product that is so valuable to Amgen. As Neuberger J put it thus,

> …consistently with the whole thrust of the specification, and, indeed with commercial common sense, indicates that the patentee is getting at the production of Epo.\(^{202}\)

Furthermore, the argument collides front-on with Fox LJ in Merrill Lynch. There he held that the “end result … must not itself be an item excluded by s.1(2)”\(^{203}\). On the facts of the case before

\(^{198}\) Claim 1 “A DNA sequence for use in securing expression in a procaryotic or eucaryotic host cell of a polypeptide product having at least part of the primary structural confirmation [sic] of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticuloocytes and red blood cells and to increase hemoglobin [sic] synthesis or iron uptake, said DNA sequence selected from the group consisting of: (a) the DNA sequences set out in Tables V and VI or their complementary strands; (b) DNA sequences which hybridize under stringent conditions to the protein coding regions of the DNA sequences defined in (a) or fragments thereof; and (c) DNA sequences which, but for the degeneracy of the genetic code, would hybridize to the DNA sequences defined in (a) and (b).”

\(^{199}\) Andrew Waugh QC, 668 lines 23-24.

\(^{200}\) Ibid, 674 lines 6-15 (Emphasis added).

him he held that the production of a ‘trading system’ was excluded from being an ‘invention’ within s.1(1) UK Act because it came within s.1(2)(c). Specifically, he held that

The fact that the method of doing business may be an improvement on previous methods of doing business does not seem to me to be material. The prohibition in section 1(2)(c) is generic; qualitative considerations do not enter into the matter. The section draws no distinction between the method by which the mode of doing business is achieved. If what is produced in the end is itself an item excluded from patentability by section 1(2), the matter can go no further.  

Clearly, the end result of the primary claim of the Amgen patent is rEpo which is identical to uEpo, itself a ‘product of nature’. 

Unlike the artificial bacterium in Chakraberty, the modifications made to the genetic material made ‘suitable for’ the mass production of rEpo was not materially different to the corresponding natural Epo genetic material. Accordingly, while the modified genetic material maybe ‘artificial’ in the sense of being made ‘suitable for’, it is not capable of being an ‘invention’ because it merely replicates the function of the corresponding natural genetic material, that is, codes for rEpo. Therefore, the degree of artificiality of the ‘artificial’ genetic material made ‘suitable for’ the method of claim 1 is insufficient to transform it into an ‘invention’.

Consistency with Merrill Lynch means that if the end result of the Amgen patent is something that has the same properties as the corresponding natural protein, the technical contribution is immaterial in terms of defining the end result.

Andrew Waugh QC tried to distinguish Genentech by arguing “if one does go back to Genentech, one sees the claims were very different to the claims in this case. There was no sequence information written into the particular claims.” Now, while he was correct about the claim language, the fact remains that the specification in the Genentech patent did disclose the relevant genetic sequences for t-PA. Therefore, his distinction was a red herring.
He also tried to distinguish *Genentech* by arguing that only in the Patent Court was the “mere discovery” point raised against claim 1, implying that TKT had conceded this point in the appeal and that its limited ‘discovery’ argument with respect to infringement and insufficiency in the appeal was nothing more than an attempt to raise the full argument through “a side door.” In this respect, it was submitted that the relevant law was not *Genentech*, but the UK Court of Appeal in *Gale* and *Fujitsu* and the TBA in *Vicom*. Accordingly, the emphasis of the Amgen argument focused on the ‘technical application’ of the gene sequence in the mass production of rEpo.

The fact of the matter is this inventor has provided new DNA sequences which were not available to the public before and has published them in this patent and claimed them as suitable for the expression of EPO in a host cell. On that basis, as a chemical, TKT have little factories that make new copies of this chemical, albeit 14 on average per little factory. They are making the chemical. They are hooking that chemical up to other chemicals that will activate it and cause it to do something else, but *at the end of the day this is precisely the technical application of claim 1 which is not excluded by patentability*.

Unfortunately, what this argument failed to take into account was that it was *Genentech* that concerned ‘discovery’ in s.1(2)(a) *UK Act* and its relationship to ‘invention’ in s.1(1) *UK Act*, whereas *Gale*, *Fujitsu* and *Vicom* all concerned ‘computer programs’ or related technology within s.1(2)(c) or art. 52(2)(c) *EPC* and their relationships to ‘invention’ in s.1(1) *UK Act* or art. 52(1) *EPC*. This distinction is not insignificant because the subject matter of the Amgen patent was intrinsically natural, as was the subject matter of the Genentech patent, whereas, the subject matter of the Gale, Fujitsu and Vicom patents were all intrinsically artificial. The distinction between something intrinsically natural and something intrinsically artificial is relevant in defining what is a ‘technical contribution’ because the word ‘technical’ suggests a level of absolute human intervention. With respect to something intrinsically artificial, the level of human intervention is absolute – it exists only because of human intervention. However, this is not so with respect to something intrinsically natural that exists irrespective of human intervention. While recognising that these are two extreme ends of the spectrum so that it is possible for something intrinsically natural to become artificial to some degree, even so the limitations which Fox LJ in *Merrill Lynch*

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206 *Ibid*, 675, lines 8-10. “It was only in this jurisdiction that Roche took the point that claim 1 was a mere discovery. Paragraph 540 [of Neuberger J’s judgment] was unchallenged on appeal”.


208 *Ibid*, 675, lines 20-23. “The law has been analysed in *Gale*. It has been analysed in *Fujitsu* and *Vicom* and those other cases, which were not rescrutinized in the Court of Appeal and this was the result of that analysis”.


210 The word ‘technical’ is defined to mean “of, relating to, or specialising in industrial, practical or mechanical arts and applied sciences.” Collins Dictionary of the English Language, Collins Publishers, Sydney, 2001.
incorporated into the ‘technical contribution’ test serve to defeat the validity of the Amgen patent because the end result falls fairly and squarely within the prohibition in s.1(2)(a) UK Act.

The resolution of this conundrum is to be found in the decision of the US Supreme Court in Chakrabarty and the requirement that the level of human intervention be significant. As was explained in Chapter 3, the bacterium in Chakrabarty was not merely isolated nor was its genetic sequence merely elucidated, rather the very essence of what made the genetically modified bacterium artificial was the consequential change to its function. This change was significant because the artificial bacterium performed a function that no natural bacterium had ever performed. There was simply put, no natural precedence.

In the Amgen patent, the sequence data contained in Table VI is nothing more than the elucidation of the genetic sequence of the Epo gene as it exists in nature.²¹¹ Accordingly, the Epo gene sequence is completely devoid of any human intervention and as such cannot be a ‘technical contribution’ within the meaning of the term as defined in Gale, Fujitsu or Vicom. Yet, it is the copying of the Epo gene sequence that Amgen repeatedly relied upon in support of its infringement case against TKT.

On the way the learned judge approached it, because the learned judge did find that TKT infringed and he found that it was not invalid as a discovery on the same basis, I do ask my Lords to come back and test it this way, with the fact that every time the R223 cells, which have got the DNA in them, which they never had before infringe, it is because they have copies of the DNA sequences of claim 1.²¹²

Furthermore, the fact that “copies of the DNA sequences of claim 1” are produced by means of a ‘technical process’ does not modify or enhance the relevant DNA sequences in any way.

Finally, Amgen used the language of art. 5 Directive to argue that the production of a ‘natural element’ by means of a technical process is patentable subject matter because the Directive “is understood be clarificatory of the law”.²¹³

This Thesis disputes the claim that the Directive is ‘clarificatory’. Rather, it argues that the Directive represents a significant modification to the EPC and the patent laws of complying EC states. The Directive is the attempt to undertake the necessary ‘repairs’ to the EPC which Mustill

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²¹¹ "The Epo gene used to produce rEpo is the same Epo gene as the human body uses to produce uEpo" Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc (1989) 13 U.S.P.Q.2D 1737.

²¹² Andrew Waugh QC, Transcript of the House of Lords Appeal in Kirin-Amgen, Inc v Hoechst Marion Roussel Ltd and others, July 13, 2004, 676 lines 6-12.

²¹³ Ibid, 677, line 14.
LJ spoke of in Genentech, and in this regard is the legislative equivalent of the policy announced in the 1988 joint communiqué of the EPO, USPTO and JPO. The production of natural DNA by means of a technical process as patentable subject matter within art. 52 EPC was not the law in 1984 when the Amgen patent application was filed. Indeed one of the principle architects of the Directive, Dominique Vandergheynst, has explained that the Directive was a “true revolution … between the ethical dimension and a technological sector of which certain aspects cannot but arouse control by public powers.” Moreover, the fact that it took ten years and two attempts for the European Parliament to pass it into effect tends to contradict Amgen for one would think that if it were merely ‘clarificatory’ the Directive would have been a straightforward initiative. Finally, the Directive remains surrounded in controversy even today, some six years later, as seven of the originating fifteen EC member states still steadfastly refuse to comply with it.

House of Lords – October 21, 2004 (Postscript to the thesis as examined – inserted at the recommendation of Prof. W. R. Cornish)

The thesis was submitted prior to the Appellate Committee advising the House of Lords of its decision in the appeal on October 21, 2004 and accordingly the above analysis was conducted without the benefit of the Committee’s decision. Given that the significance of that decision it is appropriate that Lord Hoffmann’s speech on behalf of the entire Committee be considered post-examination. Where there is a reference to this decision in the Thesis it has been inserted after examination.

The House of Lords agreed with the Court of Appeal on the issue of infringement holding that neither claims 19 nor 26 were infringed by TKT’s process, but disagreed with it on the issue of validity.

In their Lordships’ opinions, the proper construction of claim 1, the primary claim, was to be decided by “what the person skilled in the art would have understood the patentee to be using the

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214 ‘Purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds.’ 1988 Joint Statement of USPTO, EPO and JPO. See footnote 9, Nuffield Council of Bioethics Discussion Paper The Ethics of Patenting DNA, 26, para 3.14.


216 Ibid.

217 In July 2003, the European Commission referred Germany, Austria, Belgium, France, Italy, Luxembourg, the Netherlands and Sweden to the Court of Justice of the European Communities for their failure to transform arts. 1 to 11 of the Directive into their national patent laws by July 2002. In
language of the claim to mean”\textsuperscript{218} and confirmed that Lord Diplock’s decision in \textit{Catnic Components Ltd v Hill & Smith Ltd}\textsuperscript{219} continued to be good law even though the now applicable patent statute, the Patents Act, 1977 (UK) ushered in provisions which were consistent the \textit{EPC}. In particular, their Lordships made it clear that Article 69 \textit{EPC}, which provides that “[t]he extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims” and the \textit{Protocol on the Interpretation of Article 69}, did not necessarily extend the scope of the claim to be at one with the scope of the specification. Lord Hoffmann explained

> The purpose of a patent specification, as I have said, is no more nor less than to communicate the idea of an invention. An appreciation of that purpose is part of the material which one uses to ascertain the meaning. But purpose and meaning are different. If, when speaking of the widest purpose, Jacob LJ [in Rockwater Ltd v Technip France SA (unreported) [2004] EWCA Civ 381, at paragraph 41, … says … that to be ‘fair to the patentee’ one must use ‘the widest purpose consistent with his teaching’] meant the widest meaning, I would respectfully disagree. There is no presumption about the width of the claims. A patent may, for one reason or another, claim less than it teaches or enables.\textsuperscript{220}

On the facts of the appeal before them, their Lordships were unpersuaded by Amgen’s construction of claim 1 because the notional skilled person would have understood that the claim required the use of exogenous Epo DNA in a \textit{host cell} and that this specific limitation in the scope of the claim was a matter for the patentee. In this regard, ‘purposive construction’ could not be applied so as to bring the process used by TKT to manufacture rEpo within the scope of claim 1.

Therefore, their Lordships explained that application of ‘purposive construction’ was constrained by the manner in which the patentee chose to define the scope of the claim and did not permit “extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims.”\textsuperscript{221} If the scope of protection defined by the claims, as understood by the notional skilled person, was narrower than the description of the invention in the specification, it

\textsuperscript{218} Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2004] All ER (D) 286, para 34 (House of Lords).

\textsuperscript{219} Catnic Components Ltd v Hill & Smith Ltd [1982] RPC 183, particularly per Lord Diplock, 243, “A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge.”

\textsuperscript{220} Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2004] All ER (D) 286, para 33.

\textsuperscript{221} Ibid, para 34.
was an error to construe the claim ‘purposively’ for the aim of providing “fair protection for the patentee”.  

So while Neuberger J, the trial judge, held that “the whole thrust of the specification, and, indeed with commercial common sense, indicates that the patentee is getting at the production of EPO”, according to their Lordships, the invention of claim 1 was not the isolated DNA sequence of the Epo gene. Their Lordships, criticised the trial judge’s claim construction and agreed with the Court of Appeal, that the invention of claim 1 was to a specific process for the recombinant manufacture of rEpo not to the recombinant manufacture of rEpo generally. In their Lordships’ opinions, while the specification was cast in broad terms, the primary claim was not because a claim to the production of rEpo howsoever made was tantamount to a claim to the isolated DNA sequence of the Epo gene, and this could never be an ‘invention’ within s.1(1) UK Act. 

In their opinions, even though the primary claim was to “a perfectly good and ground-breaking process for making [Epo] and its analogues, [Amgen] were determined to try to patent the protein itself, notwithstanding that, even when isolated, it was not new”. But this did not mean that they believed the primary claim to be valid and as it was not in issue in the prior proceedings nor in the appeal, the validity of the primary claim was moot.

Their Lordships emphasised the word ‘new’ with respect to rEpo, the physical substance. The fact that the DNA sequence of the Epo gene, which was an essential feature of the primary claim, was (a) isolated and (b) unknown at the priority date did not save the patent. This meant that as Epo per se, that is, the end result, was not itself ‘new’, any claim to any process for its production was equally invalid even though the gene that coded for Epo and the genetic sequences of both the Epo gene and Epo were unknown at the priority date.

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222 See ‘The Protocol on the Interpretation of Article 69’. Also per Lord Hoffmann: “The Catnic principle of construction is therefore in my opinion precisely in accordance with the Protocol. It is intended to give the patentee the full extent, but not more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim.”

223 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2002] RPC 1 per Neuberger J, para 624 (UK Patents Court).

224 First, I think that the judge’s construction pays no attention to the claims. It does not even use them as ‘guidelines’ but goes straight to Table VI and declares that to be the invention. Secondly, I think that the Court of Appeal was right in saying that Table VI could not have been the invention. Standing alone, it was a ‘discovery...as such’ within the meaning of section 1(2) of the Act: see Genentech Inc’s Patent [1989] RPC 147, per Purchas LJ at p 204 and per Dillon LJ at p 237. … In such a case, while it may be true to say, as the Court of Appeal did ([2003] RPC 31, 62) that Table VI lay ‘at the heart of the invention’, it was not the invention. *Ibid*, per Lord Hoffmann, paras 76-77.

225 *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2004] All ER (D) 286 per Lord Hoffmann, para 132.
It is important to understand that the patentability of the process of the primary claim was considered, by both the Court of Appeal and the House of Lords to be a technology that was *prima facie* an ‘invention’ within s.1(1) *UK Act*. Moreover, their Lordships considered that it was a “ground-breaking” process. In this context their Lordships implied that they considered the Amgen process to meet the novelty and inventive step conditions of s.1(1)(a) and (b) *UK Act*. Furthermore, the evidence at trial conclusively proved that the Amgen process enabled the production of Epo in quantities that were otherwise unavailable at the priority date and that rEpo had demonstrated therapeutic effects on humans which uEpo had not experimentally replicated. This evidence supported the argument that the industrially applicable criterion of s.1(1)(c) *UK Act* was also satisfied.

Despite this, their Lordships held the product claim invalid. It is suggested that they did so for the following reasons.

First, their Lordships did not distinguish between Epo as it occurred in nature and isolated Epo. In their opinions and as supported by the overwhelming trial evidence, uEpo and rEpo were indistinguishable either physically, biologically or genetically. The existence of natural Epo as a substance was known before the priority date.\(^{226}\)

Second, their Lordships did not distinguish between the physical substance, Epo and the DNA sequence of the Epo gene that coded for it. The fact that the complete genetic sequence of the Epo gene was unknown at the priority date was irrelevant because the end result of the claimed process was merely the physical form of the substance produced by the gene that corresponded to the isolated DNA sequence of the Epo gene. In other words, while the isolated DNA sequence of the Epo gene was new at the priority date, that information was analogous to the physical substance which was the end result of the claimed process and this was not ‘new’.\(^{227}\) This suggests that new information about an old substance does not make an old substance new.

Arguably the decision confirms that under pre-Directive s.1(1) *UK Act* an isolated DNA sequence and the protein for which it coded for (a) can never be an ‘invention’ and (b) cannot be claimed as part of a process unless the process produces something that is ‘new’ so as to be physically, biologically and genetically distinguishable from existing biological materials. It also lends support for the reasoning of Purchas LJ and Mustill LJ in *Genentech*.

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\(^{226}\) *Ibid*, per Lord Hoffmann, para 96.

\(^{227}\) *Ibid*, per Lord Hoffmann, para 132.
Erythropoietin in Australia

The 1998 Federal Court of Australia decision in *Genetics Institute, Inc. v Kirin-Amgen, Inc (No 3)*\(^{228}\) has to date been the only judicial consideration of the Australian equivalent to the Amgen patents. This case was an appeal from the decision of the Australian Deputy Commissioner of Patents concerned a pre-grant Opposition reported in *Kirin-Amgen Inc. v. Board of Regents of University of Washington*.\(^{229}\) The appeal did not involve the issue of ‘invention’. The appeal was confined to a consideration of whether the invention claimed in the patent application was (a) fairly based on the matter disclosed in the specification, (b) fully described and (c) clearly and succinctly defined. Nevertheless, a consideration of the reasoning of Heerey J in this appeal is necessary as it is another example of the confusion that has beset courts throughout the world and that has been brought on by the perceived need to justify the patenting of genes and their products.\(^{230}\)

Heerey J understood that the essential feature of the claims in question was the isolation of the human Epo gene and its genetic sequence, but along with this understanding came the knowledge that Epo existed well before the priority date of the patent application in issue. He confirmed his understanding that “[t]he existence of Epo was postulated in 1906 and confirmed in 1953”\(^{231}\) and that “by 1975 it was known that small amounts of Epo were excreted by the kidneys and that urine provided a source for urinary Epo”.\(^{232}\) However, the fact that “neither blood nor urine is a practical source of Epo for therapeutic use,”\(^{233}\) and that it was not “until recombinant Epo (rEPO) became available [that] there existed a need for a product which could fulfill the protein's therapeutic role,”\(^{234}\) persuaded him to the view that Dr. Lin’s work was meritorious and justified patent protection. Heerey J implicitly accepted the argument that the production of human Epo by recombinant means transformed the product of nature, human Epo to a product of man, rEpo even though the issue of ‘invention’ was not a matter before him in the appeal. This is made abundantly clear in the decision by his extensive, and rather irrelevant references to the methodology applied by Dr. Lin some fifteen years earlier. The primary claim in issue in the appeal was claim 1. This read as follows:

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\(^{228}\) *Genetics Institute, Inc. v Kirin-Amgen, Inc (1998) 156 ALR 30 (Federal Court of Australia).*

\(^{229}\) *Kirin-Amgen Inc. v. Board of Regents of University of Washington (1995) 33 IPR 557 (Deputy Commissioner of Patents – Australian Patent Office).*

\(^{230}\) See P. Drahos, *Biotechnology Patents, Markets And Morality*, (1999) 21(9) EIPR 441-44 were he argues that “[a] crucial aspect to the expansion of the patenting in biotechnology has been the development of juridical arguments and theories that have enabled applicants for biotech patents to overcome existing bars.”

\(^{231}\) *Genetics Institute, Inc. v Kirin-Amgen, Inc (1998) 156 ALR 30 per Heerey J, 31 (Federal Court of Australia).*


\(^{233}\) *Ibid.*
A purified and isolated polypeptide having the primary structural conformation and one or more of the biological properties of naturally-occurring erythropoietin and characterized by being the product of procaryotic or eucaryotic expression of an exogenous DNA sequence.

The question which this claim required an answer to was whether it was ‘fairly based’ upon the disclosure in the specification. In other words, was the claim justified by the disclosure in the specification. Heerey J held that it was because the critical information which the ‘cDNA’ sequence provided was contained in the DNA protein-coding sequence, that is, the protein coding sequence of human Epo and that “once the protein coding sequence is known, the same route (gDNA) does not have to be followed or need the tissue source be the same.”

Heerey J then proceeded to consider the House of Lords decision in Biogen, not because it was binding upon him, but because he considered it relevant to this issue of ‘fair basis’. In Biogen, the House of Lords took the step of interpreting s.72(1)(c) UK Act (insufficiency) in such a way that the issue relevant to s.14(5)(c) UK Act (fair basis) was incorporated into insufficiency.

In Biogen the House of Lords found the patent invalid because the scope of the monopoly of the claims was held not to be justified by the disclosure in the specification. Heerey J explained his understanding of the objection to the Biogen patent thus,

The principal claim in the patent was, as Lord Hoffmann pointed out, for any recombinant DNA molecule which expressed the genes of any HBV antigen in any host cell. Moreover the invention had claimed a generalisation of the method actually used.

What was crucial, so Heerey J believed, was the fact that in Biogen the patent did not disclose any sequence information, so there was no ‘principle capable of general application,’ whereas this information was disclosed in the Amgen patent. Thus, he concluded that the Amgen patent disclosed a ‘principle capable of general application’ which supported the claims to an entire class of products, namely rEpo. The equation of a ‘principle capable of general application’ to the genetic information of a gene or genome is an interesting adaptation of Biogen; however, it is wrong. There is nothing in Lord Hoffmann’s speech that supports this interpretation. What Lord Hoffmann meant by his conclusion that, “[t]he claimed invention is too broad. Its excessive breadth is due, not to the inability of the teaching to produce all the promised results, but to the

234 Ibid.
235 Ibid, 43.
236 “But the substantive effect of section 14(5)(c), namely that the description should, together with the rest of the specification, constitute an enabling disclosure, is given effect by section 72(1)(c). There is accordingly no gap or illogicality in the scheme of the Act.” per Hoffmann LJ in Biogen v Medeva [1996] RPC 1. See also A. McInerney, Biotechnology: Biogen v Medeva In The House Of Lords, (1998) 20(1) EIPR 14-21.
fact that the same results could be produced by different means."\(^{238}\) is that the claims in the Biogen patent were directed to the HBV antigens (proteins) howsoever produced and this was too broad because it was possible, as Medeva did show, to produce those same proteins by other means.\(^{239}\) Even if the genetic sequence of the HBV genome had been disclosed and claimed in the Biogen patent, the sequence would not have amounted to a ‘principle capable of general application,’ for the simple reason that it would have been another way of making, as Purchas LJ held in Genentech, “a claim for protection of the discovery as such.”\(^{240}\)

**Summary**

This analysis of the Epo litigation reveals inconsistencies and confusion in the construction of patent claims and the interpretation and application of patent law in multiple jurisdictions. The results of the UK Patents Court, the UK Court of Appeal and the House of Lords in *Amgen* is a perfect example of the problems which confront the courts and the patent system. At first instance three claims were held invalid and one infringed and on appeal to the Court of Appeal, all claims were held valid but none infringed, and on appeal to the House of Lords while the product claims were held invalid, the process claims (not in issue as to their validity) were held not infringed.

The other glaring deficiency in the development of the law in this area has been the almost complete absence of analysis of the issue of ‘invention’ by the courts, and where there has been such analysis, the use of the ‘technical contribution’ or ‘practical application’ test has highlighted a judicial tension that a comparison of the UK Court of Appeal decisions of *Genentech* and *Chiron* clearly demonstrate. In the United States, the US Supreme Court in *Chakrabarty* held that for a natural phenomenon, such as a bacterium, to meet the patentability parameter of ‘invention’ in s.101 US Act the end result had to display markedly different characteristic than any found in nature, and in the United Kingdom the House of Lords in *Biogen* held that ‘invention’ was a separate ‘condition’ of patentability to the ‘conditions’ of novelty, inventive step and industrial applicability and in this regard did not overrule the Court of Appeal in *Genentech*. Yet, the CAFC and the UK Courts of Appeal have consistently ignored these two authorities.

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\(^{238}\) *Biogen Inc v Medeva plc* [1997] RPC 1, per Lord Hoffmann, 51 line 49 – 52 line 2 (House of Lords)

\(^{239}\) This interpretation was subsequently confirmed by Lord Hoffmann in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others* [2004] All ER (D) 286, paras 102-117.

\(^{240}\) *Genentech Inc’s Patent* [1989] RPC 147, 228 line 16, 14.10 (UK Court of Appeal).
The scientific work that led to the isolation of the causative agent of non-A non-B Hepatitis (NANBH) started in January 1987 with the cloning of a minute fragment of the viral protein of what is today called hepatitis C virus genotype 1a (HCV1a). This work was conducted by Dr. George Kuo under the direction of Dr. Michael Houghton, both employees of Chiron Corporation (Chiron), a Californian biotechnology company. These scientists, together with Dr. Qui Lim Choo, another Chiron employee, were named as the ‘inventors’ of HCV in a US patent application filed by Chiron with the USPTO on November 18, 1987. Chiron subsequently filed five further US patent applications, the last in this series filed on November 14, 1988. These six US patent applications supported the Patent Cooperation Treaty (PCT) patent filing of November 18, 1988 which became the genesis of corresponding patents throughout the world.

The patents that are considered in this chapter have been the subject of litigation or opposition. As a consequence, it is possible to consider the arguments that were raised against their validity and the manner in which the courts and patent offices dealt with them. However, before embarking upon this discussion it is necessary to first explain hepatitis C, a disease that infects only humans and chimpanzees.

**Hepatitis C Virus**

What has been called hepatitis C since about 1989 was first called non-A non-B hepatitis, or NANBH. Although hepatitis, a disease of the liver has been part of the medical and scientific literature for decades what was not known until the mid-nineteen seventies was that in addition to hepatitis B virus and hepatitis A virus there was at least a third causative agent of this disease. The causative agent of hepatitis B was isolated and characterised by Professor Blumberg in 1967 and

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1. The small fragment was called ‘clone 5-1-1’ and had one continuous open reading frame (ORF) which encoded a polypeptide of approximately 50 amino acids, whereas the HCV1a virus “is a positive-sense, single-stranded RNA molecule approximately 9,400 nucleotides in length which encodes a polyprotein of about 3100 amino acids.” See L.J. Fanning and F. Shanahan, *The Hepatitis C Virus: Master of Diversity and Challenging Adversary*, Medscape Gastroenterology, 2000. Clone 5-1-1 came from the non-structural 4 (NS4) region of the HCV genome.

2. Professor Blumberg explained in his affidavit filed in *Murex Diagnostics Australia Pty Ltd v Chiron Corporation* (Federal Court of Australia, NSW District Registry, NG 106 of 1994), that “HBV was discovered in our laboratory at Fox Chase Cancer Center as a consequence of a general research program whose goal was to determine inherited biochemical and immunological differences in the blood which differentially affected susceptibility to disease. During the course of these studies we found, in 1967, an antibody to the surface antigen of HBV (abbreviated HBsAg) that is, the protein that coats the outside of the virus, in the serum of a patient who had developed the antibody after exposure
the causative agent of hepatitis A was isolated and characterised by Dr. Feinstone in 1972. It is interesting to note that neither scientist nor their employers filed patent applications claiming either virus, as isolated by them, as their ‘invention’, although Professor Blumberg was awarded the Noble Prize for Physiology or Medicine in 1976 in recognition for his studies concerning mechanisms involved in the origin and spread of infectious diseases and, specifically, for the ‘discovery’ of the hepatitis B virus and for the development of methods for detection of HBV and the vaccine for HBV.

Professor Blumberg explained in *Murex Diagnostics Australia Pty Ltd v Chiron Corporation and Another* (Murex) that after the development of diagnostics assays for HBV and HAV and their use in the screening of blood and blood products that “[i]t was soon recognized that, although a significant percentage of post-transfusion hepatitis cases had been eliminated, the problem persisted” and so “the search for a non-A, non-B hepatitis virus began”.

By the late 1970s, Dr. Bradley, a scientist at the Centers for Disease Control and Prevention (“CDC”), a US Government agency that is responsible for the detection and control of infectious diseases in the United States, had already been searching for possible causes of NANB hepatitis and had participated in primate studies in order to determine cross-infectivity between humans and chimpanzees. This work, although in its infancy, was to play a significant role in the isolation and characterisation of HCV1a, the history of which is partially described in the Chiron HCV patent specifications.

Estimates of post-transfusion hepatitis at the time suggested that the incident rate to HBV as a consequence of multiple transfusions. During the course of these transfusions he had apparently received in the donor blood, HBV virus and also particles which contained only the surface antigen of HBV. The transfused patient had either developed an asymptomatic HBV infection, or an acute infection from which he recovered in a relatively short time. During this recovery period the patients immune system had developed an antibody. The serum collected during this period which contained the antibody could be referred to as ‘convalescent serum’ or ‘post exposure serum’.”

Blumberg, 2.1 (Affidavit filed in Murex).

Dr Bradley explained in his affidavit filed in *Murex Diagnostics Australia Pty Ltd v Chiron Corporation* (Federal Court of Australia, NSW District Registry, NG 106 of 1994), that Dr. Stephen Feinstone of the National Institutes of Health in Bethesda Maryland USA had first detected hepatitis A virus. Bradley, 3.3 (Affidavit filed in Murex).


*Murex Diagnostics Australia Pty Ltd v Chiron Corporation* (Federal Court of Australia, NSW District Registry, NG 106 of 1994.

Blumberg, 3.1 (Affidavit filed in Murex).

was between ten and twenty percent in the United States, and in Japan between one and six percent of all blood donors were carriers of the disease. There is no doubt that by this time post-transfusion NANBH was recognised as a serious global health threat and that the development of a reliable diagnostic immunoassay was of paramount importance.

**Dr Bradley’s initial NANBV experiments**

In 1977, Dr. Bradley was able to obtain samples of a Factor VIII product that had been confirmed as the source of NANBH transmissions in two haemophiliac patients. This source material was important because it contained the causative agent of this disease. Dr. Bradley’s idea was to visualise and characterise the agent using electron microscopy and immune electron microscopy, the standard techniques of the time. However, he was unable to visualise any suspect agent from the sample biological material. To enhance his chances he devised an experiment using four laboratory chimpanzees, which were each infected using the tainted Factor VIII product. He postulated that the elevation in these animals of alanine aminotransferase (ALT), a liver enzyme that was used as a marker of hepatitis infection in humans, would indicate infectivity in these animals. Between a period of thirteen to seventy days all four animals displayed elevated ALT levels. He then used liver tissue and plasma samples taken from these animals to see if he could visualise the responsible agent. Although, he was unsuccessful he noticed that the liver cells had changed in a manner consistent with acute viral hepatitis. Having ruled out that these changes were caused by HAV, HBV or other known possible causes of hepatitis, Dr. Bradley concluded that the tainted Factor VIII products “indeed contained one or more transmissible agents capable of causing NANBH.”

The continued lack of visualisation, however was a problem for Dr. Bradley and so he devised a series of experiments designed to increase the concentration of the responsible agent in a further effort to improve his chances. Again using electron microscopy and ALT levels he observed in the biopsied liver samples the membrane changes to the liver cells, but he also noticed dense fibrillar masses and tubules. These tubules, he concluded were associated with infection from the

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8 Bradley, 4.1 (Affidavit filed in Murex).
9 Arima, 22 (Affidavit filed in Murex). Professor Arima also testified that “In Japan, about 60% of chronic hepatitis patients (about 720,000 patients), about 40% of liver cirrhosis patients (about 100,000 patients) and about 40% of liver cancer patients (about 7,000) were patients having NANBH. Further, the mortality rate attributed to NANBH reached 16 thousand per year.”
10 Factor VIII is a blood product administered to haemophiliacs to restore normal clotting activity.
11 Bradley, 4.4-4.5 (Affidavit filed in Murex).
responsible agent and so he coined the term ‘tubule forming agent’ (TFA). He “believed that elevated ALT values during the chronic phase of the disease could be used as a basis for predicting relatively high titers of the TFA in infected chimpanzees,”\(^\text{13}\) namely that by taking biological samples from the animals at periods of high ALT in the chronic phase of infection, the concentration of the TFA would be maximised.\(^\text{14}\) In this regard he had plasma collected from two chimpanzees, called ‘Don’ and ‘Rodney’. Over the subsequent periods of eleven and six years respectively he collected fifteen litres from Don and eight litres from Rodney.

**Dr Bradley, the CDC and their collaboration with Chiron (1982-1990)**

Dr. Bradley’s published results received world-wide attention,\(^\text{15}\) in particular, the attention of Dr. Houghton at Chiron who, “in November 1982, at the suggestion of Dr Bill Rutter (Chairman of the Board) and Dr Dino Dina (Director and Head of Research) … instituted a collaboration with Dr Bradley of the Centers for Disease Control.”\(^\text{16}\) Dr. Houghton appreciated that “Dr Bradley was a prominent figure in the field of non-A, non-B hepatitis [who had] demonstrated the serial transmission of NANBH in chimpanzees [and who] had access to the CDC’s chimpanzee colony and was therefore able to supply [Chiron] with raw material for [its] studies”.\(^\text{17}\) He understood that the objective of the collaboration with the CDC was to “clone HCV,”\(^\text{18}\) that is, to isolate the causative agent of NANBH using molecular cloning techniques in concert with the enriched chimpanzee biological materials specifically developed by Dr. Bradley at the CDC. Dr. Bradley’s role in the collaboration went beyond merely being the source of ‘raw materials’. He attended joint meetings, was involved in discussions concerning results of the molecular biological experiments, discussed theories and ideas\(^\text{19}\) and critically provided an enriched three litre plasma pool derived from the plasma collected from chimpanzee Rodney over a six year period. This last aspect of the collaboration was extremely important because Dr. Kuo had by June 1985, “hypothesised that a way to clone the NANBH agent and a way to identify these clones might be to clone cDNA into the lambda gt 11 expression vector [which would] amplify antigen and thereby

\(^{13}\) Bradley, 4.11 (Affidavit filed in Murex).


\(^{15}\) Arima, 28; Houghton, 2.8.9; Locarnini; Blumberg (Affidavits filed in Murex).

\(^{16}\) Houghton, 2.8.8 (Affidavit filed in Murex).

\(^{17}\) Houghton, 2.8.9 (Affidavit filed in Murex).


\(^{19}\) Ibid, 687-689.
overcome the potential problem of low antigen concentration.” 20 Furthermore, Dr. Bradley had by July 1985, after discussions with Dr. Houghton and his team, agreed to send Chiron “pooled convalescent chimpanzee sera.” 21

Dr. Bradley considered the enriched Rodney plasma pool to be “the common factor involved in every step of the … cloning process” 22 because it “was used to generate cDNAs, the many individual genetic elements within the source [that] become physically integrated into the cloning process and remain there throughout the process.” 23

In October 1985 Dr. Houghton commenced preparing the first lambda gt-11 expression libraries using Rodney plasma, but encountered difficulties dealing with the resulting biological material. In November 1986 he prepared a second library, but had made a number of changes to the methodology he employed “in an attempt to improve the overall efficiency”. 24 Having made the library, in January 1987 he asked Dr. Choo to screen the library, which was dubbed the ‘C’ library, with serum from a chronically infected NANBH patient, dubbed patient ‘L’. 25 The idea was to use serum which contained a high concentration of antibodies to the infective agent as a screening material against a library containing clones made with high concentrations of the genome of the infective agent (antigenic sites) to enhance the likelihood that the patient ‘L’ antibodies would hybridise (in other words, bind) to the antigen in the ‘C’ library, like a lock and key.

On January 28, 1987 Dr. Choo was able to identify five positive clones, one of which was dubbed ‘clone 5-1-1’. 26 Having achieved this result, Dr. Houghton’s team went about verifying the result so as to confirm that clone 5-1-1 was a true clone of the causative agent of NANBH. This work continued through the rest of 1987 and into 1988 and required further biological material from the CDC. This was necessary work because according to Dr. Kuo “[c]lone 5-1-1 was just another putative positive [that] [n]o-one at that time believed … was truly a clone derived from the causative agent of NANBH.” 27 The additional confirmatory work included the production of a prototype diagnostic assay. This assay was tested against the ‘Alter panel’ that “had been set up by Dr. Harvey Alter of the [National Institutes of Health] in the early 1980s and was widely used.

20 Houghton, 5.13 (Affidavit filed in Murex).
21 Houghton, 5.15 (Affidavit filed in Murex).
22 Bradley 2, 35 (Affidavit filed in Murex).
23 Ibid.
24 Houghton, 11.1 (Affidavit filed in Murex).
25 Houghton, 11.7 (Affidavit filed in Murex).
26 Houghton, 11.9 (Affidavit filed in Murex).
27 Kuo, 37 (Affidavit filed in Murex).
as the qualifying panel for putative NANBH assays. The panel consisted of proven infectious sera from chronic NANBH carriers, infectious sera from implicated donors and infectious sera from acute phase NANBH patients in duplicate. Samples were also included from highly pedigreed negative controls and other disease controls.28 The assay was subjected to two ‘Alter panels’ and having passed both, confirmed that NANBV genomic material was contained in the assay and that clone 5-1-1 was a true clone of NANBV. Final confirmation was advised by letter from Dr. Alter to Chiron on June 10, 1988.29

**Related Issues Concerning The Collaboration**

In terms of the role which the source material played in the isolation of HCV1a it is important to recognise, as Dr. Bradley described that,

> The genetic code of clone 5-1-1 was within the Rodney high titre plasma all along. The cloning tool merely captured it as a separate element. Chiron did not create clone 5-1-1 out of thin air—they found it in a place that we all knew contained NANBH viral sequences, like the sequence corresponding to clone 5-1-1. It is a play on words to suggest that providing a good source material is one thing, and molecular cloning is another. They were very clearly one and the same in the context of our unified multidisciplinary approach to identifying a *bona fide* piece of the NANBH virus.30

What this meant was that Chiron scientists had not created the genetic sequence or protein of HCV1a, rather they discovered it using molecular biological techniques and critical to that discovery was the pedigreed ‘Rodney’ plasma pool provided exclusively to Chiron for use with those techniques.31 It also meant that the genetic material that was contained within clone 5-1-1 was identical to the corresponding natural genetic material because if it was not the anti-HCV antibodies from patient ‘L’ would not have hybridised to the clone. It must be understood that the cloning experiments conducted by Chiron assumed that human antibodies would be produced in response to HCV infection and furthermore that those antibodies would recognise or bind to the

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28 Kuo, 41 (Affidavit filed in *Murex*).
29 *Ibid*.
30 Bradley 2, 35 (Affidavit filed in *Murex*).
31 “What I’m saying is that I believe that the success of the cloning procedure was in part based on having a well characterised sample. … So it’s in retrospect but I would say that, you know, that material was critical to our success.” Dr. G. Reyes, under cross examination by Chiron counsel in *Murex*, Transcript July 12, 1996, 911. Dr. Reyes was giving evidence of the cloning experiments that he had conducted using biological material from chimpanzee ‘Don’ provided to him by Dr Bradley. Dr. Reyes was a molecular biologist working for Genelabs Inc, a competitor of Chiron in the mid-1980s. Furthermore, Dr. Reyes swore in his second affidavit that “[i]n my opinion, the material developed by Dr. Bradley and provided to Chiron by the CDC was also critical to the success of the cloning strategy described in the affidavits of Dr. Houghton and Dr. Kuo.”, 13 (Affidavit filed in *Murex*).
antigenic binding sites of HCV1a. Without these assumptions there was no point to the experiments because without antibodies there would have been no possibility of hybridisation.

In terms of the patenting strategy employed by Chiron, it is important to remember that under US patent law the ‘mental conception’ and ‘reduction to practice’ of the invention as defined by s.101 US Act are the minimum thresholds of the process of invention as defined by s.100 US Act. Accordingly, unless these thresholds are satisfied the invention is incomplete and cannot be the subject of a patent application. Interestingly, Chiron first filed a patent application concerning HCV on November 18, 1987 establishing its earliest priority date world-wide, however, according to Dr. Kuo it was not until June 10, 1988 that Chiron had confirmation that clone 5-1-1 and the clones subsequently identified through the use of clone 5-1-1 were true HCV1a clones. The implication was obvious: How could Chiron nominate Drs. Houghton, Kuo and Choo as the inventors of HCV when they did not have complete proof of what it was that they claim to have invented?

In terms of nominating the inventors, the question that must be answered is: How was Dr. Bradley excluded as an ‘inventor’ by Chiron? Apart from the role that Dr. Bradley played in providing the source material used for the successful cloning experiments, the CDC and Chiron were working in a collaboration “the objective [of which] was clone HCV”. Moreover, as Dr. Bradley pointed out, “Chiron did not create clone 5-1-1 out of thin air”, rather “[t]he genetic code of clone 5-1-1 was within the Rodney high titre plasma all along”. It may be a matter of semantics, but surely if there was an ‘invention’ at all, how could the process of invention be so neatly distinguished between the provision of source materials on the one hand and the application of the molecular cloning techniques to that source material on the other? This is particularly puzzling when it is appreciated that Chiron did not claim the molecular cloning methodology as the ‘invention’ but

32 “Dr. Houghton was basically using the same set of assumptions that I and my colleagues at Genelabs were using for our calculations and in our procedures. These assumptions were (a) that the agent was a virus; (b) that there was a sufficiently high titer of the virus in the CDC chimpanzee plasma to clone the virus; (c) that detectable levels of antibodies would be produced to infection from the virus and (d) these antibodies could be used to identify a virus specific clone using expression cloning protocols.” Dr G Reyes, second affidavit, 15 (Affidavit filed in Murex).

33 S. 101 defines patentable subject matter or ‘invention’ as “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof…”

34 S.100 defines ‘invention’ to mean ‘discovery or invention’.


36 Bradley 2, 35 (Affidavit filed in Murex).

37 Ibid.
instead claimed isolated HCV viral proteins and any industrial or medical application of those proteins as ‘inventions.’

**The Chiron HCV Patents**

Four Chiron HCV patents will be discussed in this Chapter. These four patents are not the only Chiron HCV patents, as there are many more. However, they provide a focus because each has been the subject of litigation or opposition, or is closely related to a patent that has been. Relevantly, this Thesis has examined patent law in the United States, Europe, the UK and Australia and its relationship with art. 27.1 TRIPS and so it is appropriate that the four patents are from these jurisdictions. As in the case of Chapter 3, the litigation or opposition surrounding these patents raised many patent law issues, but this Chapter will consider the issue of ‘invention’, although as suggested above, the issue of ‘inventorship’ will be included in the analysis because of its obvious relationship to ‘invention’.

**HCV in the United Kingdom**

*The Patents Court trial (July 1993)*

Patent GB 2,212,511 entitled ‘Hepatitis C Virus’ was a derivative of PCT patent application 8827024.4 filed on November 18, 1988. Its earliest priority date was established by US patent application 122,714 filed with the USPTO on 18 November 1987. The patent explained that “[t]he invention pertains to the isolation and characterization of a newly discovered etiologic agent of NANBH, hepatitis C virus (HCV)” and the primary claim defined the scope of the monopoly to any protein that is:

\[
\text{...in substantially isolated form comprising a contiguous sequence of at least 10 amino acids encoded by the genome of hepatitis C virus (HCV) and comprising an antigenic determinant, wherein HCV is characterized by:}
\]

(i) a positive stranded RNA genome;

(ii) said genome comprising an open reading frame (ORF) encoding a polyprotein; and

(iii) said polyprotein comprising an amino acid sequence having at least 40% homology to the 859 amino acid sequence in Figure 14.
Chiron Counsel’s submissions – R. Jacobs QC and D. Kitchen

As to the meaning of this claim, an examination of the opening speech of counsel is useful because there can be no doubt that Robin Jacobs QC explained the scope of the monopoly in terms consistent with his instructions.

First, the term ‘antigenic determinant’. Counsel defined this term as the “bit of the antigen which will react” with or is “bindable by anti-HCV antibody” produced by the human body in response to HCV infection. He explained that “reactions between proteins depend upon a number of different things, the shape, the primary structure, whichever protein - the string of beads, which order the string is in - and they tend to be about, … 5, or a bit … amino acids long.”

Second, the term ‘continuous amino acid sequence’. Counsel defined this term as “the amino acids [which] follow one after the other … anywhere in the polypeptide.”

Third, the term ‘40% homology’. Counsel defined this term as “a string of amino acids and you ask whether another string is similar or not. You can have degrees of similarity; homology relates to that - one string versus another string.”

Four, the term ‘isolated’. Counsel defined this term “in the sense that the polypeptide is free from the cellular constituents. It is not mixed up with a load of other proteins, and so on”.

Five, the term ‘encoded by’. Counsel defined this term as “require[ing] the amino sequence to be identical to that other peptide (protein) encoded by the genome,” namely an antigenic determinant of HCV.

Counsel described the primary claim as a ‘product’ claim. In fact, it was a claim over literally millions of proteins that met the claim criteria. Although it was not a claim to isolated HCV per se, it was a claim to all ‘substantially isolated’ proteins that contained a binding site that would react immunologically (hybridise) with any antibody produced in response to hepatitis C or hepatitis C-like infections. The motivation for the ‘limitation’ of ‘substantially isolated’ was

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38 Official UK Patent Court transcript of July 5 and 6, 1993; the Opening Speech of Mr. R. Jacobs Q.C., senior counsel for Chiron Corporation, before Justice Aldous in Chiron Corporation v Organon, Murex Diagnostics and United Biomedical Inc.
39 Ibid.
40 Ibid.
41 Ibid.
obvious. Chiron had to establish that the subject matter of the patent was an invention within the meaning of s.1(1) UK Act and this it could not do if the primary claim was to such proteins per se. In this regard, it is very important to note that counsel explained that the primary claim had “nothing to do with recombinant DNA technology.” Rather it was a claim to any ‘substantially isolated’ protein that satisfied the claim criteria howsoever produced.

Regarding the issue of ‘invention’, counsel referred to the decision of the UK Court of Appeal in Gale and argued that the ‘technical contribution’ approach adopted by the TBA in Vicom was followed in Gale. Counsel argued that the primary claim fell within Gale because the “product itself produced a technical result which was novel.” He attempted to distance Genentech by arguing that “Mustill LJ went wrong, when one looks at it from the point of view of what the patent system [is]” because “anything which has a practical application, a real physical artefact, is not itself an excluded thing” within s.1(2) UK Act.

Counsel stressed that the primary claim was a claim to a “useful artefact that emerge[d]” from “non-obvious research” and that the Opposition Division of the EPO decision in Amgen had accepted this as a test for ‘invention’ within art. 52 EPC but Aldous J responded by suggesting that while the EPO were bound to follow Vicom, the leading case in the UK was the Court of Appeal decision in Merrill Lynch. To further this argument counsel referred to the decisions of the District Court and CAFC in Amgen, particularly to the District Court discussion about the ‘reasonable expectations of success’ in cloning the Epo gene. However, it was clear that Aldous J was uncertain about his argument because according to Aldous J “the facts [in Amgen] are all different. They do not deal with any of the points like discovery as such, or anything like that.” In this respect, Aldous J was correct.

The Patents Court (October 1993) – Aldous J

From the beginning of his decision Aldous J displayed some confusion about the subject matter of the primary claim. He explained,

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42 Ibid.
44 Mr. R. Jacobs QC, July 6 1993, 51.
46 Ibid.
48 These cases were discussed in Chapter 4.
The essentials to understanding recombinant DNA technology are set out in the Genentech case between pages 158 and 169. A person having read those pages will have been introduced to recombinant DNA technology, but not to viruses and hepatitis. What he meant by the proviso “but not to viruses and hepatitis” in the context of recombinant DNA technology is puzzling, because the technology applied generally to all proteins, irrespective of origin.

Aldous J then explained that “[t]he patent discloses the nature of the major causative agent of NANBH, namely, hepatitis C virus (HCV) and that it is a virus with a RNA genome” and that it grants “a monopoly covering … immunoassay kits for detection of blood samples infected with HCV …[which] is of considerable commercial value to the Plaintiffs and of importance to the public”. While correct, the salient point was that claim 1 (the primary claim) upon which all the polypeptide claims, including the immunoassays claims, were dependent had nothing whatsoever to do with “immunoassay kits for detection of blood samples infected with HCV”; rather it was a product claim directed to isolated HCV proteins per se howsoever produced. Therefore, the issue was not whether Chiron was entitled to a monopoly over a technology that was of “importance to the public.” Perhaps, if the primary claim was directed to the application of an HCV protein in an immunoassay kit, his explanation may have been understandable, but it was not. The issue was whether the primary claim to ‘substantially isolated’ HCV proteins per se was a claim to an ‘invention’ within s.1(1) UK Act.

The primary claim was to all isolated proteins of at least 10 continuous amino acids that contained an HCV antigenic determinant howsoever produced. Despite this Aldous J explained, in the present case, the claims are … are limited to products, kits, methods of testing, vaccines and cell cultures. The submission that the claims are concerned with discoveries as such is untenable.

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51 Ibid.

52 For example the TBA in T0188/97 F. Hoffmann-La Roche & Co AG v Chiron Corporation (February 8, 2001), 97, 67 held that claim 1 (which was identical to claim 1 of GB2,212,511B was to ‘any’ HCV protein that contained an epitope “be it natural or obtained by chemical synthesis or by expression in a recombinant organism”.

53 Ibid (Emphasis added).
Accordingly, he accepted Chiron’s submission that the primary claim was to a product, albeit one that could only be distinguished from its natural counterpart by the words “substantially isolated.”

In support he cited the decision of Fox LJ in Merrill Lynch with approval. This aspect of Fox LJ’s decision has already been discussed in Chapters 3 and 4 and need not be repeated here other than to make the point that this reference was made as support for his assertion that “the claims are concerned with a technical aspect of the discovery”. This, in his opinion distinguished the ‘discovery’ of HCV from the invention defined in the primary claim. However, for the same reasons explained in Chapters 3 and 4 his reasoning was wrong.

First, the primary claim did not ‘concern’ a ‘technical aspect’ because it was nothing more than biological material and even if isolated, the material was identical to a product of nature.

Secondly, Merrill Lynch concerned s.1(2)(c) UK Act and not s.1(2)(a) UK Act (just as Vicom concerned art. 52(2)(c) EPC) and therefore was not directly relevant to the technology in issue in Chiron. But more importantly, Merrill Lynch made it very clear that if the end result of the “technical contribution” or “practical application” was something excluded by s.1(2)(c) UK Act then, irrespective of the “technical contribution” which it made to ‘the product’ it was not capable of being an ‘invention’ within the meaning of s.1(1) UK Act. In Chiron, not only did the primary claim have nothing to do with a ‘technical’ contribution, but it was nothing more than a description of “substantially isolated” HCV proteins, which were identical in every material respect to the corresponding natural HCV proteins. As such, while the primary claim concerned something artificial in the sense of being ‘isolated’ it was not an ‘invention’ because it lacked the necessary degree of artificiality for ‘invention’. For precisely the same reasons that Purchas and Mustill LJJ gave in Genentech, the claim was not a claim to an ‘invention’.

Clearly, not only did Aldous J not apply Genentech, a decision which he was bound to apply on the facts of Chiron, he did not actually apply Merrill Lynch, a decision which he was not bound to apply.

In Chiron, it was emphasised by counsel that the causative agent of NANBH was ‘unidentified’, and this argument was used to support its case for broad patent protection, but it was also used by

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54 Chiron Corporation v Murex Diagnostics Limited (No 3) [1996] RPC 535, per Aldous J, 575 lines 6-9 (UK Patents Court).
TKT in the *Amgen* appeal in the House of Lords in an attempt to distinguish *Genentech* and *Chiron* from the facts in *Amgen*.

### David Kitchen QC in the House of Lords in *Amgen*

David Kitchen QC was senior counsel for TKT, but he was also junior counsel for Chiron. In the *Amgen* appeal in House of Lords he attempted to distinguish *Genentech* and *Amgen* from *Chiron*. He submitted that in *Chiron* the substantially isolated HCV proteins were unidentified, and therefore were *new*, whereas in *Genentech* and *Amgen* both natural t-PA and Epo were “available to the public and therefore” were *old*. On this basis he argued, that *Amgen* did not have the right to patent isolated Epo ‘howsoever made’ because “[t]hey were not the people to find the protein that is used in the body to promote the production of red blood cells.” Of course, the implication was that Chiron were the first people to identify the causative agent of hepatitis C and therefore had every right in the world to patent HCV ‘howsoever made’.

Clearly, this point of distinction was not lost on Purchas LJ in *Genentech*. There he explained,

> The authorities seem to support the proposition that where the discovery is of a *new substance*, a patent can be claimed for that substance ‘however made’ and will be valid as long as the specification discloses one method of manufacture, even if that method be not the most favoured one. This proposition does not apply, however, where, as in the case of t-PA, the discovery is merely part of the process by which a product *already known to exist with properties already described* can be manufactured. *In the latter case the discovery can only form the basis of an invention limited to the method of producing the known artefact, i.e. a process patent.*

So on the basis of the authorities considered by Purchas LJ, Court of Appeal favoured the point which counsel made. However, despite understanding the point of distinction Purchas LJ did not consider the prior availability of the protein to be decisive in *Genentech*.

Purchas LJ confirmed that the authorities drew a distinction between a ‘process’ and a ‘product’. He reasoned that the authorities supported the proposition that if the substance was ‘old’ (as in t-PA) then the discovery could form part of an invention but only if the invention was a ‘process’.

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58 *Genentech Inc’s Patent* [1989] RPC 147, per Purchas LJ, 228, 14.10.
whereas if the substance was ‘new’ then the discovery could form part of a ‘product’ “howsoever made” but only if there was one well defined method of production disclosed.

But, the authorities which Purchas LJ considered in Genentech concerned technologies that were about things that were intrinsically artificial and mechanical such as lace machines, not intrinsically natural and biological such as t-PA, Epo or HCV. Even so, Purchas LJ held that it was necessary to understand the wording of the claims “in order to see whether the essential characteristics of the invention in the claim are in line with the criteria in the decision in Vicom and the judgments in Hickton’s case” and if not, “the claim cannot be describing a process or product which could be an invention for the purposes of the Act” because “[i]t would either be a claim for the discovery ‘as such’, or it would not refer to anything done by the patentee which could be an invention.”

On the facts in Genentech, and there it must be remembered that the primary claims were also product claims, Purchas LJ held that:

The question to be asked is whether the ‘invention’, as claimed within the criteria of section 125 of the 1977 Act, is a method embracing a new discovery, in which case it escapes disqualification under section 1(2)(a); or whether it is merely a claim in the form: ‘I claim this discovery harnessed to make useful artefacts’, in which case it amounts to a claim to the discovery ‘as such’ and, therefore, is not an ‘invention for the purposes of this Act’.

Having asked himself that question, he decided that the product claims to t-PA were of the latter variety. The question for present purposes is this: Did he come to that decision because natural t-PA was already known and publicly available? No, he did not.

The distinction, which David Kitchen QC invited their Lordships to draw in Amgen, is not applicable. It mattered not to Purchas LJ that natural t-PA was old in the sense of being “publicly available” because in his opinion “[t]he discovery of the figure 5 data was new.” He held,

Once it is accepted as ‘new’ in the sense ‘not available to the art”, it is probably best considered in its own particular light. As I have already pointed out, the figure 5 data was not part of the state of the art at the relevant date. In my judgment it does not lose its quality as a discovery merely because it was information about something which was known to exist and

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60 Genentech Inc’s Patent [1989] RPC 147, per Purchas LJ, 226, 14.03 (UK Court of Appeal).
61 Ibid, 224 lines 22-28, 14.03.
62 Ibid, 211 lines 1-2, 12.11.
had in small quantities been isolated from other substances, including proteins with which it existed in nature.\(^\text{63}\)

Similarly, in *Amgen* and *Chiron* the discovery of the genetic sequence of the Epo gene or HCV was also new in that this information was also *not publicly available*.

In Purchas LJ’s opinion, the figure 5 data, which was the relevant genetic sequence to t-PA was a discovery and it was this information which was central to the primary t-PA product claims. This is precisely analogous to the facts in *Amgen*, for there the Table IV data, which was the relevant genetic sequence to Epo was also a discovery which was central to the primary claim for Epo, albeit a product claim to a component used in a recombinant process. Likewise, in *Chiron* the figure 14 data, which was the relevant genetic sequence to HCV proteins containing an ‘antigenic determinant,’ was also a discovery which was central to the primary HCV claim, a product claim akin to that in *Genentech*.

This point of distinction was emphasised even more by the fact that in *Genentech, Chiron* and *Amgen*, each of the respective patentees relied upon, indeed emphasised, how the newly elucidated genetic sequences were a kind of ‘holy grail,’ suggesting that without this information the production of the relevant proteins using recombinant technologies would not have been possible. Specifically, the crucial step forward according to each of these patentees was in the cloning or identification of the relevant gene or genome that held the nucleotide information (DNAs/RNAs) that coded for the respective proteins (amino acids). For Genentech, this was the discovery of the t-PA gene.\(^\text{64}\) For Chiron it was the discovery of an HCV epitope.\(^\text{65}\) For Amgen it was the discovery of the Epo gene.\(^\text{66}\) Once this step had been successfully taken, the elucidation of the genetic sequence followed, and from there the production of the relevant proteins. In the search of the relevant gene or genome, each of the patentees made it clear that the availability of t-PA or

\(^{63}\) *Ibid*, 213 lines 40-46, 12.16.

\(^{64}\) “Genentech had identified the structure of t-PA and of the DNA which coded for it by December 1981. None of the other teams, for one reason or another, had succeeded in identifying the full structure of t-PA or of the DNA coding for it by the priority date of the patent, which was in May 1982.” (1.04) “By screening the clone libraries the genetic engineer hopes to isolate clones of the target DNA which can then be further manipulated and incorporated into another vector known as an expression vector.” (3.06) per Purchas LJ in *Genentech Inc’s Patent* [1989] RPC 147.

\(^{65}\) “Once a particular gene or nucleotide sequence has been identified and cloned it is possible to take DNA sequences from the ends of the segment already cloned for use as probes. Such probes are used to screen a genomic library by hybridisation to identify the neighbouring sequences. By repetition it is possible to identify the whole of the sequence. Though by its very nature this process is time-consuming it is, as all the expert witnesses agreed, perfectly routine.” See *Chiron v Murex (No 12)* [1996] RPC 535 per Morritt LJ (UK Court of Appeal).
Epo proteins, or even some amino acid sequence information about these proteins did not diminish the significance of their ‘invention.’ In Chiron the patentee stressed how the lack of reliable scientific information about the characteristics of the causative agent of NANBH made the search of the ‘illusive agent’ something akin to “looking for a needle in 10,000 haystacks.”

Clearly, the elucidation of the genetic sequence of these biological materials was new in each of the three cases. Furthermore in each of the three patents the relevant genetic sequence was disclosed in the patent specification and in the cases of Amgen and Chiron, specifically mentioned in the primary claims.

What mattered to Purchas LJ was that the primary claim to recombinantly produced t-PA was, in his opinion, nothing more than “a claim to the protection of the discovery as such” and this he concluded was so because the claim was not limited to a well defined method of production. The Genentech patent caught within its scope artificial t-PA howsoever made. It was indistinguishable from natural t-PA. So it was the lack of distinction between artificial t-PA produced by recombinant means and natural t-PA produced by the human body that made it impossible to have a well defined method of production because ipso facto to produce one was to produce the other. Therefore, the ‘discovery’ of the new sequence to t-PA was the ‘invention’ and accordingly came within the prohibition in s.1(2)(a) UK Act. The same is equally true for HCV and Epo.

On the other hand if the genetic sequence of t-PA had been used in a well defined method of production to produce something markedly different to natural t-PA, such as an enhanced version of t-PA or t-PA with superior biological properties than natural t-PA, the method of production and the end result would have been ‘inventions’ within s.1(1) UK Act. This is because the method of production would then be distinguishable in terms of the end result and therefore definable as a consequence.

It is for this reason that Aldous J erred in Chiron. The substantially isolated HCV proteins, which were the subject of claim 1, were identical to natural HCV proteins. It mattered not that HCV was

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67 “Professor Mills, Director of the MacFarlane Burnett institute, will describe the Chiron work as like looking for a needle in 10,000 haystacks. That is in his affidavit at paragraph 42. It is still not entirely clear why Chiron achieved the single success which it did. Based on Chiron’s experience its single success out of five attempts represents one clone in more than five million. Subsequent study, with the assistance of a knowledge derived from the invention indicates that there were up to 500 HCV clones in the library from which clone 511 was identified. If the procedure was as straight forward as alleged by Murex many positive clones should have been identified but it is still not clear why only clone 511 was
not fully characterised nor identified before the discovery of the part of its genomic sequence. The primary claim of the Chiron patent was a claim that was tantamount to the ‘discovery’ as such.

_The Court of Appeal (November 1995)_

While the Court of Appeal held that:

> In our judgment all the claims in this case cover inventions properly so called and not discoveries as such. In the cases of claims 1 to 12 the claim is to a polypeptide which is the physical expression of the part of the genetic sequence of the HCV virus containing an antigenic determinant.

Meaning that, a substantially isolated HCV protein is an invention because it is ‘the physical expression’ of HCV that contains an antibody binding site. This reasoning is not only difficult to understand but it is spurious because even so, the description of the claims is nothing more than a description of natural HCV.

The Court cited Aldous J’s reference to Vicom and Merrill Lynch with approval and cited Gale with approval, but in doing so it did not explain how “the physical expression of the part of the genetic sequence of the HCV virus containing an antigenic determinant” came within the “technical contribution” or “practical application” test supported by these authorities. Rather, the Court held that “[t]here is nothing in either of these cases to suggest that the physical structure or chemical formula of the product resulting from the discovery must be disclosed” meaning that Chiron did not even have to disclose the antibody binding sites on the HCV genome in order to come within the concept of ‘invention’.

Its reasoning is, with respect, nonsensical for apart from the fact that the primary claim had nothing to do with any technical application, the complete absence of any information in the patent specification identifying even one antibody binding site, made the claim nothing more than an ambit claim over ‘substantially isolated’ HCV proteins. In this regard, the Court ignored the real import of both Fox LJ’s reasoning in Merrill Lynch and Nicholls LJ’s reasoning in Gale.

In referring to Gale, the Court failed to appreciate that the ‘practical application’ test as applied by Nicholls LJ in Gale required more than the mere application of an algorithm in a computer to identified.” Per Francis Douglas QC, counsel for Chiron, 41-42 Federal Court Transcript, June 24, 1996; Murex Diagnostics Australia Pty Ltd v Chiron Corp. [NG 106/94 Federal Court of Australia].

68 _Chiron Corporation and Others v Murex Diagnostics Ltd and Others (No 12) [1996] RPC 535_ (Emphasis added) (UK Court of Appeal).
make it an ‘invention’, just as Purchas LJ in Genentech required more than the ‘discovery’ of a genetic sequence of the t-PA gene to make isolated t-PA, an ‘invention’. Rather than following Purchas LJ in Genentech, the Court applied the version of the ‘practical application’ test as propounded by Dillon LJ, who was in the minority in Genentech. This error was further compounded by the fact that neither Merrill Lynch, Vicom nor Gale concerned s.1(2)(a) UK Act (art. 52(2)(a) EPC), but concerned s.1(2)(c) UK Act (art. 52(2)(c) EPC). This led the Court to make a number of errors.

Firstly, Purchas LJ invalidated the Genentech patent because claims 1 to 6 were claims to a product that could be produced by any recombinant technology and this made them claims to a ‘discovery’. Each of these claims were claims to isolated t-PA howsoever produced, just as in the Chiron patent claims 1 to 12 were claims to isolated HCV polypeptides howsoever produced. According to Purchas LJ in Genentech, whether the product claims were claims to ‘inventions’ as opposed to ‘discoveries’ depended on there being disclosed in the patent a “clearly identified and defined” method of production of the product so as to “exclude any speculative element”. The Chiron patent did not specify any recombinant method of production. Literally, the production of isolated HCV polypeptides by any technology comes within the primary claims.

Secondly, the reference by Nicholls LJ in Gale to a ‘practical application’ of an algorithm in the context of s.1(2)(c) UK Act was a reference to the terminology used by Dillon LJ in Genentech who was in the minority on the issue of invention in that case.

Thirdly, the ‘practical application’ test that Dillon LJ propounded was not part of the ratio decidendi of Genentech. Neither Mustill LJ, who considered the issue of invention per se within s.1(1) UK Act separate from the issue of discovery in s.1(2)(a) UK Act nor Purchas LJ who considered the issue of invention in s.1(1) UK Act from the perspective of s.1(2)(a) UK Act used the term ‘practical application’ in their respective decisions. To the extent that Purchas LJ considered the distinction between an ‘invention’ and a ‘discovery’, he was not of the opinion that all that was required to transform a discovery into an invention was the mere manifestation of the discovery in, for example, a product. What he required was more. He acknowledged that isolated t-PA, which was defined in claims 1 to 6 of the Genentech patent, was a product but even so, it remained a ‘discovery’ within s.1(2)(a) UK Act.

Although Purchas LJ did not use the term ‘practical application’, if the term was to have a meaning consistent with his decision, the manifestation of the discovery of the genetic sequence of the human gene in an isolated human protein product required a nexus to a clearly identified and defined method of production. Unless, this condition was satisfied then the isolated t-PA product was incapable of being an ‘invention’ within s.1(1) UK Act.
Fourthly, despite the reference by Nicholls LJ in Gale to Dillon LJ in Genentech, his reasoning and decision was actually consistent with the reasoning and decision of Purchas LJ in Genentech. The patent in Gale was held to be invalid by the Court of Appeal as it was not an ‘invention’ within s.1(1) UK Act it being excluded by s.1(2)(c) UK Act, just as Purchas LJ held the Genentech patent invalid because there was no invention, only a discovery within s.1(2)(a) UK Act. It seems that while Nicholls LJ borrowed the term ‘practical application’ from Dillon LJ, he followed the reasoning of Purchas LJ. Nicholls LJ decided in Gale that the subject algorithm was a computer program and not an invention not because a computer program was not capable of being incorporated in a computer, but rather because, the instructions contained within the algorithm “do not embody a technical process which exists outside the computer”.

Finally, Genentech and Chiron concerned different technologies to Merrill Lynch and Gale. Genentech was concerned with whether the genetic information of a human protein was, when used to produce a human protein by recombinant technology, a ‘discovery’ within s. 1(2)(a) UK Act, whereas, Gale was concerned with whether an algorithm, when used in a computer, was a ‘computer program’ within s. 1(2)(c) UK Act. Of course, the effect of Genentech, Merrill Lynch and Gale on the patents in issue was the same because of the relationship between s.1(1) and s.1(2) UK Act. Once the subject matter of the patents was held to be excluded by s.1(2) UK Act the patents were invalid because they each failed to comply with the first and fundamental condition of patentability in s.1(1) UK Act, i.e., that there be an ‘invention’.

Unfortunately, because of the Court of Appeal in Chiron (No 12) UK patent law was distorted. By adopting the terminology of Nicholls LJ in Gale the Court superficially dealt with the issue of invention by the simple categorisation of the HCV polypeptide claims as products. This superficial analysis led the Court into error, an error that neither Purchas and Mustill LJJ in Genentech nor Nicholls LJ in Gale made.

Although the ground for error was laid first by Dillon LJ in Genentech it was compounded by Aldous J in Chiron (No 3) and then reinforced by the Court of Appeal in Chiron (No 12). Notably, the Court of Appeal that heard Gale reversed Aldous J but the Court of Appeal that heard Chiron affirmed him. In this regard it is important to consider Aldous J’s decision in Gale in more detail.

**Aldous J in Gale**

Nicholls LJ in Gale quoted from the lower court decision of Aldous J. There Aldous J held,

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69 In Gale’s Application [1991] RPC 305 per Nicholls LJ, 327 lines 51-52 (UK Court of Appeal).
I have come to the conclusion that the ROM claimed cannot be considered as a claim to an invention which is no more than an invention relating to disqualified matter defined in section 1(2) of the Act. The ROM is an article which can be manufactured. It has one dedicated function. It is an article whose structure has been altered during manufacture so as to perform the function of this method or program defined by the claim. A claim in a patent to such an article cannot to my mind be called a claim relating to a mathematical method or a method for performing a mental act, nor a program for computer.  

Not only was Aldous J’s reasoning expressly rejected by Nicholls LJ but it was also rejected by Parker and Sir Nicholas Brown-Wilkinson VC LJJ, who constituted the Court of Appeal in Gale. However, despite the unanimous rejection by the Court of Appeal of his reasoning in Gale, Aldous J persisted with this same reasoning in Chiron, some two years later. When Chiron (No 12) eventually reached the Court of Appeal, the difference on this occasion was that the Court failed to properly consider Genentech and Gale and simply affirmed the erroneous reasoning of Aldous J. in Chiron (No 3) which is directly attributable to the Court’s superficial analysis of the authorities concerning the issue of ‘invention’.

The Court of Appeal in Chiron and the House of Lords in Biogen

At the time that the Court of Appeal heard the appeal in Chiron (No 12), their Lordships speeches in Biogen had not been made and although the issue of ‘invention’ was not strictly before the House, the issue was nevertheless raised by Lord Hoffmann and by Lord Mustill in their speeches. Consequently, the Court of Appeal in Chiron (No 12) did not have the benefit of their Lordships speeches regarding the issue when they delivered their decision. Moreover, the question reserved by the Court of Appeal in Chiron (No 12) for consideration by the House of Lords - “[a]re any of the claims, in particular claim 1 invalid as relating to a substance found in nature?” - was never considered by the House of Lords as the application for leave to appeal that followed Chiron (No 12) was discontinued in August 1996 as a consequence of a worldwide settlement.

Therefore, the decisions of Purchas and Mustill LJJ in Genentech which were referred to in Biogen remain the leading authorities in the UK on the issue of ‘invention’ in respect to patents granted prior to the Directive amendments to the UK Act\(^71\) that claim isolated biological materials as ‘inventions’.

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\(^70\) *In Gale’s Application* [1991] RPC 305 per Nicholls LJ 320 lines 8-15 quoting Aldous J (Emphasis added).

Chapter 5: Case Study 2 – The Patenting of Hepatitis C Virus

Petition to the House of Lords (1996)

The decision of the Court of Appeal was the subject of a petition for leave to appeal. The petition was granted conditional leave and final leave was being considered by their Lordships when the petition was discontinued in late August 1996 as result of world-wide settlement being reached between Chiron and Murex. Nevertheless, the arguments contained in the petition are worthy of consideration given that provisional leave was granted and that their Lordships had decided Biogen a few months earlier.

Murex and UBI argued that the primary claim was a claim to a monopoly in “all the fruits of the application” of a discovery and referred to the Court of Appeal decision in Genentech which “if the opinion of Mustill LJ in that case is correct, your Petitioners would appear to be entitled to succeed in any event [although] [t]hey ought to succeed even on the reasoning of Purchas LJ [whose decision] was distinguished by Court of Appeal in the instant case but (with the greatest respect) not soundly.”

It argued that the Court of Appeal was wrong because the effect of its decision was to classify isolated HCV proteins that contained antibody binding sites as an ‘invention’ without the patent having to specify or identify the amino acid sequence of those sites, that is, provide a ‘formula’ for the sites. The problem for subsequent researchers, argued the Petition is that “not only is the formula for each [site] different, but the physical shape of [the site] is different, as are its biological properties.” Moreover, the scope of the primary claim meant that it “made no difference” that the primary judge struck out the vaccine claims because “although not specifically directed to vaccines, [the claims] are wide enough to cover them all the same”. The justification which the Court of Appeal gave for this latitude in terms of the primary claim is that the application of an isolated HCV protein in an effective vaccine would amount to an inventive improvement which should be caught by the scope of the claim, but the Petitioner posed the question: “Why should a [binding site] with completely different physical and biological properties, and having a completely different formula, be characterised as an ‘improvement’ in any relevant sense?”

How the House of Lords would have decided the Appeal is a matter of speculation, however, it is clear that the Court of Appeal decision in Genentech was good law and given that the House of

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72 Petition to the House of Lords, Murex Diagnostics Limited v Chiron Corporation.
73 Ibid.
74 Ibid.
Lords in *Biogen* made a favourable reference to it, it is suggested that *Genentech* would have been influential in its decision.

Furthermore, in view of the House of Lords decision in *Kirin-Amgen* it is probable that the Court of Appeal decision in *Chiron* would have been overruled.

**Hepatitis C Virus in Australia**

Although Australian patent 624,105 (AU624,105) was given the title, “NANBV Diagnostics and Vaccines,” it could just as easily have been given the title “Hepatitis C Virus” because the specification was virtually word-for-word identical to the specification of the corresponding UK patent GB2,212,511. The main difference between the two patents were the granted patent claims. Both patents started life as a PCT patent application with the same patent claims, but because the process of examination in the UK Patent Office is different to that in the Australian Patent Office, *Chiron* was required to amend the claims during the examination phase in the UK, whereas in Australia, the perfunctory process employed by the Australian Patent Office resulted in the grant of a patent, the claims of which were unchanged. This is an important fact to note because it demonstrates that a set of claims that can be acceptable to one patent office may be unacceptable to another. In the case of AU624,105 the two major primary claims were claims 1 and 12. These read as follows:

Claim 1: A purified HCV polynucleotide.

Claim 12: A purified HCV polypeptide.

Given that a polypeptide by definition is ‘more than one’ amino acid, it is difficult to understand how a patent examiner could have permitted such a claim when there are only twenty amino acids in existence and these are universal to all proteins whether human or not. Given the universality of amino acids it is simply impossible to distinguish the source if there are only two. Moreover, these two claims demonstrate how the application of the ‘purified’ or ‘isolated’ distinction between a product of man and a product of nature is nothing more than exercise in semantics. The examiner obviously believed that the claims were ‘restricted’ to ‘purified’ amino acids or nucleotides, that is, non-natural amino acids or nucleotides, but if he truly believed this, then it is reasonable to question the examiners credentials because, purified or not, it was and is simply impossible using that criterion alone to make the distinction which the claims invited.

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Ibid. 166
Nevertheless AU624,105 was granted in 1992. Interestingly, a completely new set of claims were substituted in 1997 after the patent was challenged in Murex. The 1997 claims more closely resemble the corresponding GB and European patent claims and it is these claims that apply today.  

The patent specification described the impact of the ‘invention’ to human health thus:

The demand for sensitive, specific methods for screening and identifying carriers of NANBV and NANBV contaminated blood or blood products is significant. Post-transfusion hepatitis (PTH) occurs in approximately 10% of transfused patients, and NANBH accounts for up to 90% of these cases. The major problem in this disease is the frequent progression to chronic liver damage (25-55%). Patient care as well as the prevention of transmission of NANBH by blood and blood products or by close personal contact require reliable diagnostic and prognostic tools to detect nucleic acids, antigens and antibodies related to NANBV. In addition, there is also a need for effective vaccines and immunotherapeutic therapeutic agents for the prevention and/or treatment of the disease.

This statement was accurate when the PCT patent application was filed in Australia, but by 1990 the availability of the Chiron licensed HCV immunoassays in Australia meant that the Australian Red Cross, laboratories and hospitals finally had a diagnostic tool that enabled them to eliminate HCV infected donations from the blood supply and arrest the spread of post-transfusion HCV (‘PT-HCV’). However, despite the production of the first generation HCV immunoassays, they were not perfect. The problem was that the first generation HCV immunoassays were not as sensitive nor specific as they needed to be with the result that there remained a significant incidence of PT- HCV in the Australian blood supply.

Even by 1991, a year after Chiron scientists had published nearly all of the HCV genetic information then available, scientists in Australia working on HCV needed to develop more

76 In February 2001 the TBA held the equivalent claims in EP 0,318,216 invalid. See T0188/97 F. Hoffmann-La Roche & Co AG v Chiron Corporation (February 8, 2001).
77 See Australian Patent 624,105 at page 7.
78 Locarnini 1, 6.11 (Affidavit filed in Murex). “The current Chiron anti-HCV screening assay which is no more than 90% sensitive, is clearly unacceptable and must be improved upon. Sensitivity is defined as the ability of a diagnostic test to actually find those who are truly infected to be positive, whereas specificity is to find those that are truly not infected to be negative, so when the test is evaluated for sensitivity one finds a high risk group that are likely to be infected. For specificity, one finds a low prevalence group”. See also Locarnini and Breshlin, Comparison of Three Second Generation Immunoassays for Detection of Hepatitis C Virus Antibody, (1993-February) AJ Med. Sci, Vol 14 and the National Health & Medical Research Council, Report On The Epidemiology, Natural History And Control Of Hepatitis C, November 1993.
sensitive and specific tests for the detection of HCV infection, but they faced a legal barrier: how could they and not breach the primary claims of AU 624,105? Professor Blumberg, a Nobel laureate put it thus,

I have reviewed Chiron’s Australian Patent No. 624105 [and] [In my opinion, the claims in this patent … represent a view in scientific thought, i.e., that ‘anything that is done with the HCV virus is covered by this patent and all research and development on the virus is subservient to it.’ This patent essentially does not distinguish between genotype and phenotype, whereas geneticists are very aware that such a distinction should be made. It is the reductionism argument taken to the extreme and it is not supported by the great weight of the history of scientific discovery in biology and medicine. To the extent that this extreme view is backed-up by broad claims, which it is in this patent, the effect will likely be inhibition of research on HCV. Based on the unusually broad nature of the patent, if I were a research director for anti-virals and had the option of working on several viruses, the existence of this patent would weigh against my deciding to undertake HCV research. A company, or even an academic laboratory, might well be deterred from conducting research on HCV because the patent is, in effect, intimidating. With the patent as it stands, any investigator, particularly in commercial laboratories (where much of the work on hepatitis has been done) would have to seriously consider that Chiron would bring an action against them if they attempted any commercialization of anything related to HCV.80

Professor Blumberg used the word ‘commercialisation’ to suggest that only commercially directed research would be caught by the patent, but as Australia had and has no statutory research exemption,81 the truth is that any research using any genetic material in HCV research would have been caught by the patent.82

Although information about the Chiron HCV patent had been in the public domain since mid-1989, it was clear that the information contained in that patent did not provide the information necessary to produce an HCV diagnostic test that would eliminate all or practically all cases of PT-HCV. Yet, Chiron was by end of 1992 the owner of a patent of invention in Australia that covered everything that could be produced, made, used and sold that had anything to do with HCV.

80 Blumberg 1, 5.1-5.2 (Affidavit filed in Murex).
81 Cf: Note that the AU Act, s.78 does provide a research exemption for patent infringement but it is limited to patents for pharmaceutic substances that have been granted an extension of term beyond the normal twenty year period.
82 The Australian Council for Intellectual Property is presently conducting an Inquiry into the issue of patent infringement exemptions for research. It has identified the possibility that such as exemption is available at common law, but whether it applies and the scope of its application is unclear. See ACIP Experimental Exemption Issues Paper, February, 2004. Also see the second submission to the ACIP Inquiry by Luigi Palombi, February, 2005.
Competition to Chiron license HCV immunoassays

Murex Diagnostics Australia Pty Limited was a subsidiary of a Canadian company called International Murex Technologies Corporation (“IMTC”). Another subsidiary was Murex Diagnostics Limited in England. The English company manufactured and sold an HCV diagnostic immunoassay in the UK and Europe and exported it to the Australian company which then sold and distributed it in Australia. The Murex HCV immunoassay had been developed by the English company using its own in-house research and technical facilities. These facilities were extensive and had been owned by Wellcome until acquired by IMTC in 1991.

The isolated HCV protein that was used in the Murex HCV immunoassay was derived from a human patient in the UK who had been infected with HCV1b whereas the Chiron licensed HCV immunoassays contained the ‘c-100 polypeptide’ that had been derived from a laboratory chimpanzee Rodney that had been infected with HCV1a.83

Issues of Public Health

This distinction in the two types of HCV immunoassays was very important because the Murex HCV test provided diagnostic laboratories with an alternative commercially produced immunoassay that enabled them to undertake a secondary diagnosis of the disease. For example, if the Chiron licensed HCV test produced a mildly positive result, the use of the Murex HCV test could be used as a confirmatory test, so as to ensure the reliability of the provisional diagnosis. Professor Locarnini explained the reason for the need of a secondary HCV immunoassay,

The Hepatitis C Task Force recommendations contained in the November 1993 report focus on the laboratory diagnosis of hepatitis C, case definitions, epidemiology and control mechanisms of hepatitis C in Australia. The Hepatitis C Task Force, after receiving submissions and reviewing the literature, indicated that a number of important public health issues had come to light. The Hepatitis C Task Force found that Australian strains of hepatitis C are probably different from strains circulating in the northern hemisphere. Consequently, the first recommendation of the report was that Australian research laboratories ‘be encouraged to undertake full nucleotide sequence studies on Australian strains of hepatitis C virus’. The reason for this recommendation was that cases of post-transfusion hepatitis C were occurring in the community that were being

83 Simmonds 1, 6.1 (Affidavit filed in Murex). “Different immunological screening assays use antigenic material from different sources. The Murex HCV assays uses antigenic material derived from a human donor in the UK and is of HCV genotype now known as type 1b. In the United Kingdom genotype 1b is one of the most prevalent genotypes. That is the sequence that Murex first isolated and that Murex antigens are based on. The Chiron based assays use antigenic material derived from a chimpanzee in the USA and is of HCV genotype type 1a, which is the most predominant type in the USA.”
missed by the existing, ‘second generation’ screening tests. The reason for this is still unknown today. The Ortho/Abbott second generation screening kits were introduced in Australia in May 1991. The Abbott “third generation” screening kits are presently being introduced in Australia.  

The effectiveness of the Chiron licensed HCV immunoassays were being restricted by the genetic diversity of HCV throughout the world and by the HCV protein contained in those immunoassays. This was due to the human immune response to HCV infection. Not only did the human body produce different antibodies at different stages of infection, but the genetic diversity of HCV was so vast that a protein containing an antibody binding site derived from HCV-la may not have been effective to enable an antibody produced in response to infection from HCV-3b to bind to that HCV-la site.

Of course, the Murex HCV test was not the solution to the public health issue, but it was a part of the solution. The solution was for Chiron to have permitted the production of many HCV immunoassays, but this it refused to do. Despite Murex offering to enter into a patent license with Chiron on numerous occasions, Chiron refused. Moreover, Chiron refused to enable its own licensees, such as Abbott Laboratories, to produce HCV immunoassays that would have addressed the genetic diversity of HCV.

84 Locarnini 1, 6.8 (Affidavit filed in Murex).
85 Simmonds 1, 5.4 (Affidavit filed in Murex). “In the United States of America there is predominantly HCV type 1a and 1b. In Europe (including the United Kingdom) there is predominantly HCV types 1a, 1b, 2 and 3. In the Middle East there is predominantly types 3 and 4. Individuals from countries like Pakistan, India and Bangladesh are most frequently infected with and other subtypes of type 3a. Type 4 is frequent in central Africa, type 5 is frequent in South Africa and type 6 is frequent in South East Asia (including Vietnam). In Australia there are basically 3 HCV types, type 1, type 2, and type 3. I believe type 5 and 6 have also been reported in Australia. There are no strict geographical boundaries limiting the various HCV types.”
86 Simmonds 1, 6.4 (Affidavit filed in Murex). “My colleagues and I found that a large proportion of infected individuals were missed by the early assays (based on the Chiron’s sequence data) because they contained antibodies generated against HCV genotypes other than type 1. If you incubate a type 2 serum against type 1 peptides containing 5-1-1 epitopes, recognition of the serum is generally very weak or may not be observed at all.”
87 Locarnini 1, 6.17 (Affidavit filed in Murex). “With hepatitis C it is now suspected, due to the fact that anti-HCV screening assays/diagnostic kits have not achieved sensitivity above 90% and the numbers of indeterminants that have been recorded, that many of the immune responses are conformation dependent. In other words there are nuances of the three-dimensional folding which are critical to antibody detection. It is extremely difficult to reproduce the natural three dimensional folding of a protein containing an epitope in E.coli or yeast fusion protein systems. With such systems all that is produced is a linear epitope of one small fragment of the genome of a strain of HCV inserted in the E.coli or yeast expression protein. The difficulty with hepatitis C is that a person is not infected with E.coli containing clone 5-1-1 proteins, or c-100-3 proteins; that person is infected with the whole native hepatitis C virus of a particular genotype.”
The Australian Murex Case

A revocation action was brought by Murex Diagnostics Australia Pty Ltd (“Murex Australia”) against Chiron Corporation and Ortho Diagnostic Systems, Inc for the purpose of challenging the validity of AU624,105.88 It commenced on March 3, 1994 and ended nine weeks into the trial on August 28, 1996. The settlement that resolved this and all other litigation between the parties resulted in Chiron granting Murex global licenses to manufacture a serotyping HCV assay and a restricted license to manufacture and supply its HCV immunoassay.

Manner of Manufacture

The Australian patent was challenged on numerous grounds including that the ‘invention’ was not a ‘manner of manufacture within the meaning of section 6 of the Statute of Monopolies’. In this regard it was alleged that the claims were to a ‘mere discovery’; that the invention was incomplete in that ‘[t]he specification does not disclose the nucleotide sequence of the RNA genome of HCV at all, and further, it only discloses the complementary DNA sequence of part of the genome of HCV’; that some of the claims were to a ‘living natural organism’ and that claims to antibodies were ‘no different to naturally occurring antibodies’.

The two leading Australian authorities were National Research Development Corporation v. Commissioner of Patents89 (NRDC) and NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited90 (Philips). NRDC was decided by the High Court of Australia in 1959 when the applicable patent legislation was the Patents Act, 1952, whereas Philips was decided by the same Court in 1995 when the applicable legislation was the Patents Act, 1990. However, despite the new patent legislation, NRDC remained good authority because the ‘manner of manufacture’ test that applied in the 1952 law was retained in the 1990 law.

Philips focused on the issue of whether the word ‘new’, as in ‘manner of new manufacture’ contained within the express definition of ‘invention’ in AU Act, meant that before something could even be considered to satisfy the parameters of patentability provided by s.18(1), it must first be an ‘invention’. The issue arose because of the prerequisite in s.18(1) that “... a patentable invention is an invention that ...”. Therefore, the argument which the Court was invited to

88 Murex Diagnostics Australia Pty Limited v Chiron Corporation & Another (Federal Court of Australia Action No: NG 106 of 1994).
89 National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252 (High Court of Australia).
consider was that unless the subject matter of the patent satisfied “a general threshold requirement of ‘newness’ or ‘inventiveness’” it was unnecessary for there to be a consideration of “either s.18(1)(a)’s requirement of a ‘manner of manufacture’ or s.18(1)(b)’s requirements of [novelty and inventive step being] a comparison with a defined ‘prior art base’.”

Like NRDC, the patent in Philips concerned a product of man, namely, phosphors. The issue, however, was whether the use of phosphors in highly loaded low-pressure mercury vapour discharge lamps, arguably a new use of phosphors, was ‘an invention’ within s.18(1). It was an analogous situation to the facts in NRDC, but the Court in this instance drew a distinction between whether it was a ‘manner of manufacture’ which is the question considered in NRDC and whether it was a ‘manner of new manufacture’. This was a most controversial distinction because if the distinction was valid, then the question which the High Court posed in NRDC as definitive on the issue of ‘invention’, namely, “Is this a proper subject of letters patent according to the principles which have been developed for the application of s. 6 of the Statute of Monopolies?” could only be answered in the context of the 1990 law if the ‘subject of the letters patent’ first satisfied “a general threshold requirement of ‘newness’ or ‘inventiveness’”.

The Court decided in Philips that the use of phosphors (which were known to possess luminescent qualities) in highly loaded low-pressure mercury vapour discharge lamps was no more than the mere “new use of a known product” and therefore was not ‘an invention’ within s.18(1) AU Act. In terms of defining the ‘invention’ for the purpose of the scrutiny which Philips required, s.18 made this clear by the words “…so far as claimed in any claim…”. So the relevant invention was that defined by the claims. Given that claims 1 and 12, the polynucleotide and polypeptide claims, were the cornerstones of all of the granted claims, the question which the Federal Court was required to consider in Murex was whether the subject matter of these two claims were ‘inventions’ within the meaning of the word in s.18(1) AU Act?

According to Philips an answer to this question required a reading of the patent specification and “if it is apparent on the face of the relevant specification that the subject matter of the claim is, by reason of absence of the necessary quality of inventiveness, not a manner of new manufacture for the purposes of the Statute of Monopolies” then it is not ‘an invention’. On the facts of Murex the

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90 *NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited* (1995) 183 CLR 655 (High Court of Australia).
Chapter 5: Case Study 2 – The Patenting of Hepatitis C Virus

question was: Did a purified HCV polynucleotide or polypeptide, based upon a reading of the specification, display ‘the necessary quality of inventiveness’?

As to what constituted ‘the necessary quality of inventiveness’ the Court held that the answer was not based upon a consideration of the parameters of patentability of ‘novelty’ or ‘inventive step’ in s.18(1)(b) AU Act because the “more specific requirements of novelty and inventive step” are only to be considered after the prerequisite parameter of ‘invention’ is satisfied.

It is arguable that had Murex proceeded to judgement that the binding authority of Philips would have required a finding that the claims did not concern an ‘invention’ within s.18(1) AU Act because “[d]iscovery it may be, but invention it is not.”

The fact remains that the elucidation of the genetic sequence of HCV 1a was nothing more than a chemical shorthand description of HCV, which no one invented nor formulated nor created nor modified. What Chiron did in collaboration with the CDC was to devise a method of finding or isolating a partially characterised virus that caused the human disease of hepatitis. While Chiron described this isolation method as ‘novel’, and this was disputed by Murex, there is not one claim in any Chiron HCV patent anywhere in the world, let alone AU624,105, that made a claim to this ‘novel’ methodology as an ‘invention’. To the contrary, in the patent specification Chiron explained that “[t]he description of the method to retrieve the cDNA sequences is mostly of historical interest.” The importance of this sentence

94 Re D. Co.’s Application (1921) 38 RPC 397, per Sir Ernest Pollock S-G, 399.

95 It was partially characterised because it had been described by Dr. Bradley in various publications. For example Professor Arima testified, “I saw many patients infected with NANBH and was of the opinion that the aetiological agent of NANBH was a virus. This opinion was supported by Dr. Bradley’s transmission studies of NANBH which I was aware at that time: Bradley DW et al (1979) Experimental Infection of Chimpanzees with Antihemophilic (Factor VIII) Materials: Recovery of Virus-Like Particles Associated with Non-A-Non-B Hepatitis Journal of Medical Virology 3:253-269; Arima, 25 – “In 1985, Bradley summarised the physiochemical and pathogenic properties of the tubule-forming post transfusion agent in an article entitled The Agent of Non-A-Non-B Hepatitis Journal of Virological Methods, 10 307-319 (1985)”; Arima, 29; “Bradley concluded that the TFA was a kind of togavirus or toga-like virus, which I knew at the time to be a small RNA virus with a lipid envelope. By comparing the aforementioned properties with the characteristics of the then known viruses, I hypothesised that the TFA might be a flavivirus similar to Japanese encephalitis virus, and likewise a small blood borne RNA virus;” Arima, 30 (Affidavit filed in Murex).

96 The patent specification of AU624,105; GB2,212,511; EP0,318,216 and US5,350,617; US6,027,729 and US6,074,816 all state: “The invention pertains to the isolation and characterization of a newly discovered etiologic agent of NANBH, hepatitis C virus (HCV). More specifically, the invention provides a family of cDNA replicas of portions of HCV genome. These cDNA replicas were isolated by a technique which included a novel step of screening expression products from cDNA libraries created from a particulate agent in infected tissue with sera from patients with NANBH to detect newly synthesized antigens derived from the genome of the heretofore unisolated and uncharacterized viral agent, and of selecting clones which produced products which reacted immunologically only with sera from infected individuals as compared to non-infected individuals.”

cannot to be underestimated. This was an unconditional disclaimer to the effect that the applied methodology did not form part of the invention.

Chiron, obviously did not argue that the invention was HCV per se. Rather, counsel for Chiron in *Murex* opened before Burchett J arguing that the principle claims were ‘product’ claims and that these “particular molecules [or products] [are] useful for the detection of HCV”. He then explained that “[t]he method employed by the Chiron team which was ultimately successful [in isolating the virus] … had never been employed to identify a causative agent of a disease which was not well characterised in circumstances where the existence, specificity and identity of an antibody had not been demonstrated or defined”.

The problem with this argument was that the primary claims were (a) not descriptive of a product of man, but of a product of nature, (b) the molecules which were the subject of the claims were identical to those in nature,(c) the said molecules were not limited to the use in the detection of HCV and (d) they did not claim the methodology employed to deduce their genetic structure.

Chiron’s entire case was based upon the premise that it was entitled to a patent over HCV proteins howsoever produced because it was the first to produce an immunoassay for the detection of HCV, albeit, not one that was able to detect all HCV’s in infected biological materials, only some. Arguably, if the sole contribution to the advancement of human health was an HCV immunoassay, then it should have applied for a patent that was limited to HCV immunoassays, but it did not.

The categorisation of the two primary claims as ‘products’ was an obvious attempt to bring the claims within what counsel understood to be the ‘principles’ of *NRDC*, namely that ‘purified HCV nucleotides and polypeptides’ were artificial and vendible products and therefore a ‘manner of manufacture within s.18(1)(a) *AU Act*. However, this categorisation failed to address an important distinction between the facts in *Murex* and the facts in *NRDC*, namely that in *Murex* the alleged ‘products’ were proteins substantially identical to those of a naturally occurring virus, whereas in *NRDC* the end result of the claimed process that made use of an existing herbicide that achieved a

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98 Mr. Francis Douglas QC, Federal Court of Australia transcript June 24, 1996, 39.
99 Ibid.
100 “The effect produced by the appellant’s method exhibits the two essential qualities upon which ‘product’ and ‘vendible’ seem designed to insist. It is a ‘product’ because it consists in an artificially created state of affairs, discernible by observing over a period the growth of weeds and crops respectively on sown land on which the method has been put into practice. And the significance of the product is economic” *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 277.
new result was the ‘product’. Both the process and the product of that process in NRDC were intrinsically artificial because they were completely man-made. Moreover, the end result of the process was also artificial in that it had the specific effect of destroying particular weeds without damaging particular crops. But the real issue in Murex was not only whether the alleged ‘products’ were artificial or not, but also whether the degree of artificiality exhibited by the viral materials made them ‘inventions’ within the principles of NRDC and Philips. In this regard, just as the High Court in NRDC looked to the US Supreme Court in Funk Brothers for guidance, it was open for the Federal Court to look to Chakrabarty and Genentech for guidance. Accordingly, both Chakrabarty and Genentech were decisions that explained that it was not enough for a product of nature to be artificial for it to be an ‘invention’. The fact remains that purified or isolated HCV proteins while being in an artificial environment and in this respect, themselves artificial, are indistinguishable from natural HCV proteins. This is far removed from the genetically modified bacterium in Chakrabarty that was capable of degrading crude oil, something not found in nature.

**Hepatitis C Virus in the European Patent Office**

Like AU624,105, the corresponding EP0,318,216 was entitled “NANBV Diagnostics and Vaccines” and like both GB2,212,511 and AU624,105, the patent specifications were virtually word-for-word identical. Where they differed was in the claims. The UK claims were practically identical to the granted claims of EP0,318,216, but the Australian claims were almost identical to the applied-for claims.

In particular the European polypeptide claim, claim 1, was identical to the corresponding primary claim in UK patent which, as discussed earlier, was upheld as a valid claim by both the UK Patents Court and the UK Court of Appeal.

In T0188/97 F. Hoffmann-La Roche & Co AG v Chiron Corporation, the TBA considered EP0,318,216 in the context of an appeal from the “interlocutory decision of the Opposition Division of the European Patent Office posted 18 December 1996 concerning maintenance of European patent No. 0,318,216 in amended form”. However, even though Chiron filed an

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101 For a more detailed analysis see the discussion of NRDC in Chapter 3. It is important to note that in NRDC patent there was no claim to the known chemicals that were the active ingredient of the herbicide, nor to the herbicide itself. So there were no claims that prevented anyone from making the chemicals or the herbicide per se. The claims were method claims to the use of those chemicals in a herbicide to achieve a specific result in the cultivation of defined crops and so the ‘product’ of the method claims which was the defined effect.

102 T188/97 F. Hoffmann-La Roche & Co AG v Chiron Corporation (February 8, 2001) (TBA).

103 This is the description of the decision under review by the TBA in the headnote.
amended set of 81 claims in response to the Opposition, claim 1 remained the same as originally granted. Art. 52(1) EPC was not considered in this appeal, accordingly, the issue of ‘invention’ was not relevant to the evidence produced in the course of the Opposition nor the Appeal. The parties and the TBA therefore assumed that the subject matter of the patent was an ‘invention’. The question, which the TBA had to resolve, was whether the ‘invention’ was a ‘patentable invention’ and in this regard the TBA focused on ‘novelty’, ‘inventive step’ and ‘sufficiency’.

In this regard, the arguments raised by the parties and the analysis, by the TBA, of their arguments in the context of the submitted evidence and the primary claim is most revealing.

Firstly, Chiron argued that there was “[n]o evidence … that there existed viruses other than HCV, the entire polyprotein of which would have at least 40% homology to the entire HCV polyprotein.” This argument is extraordinary given that a natural phenomenon, such as a virus, is not patentable subject matter. The association of the criterion of ‘40% homology’ to the ‘entire HCV polyprotein’, which is simply another way of describing HCV as it occurs in nature, and the evidence that no other viruses existed (in nature it is supposed) that satisfied this criterion, strongly suggests that the subject matter of claim 1 are proteins identical to those of HCV as existing in nature. The fact that the proteins of claim 1 are ‘substantially isolated’ makes absolutely no difference to what they are and where they come from.

Secondly, Chiron argued that a “skilled person would have no difficulty in understanding that a polypeptide carrying an HCV antigenic determinant was a polypeptide which contained an epitope encoded by the HCV genome which epitope was recognized by antibodies (Abs) present in individuals infected with HCV.” The fact that an HCV ‘epitope’ (which is another way of describing ‘an HCV antigenic determinant’) is recognised by human antibodies is a further indication that the subject matter of claim 1 are proteins that are identical to those that occur naturally, for the simple reason that if they are not, human anti-HCV antibodies will not recognise (or bind to) the antigenic determinants contained within the said proteins.

Thirdly, Chiron argued that “[t]he viral isolate referred to in the claim needed not be an HCV virus. It could also be a virus, the polyprotein of which happened to have 40% homology to the polyprotein encoded by the viral isolate from the genome of which the cDNA bank was prepared.” In this passage, the words ‘viral’ and ‘virus’ are references to natural phenomena. Moreover, given the earlier argument that there was no evidence that any other viruses existed that

104 Mr. Francis Douglas QC, Federal Court of Australia transcript June 24, 1996, 25 (Emphasis added).
105 Ibid, 26 (Emphasis added).
“happened to have 40% homology to the polyprotein” of claim 1, the proposition that the isolate “needed not be an HCV virus” is inconsistent. If there was no evidence to the contrary, clearly the viral isolate of claim 1 was nothing more than an isolate of HCV as it exists in nature.

Fourthly, Chiron argued that “[n]ever before had a pathogen been cloned before it was identified by classical methods”, however, irrespective of the method used to isolate the virus, ‘clone 5-1-1’ – the viral isolate – was derived from a pathogen (HCV) which was a natural phenomenon.

Fifthly, Chiron argued that “[n]o one succeeded to get one positive clone without using the invention as disclosed in the patent in suit”. The ‘invention’ which Chiron referred to was the viral isolate, clone 5-1-1, which it argued provided the amino acid sequence that enabled others to create probes to also isolate HCV. This argument is consistent with clone 5-1-1 being nothing more than a natural phenomenon because its amino acid sequence is identical with the corresponding amino acid sequence of HCV.

Finally, Chiron argued that “once the first clone was isolated and sequenced, the task of obtaining further clones and, eventually, the whole genome, became a routine task.” This argument begs the question: the whole genome of what? The answer is, HCV. What it suggests is that the focus of the experiments that led to isolation of a ‘viral isolate’ and the subsequent sequencing of the whole genome was directed to HCV, a natural phenomenon.

Having considered the arguments the TBA rejected all of the amended 81 claims and reversed the Opposition Division of the EPO had upheld in its 1996 decision. All of these claims were held to be invalid. This rejection included the primary claim as originally granted. In reversing the Opposition Division of the EPO the TBA came to the opposite conclusion of the UK Court of Appeal in Chiron. However, in accordance with art. 123(2) EPC, Chiron was permitted to amend the patent claims provided the subject-matter did not extend “beyond the content of the application as filed”. The final amended claims that were approved by the TBA consisted of 5 claims that were limited to the application of HCV nucleotides in nucleic acid diagnostic tests. The TBA permitted this final amendment because it accepted that the subject matter of the amended claims

107 Ibid, 32 (Emphasis added).
108 Ibid (Emphasis added).
109 Ibid (Emphasis added).
came within the concept of the ‘invention’ disclosed in the specification, namely, “isolating and characterising the full genome of HCV, and of isolating other HCV strains.”

The TBA decision was contrary to the decisions of both the UK Patents Court and the UK Court of Appeal in Chiron. This result, however, was not unprecedented. In the case of the Genentech patent and the Biogen patent, the TBA held them valid, but the UK Court of Appeal and the House of Lords held them invalid. Although it was the TBA on this occasion that rejected the claims and not the UK Courts, it is significant that effectively the same patents could receive such diverse treatment within the context of the EPC and the complementary domestic patent law of an EC member. Does this suggest that a problem exists within the EPC and the administration of patents granted by virtue of the EPC? The answer is obviously, yes. Anthony McInerney has suggested that “[b]iotechnology has ‘ruptured’ the patent system which has struggled to adjust the application of the system to this new technology” and points to these types of conflicting decisions concerning the same patents as “clear illustration[s] of a tension in different views as to the overriding rationale for the patent system” which “[i]n turn, leads to inconsistency in the interpretation of the validity of biotechnology patents.” Although he examined the Biogen patent, the result with respect to the Genentech t-PA patent and the Chiron HCV patent lend support and credibility to his thesis. Moreover, this ‘tension’ is not confined to the TBA and the UK courts, but exists between the UK courts themselves. With the exception of Genentech, where both the Patents Court and the Court of Appeal held the Genentech t-PA patent invalid and Chiron where both the Patents Court and the Court of Appeal held the Chiron HCV patent valid, in both Biogen and Amgen, the Patents Court and the House of Lords and the Court of Appeal respectively have disagreed with regard to validity, and in the case of Amgen have also with disagreed with regard to infringement. This judicial tension evident between the UK courts is no more apparent than in the decisions of the Court of Appeal and the House of Lords in Biogen. There the Court of Appeal held the patent valid only to be reversed by the House of Lords. Furthermore, although only mere speculation, it is suggested that had Chiron proceeded to the House of Lords that the Chiron HCV patent would have received similar treatment to Biogen. What is perhaps most remarkable about this ‘tension’ is that it is not confined to the issue of ‘invention’ but is more relevantly confined to the issue of ‘insufficiency’.

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110 The TBA held, “The reproducibility of the subject-matter of claims 1 to 5 depends on the reproducibility of isolating and characterising the full genome of HCV, and of isolating other HCV strains. This has already been acknowledged in points 55 to 65 above.”, 72, 85.


112 In Chiron the TBA rejected the 81 patent claims approved by the Opposition Division because “In the Board’s judgment, the sheer amount of time and effort necessary to carry out the claimed subject matter over its whole scope is well beyond what the average skilled person would consider as undue burden although potentially useful techniques existed. And the patent in suit fails to give adequate information on how to isolate conformational epitopes and how to produce qualifying panels. Thus, the description
The characterisation of the ‘invention’ of the patent in these words is undoubtedly a reference to HCV per se, a natural phenomenon, although the reference is couched in terms of the process of ‘isolation’. Clearly, the TBA was of the opinion that the work that led to the ‘isolation’ of HCV and its subsequent ‘characterisation’, which is another way of describing its genetic sequencing, was the invention and the inventive step was the isolation of clone 5-1-1. The TBA held,

In the Board's judgment, the route chosen by [Chiron] which led to the cloning HCV DNA in absence of a known infectious agent, of an antibody to titer it or even of any sera which could be thought to contain significant quantities of such antibodies was not obvious. And, therefore, the provision of HCV DNA sequences was inventive [and] inventive step lay…in obtaining the first HCV clone.113

In this regard, the TBA and the UK Court of Appeal in Chiron were in agreement. However, because art. 52(1) EPC was not in issue in the Opposition nor in the subsequent appeal to the TBA, there was nothing in the decision that explained the TBA’s rationale. The decision of the UK Court of Appeal may shed some light on the issue because due to s.130(7) UK Act, the UK Act “is to be interpreted, so far as possible, so as to produce in [the UK] the same effect as the EPC” and the “relevant article in the European Patent Convention is Article 52(2), which, as far as relevant provides ‘(2) The following in particular shall not be regarded as inventions within the meaning of paragraph (1): (a) discoveries …’”.114

Interestingly, the UK Court of Appeal described as a ‘discovery’115 what the TBA described as the ‘inventive step’, namely, the isolation of clone 5-1-1. Nevertheless, the UK Court of Appeal referred to the decision of Aldous J with approval, who had in turn referred to the decision of Fox LJ in Merrill Lynch with approval, who in turn had referred to the TBA decision in Vicom with approval. It seemed that all roads led to Vicom.

Of course, as has been already discussed, Vicom was a case that concerned art. 52(2)(c) EPC (i.e., what is a ‘computer program’) and not art. 52(2)(a) EPC (i.e., what is a ‘discovery’) just as Merrill Lynch had concerned s. 1(2)(c) UK Act and not s. 1(2)(a) UK Act which explains the reference of Fox LJ to ‘a substantial increase in process speed’ as an example of the ‘technical contribution’ of

is not sufficient for the subject-matter of claim 1 to be reproduced without undue burden or exercise of inventive skills” [para 73] which is completely opposite to the Court of Appeal which held “[t]he consequence is that the invention as actually claimed is capable of being performed by a person skilled in the art because it is a claim to a polypeptide which can be both made and identified by routine means. Accordingly in our judgment claim 1 is not invalid on the ground of insufficiency.”

113 Ibid, 76, para 97-98.
114 Chiron Corporation and Others v Murex Diagnostics Ltd and Others (No 12) [1996] RPC 535.
115 The UK Court of Appeal held, “It was known that the entire sequence contained one antigenic determinant for that was the nature of the discovery made from the reaction of clone 5-1-1.”
the ‘invention’ to the ‘known art’. Perhaps in the context of a computer program or such like, a link to some ‘technical contribution’ that a computer program may make to the functioning of machine or computer, both themselves intrinsically artificial, is understandable, but with respect to something that is intrinsically natural, such as a virus, such a link is extremely difficult to understand unless what results from the ‘technical contribution’ is transformed from something natural into something artificial, such as the oil degrading genetically modified bacterium in Chakrabarty. But that is not the case on the facts in Chiron. All that resulted from the process of isolation of clone 5-1-1 was a better understanding of the virus i.e., its characterisation, but that step did not modify nor enhance the virus (as in Chakrabarty) in a way that can be described as a ‘technical contribution’. It did not produce a better virus or a virus that displayed characteristics not found in nature (as in Chakrabarty). It simply enabled the provision of information that was useful to further research and development. An example of the immediate use of that information was in diagnostic assays, but to suggest, as Chiron did in 1993 in the UK Patents Court and in 1996 in the Federal Court of Australia, that the characterisation of HCV was all that needed to be known to develop ‘vaccines’ was then and remains today, a ridiculous assertion. The point is that Chiron could have sought patent protection for a diagnostic assay but it did not. It sought patent protection over the mass production of HCV viral proteins and all genetic variations per se howsoever produced.

**Hepatitis C Virus in the United States**

All three of these granted US patents have as their genesis US patent application 122,714 filed on November 18, 1987. The ‘671 patent is entitled, “HCV immunoassays employing C domain antigens” and expires on August 8, 2013. The ‘596 patent is entitled, “NANBV diagnostics: polynucleotides useful for screening for hepatitis C virus” and expires on March 30, 2013. The ‘729 patent is entitled, “NANBV Diagnostics and Vaccines” and expires on May 14, 2015. All three share a common ancestry and all are derived from the same ‘discovery’, clone 5-1-1. Moreover, the specification of each patent is identical in all material respects. The differences in the patents are confined to the claims and in this regard these US patents are no different to the

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116 As proof of the ridiculous nature of the assertion, Dr. Houghton as co-author acknowledged in Abrignani,S.; Houghton,M.; Hsu,H.H., (1999), *Perspectives for a vaccine against hepatitis C virus*, J. Hepatol. 31 Suppl 1; 259–263 that “There is no vaccine for HCV … Although an ideal vaccine should protect from infection, in that it should elicit sterilizing immunity, this is quite an ambitious goal in the PCR era”. In the UK Patents Court in 1993 Dr. Houghton had testified that his team at Chiron had developed a prototype HCV vaccine in an attempt to justify claim 15 of GB2,212,511. Aldous J rejected Chiron’s claims because on the evidence the process of HCV vaccine development would take 30 man years of research. Despite that rejection in 1996 Dr. Houghton again testified in the Australian Federal Court in *Murex* that “the figure of 30 man years which I gave at the UK trial was, in fact, the time taken by a team of scientists and laboratory technicians working over a period of two to three years. I believe that this is not an undue length of time for the amount of progress which we have made [in the development of a vaccine].” It is now 2004 and there is still no HCV vaccine in sight.
corresponding HCV patents discussed earlier in this Chapter. The primary claims of each patent is as follows:

‘671: An immunoassay for detecting antibodies that bind to a hepatitis C virus (HCV) polypeptide comprising (a) providing an antigen comprising the C domain polypeptide encoded by HCV cDNA deposited under ATCC No. 40394 or an immunologically reactive fragment thereof of at least 8 contiguous amino acid residues; (b) incubating said antigen with a biological sample under conditions that allow for formation of an antibody-antigen complex; and (c) detecting any antibody-antigen complexes comprised of said antigen.

‘596: A purified preparation of an oligonucleotide, wherein the oligonucleotide is capable of selectively hybridizing to the genome of a hepatitis C virus (HCV), or its complement, relative to other viral agents, and further wherein the oligonucleotide comprises a contiguous sequence of at least 10 nucleotides fully complementary to either strand of the nucleotide residue sequence depicted in FIG. 1.

‘729: An isolated polypeptide comprising an amino acid sequence of at least 12 contiguous amino acids encoded by a hepatitis C virus (HCV) genome.

In summary, the primary claim of ‘671 is to the use of HCV proteins consisting of at least 8 amino acids containing an antigenic determinant in any kind of immunoassay. The primary claim of ‘569 is to a probe that is capable of capturing or detecting HCV proteins. Finally, ’729 is to any HCV protein that consists of at least 12 amino acids.

Although each of these claims define the HCV protein in slightly different ways, they each have as their cornerstone HCV proteins – that is, the very same proteins that are the cornerstones of the corresponding HCV patents already discussed.

Accordingly there is no need to repeat the earlier reasoning of what is an undeniable fact. The HCV proteins that are the subject of the claims are identical to their natural counterparts in every material respect. The only distinguishing feature, in the context of the claims, is their stasis. In claim ‘671 the proteins are ‘isolated’ in an immunoassay. In claim ‘569 the proteins are ‘purified’. In claim ‘729 the proteins are ‘isolated’.

Interestingly, none of these patents has been the subject of litigation in the United States and each are presumed to be valid on grant, but that does not mean that they cannot be revoked by a US Federal Court. One reason for the lack of litigation to date maybe due to the fact that under US patent law standing to sue to revoke a granted patent is not automatic, as it is in Australia and the United Kingdom. As such, interest groups have no standing to bring revocation proceedings. Standing to revoke is usually reserved to parties that are alleged to have infringed a US patent and, unsurprisingly, those parties are usually competitors in the same field as the patent owner.
The question therefore remains: is a claim to a viral protein patentable subject matter within s.101 US Act\textsuperscript{117}. In terms of these patents the issue is whether an isolated or purified viral protein is a new and useful manufacture or composition of matter.

The starting point of this analysis is \textit{Chakrabarty}, which held,

\ldots the patentee has produced a new bacterium with \textit{markedly different characteristics from any found in nature} and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under \textit{§ 101}.\textsuperscript{118}

What follows from this are three fundamental components:

Firstly, the natural bacterium was \textit{significantly} modified. It was not a matter of simply ‘isolating’ the bacterium from its natural environment. It involved the insertion of two plasmids, each of which was an artificial state of affairs.

Secondly, the genetically modified bacterium displayed \textit{markedly different characteristics from any found in nature}; and

Thirdly, that the \textit{markedly different characteristics} have the \textit{potential for significant utility}. This \textit{significant} utility was directly attributable to the \textit{new} characteristics of the genetically modified bacterium.

The totality of these components produced the ‘invention’. It was not any one of these that brought the subject matter of the Chakrabarty patent within s.101 \textit{US Act}, but the combination of all three. What this means is that an artificial bacterium \textit{per se} is not enough to satisfy the first parameter of patentability of invention. More is required. The Court made it clear that unless the result of human intervention with respect to a natural phenomenon, such as a bacterium, is something with ‘markedly different characteristics to any found in nature,’ the subject matter of the patent cannot be an ‘invention’ within s.101 \textit{US Act}.

In terms of s.101 \textit{US Act}, the word ‘new’ is the relevant prerequisite and the Court distinguished the subject matter that satisfied this prerequisite from the subject matter that did not, by examining the subject bacterium and comparing its characteristics in its natural state with those in its man-

\textsuperscript{117} 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 thereof, subject to the conditions and requirements of this title. S.101 \textit{US Act}.
made or artificial state. This genetically modified bacterium could only be ‘new’ if its characteristics were ‘markedly different’ from those of the natural bacterium. This is the threshold of artificiality under s.101 US Act set by Chakrabarty. The Court used the words ‘markedly different’ as opposed to ‘different’ to indicate that minor or insignificant differences between the natural bacterium and artificial bacterium would not be sufficient to meet the ‘new’ prerequisite. The genetic modification had to be significant.

However, that degree of artificiality described in Chakrabarty and reinforced in Pioneer (discussed in detail in Chapter 2) is not present in any one of the three Chiron US HCV patents. The fact remains that the proteins that are defined in the patent specifications and which are an essential element of all of the primary claims are identical in every material respect to the corresponding proteins of HCV, a natural phenomenon. There is not one single modification made to the proteins themselves that enhances their ability to perform in a manner unrelated to their performance in their natural environment. There is no separate result produced that is germane to the viral proteins per se. There is no remarkable advantage in the way the viral proteins perform or react biologically with other biological agents, such as human antibodies. This is especially true of the primary claim in the ‘729 patent which merely describes an HCV protein consisting of at least 12 amino acids with no reference to its method of production or its use. While the primary claims of the ’671 and ’596 patents do relate to the use of HCV proteins in (a) HCV immunoassays and (b) DNA probes, there is nothing remarkable about the use of the proteins in those applications nor is there any enhancement in the reaction of the HCV proteins with other biological elements, such as human antibodies in the case of the immunoassays and nucleic acids as in the case of oligonucleotide probes. For example, there is no reference in the primary claim or specification in the ’671 patent of the strength of the antigen-antibody reaction – literally any reaction, no matter how weak would be sufficient to bring an immunoassay within the scope of the monopoly of the primary claim.

Mental Conception and Reduction to Practice

In terms of US patent law the requirement that the first and true inventor be named as ‘the inventor’ is critical to the validity of a US patent, and this requirement means that the point of invention is also critical because it is the right of the first and true inventor to have priority to the defined invention over all others. This was essentially the ‘battle over turf’ that Young J described as the basis of Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc.119 In that case

118 Ibid, 310 (Emphasis added).
Genetics Institute alleged that its scientist, Dr. Fritsch was the first to clone the human Epo gene. The relevant provision in the US Act is s. 102(g) which reads,

A person is entitled to a patent unless … (g) before the applicant's invention thereof the invention was made … by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Although in respect to the Chiron HCV patents no claim has ever been made that Drs. Houghton, Kuo and Choo were not the first and true ‘inventors’ of isolated HCV proteins, a claim was made by Dr. Bradley, an employee of the CDC, Chiron’s collaborating partner in the HCV cloning project, that they were not the only ‘true’ inventors and that Dr. Bradley was also entitled to be named as a co-inventor. That dispute was settled between the CDC, Dr. Bradley and Chiron by way of an agreement dated April 3, 1990 which resulted in both the CDC and Dr. Bradley assigning to Chiron “their entire right, title and interest in and to, any and all claims, actions and the like based in law or equity known or unknown, now existing or which might arise hereafter, (a) against Chiron or Chiron’s employees (past or present), Chiron’s directors (past or present) or licensees arising from actions occurring prior to the date of this Agreement and related to any collaboration among Dr. Bradley, CDC and Chiron; or (b) regarding the inventorship, ownership or control of Chiron Patents or foreign counterparts thereof. CDC and Dr. Bradley hereby assign to Chiron any and all right and interest in or to Chiron Patents and the inventions claimed therein.”

In consideration of this assignment, Chiron paid the CDC $1,912,500US and Dr. Bradley $337,500US.

Although Dr. Bradley did eventually sue Chiron in the US courts to assert his claim, his attempt failed because the CAFC held that Dr. Bradley’s assignment was not able to be rescinded on the grounds of mistake, fraud and failure of consideration. So although Dr. Bradley has been

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120 Clause from Agreement between Chiron Corporation and Daniel Bradley and the CDC, April 3, 1990.
121 Daniel W. Bradley v Chiron Corporation, William J Rutter, Edward E. Penhoet, Michael Houghton, Qui Lim Choo, Geroge Kuo and Ortho Diagnostics Systems, Inc, United States District Court for the Northern District of California, before Wilken J. (unreported)
123 The CAFC held, “The district court, analyzing the recitations in the complaint and the applicable law, concluded that Dr. Bradley had not alleged facts that could support rescission of the settlement agreement on the grounds of mistake. The court observed that Dr. Bradley did not plead misrepresentation by Chiron, voluntarily entered into the agreement, did not seek legal advice before signing the agreement, and proposed no plausible alternative meaning to support his asserted mistake. We agree that Dr. Bradley failed in the first amended complaint to allege facts sufficient to show that he
effectively barred by the CAFC to argue the merits of his claim to the invention, there has been no ruling as a matter of fact or law, as to whether Dr. Bradley was a co-inventor of the invention in Chiron HCV US patents. Accordingly this issue remains open for third parties to raise and can be discussed in the context of this Thesis. This is precisely what occurred in Murex in Australia.

This issue is important for two reasons. First, it brings into question whether Chiron scientists, without Dr. Bradley, had the ‘complete mental conception and reduction to practice’ of the invention at all. Secondly, whether at the time of the first US patent filing on November 18, 1987 the Chiron scientists had, in any event, the ‘complete mental conception and reduction to practice’ of the invention. In this respect, it is to be noted that the first patent filing was the basis of the earliest priority date world-wide and this date is critical in the assessment of the invention’s ‘novelty’ and ‘inventive step’.

Moreover, irrespective of Dr. Bradley’s assignment of inventorship rights in April 1990, the fact is that as at the earliest priority date, Dr. Bradley and the CDC retained their respective rights to the invention. This raises the question: How can that date be the earliest priority date if as a matter of law and fact Dr. Bradley was a true co-inventor?

Although these issues appear to be beyond the scope of the Thesis, they are relevant because they assist in explaining the absurdity and contrivance of the argument propounded by commentators such as Stephen Crespi[124] that the act of invention can be equated with the act of isolation of a natural phenomenon. Of course, if this Thesis is correct, there was no ‘invention’ as at November 1987 or ever because the subject matter did not come within Chakrabarty and s.101 US Act, but assuming that there was, the role that Dr. Bradley played in the events that led to the ‘inventive step’, that is, the isolation of clone 5-1-1 in January 1987 is relevant for the simple reason that “Chiron did not create clone 5-1-1 out of thin air”.[125] Rather, as Dr. Bradley explained in his affidavit in Murex, “they found it in a place that we all knew contained NANBH viral sequences, like the sequence corresponding to clone 5-1-1. It is a play on words to suggest that providing a good source material is one thing, and molecular cloning is another.”[126] In this regard, Dr. Bradley’s work in developing the enriched viral chimpanzee plasma pools used to create the ‘C’ library from which the genetic materials of clone 5-1-1 were contained, was as much a part of the

did not neglect his legal duty in connection with the asserted mistake of fact, and that the premises of mistake of law are not present. The district court correctly held that the allegations of the first amended complaint were insufficient to support a claim based on mistake of either fact or law.”

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125 Bradley 2, 35 (Affidavit in Murex).
126 Ibid.
complete mental conception and reduction to practice of the invention as was the molecular cloning work conducted by Drs. Houghton, Kuo and Choo.

So if by November 1987, Chiron scientists had not completed the mental conception of the invention nor reduced it to practice or if Chiron did not have the complete title to the invention, the first patent application could not support the priority date nor any patent application that was a derivative of it.

First, assuming that Chiron’s position was correct and that Dr. Bradley was not a co-inventor, what did Drs. Houghton, Kuo and Choo know about the ‘invention’ by November 1987? The answer to this question is found in the affidavit of Dr. Kuo filed in Murex. In his evidence in chief Dr. Kuo explained that in January 1987 when Dr. Choo had succeeded in identifying ‘five potential clones’ and particularly clone 5-1-1 “No-one at that time believed [that clone 5-1-1] was truly a clone derived from the causative agent of NANBH.” By ‘no-one’ it must be presumed that he included the inventors. He added that “[e]ventually we became convinced that 5-1-1 was derived from the genome of the NANBH agent, which was subsequently named hepatitis C virus” but he did not provide a date, at that point in his evidence, as to when that ‘conception’ took place. Rather, he explained that it was necessary to verify the identity of the clone because “[o]ver the history of the NANBH cloning project at Chiron there had been numerous false leads and we were wary about drawing hasty conclusions.” This wariness was understandable in the circumstances, but it suggests that the inventors needed to convince themselves that clone 5-1-1 contained the genetic material of the causative agent of NANBH and it seems fair to conclude that until that point was reached, the inventors had not completed the mental conception of the invention nor had they reduced it to practice.

Dr. Kuo then explained that a prototype immunoassay was developed using the genetic material that was contained within clone 5-1-1 and other genetic material that had been derived from additional cloning experiments. Eventually a polypeptide containing a blend of these materials, dubbed c100-3, was used in the decisive test, that is, the ‘Alter panel’. Dr. Kuo explained that Dr. Harvey Alter at the National Institutes of Health, a US government agency, had developed a panel that “consisted of proven infectious sera from chronic NANBH carriers, infectious sera from implicated donors and infectious sera from acute phase NANBH patients in duplicate. Samples were also included from highly pedigreed negative controls and other disease controls.”

127 Kuo, 37 (Affidavit in Murex).
128 Ibid.
129 Ibid.
130 Kuo, 41 (Affidavit in Murex).
tested the prototype immunoassay against the Alter panel, but confirmation took place in the form of two letters from Dr. Alter dated May 18, 1988 and June 10, 1988. It is clear from Dr. Kuo’s evidence that it was at this point in time that he and the other inventors had conclusively established a connection between the genetic materials contained in clone 5-1-1 and NANBH. Dr. Kuo explained that “[t]his was the first time that any non-A, non-B hepatitis diagnostic test had passed the Alter panel, as confirmed in Dr. Alter’s letter of 24th July 1991.”

Therefore, the earliest date of the ‘complete mental conception and reduction to practice’ was May 18, 1988. By this time, Chiron had filed three US patent applications that made up the series of six US patent applications that supported all of Chiron’s first HCV patent filings around the world.

Beyond this, however was another issue. Even by the time Chiron had filed the last of the six US patent applications in November 1988, only 77% of the genetic material of HCV1a had been sequenced. That means that at the time that the PCT patent application was filed, the inventors had not completed the mental conception of the invention because they did not have the sequence to the complete genome of the virus. It seems appropriate that if the PCT patent claims included a patent claim to ‘purified HCV’, that the inventors should have described the complete genome of HCV1a in the patent specification, however, it did not.

Secondly, assuming that Chiron’s position was wrong and that Dr. Bradley was a co-inventor, by November 1988 when the PCT patent application was filed Chiron did not have title to the complete invention. It had no title in law to file the patent application because partial title was not perfect title. All the inventors needed to have been named and all needed to have assigned their rights to the invention to Chiron. This is an issue which Chiron was deeply concerned with in Murex and perhaps explains the reason for the settlement that it reached with IMTC, the parent Murex company, in August 1996. However, the evidence that was filed and the subject of cross-examination in Murex is useful in demonstrating the speciousness of the argument that ‘isolation’ equals ‘invention’.

The evidence of Dr. Bradley explained the pedigree of the genetic material contained in clone 5-1-1 and the ‘C’ library. It was derived from source material, Factor VIII, that was responsible for NANBH infection in humans and experimental chimpanzees housed at the CDC laboratories. This same source material was used to infect chimpanzee ‘Rodney’ from which plasma was obtained over a long period of time using protocols that Dr. Bradley had developed. This pooled chimpanzee plasma was then subject to further refinements so that the material given to Chiron as part of a collaborative effort to ‘clone HCV’ contained the most concentrated source of the candidate virus to be used in cloning experiments. Those experiments, performed by Chiron scientists, enabled the isolation of clone 5-1-1, which was eventually proven to contain NANBV genetic material. What was contained in clone 5-1-1 was derived from a virus, a natural
phenomenon - a product of nature. The isolation of this material in a laboratory did not modify or enhance the performance of this material. It did not enable this material to display characteristics not found in nature. To the contrary, it performed in the identical manner – it bound to a human produced anti-HCV antibody – and it was this precise binding that enabled the development of the prototype immunoassay that Dr. Kuo explained satisfied the Alter panel test which itself was composed of biological material that contained HCV antibodies. As Dr. Bradley confirmed, Chiron scientists, “found it in a place that we all knew contained NANBH viral sequences”. ¹³¹

In the final analysis, the question must be asked: what is it that the ‘inventors’ of isolated HCV mentally conceived and reduced to practice? Answer: a product of nature.

¹³¹ Bradley 2, 35.
At some point, we may need intellectual property rights that permit the creators of information products to capture the value of the information itself in order to motivate socially valuable investments. But if we have arrived at that point, then we need to look beyond the patent system for a suitable model.

PART I

This Thesis suggests that the ‘international’ patent regime arrived at that point well over twenty years ago, but in the absence of an alternative intellectual property regime, the biotechnology industry was forced to rely upon patents. Encouraged by patent attorneys and lawyers ready to exploit a potential new market, together with a need to create wealth in the form of intellectual property assets, the biotechnology industry started filing patents in a field that was in its infancy. With the promise of new medicines, treatments and cures for mankind and with the ability to use genetic engineering to mass produce proteins, the world was full of admiration for what was seen at the time as a wonderful new science.

In the twenty or more years since the world has witnessed the birth of modern biotechnology, patent systems around the world and those that administer and promote them, namely patent offices and patent attorneys, have displayed increasing ambivalence towards the parameters of patentability, particularly with respect to the invention. In an attempt to overcome the long-time recognised prohibition that excluded ‘discoveries’ or “[t]he laws of nature, physical phenomena, and abstract ideas” from being inventions, the ‘patent community’ across the world contrived a distinction between a product of nature and a product of man to facilitate patent applications that were directed to genetic sequences and proteins. That device, has been used by the patent community to permit the grant of patents over thousands of viral and human proteins, such as Human Immuno-deficiency Virus (HIV)-0, HIV-2, Hepatitis C Virus, Hepatitis G Virus, SARS virus, BRCA-1 and BRCA-2 human genes (breast and ovarian cancer markers) and the

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3 Peter Drahos defines the ‘patent community’ to include “patent attorneys and lawyers, patent administrators, and other specialists who play a part in the exploitation, administration and enforcement of the patent system. They form a community by virtue of their technical expertise and general pro-patent values. Regular users of the patent system (like the pharmaceutical companies) might also be said to be part of this community.” P. Drahos, *Biotechnology Patents, Markets And Morality*, (1999) 21(9) EIPR 441-444, 442.
Erythropoietin gene. Rebecca Eisenberg’s argument, that the device which this Thesis has dubbed the ‘isolation contrivance’ is not ‘a lawyer’s trick,’ ignores the fact that it is a semantic tool and one which the ‘patent community’ has improperly exploited.

Recently, an Australian company used the isolation contrivance to patent over ninety-five percent of the human genome in the form of ‘junk DNA’. In justifying the patents, Dr. Mervyn Jacobson, the Chief Executive Officer of Genetic Technologies, explained that he believed that “what we’re doing is wonderful” and could not understand “why people stop to criticise.” These ‘people’, however, are not uninformed bystanders, but are experts in biotechnology. One of them, the winner of the Nobel Prize for Physiology or Medicine in 2002, Professor Sir John Sulston, explained that,

There’s always a tension between those who would like to garner wealth, and they contribute a lot to society. There’s also those who say, ‘I believe in the common good. I want that to be enlarged.’ They contribute a lot to society. The tension, the debate, between these two views is extremely important to our progress.

Others included Dr. Francis Collins, the Director of the Human Genome Project, who explained to an audience of experts at the 19th International Congress of Genetics held in Melbourne in July 2003 that “[t]he real question, it seems to me – ‘Is this good for the public?’ If pursuing an aggressive stance with this patent slows down the progress of scientific research, then the public is injured and you and I should object.” However, these concerns have only surfaced in recent years as geneticists have come to accept that what was first dubbed ‘junk DNA’, that is, literally useless genetic material, actually plays an important role in the human genome and one that is critical to human protein development. For Genetic Technologies, the patent owner of ‘junk DNA’, this realisation improved the company’s financial status as it has been able to demand, on the threat of patent infringement proceedings, financial remuneration for the use of this genetic material in research and any commercial application of that research. For Professor Sir John Sulston, this

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4 Excerpt from transcript of an interview shown on Australian Broadcasting Corporation Four Corners program Patiently a Problem which went to air on Monday, August 4, 2003.
5 Ibid.
6 Ibid.
7 For example, Genesis Research and Development Corporation, a New Zealand company received a letter in early March 2002 from Genetic Technologies because almost all its R&D falls within the scope of Genetic Technologies non-coding DNA patents. The letter read in part “In order to permit the continued development of your genetic and genomic activities, we would like to discuss a mutually beneficial licensing arrangement.” Dr. Jim Watson, CEO of Genesis explained in an interview in the ABC TV program Four Corners that “it’s an aggressive sales pitch, there's also an issue which is fairly intimidating, I think, to face, and that is GTG make no bones about the fact that they have taken out insurance that would cover any litigation costs that they might be liable for should any group challenge their patent claims in a court, and that's rather unusual.” Also both the Universities of Utah, USA and the University of Sydney, Australia have entered into patent license agreements with Genetic
means that “it’s going to be obviously extremely destructive [and] it’s going to prevent a lot of
important work in health care and indeed wealth creation.”

The isolation contrivance, a device developed by the ‘patent community’ to overcome the
exclusion on the patenting of Directive technologies has been so successfully employed
throughout the world, that today not only do lay people not understand that the first and most
important parameter of patentability is, the invention, but the scientific community which has
been galvanised into attacking the ‘junk DNA’ patents have focused their attacks, not on the fact
that such genetic material is a ‘product of nature’, but on the grounds of an apparent lack of
 novelty or utility. Moreover, the general ignorance of the existence, let alone the importance of
the invention parameter, has been advanced by the World Health Organisation (WHO) explaining
that the distinction between ‘discoveries’ and ‘inventions’ “no longer prevents the granting of
patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the
identification of the genetic sequence not its mere occurrence”. According to the WHO, the only
controversial issue surrounding the “[m]any patents … issued on viruses and genetic sequences”
concerns “genomic sequencing[as it] becomes more routine and less ‘inventive.’”

Technologies. See transcript of an interview broadcast on the Australian Broadcasting Corporation
ABC TV Four Corners program entitled, Patiently a Problem which first went to air on Australian

8 Ibid.
9 Jonathon Holmes, the television reporter on the ABC TV Four Corners program entitled, Patiently a
Problem which first went to air on Australia national television on Monday, August 4, 2003 explained
that “[t]o be awarded the protection of a patent, an invention must pass three vital tests. It must be
novel at the time the application is filed. It must not have been obvious to other skilled researchers. And
it must have a clear utility.”

10 Professor Sir John Sulston said, “We knew that all the protein-coding bits of genes do is to produce
protein - they have to have instructions to turn them on and off. Those sequences lie well outside the
protein-coding sequences, sometimes thousands, tens of thousands of bases away. People knew about
those. So in principle we knew very well that the junk DNA was not junk.” Further, Professor Joseph
Sambrook from the Peter McCallum Cancer Institute said, “It’s a bit of a puzzle for me to see how you
could claim that some of the things in the patent are novel. A lot of them, I think, are not, and had been
well-established and almost mundane by the time the patent was filed.” Further, Dr. Graeme Suthers, a
clinical geneticist said, “My perspective is that non-coding DNA has been around, for millions of years.
The techniques for analysing it were developed over the last 50 years. The usefulness of non-coding
DNA in biomedical research has been recognised for decades.” Moreover, scientists around the world
are incredulous that patents concerning ‘junk DNA’ have been issued. Dr. Jean-Jacques Cassiman, a
leading Belgium geneticist from the University of Leuven described the patenting of non-coding human
DNA as ‘ridiculous’ and explained, on being advised for the first time of its patenting said that he did
not “understand the patent offices who gave a patent on this, if this is right.” As per ABC TV Four
Corners program entitled, Patiently a Problem which first went to air on Australian national television

11 World Health Organisation 2003 position statement on Patent Applications for the SARS Virus and
Genes.
12 Ibid.
The distortion of the parameters of patentability by the ‘patent community’ has not, however, been exclusively reserved for the ‘invention’ parameter but has, in the case of biotechnology, been extended to the residual parameters: namely, novelty, inventive step and utility. For example, the Nuffield Council of Bioethics concluded in its Discussion Paper that “the application of these criteria to DNA sequences has not been sufficiently stringent [so that] … [t]he law in many countries, including the US and Europe, has tended to be generous in granting patents which assert rights over DNA sequences.”

The result has been that “many [granted] patents that assert rights over DNA sequences … are of doubtful validity,”

but due to a number of reasons, including the costs and risks associated with patent litigation and/or the licensing strategies of patent owners, who are generally part of the biotechnology and pharmaceutical industry, these “invalid patents may never be challenged or revoked.”

The Council saw the ‘stringency’ problem more as a function of the administration or application of patent law, rather than as a deficiency in existing patent law. In its opinion, if the ‘patent community’ would only properly apply existing patent law, the “number of patents that assert rights over DNA sequences would be … reduce[d] substantially.” Unfortunately, this plea to the patent community while understandable, was only a part of the solution to the problem created by the grant of these ‘invalid’ patents because the Council failed to question the codification of the isolation contrivance in the Directive and the semantics between art. 5.2 and art. 5.1 Directive.

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13 Nuffield Council on Bioethics, The Ethics of Patenting DNA: A Discussion Paper, July 2002, para 6.17. CF: M.J. Howlett and A.F. Christie, An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequence (ESTS), (2003) International Review of Industrial Property and Copyright, Vol. 34, 581-602. The authors argue that their research demonstrates that the parameters of novelty, inventive step and utility are sufficiently stringent. They conclude that “Given the few hypothetical claims found valid in the comparative study, it seems that the practice of the patent offices is such that not many ESTs will pass the stringent requirements for patentability. Accordingly, it seems that the fear of numerous EST patents inhibiting later research is also unfounded.”

14 Ibid, Executive Summary, vi.


16 Ibid.


18 Art. 3.1 Directive ‘Inventions which are new, involve an inventive step and are susceptible of industrial application are patentable even if they concern a product consisting of or containing biological material (‘biological material’ means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system). Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention.’ (emphasis added). This is an excellent example of the ‘isolation contrivance’.

19 ‘An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.’ This is an extension of art. 3.1 Directive, but is specifically dealing with human biological material.
in its inquiry. So the Council accepted the ‘isolation’ contrivance as a matter of patent law, concluding that “the procedures involved in the early days of cloning genes were certainly inventive and arduous” and “[f]or this reason, patents awarded in those early days need not now be called into question.”\(^\text{21}\)

In so doing, however, the Council missed the point: that is, even if the cloning procedures were the subject of the patent claims “in the early days”, the recombinant proteins derived from those cloning procedures were captured within the scope of the monopoly and this was precisely what the UK Court of Appeal in Genentech, held to be invalid.

In other words, the cloning procedures are merely part of the ‘isolation’ contrivance aimed at monopolising the mass production of a recombinant protein. Therefore by conceding as unnecessary, the calling into question of the early patent awards, the Council failed to grasp the nettle and wasted a perfect opportunity to address, what this Thesis argues, is the root cause of the problem. Rather, by focusing on the residual parameters, the Council played into the hands of the patent community and allowed itself to become distracted by the debate about the novelty, inventive step and utility. In being distracted the Council ignored a fundamental cornerstone of patent law: that is, that if the subject matter of a patent is not an ‘invention’ per se, then the residual parameters of patentability are irrelevant.\(^\text{22}\) Both Mustill and Purchas LJJ in Genentech saw through the ‘smoke and mirrors’ of the primary t-PA claims, but unfortunately the Council did not.

The Council explained that:

> Scientific knowledge about genetic information which is encoded in some naturally-occurring phenomenon [such as a human gene or viral genome] is not eligible for patenting as such, [but] it does not follow that an artificial phenomenon that does not occur naturally (such as a

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\(^\text{20}\) ‘The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.’


\(^\text{22}\) The House of Lords in Biogen cautions judges from ruling on the issue of ‘invention’ without examining the other parameters of patentability, however, this approach is unsatisfactory because it blurs the distinction between an ‘invention’ on the one hand and a ‘patentable invention’ on the other. The High Court of Australia in NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited (1995) 183 CLR 655 makes it clear that the technology which is the ‘invention’ must be new, but this is not the same as satisfying the parameter of patentability of ‘novelty’. The two are distinct and separate. The latter is a much more specific requirement. The Court held that if the subject technology, on the face of the specification, is not an ‘invention’ that is the end of the matter and the residual parameters are irrelevant. Once it is determined that there is an ‘invention’ the purpose of the residual parameters is to determine if the ‘invention’ is a ‘patentable invention’. See Chapter 2 for a more detailed explanation.
molecule that has been isolated and cloned) that encodes genetic information may not be eligible. This distinction may appear a fine one; but the underlying point is crucial to an understanding of the evolution of the patent system.23

While knowledge of the argument may be crucial in understanding how the patent community has distorted and misapplied patent law, the suggestion that there is a ‘fine distinction’ between a claim to a natural human gene and a claim to an artificial molecule that encodes the human gene, again misses the point. While it is correct that the isolated human gene is in an artificial stasis because its information is housed within a molecule that does not exist in nature, that information that codes for a specific protein, such as Epo, is identical or materially identical to the natural human gene.24 This was made clear as far back as 1989 when the US District Court for the District of Massachusetts held in Amgen25 that:

…the overwhelming evidence, including Amgen’s own admissions, establishes that uEPO and rEPO are the same product. The EPO gene used to produce rEPO is the same EPO gene as the human body uses to produce uEPO. (Tr. 25, 14). The amino acid sequences of human uEPO and rEPO are identical. (Chugai’s Req. Adm. to Amgen No. 436; Egrie Dep. Tr. 2-165). There are no known differences between the secondary structure of rEPO produced in a CHO cell and EPO produced in a human kidney. (Chugai’s Req. Adm. to Amgen No. 437).26

There was no rocket science in respect to this finding. Truly, the ‘fine distinction’, which the Council referred to in its Report, was nothing more than an exercise in semantics. Interestingly, in its 2004 Report entitled Patenting Human Genes and Stem Cells, the Danish Council of Ethics described the language of art. 5 Directive as “a creatively worded ploy to avoid the criticism leveled at patents on human material”27 because even though art. 5.1 Directive confirms that human biological materials, such as genes cannot be patented, art. 5.2 Directive confirms that isolated human biological materials can be patented. The Danish Council concluded that,

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23 Ibid, para 3.20. The Council is defining the ‘isolation contrivance’.
24 True it is that the protein coding region is generally sandwiched between genetic modifications, such as promoter sequences, but these genetic modifications do not modify nor enhance the protein coding region in any way. What these modifications do is merely enable to the protein coding region housed within the artificial molecule to express the protein of interest. These genetic modifications are a necessary function of the methodology to produce the protein of interest, and are irrelevant to the protein coding sequence per se.
26 Ibid, (Emphasis added).
In the members’ view, it cannot be said with any reasonableness that a sequence or partial sequence of a gene ceases to be part of the human body merely because an identical copy of the sequence is isolated from or produced outside of the human body.\textsuperscript{28}

Moreover, even if this distinction is real, the crucial point which the Nuffield Council failed to consider is that an artificial molecule that houses a human gene will not satisfy the test of artificiality in Chakrabarty unless (a) the level of human intervention in producing the artificial molecule is significant; (b) artificial molecule \textit{per se} displays markedly different characteristics to any found in nature and (c) the markedly different characteristics have the potential for significant utility.

If all the artificial molecule does is enable the production of the identical natural protein, the artificial molecule is merely replicating the function of the human gene, albeit in an artificial stasis or molecule. Critically, it is not displaying characteristics that are not found in nature or are different to it. It must be remembered that in Chakrabarty, the genetically modified bacterium in that case did not function in the way that the unmodified bacterium did. To the contrary, it was capable of degrading crude oil, something that the unmodified bacterium could never do. Importantly, it was this new capability that established the modified bacterium’s usefulness for the purposes of s.101 US Act.

In other words, even if the Council’s distinction was valid, the isolation of a natural phenomenon, such as a human gene or viral genome, or the performance of genetic modifications that enable the human gene or viral genome to replicate, in an artificial stasis, the function of that gene or genome in its natural stasis, are not steps that are capable of establishing ‘invention’. Much more is required. In the context of biotechnology, the threshold of artificiality established by the US Supreme Court in 1980 in Chakrabarty and reinforced in 2001 in Pioneer not only makes perfect sense for otherwise ‘anything’ could be an ‘invention’ within the meaning of s.100 and the criteria of s.101 US Act, but importantly, it is consistent with a line of US Supreme Court authority commencing in 1874 with American Wood\textsuperscript{29} and with the US constitutional requirement of ‘originality and ingenuity’.\textsuperscript{30} True it is, that the Court in Chakrabarty adopted the words of P.J. Federico, a principle draftsman of the US Act, that “anything under the sun that is made by man” is


\textsuperscript{29} \textit{American Wood-Paper Co. v. Fibre Disintegrating Co.} 90 U.S. (23 Wall.) 566 (1874).

patentable subject matter, but in doing so it did not mean that literally anything is patentable subject matter if it is made by man. Rather, it qualified those words so that for a ‘product of nature’ to be an ‘invention’ within s.101 US Act, (in other words to be a ‘product of man’) the product of nature must be the subject of human intervention that is ‘original and ingenious’ and critically, results in the “new and useful” ‘product of man’ “displaying markedly different characteristics from any found in nature”. This is the threshold of artificiality that is encapsulated by the words “markedly different characteristics”. Therefore, the words “anything under the sun that is made by man” need to be understood in the context of the facts in Chakrabarty and lawyers and judges that have repeated those words in support for the ‘isolation contrivance’ have misrepresented US patent law.

Moreover, this threshold of artificiality has commonality in the patent law of other countries as both the UK Court of Appeal in Genentech and the High Court of Australia in Philips confirm. These US, UK and Australian Court authorities reinforce the ‘universal’ principle of patent law that a patent must, before anything else, concern an ‘invention’. Therefore, the inclusion of the ‘invention’ parameter of patentability in art. 27.1 TRIPS was not an accident.

32 See for example M. Andrea Ryan, Vice President, Warner-Lambert Company and President-elect of the American Intellectual Property Lawyers Association who testified before a hearing of U.S. House of Representatives Sub-Committee on Courts and Intellectual Property entitled “Gene Patents and Other Genetic Inventions”, held on July 13, 2000 that “[a]ccording to the Supreme Court ruling in Chakrabarty and established patent law, any product of nature is patentable if it is transformed in some way by man … Thus, for several decades, the patent law issue has not been whether an isolated or purified product obtained from nature, such as a gene-based invention, is eligible for patenting” (Emphasis added).
33 See Merck & Co. v. Olin Mathieson Chemical Corp (1958) 253 F.2d 156 (4th US District Circuit) which interpreted the word ‘new’ in s.101 US Act to be identical to the residual parameter of patentability of novelty in s.102 US Act holding that ‘purified vitamin B-12’ was a composition that has “… all of the novelty and utility required by the Act for patentability. They never existed before; there was nothing comparable to them. If we regard them as a purification of the active principle in natural fermentates, the natural fermentates are quite useless, while the patented compositions are of great medicinal and commercial value” [164] so that “all of the tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials. The matter of which patentable new and useful compositions are composed necessarily includes naturally existing elements and materials.” [161-62.] (Emphasis added)
35 See N. Pires de Carvalho, The TRIPS Regime of Patent Rights, Kluwer Law International, 2002. In the foreword to his book, the author confirms that its purpose is “not about what the Agreement should be, but about what it actually is.” (Emphasis is that of N. Pires de Carvalho) At Part II Section 5, 141-262, 146 para 27.8 the author explains that “…The first [parameter] is that patentable subject matter must correspond to the very notion of invention, as opposed to that of discovery. Inventions are … artificial creations that stem the need to solve technical problems. In contrast, discoveries are not the result of creation – even if creativity has been needed to reveal information concealed in nature.” In footnote 408 at 146, para. 27.8 he explains that “[i]t is artificiality, not inventiveness, that distinguishes inventions from discoveries” and that “[w]hen Justice Burger noted, in Diamond v Chakrabarty that
restatement of this most fundamental principle of patent law, which by effect of the WTA requires all signatory countries to ensure the conformity of [their] laws, regulations and administrative procedures with [the] obligations as provided in TRIPS.\textsuperscript{36}

In this context, the problem for the European Community and its member countries is that the Directive presumes that isolated genetic materials are ‘inventions’ for the purposes of the EPC and the patent laws of compliant Member States. It is this presumption which violates art. 27.1 TRIPS. Firstly, because the word ‘invention’ in art. 27.1 TRIPS does not include Directive technologies and secondly, because the presumption that such technologies are ‘inventions’ under the EPC discriminates in favour of biotechnology contrary to the stipulation that the patentability parameters contained in art. 27.1 TRIPS apply “without discrimination” across “all fields of technology”.\textsuperscript{37}

The consequences of this violation by the Directive are matters for debate that lie outside of the ambit of this Thesis, however, it is possible that a consequence is that the Directive is invalid. This possibility was foreshadowed by the Court of Justice of the European Communities in The Netherlands v European Parliament,\textsuperscript{38} which held that, “... the legality of a Community instrument can be called in to question on grounds of breach of international agreements to which the Community is a party … if the provisions of those agreements have direct effect.”\textsuperscript{39} There can

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\textsuperscript{36} Art. XVI.4 World Trade Agreement.

\textsuperscript{37} See N. Pires de Carvalho, The TRIPS Regime of Patent Rights, Kluwer Law International, 2002. At Part II Section 5, 141-262, 141 para 27.1 the author explains that “[i]n the course of the exchange of preliminary views on the scope of work of the Negotiating Group of TRIPS, concerns about discrimination against certain fields of technology were among those aspects the most strongly emphasised by some delegations ...”. Although the authors suggests at 142 that the “initiatives to reduce or eliminate that discrimination” go back to “the revision of the Paris Convention, held in Lisbon in 1958” and particularly to “the Swiss group of the Association Internationale pour la Protection de la Propriété Industrielle which “submitted a proposal under which Union Members should admit the patentability of chemical products regardless of the respective manufacture processes” this Thesis maintains that the prohibition against technological discrimination is both positive and negative in effect and purpose.

\textsuperscript{38} The Netherlands (supported by Italy and another) v European Parliament and another (supported by the European Commission) [2002] All ER (EC) 97 [Court of Justice of the European Communities]

\textsuperscript{39} Ibid, para 51. Furthermore, the Court of Justice held that “… an obligation imposed on the member states by the directive to breach their own obligations under international law, while the directive itself

\end{footnotesize}
be no doubt that art. 27.1 TRIPS has a ‘direct effect’ on the EPC and the Directive, which are both Community instruments.

The Directive, however, is not the only example of breaches of the WTA. The Agreement makes it clear that not only must the intellectual property laws of signatory countries conform with TRIPS, but so must their regulatory and administrative procedures. Accordingly, signatory countries have an obligation to ensure that their national patent offices and the administrative and regulatory regimes which support them and facilitate their function, such as the Courts, permit the granting of patents only if they concern an ‘invention’ within art. 27.1 TRIPS and revoke those that do not.

In this context, the grant by the USPTO and the EPO of patents that claim isolated genes, genomes and proteins as inventions and the adoption of policies designed to promote their patenting, are further violations of the Agreement. Moreover, the upholding by the Courts in Europe and the US, or by the TBA in the case of the EPO and the Board of Patent Appeals in the case of the USPTO, of the validity of such patents merely compound and reinforce the patent office violations of the Agreement.

In the United States, the latter is of particular concern because s.101 US Act, as interpreted by the US Supreme Court in Chakrabarty and Pioneer, prohibits the patenting of natural phenomena unless these phenomena are subjected to a level of human intervention that modifies them significantly. Therefore, the isolation of natural phenomena and the production of recombinant forms of the natural phenomena, like rEpo, simply do not meet this threshold because the act of isolation does not sufficiently modify the natural phenomena in the first place and the recombinant forms of the natural phenomena display essentially the same, if not the identical, characteristics of their natural counterparts. Yet, despite the unequivocal authority of the US Supreme Court, the USPTO has ignored that authority and adopted a deliberate policy resulting in the grant of thousands of patents concerning isolated natural phenomena. The problem for the US Courts is

claims not to affect those obligations …” is a further line of attack on the validity of the Directive[55]. (emphasis added)


In his testimony before a hearing of U.S. House of Representatives Sub-Committee on Courts and Intellectual Property entitled “Gene Patents and Other Genetic Inventions”, held on July 13, 2000, Q
that revocation of a patent is dependent upon the grounds that are relied upon by the party that challenges its validity. In this regard, it is important to understand that for some reason, possibly related to self-interest,\textsuperscript{43} the failure to comply with s.101 \textit{US Act} has not been raised and therefore there exists today a body of US patent law jurisprudence that has been used to support the notion that “eligibility issues no longer play a significant role in developing [patent] case law”\textsuperscript{44}. Supporters of this ‘myth’ suggests that a novel DNA sequence or gene or protein are patentable because the patents meet the parameters of s.102 \textit{US Act} (novelty) and 103 \textit{US Act} (non-obviousness)\textsuperscript{45} and so, either unwittingly or deliberately, the US Courts have played a role in the violation of TRIPS.

In the context of the \textit{EPC}, a patent system that permits the grant of patents by the EPO without an independent review of the decisions concerning the acceptance and grant of a patent by any European Court also contravenes the WTA to the extent that the system permits or facilitates the grant of patents that claim isolated genes, genomes and proteins as ‘inventions’. The lack of independent judicial scrutiny of the EPO examiner decision before grant and the appellate decisions after grant is flawed in that it fails to recognise the obvious conflict of interest.\textsuperscript{46} Accordingly, while it is possible for a national European court to revoke a ‘European’ patent it must be understood that first, it is the revocation of the national patent, not the European-wide patent as granted by the EPO, and so is confined to the jurisdiction in which the revocation action is brought and secondly, the grounds of revocation are more limited than the grounds of

Todd Dickinson from the USPTO explained that “[o]ver the past twenty years, many patent applications have been filed that are drawn to subject matter relating to genes. The filing rate of applications relating to genes has dramatically increased in the past few years. Currently, over 20,000 applications relating to genes are pending before the USPTO. Since the first gene related applications were filed, approximately 6,000 patents have issued which are drawn to full-length genes from human, animal, plant, bacterial and viral sources. Of these 6,000 patents, over 1,000 are specifically drawn to human genes and human gene variations that distinguish individuals.”

\textsuperscript{43} For example, the principal challenger to the Amgen Epo patent in the US was Genetics Institute, Inc a competitor that had been granted a US patent concerning Epo and rEpo. Therefore, Genetics Institute had a vested interest in not challenging the Amgen patent on s.101 \textit{US Act} grounds.


\textsuperscript{46} The conflict of interest occurs because in 1988 the EPO adopted a policy that accepted the ‘isolation contrivance’ as a legitimate means of transforming a natural phenomenon into patentable subject matter within art. 52 \textit{EPC}. See also footnote 61.
opposition. According to the judicial scrutiny of a ‘European’ patent which occurs only after grant in the context of a revocation action, it is not a review of the EPO decisions to grant, but is a separate and de novo ‘re-examination’ of the granted patent based on grounds that are not necessarily the same as those relevant for the purposes of grant. The effect of this separation of review between the EPO and the national courts is that both decisions can stand side-by-side and as has occurred on more than one occasion, these decisions can be diametrically opposed in both their results and interpretation of the EPC. Apart from the undesirable nature of such conflict, the lack of a mechanism within the EPC that permits the review of pre and post grant EPO decisions is a significant flaw in that system.

In Australia, the lack of any judicial authority of the application of s.18(1) AU Act in the context of patents that claim isolated genes, genomes and proteins as ‘inventions’ has permitted the Australian Patent Office (APO) to develop a patent policy similar to the policy advocated in 1988 by the USPTO, the EPO and the JPO.

The APO policy is explained in an information sheet entitled, “Australian Patents For: Microorganisms; Cell lines; Hybridomas; Related biological materials and their use; & Genetically Manipulated Organisms.” The document states:

The range of patentable inventions involving microorganisms, cell lines, hybridomas and other related biological material includes:

- Bacteria and other procaryotes, fungi (inc. yeast), algae, protozoa, plasmids, viruses, prions;
- DNA, RNA, genes, viruses, vectors, chromosomes, prions, cell organelles and other non-living material existing in, and in reproducible form, microorganisms or like biological material;

47 Cf: Biogen, Inc v Medeva plc: “Section 14(5)(c) UK Act has, by judicial interpretation, been elevated to a ground of revocation under the Patents Act despite the express words of section 72 UK Act”, see A. McInerney, Biotechnology: Biogen V Medeva In The House Of Lords, (1998) 20(1) EIPR, 14-21, 19.

48 See for example the distinction between art. 83 and art. 84 EPC. The former is considered only by the EPO pre-grant and cannot be raised as a ground of revocation.

49 In the case of the Genentech and Biogen patents the TBA upheld their validity under the EPC whereas the Court of Appeal and House of Lords respectively revoked the UK patents. In the case of Chiron, the UK Court of Appeal upheld the validity of claim 1 of the UK Chiron patent, whereas the TBA disallowed the identically worded claim in the corresponding European patent. See also A. McInerney, Biotechnology: Biogen v Medeva In The House Of Lords, (1998) 20(1) EIPR 14-21.

50 Another example of significant variances in interpretation is art. 69 EPC and the Protocol for the construction of claims. Other than in Germany and the UK, the Courts of European Community Member States varies. Submission of D. Kitchen QC, counsel for TKT before the House of Lords in Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others, July 7, 2004.

51 The source of the conflict is the 1988 EPO joint statement on the clarification of the patentability of genetic material and proteins. Given that this is the stated official policy of the EPO there is a clear bias against the appellate bodies of the EPO interpreting the EPC which conflicts or contradicts this policy. See also footnote 61.
Chapter 6: The Genetic Sequence Right: A Sui Generis Solution

Non-living material existing in and reproducible from a living cell, such as, monoclonal antibodies produced from hydridomas, DNA, RNA, genes, viruses, vectors, chromosomes, prions, cell organelles;

Purified nucleic acids;

These categories not only include naturally occurring “bacteria and other procaryotes, fungi (inc. yeast), algae, protozoa, plasmids, viruses, prions”, they also include the genetic information of any of these things.

Any doubt about the approach, which the APO has adopted in its interpretation of the ‘invention’, is dispelled by the following section from the same document which reads,

Patent protection can also be obtained for inventions involving … The building blocks of living matter, such as DNA and genes (including human DNA and genes) which have for the first time been identified and copied from their natural source and then manufactured synthetically as unique materials with a definite industrial use. DNA or genes in the human body are not patentable as such, however, a DNA or gene sequence which has been separated from the human body and manufactured synthetically for reintroduction into the human body for therapeutic purposes would be patentable. The treated human body is not patentable. (Emphasis added).

This document was created by the APO without any outside consultation and represents that DNA and genes are patentable under the AU Act when there is no Australian Court authority to that effect.

The patent law of Brazil, however, is an example of a law that is consistent with art. 27.1 TRIPS in that patents concerning isolated biological material including genomes or germplasm are prohibited. However, as the Nuffield Council of Bioethics noted in its Discussion Paper, Brazil is the exception to the rule.

This Thesis agrees with Anthony McInerney’s observation that “[b]iotechnology has ‘ruptured’ the patent system which has struggled to adjust the application of the system to this new technology.” Beyond the ‘tension’ which he identified as existing between the UK Courts and the EPO in Biogen, this Thesis has explained with the aid of the two case studies in Chapters 4 and 5, that patent law in the USA, Europe, the UK and Australia is not adequately coping with the need

52 Section 1, Article 10 IX of Industrial Property Law No.9279/96 (Brazil).
55 Ibid.
to provide the biotechnology industry with a fair level of economic reward for its research and development while meeting the needs of the wider community that demands that products of nature be freely available to everyone. The distortions which have prevailed upon the patent systems of the world to satisfy the wealth creation needs of the biotechnology industry have been effected at the expense of the needs of the wider community. Today, these distortions pose a threat to independent scientific research and the hopes and aspirations that are inextricably linked to such research.\(^{56}\)

It is fair to suggest that patents have always been associated with human innovation and invention, but it is equally fair to suggest that not all human innovation and invention should be the subject of statutory monopoly that permits the patent owner to exclude all others, at the patent owners absolute and unfettered discretion, from using the patented technology for a period of twenty years. Furthermore, it is certainly not fair that patent owners have been able to extend the period of statutory monopoly well beyond 20 years for what is in effect a technology that is nothing but a close variant of the patented technology. This is occurring in the field of biotechnology and the example of the US Amgen Epo patents, provided in Chapter 4, is evidence of the ‘creeping monopoly’ over this protein. This ‘creeping monopoly’ is particularly unjustified when the human innovation was not concerned the modification of a product of nature within the degree of artificiality principles of Chakrabarty and Genentech but was concerned with the methodology used to ‘isolate’ a product of nature and the expression of a protein identical to the natural protein.

Moreover, the audacious claims made by some biotechnology companies concerning the potential applications of isolated genes, genomes and proteins has contributed to the concern of many scientists that such patents are unfair and premature. For example, when Chiron Corporation was granted US6,027,729 entitled, “NANBV Diagnostics and Vaccines” the press release it issued in response explained that the patent “is directed to hepatitis C polypeptides encoded throughout the genomes of hepatitis C viruses” and that “[s]uch polypeptides are also being used in the development of vaccines to stimulate protective immune responses, and as targets in the

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\(^{56}\) Professor Sir John Sulston explained that, “it’s very expensive to challenge [patents] and turn [them] back and in these particular cases, it can only be done if somebody chooses to mount such a challenge, at cost to themselves. … [T]here’s now a clear understanding in the genetics community that there is a divide and rule process going on. Each individual company or laboratory may feel it easier just to settle [potential patent litigation] but if they begin to get together, then they’ll realise that they should just put a stop to this. Because it’s going to be obviously extremely destructive, it’s going to prevent a lot of important work in health care and indeed wealth creation at large.” Interview with ABC journalist during the making of the Four Corners program entitled, Patently a Problem which went to air in Australia on Monday August 4, 2003. Also Professor Baruch Blumberg, explained that “[b]ased on the unusually broad nature of the [Chiron HCV patent], if I were a research director for anti-virals and had the option of working on several viruses, the existence of this patent would weigh against my deciding to undertake HCV research. A company, or even an academic laboratory, might well be deterred from conducting research on HCV because the patent is, in effect, intimidating.” The affidavit of Baruch S.
development of new anti-HCV therapeutics,” implying that the patent’s monopoly covered any HCV polypeptides used in the future development or manufacture of a HCV vaccine. Chiron has persistently made such overtures concerning HCV vaccines ever since it filed its first patent application in November 1987, despite a finding by the UK Patents Court in 1993 that claims to vaccines were unjustified and an admission in 1999 by one of the named inventors that no HCV vaccine existed.

It is clear that the concerns that have been expressed in this Thesis about these types of patents go well beyond the issue of their breadth of claim or the stringency of the patent examination process. The concerns are so fundamental to patent law that the measure adopted by the European Parliament in the form of the Directive does not address them, rather it merely contributes to the distortion of patent law in the European Community and heightens the stakes in a battle for biotechnological supremacy between the USA and the EC.

In March 2003 the European Commission Report entitled, Communication From The Commission To The European Parliament, To The Council And To The European Economic And Social Committee Life Sciences And Biotechnology – A Strategy For Europe Progress Report And Future Orientations arguing that,

> European biotechnology lags behind the US in terms of patents and collaborative R&D projects and this principal competitor of ours has a dominant lead in innovative activities, while a rapid decline in GMO field research has been reported in the EU over the last four years. This raises the risk of failing to meet the objective of the Lisbon process in the area of life sciences and biotechnology. Decisive action is now needed in a number of areas identified in this report.

In its Report the European Commission identified that one of the causes of this lag was that investment in research and development in biotechnology in Europe was significantly less than in the United States. It estimated the gap to be €124 billion, noting that since 1994 the gap had doubled. Other causes included the lack of a coordinated approach to research and development

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60 Ibid, 3.
61 Ibid, 9.
between the Member States; the fragmentation of the pharmaceutical and biotechnology markets within Europe; an insufficient level of risk capital available to biotechnology; and the lack of a unitary European patent system. Finally, the Report suggested that failure to transpose the European Biotechnology Directive into law by all Member States was “hampering the development of biotechnology in Europe in comparison to our competitors.”

The Report argued that if the European biotechnology industry was to be internationally competitive, it needed to address a number of issues not merely the patentability of biological materials, but what it failed to appreciate was that problems facing the European biotechnology industry related more to the fragmented political and economic policies between Member States than to specific issues regarding biotechnological inventions. Arguably, the very reason for US biotechnological supremacy is its unitary political, legal and economic system which has been in place for more than two hundred years.

This Thesis suggests that among the protagonists for the development of the European biotechnology industry has been the European ‘patent community’ which has assisted in the development and codification of the isolation contrivance into European patent law. This retaliative manoeuvre in the transatlantic battle for international investment and trade is an obvious response to the continued grant of Directive technologies by the USPTO, which is seen by some to be part of a broader trade and investment war.

Unfortunately, what has been lost in the heat of battle is some perspective for the consequences on patent law and independent scientific research and development. Obviously, the establishment, maintenance and enforcement of intellectual property rights is today a matter of global importance and TRIPS is testament to this. In this context it is only fair and appropriate that the obligations which are codified in TRIPS are enforced so all parties to the WTO have an opportunity to develop the laws and regulations that come under its umbrella in a multilateral forum. To simply permit the EPO, USPTO, JPO, as they did in 1988, to highjack the biotechnological patent agenda in the context of TRIPS and the WTA is repugnant.

Peter Drahos has explained, how “[p]atent offices like the European Patent Office (‘EPO’) and the U.S. Patent and Trademark Office have also been key players [in the expansion of patentable
subject matter].” 64 Clearly, patent offices are a part of what can loosely be described as an ‘international patent system’. It is their role to administer the patent system nationally or, in the case of the EPO, internationally. Moreover, they liaise directly with each other or through the World Intellectual Property Organisation (WIPO) in order to facilitate the operation of the ‘system’. But although they are ‘key players’ in the system they should neither control nor been seen to control the ‘system’. Peter Drahos 65 is right to question their motivation in expanding the realm of the system for it is true, that their function and purpose is today more closely aligned with the development of economic systems than it has ever been in the past. 66

Today patent offices and organisations such as WIPO are ambivalent towards the parameters of patentability because they have ignored the duty that they owe the country or region which they serve 67 having been persuaded by the private sector interests of global intellectual property owners. 68

Stephen Crespi, 69 has argued, however, that patent offices have properly applied patent law because the ‘philosophical’ and legal objections to ‘gene patents’ have a ‘superficial force’ “based on an oversimplification of the legal issue”. 70 He maintains that while “[i]t is true that the word ‘invented’ sounds strained when applied to something already existing …” 71 that, “[t]here is no justification for writing this sort of technological achievement out of the ambit of patent protection

65 Ibid.
67 The High Court of Australia held in Commissioner of Patents v Microcell Ltd. (1959) 102 CLR 232, 245. “… it is not to be overlooked that the Commissioner has a duty to the public as well as to the applicant for a patent, and, if it appears manifest that a valid patent could not be granted, the Commissioner not merely has power, but is under a duty, to reject the application.”
68 S.K.Sell explains that “[i]n the 1970s the World Intellectual Property Organisation enjoyed a reputation as a fairly balanced agency that weighed the interests of both OECD and developing countries. These days, many regard it as little more than a tool for promoting the interests of the proponents of the most protectionist intellectual property norms. It has come to reflect the interests of the favoured factions of capital … and indeed its biggest source of income is its Patent Cooperation Treaty service. … Businesses have increased their use of WIPO’s PCT service dramatically since the late 1980’s, and now provide 85 percent of WIPO’s operating budget.” Private Power, Public Law: The Globalization of Intellectual Property Rights, Cambridge Studies In International Relations: 88, Cambridge University Press, 2003, 20.
70 Ibid.
71 Ibid.
on the basis of an arbitrary judgment that genes are to be categorised as mere discoveries.” In his opinion, “[t]he resulting processes and products [of genetic engineering] should be accorded their proper status as inventions rather than discoveries … [as this] is well established in patent law.”

Stephen Crespi’s arguments are, however, unsound.

Firstly, it is not necessary to ‘write-out’ “this sort of technological achievement out of the ambit of patent protection” because, with the exception of the Directive and the patent laws of compliant Member States, isolated biological materials do not come and never have come within the definition of ‘invention’.

Secondly, the justification for this interpretation of ‘invention’ is found in the ever increasing problems that are being encountered by scientists that are endeavouring to negotiate through the labyrinth of gene and protein patents. Numerous submissions have been made by scientists around the world in various forums providing evidence of the research bottlenecks that these patents are creating. The Nuffield Council of Bioethics in its Discussion Paper acknowledged that these concerns are not of ‘superficial force’. More importantly the Council concluded that “many patents that assert rights over DNA sequences have already been granted but are of doubtful validity” but “[t]he effects of many of these patents are extensive, because inventors who assert rights over DNA sequences obtain protection on all uses of the sequences.”

Thirdly, the fundamental justification against the ‘writing-in’ of these technologies is the extent of the absolute and unfettered power which the patent owner may exercise with regard to all present and future uses of the isolated gene, its genetic sequence and protein manufacture. Nowhere is the truth of this concern more marked than in the case of Chiron Corporation and the hepatitis C virus. It is difficult to justify Chiron’s actions in seeking to monopolise the use of HCV proteins in an HCV vaccine when it knew that the vaccine did not exist in 1988 and, as Dr. Houghton, one of the named inventors conceded in 1999, did not exist eleven years later. Moreover, even though Chiron has more recently relaxed its commercial licensing requirements concerning HCV related research, so that its usual demand for large up-front fees are no longer required, it continues to demand royalties for any ‘successful products’ developed by its licensees independently of

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Ibid, 432 (Emphasis added)

See for example the Statement of Dr. Harold Varmus in 2000; the affidavits of Professor Blumberg in Murex in 1996; the concerns expressed by Professor Sir John Sulston at the 19th International Congress of Genetics in July 2003; Submissions made to the Australian Law Reform Commission Inquiry in March 2004.

The implication which flows from this type of licensing arrangement is clear – if Chiron can demand the royalties for the mere use of HCV proteins for use in independent research, it can also influence or control the type of research that is conducted by its licensee and the ultimate commercialisation of that research in the form of a product, medicine, drug or vaccine by its licensee.

Fourthly, prior to the passage of the Directive, it was not “well established” under the EPC that the resulting processes and products were ‘inventions’ rather than ‘discoveries’. In this respect, the unilateral action of the EPO, the USPTO and the JPO in 1988 in ‘clarifying’ the patentability of Directive technologies, which Stephen Crespi relies upon in support of his argument, was not an accurate description of the law at the time, either in Europe or the United States. Not only was the ‘clarification’ by these three patent offices, which were only a part of the ‘international’ patent system, unrepresentative, the text of the communiqué was plainly inconsistent with Chakrabarty, which had been decided only eight years earlier. Furthermore, the “deep flaws” in the “the current [European patent] regime” in terms of this “explosively new technology” were identified by the UK Court of Appeal in Genentech in 1989, one year after the ‘clarification’ indicated, at least in the UK, that patent law under the EPC and the UK Act was at that time contrary to the text of the ‘clarification’. It is likely that the release of the communiqué was a proactive move by the EPO to encourage the EC to commence a process leading to the Directive.

In these circumstances, it is fair to conclude that the passage of the Directive by the European Parliament in 1998 was not as much a ‘clarification’ of the EPC as it was the repair to the ‘deep flaws’ which Mustill LJ exposed in Genentech. As such, the Directive is the instrument through which the isolation contrivance has been written into the EPC and through which Directive technologies are now patentable subject matter within art. 52(1) EPC.

Nowhere is this point reinforced so well than by the UK Court of Appeal in the 2002 appeal in Amgen. The Court held that:

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75 See Chiron Corporation press release of June 22, 2004 that announced that it had “granted a non-exclusive license to Prosetta Corporation for the research, development and commercialization of therapeutics against certain hepatitis C virus (HCV) drug targets”. Also see Kansas City Star June 24, 2004 Research of Hepatitis C Gets a Boost by Mike Mcgraw.


77 Genentech Inc’s Patent [1989] RPC 147 per Mustill LJ.

... we draw comfort from the Directive which allows claims to biological elements ‘isolated...
or otherwise produced by means of a technical process even if the structure of that element is identical to that of a natural element’. Clearly the Directive envisages that claims can be validly directed to polypeptides produced by a process.\textsuperscript{79}

The Court was considering the validity of a pre-Directive patent, so strictly the Directive was irrelevant, but in support of its ruling upholding the validity of the patent claiming rEpo within its monopoly, the Court referred to the Directive. Clearly, if the pre-Directive law was unambiguously in accord with its interpretation of the law as it was in 1984 (the date of the Amgen patent), it need not have referred to the Directive at all. The conclusion, which this passage invites is this: It is the Directive and its corresponding amendments to the EPC that permit recombinant human proteins, even identical proteins, and the processes of their manufacture to be ‘inventions’ with art. 52(1) EPC\textsuperscript{80} and not the pre-Directive law.

This Thesis has demonstrated that a fair balance between the wealth creation needs of the biotechnology industry and the needs of the community has not been met nor will it be met by the ‘international’ patent system. Fundamentally, this is because the true economic value of the technology lies in the identical replication of natural proteins \textit{per se} and not in the enhancement of the performance of these proteins or even in the application or use of the proteins in one or more industrial or medical application. Therefore, the ‘international’ patent system has delivered wealth to the biotechnology industry but at the cost of depriving the community of the unfettered use of products of nature.

The earlier case studies concerned patents directed to the isolated form of human and viral proteins howsoever produced. With the use of the isolation contrivance, patent owners have been able to perform a sleight of hand transformation of a product of nature into a product of man. This deception has been witness to the creation of wealth in biotechnology companies and this in turn has generated investor interest which has fuelled the growth in biotechnology generally, but this wealth has been built upon a deliberate policy of stolen public assets.

Unfortunately, for those like Dominique Vandergheynst\textsuperscript{81} the distortion to the European patent system perpetrated by the Directive has been necessary to meet the “peaceful co-existence between

\textsuperscript{79} Kirin Amgen Inc v Hoechst Marion Roussel Ltd and others [2003] RPC 31 (UK Court of Appeal), 57, 34.


\textsuperscript{81} Former Responsible Official at the European Commission from 1990 to 1999 for the proposed Directive – see Forword by Dominique Vandergheynst, in G. Kamstra, M. Doring, N. Scott-Ram, A.
the Community initiative … and the irrepressible activity of the European Patent Office, as the largest issue of patents in Europe”. In his opinion, the process that gave rise to the Directive was a “true revolution … between the ethical dimension and a technological sector of which certain aspects cannot but arouse control by public powers”. What he means by “public powers” is not clear for the Directive ensures that legal ownership of genetic materials and proteins will reside within private hands for the most part of the twenty-first century.

The type of absolute and exclusive control which the ‘international’ patent system provides patent owners is simply inappropriate for Directive technologies and it is undeniable that the need for a sui generis system of intellectual property protection is necessary if a fair balance is to be achieved between the community and the biotechnology industry.

**PART II**

*Sui generis* intellectual property systems beyond the copyright, designs, patent and trade mark systems are not new. The twentieth century saw the development and implementation of semiconductor chip protection and plant variety rights.

Furthermore, proposals directed to the amendment of patent laws or the implementation of *sui generis* systems beyond the present patent systems catering specifically for biotechnology have also been suggested. However, as we enter the 21st Century the demands that biotechnology...
continues to make in terms of intellectual property protection is making the need for a sui generis system urgent. In this regard, the call for the amendment of the existing patent system has come from a number of quarters ranging from multi-disciplinary bodies such as the Nuffield Council of Bioethics\(^87\) in 2002 and the Australian Law Reform Commission\(^88\) in 2004 to various commentators in the field. The most significant amendment to a patent system has been the Directive designed by the European Commission and passed by the European Parliament in 1998. However, as this Thesis has demonstrated, this initiative, commenced before the WTA and TRIPS, fails because its central objective, the patentability of Directive technologies, contravenes art. 27.1 TRIPS and the WTA.

Moreover, amendments made to patent law or practice in the United States, such as the USPTO 2001 utility guidelines\(^89\) requiring US patent applications to satisfy one of two utility tests: the ‘specific, substantial and credible’ utility test or the ‘well-established’ utility test\(^90\) have not resolved the controversy concerning the patenting of gene fragments.\(^91\) These tests supposedly make it harder for gene fragment\(^92\) patents to issue because they ‘raise’ the threshold applicable to the utility parameter of patentability. However, while some commentators argue that this new threshold is too high because “[m]uch of the work product of the biotechnology industry is not commercially viable in the conventional sense”\(^93\) and so “may be used to reject patent applications for ESTs whose main use may be as tools for further research, rather than as any type of commercially viable product,”\(^94\) others argue that threshold is not high enough because the new


\(^{91}\) See iBrief Biotechnology: *The Fate of Gene Patents Under the New Utility Guidelines*, (2001) Duke L. & Tech. Rev. 8 which explains that ESTs are useful as nucleotide probes which are a form of ‘research tool’. The difficulty arises because the US Supreme Court in the 1966 decision of Brenner v Manson 383 U.S. 519 held that “the utility standard would not be satisfied unless ‘specific benefit exists in currently available form...’” (536) The Court also held, that “…a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” See also J.D. Foreman, *A Timing Perspective On The Utility Requirement In Biotechnology Patent Applications*, 12 Alb. L.J. Sci. & Tech. 647.

\(^{92}\) These are also known by the term ‘express sequence tags’ or EST’s.


\(^{94}\) Ibid.
utility tests do not eliminate “loopholes [which] exist with respect to technically demonstrating the utility of genetic materials”.\textsuperscript{95}

The nub of the problem for biotechnology and the objective of intellectual property laws which are to reach a fair balance between the need to provide a sufficient incentive to reward those who display creativity, ingenuity and invention while simultaneously permitting a sufficient level of disclosure and use by third parties so as to encourage further creativity, ingenuity and invention, is the simple fact that much of the commercial value of this type of endeavour in the context of biotechnology resides not in the processes or methodologies derived therefrom, but in the production of isolated or recombinant proteins that merely replicate the function or performance of natural proteins. It is the \textit{in vivo} identity that is valuable and it is this that cuts across the prohibition.

It is important to appreciate that the end result of the biotechnological processes and methodologies does not result in the production of an improved or enhanced form of the natural protein. It merely results in a recombinant form of the protein. This distinction has been long recognised by the seminal cases of \textit{Chakrabarty} and \textit{Genentech} which establish that patentability must be denied to these recombinant proteins, and although the patent offices, such as the EPO and the USPTO have been fighting a rear guard action by issuing thousands of patents directed to recombinant proteins, the fundamental and irreconcilable problem is that such proteins are not ‘inventions’. This truth must mean that the patent system cannot provide the level of intellectual property protection that the biotechnology industry needs, but more importantly, it means that the creativity, ingenuity and invention which an efficient patent system should encourage is being undermined by the issuing of invalid and consequently, illegal patents.

Stephen Crespi has suggested that “the word ‘invented’ sounds strained when applied to something already existing.”\textsuperscript{96} Of course he is right, because it is impossible to invent something that already exists, even if we do not know of its existence or are unable to grasp it. But, to suggest, as he did that “the word ‘discovered’ … glosses over the painstaking work that has to be done by the scientist before he can see the pure substance in the test tube,”\textsuperscript{97} and that therefore the ‘isolation contrivance’ is a legitimate device to transform a product of nature (i.e., a ‘discovery’) into a product of man (i.e., something capable of being an ‘invention’) is a distortion of the patent system. True it is that the word ‘discovery’ glosses over “the painstaking work that has to be done


\textsuperscript{96} S. Crespi, \textit{Biotechnology Patenting: The Wicked Animal Must Defend Itself} (1995) 17(9) EIPR, 431-441, 432.
by the scientist,” but the threshold of invention is not ‘painstaking work’. If that were the case, then literally anything could be considered potentially patentable. The simple truth is, that like it or not, the ‘international’ patent system, as defined by TRIPS, requires that whatever has been the subject of ‘painstaking work’ be an ‘invention’ and if it is not, it is ineligible for a patent.

Unfortunately, this does not address the fact that the ability to mass produce recombinant forms of proteins is commercially, medically and scientifically advantageous and there can be no doubt that the isolation of these proteins has greatly contributed to the betterment of human health throughout the world. In these circumstances it is not only fair, but appropriate that the work that has facilitated the isolation of these proteins be rewarded, if for no other reason than that the work leading to their isolation is not only ‘painstaking’ but necessarily involves a very risky form of investment.

This is the point which Stephen Crespi and the biotechnology industry\textsuperscript{98} have made time and time again. Their error, however, has been to rely upon the ‘international’ patent system, rather than to advocate for a \textit{sui generis} intellectual property right.

**PART III**

This Thesis proposes the creation of the Genetic Sequence Right or GSR as a \textit{sui generis} system of intellectual property.

Under this proposal the GSR would be administered within the present ‘international’ patent system as is done with regard to a plant variety right (PVR). A GSR would be granted to the person who is first to disclose a specified genetic sequence defining genetic material of any origin together with a description of its function and utility. A GSR would be the subject of a written application filed in the patent office of the country of application. The sequence would be entered on an international GSR electronic database. This database would be freely accessible by any person.

\textsuperscript{97} \textit{Ibid.}

\textsuperscript{98} The English BioIndustry Association has argued, “the patentability of genes \textit{per se} strikes the most appropriate balance between rewarding the inventor for their contribution to the technical field and the monopoly conferred by the patent. We admit that this is an imperfect balance, but we believe that this balance is more equitable than that achieved by denying \textit{per se} patent protection for genes or other molecules.” See BioIndustry Association (UK): statement published December 21, 2001 in response to British Medical Association’s discussion paper on Gene Patenting.
The Registered GSR would grant to the holder, the right to receive a royalty on any use of the genetic material defined by the GSR. The royalty rate would vary depending on the use. For publicly funded institutions, such as a public university that intended to use the Registered GSR for experimental purposes, the royalty rate could be 0% but for its commercial application, that rate would rise commensurately. Users of the GSR would be required to register their use with administrator of the electronic database and the originating patent office and a public record of such use would be kept and communicated to the GSR holder. The amount of the royalty would be set by a uniform published scale determined by a centralised body responsible for the administration of the GSR. This body would collect the royalty and it would distribute the royalty received to the GRS holder less a fee paid to the collecting authority.

Specific allowance could also be made for GSR holder to seek specific royalties above the approved published royalties if the holder could establish that due to factors relating to the nature of the GSR or unforeseeable events, the amount of royalties would be insufficient to recoup the owners investment in the research and development leading to the provision of the genetic sequence.

The life of the GSR would be 10 years from the date of registration. Infringement of any Registered GSRs could be dealt with through the relevant national courts. The holder would accordingly have the right to seek injunctions, declarations, or damages. Criminal provisions that would make it an offence to breach the holders GSR rights would augment the civil remedies available to the GSR holder.

Finally, if the genetic sequence which is the subject of the GSR is sourced from the biological material of a person or persons, such as an indigenous people, or sourced from a plant (which is not subject to a PVR) or animal or other organism from information provided by a person or persons, a condition of the GSR will be that such person or persons be granted the right to receive a portion of the royalties due to the GSR holder. The amount to be paid to the indigenous people would be commensurate with the contribution made to the ‘isolation’ or ‘discovery’ of the subject matter of the GSR and would be determined by an organisation established specifically to address this calculation.

The GSR proposal provides a system by which investors in genetic research can be adequately remunerated without having the power to control the uses to which that genetic information may be put. The system thereby facilitates the publication of genetic sequence information and encourages the use of genetic sequence information, however, by removing the control element, the proposed system prohibits the GSR holder from adversely manipulating the market or prohibiting or controlling further down-stream research.
As has been amply demonstrated by the experience of health care systems throughout the world in the early 1990’s with HCV diagnostics, Chiron’s refusal to license competing but complementary HCV diagnostics had serious and deleterious consequences of the lives of people who became unnecessarily infected with HCV by receiving blood or blood products and on the cost of the health care systems, both at the time and continuing. This level of control, while being appropriate for traditional types of inventions such as mechanical or engineering or electrical or even pharmaceutical in some cases, are not appropriate when the scope of the claims captures the very ingredient upon which human health is dependent. While one cannot undermine the significant benefit to humanity of the scientific work which lead to the cloning and sequencing of HCV, it needs to also be appreciated that much of the funding for that work came from public sources. It also needs to be appreciated that while significant, the information provided by the discovery of HCV is so fundamentally connected with human health that it is obscene to treat it like any other commodity.

Moreover, the proposed GSR would augment the patent system because it would not prohibit the GSR holder nor any other party applying the genetic sequence in an industrial or medical application to apply for a patent. Therefore, the development of a specific vaccine against HCV would be patentable. What would not be patentable, however, would be the processes or methodologies used to produce proteins or matter that correspond to the genetic sequence defined by the GSR nor the isolated or recombinant forms of the proteins or matter and the corresponding genetic sequence codes for.

The advantage for the GSR applicant is that there is no need to establish an ‘invention’ nor an ‘inventive step’. Novelty of the genetic sequence can be established by a search of the GSR database or other genetic databases. If the relevant genetic sequence is not publicly available nor registered then novelty would be established for the purposes of the GSR. The GSR applicant, however, would need to explain the function of the genetic sequence and its utility.

It is suggested that the GSR is preferable to the patent system because it addresses many of the concerns that surround an experimental use exemption within the patent system. For example, there is presently some debate in Australia as to whether there is a need for a specific statutory general experimental use exemption to patent infringement that extends beyond the existing limited exemption that only applies to patents for pharmaceutical substances that have been extended in operation beyond usual twenty year period. One issue that is problematic with experimental use exemptions in the context of biotechnology, is that many patents have been

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99 The Australian Intellectual Property Council has been conducting an Inquiry into a experimental use exemptions since February 2004.
granted over biological materials that are used as ‘research tools’ or in diagnostics or as part of the experimental process in the search for new drugs. In the context of each of these applications, the patented biological materials have been used by research institutions, such as universities, and the issue that has arisen is whether such use is or should be exempted from patent infringement.

Under the GSR proposal, use by a institution which has as its primary purpose a teaching or research role, will be zero rated for royalty purposes, i.e., no royalty is payable. But a commercial organisation’s use of a GSR, either directly or indirectly, will attract a royalty commensurate with such use. Therefore, if any commercial organisation contracts with a university to conduct research on its behalf or as part of a joint enterprise or collaboration, the obligation remains with the commercial organisation to pay the royalty. This removes the debate about whether universities are conducting commercial or quasi-commercial activities by being in the business of education.

The dilemma which confronts the patent system has been illustrated most aptly in the case of Madey v Duke University. In this case the CAFC considered whether the common law research exemption under US patent law applied to Duke University in respect of its use of certain equipment that was the subject of two US patents granted to Dr. Madey. The equipment had been used in a physics laboratory while Dr. Madey was associated with the University. After Dr. Madey resigned, the University continued to use this equipment without Dr. Madey’s authority and he sued the University for patent infringement. On appeal to the CAFC Dr. Madey prevailed. Crucially, the CAFC held that the University was not able to rely on the research exemption because “use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defence”.

The CAFC explained,

Our precedent clearly does not immunise use that is in any way commercial in nature. Similarly, our precedent does not immunise any conduct that is in keeping with the alleged infringer’s legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution’s legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

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101 Ibid.
102 Ibid.
The CAFC’s reasoning essentially means that any use of a patented biological material, which use is related to the business of education, in the case of a university, or the business of research, in the case of a research institute, will not come within the US common law exemption to patent infringement.

More recently, the scope of a specific statutory exemption to patent infringement was considered by both the CAFC and the US Supreme Court in Integra Lifesciences v Merck KGaA, The Scripps Research Institute and Dr. Cheresh (Merck). At issue was whether the use of patented biological materials in experiments conducted by Dr. Cheresh at the Scripps Research Institute for and on behalf of Merck KGaA in the lead up to an application for regulatory approval of a potential new anti-cancer drug was exempted from patent infringement. In this instance the US Supreme Court reversed the decision of the CAFC and held that,

At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is ‘reasonably related’ to the ‘development and submission of information under . . . Federal law.’ ß 271(e)(1).

This decision may be interpreted as an attempt to restrain the CAFC’s inclination to read the common law research exemption narrowly, however, it must be understood that the decision was not dealing the common law research exemption. Moreover, although the decision advocated a broad reading of the specific statutory exemption in issue, the decision did not please all universities or research institutions. For example, in an Amicus Curiae brief filed with the Court on behalf of the Wisconsin Alumni Research Foundation, the American Council On Education,

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103 Integra Lifesciences v Merck KGaA, The Scripps Research Institute and Dr. Cheresh (2003) U.S. App. LEXIS 27796 (CAFC) and Merck KGaA and other v Integra Lifesciences and others (2005) U.S. LEXIS 4840 (US Supreme Court). The US Supreme Court handed down its decision on June 13, 2005 is as after the date of the submission of the thesis for examination, however, its relevance to the issue requires a reference to it.

104 Merck KGaA and other v Integra Lifesciences and others (2005) U.S. LEXIS 4840, per Scalia J. (US Supreme Court).

105 “The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C.S. ß 301 et seq., is a Federal law which regulates the manufacture, use, or sale of drugs. 21 U.S.C.S. ß 355(a). Under the FDCA, a drugmaker must submit research data to the Food and Drug Administration (FDA) at two general stages of new-drug development. First, a drugmaker must gain authorization to conduct clinical trials (tests on humans) by submitting an investigational new drug application (IND). 21 U.S.C.S. ß 355(i); 21 C.F.R. ß 312.1 et seq. (2005). The IND must describe preclinical tests (including tests on animals) of the drug adequate to justify the proposed clinical testing. 21 U.S.C.S. ß 355(i)(1)(A); 21 C.F.R. ß 312.23(a)(5), (8). Second, to obtain authorization to market a new drug, a drugmaker must submit a new drug application (NDA), containing full reports of investigations which have been made to show whether or not the drug is safe for use and whether the drug is effective in use. 21 U.S.C.S. ß 355(b)(1). Pursuant to FDA regulations, the NDA must include all clinical studies, as well as preclinical studies related to a
Boston University, the Regents Of The University Of California, Research Corporation Technologies, the Salk Institute For Biological Studies, University Of Alberta and the University Of Oklahoma, it was argued that a broad reading “would nullify the commercial value of an entire class of patents -- drug research patents, which are paramount tools in the drug discovery process.” In their opinions, many patented biological materials that are useful per se as intermediary products or are a component of such products facilitating drugmakers in their search for new drugs should not be exempted from patent infringement by effect of this statutory exemption.

So it would seem that some universities no longer see themselves merely as institutions that provide facilities to teach and conduct related non-commercial research, but as players in a commercial world that rely on generating patent royalty income as part of their operations. They therefore argued, contrary to what Duke University argued in Madey, for a narrow interpretation.

So the problem for the applicability of research exemptions as safety nets around scientific and medical research, is where and how to draw the line? If universities in the 21st century are non-commercial entities or participate in commercially driven activities, then just how relevant is the rationale for the common law exemption that was first created in the 19th century? Both in the US and the UK, the common law intervened to protect those engaged in research. The rationale for this approach, although expressed differently by the Courts, were essentially identical.

First, it was felt that the patent system should not prevent experimentation that was conducted with the purpose and intent of testing the patented invention or to innovate around or beyond the patented invention. Second, it was felt that the patent system should not inhibit non-commercial scientific or recreational research.

At first glance it seems that these ideals are as applicable today as they were in the 19th century. However, unlike in the 19th century, universities and research institutions today are no longer conducting non-commercial research nor are their activities limited to testing patented inventions or developing improvements beyond them. The dilemma that this reality poses upon the

drug's efficacy, toxicity, and pharmacological properties. 21 C.F.R. β 314.50(d)(2), (5).” LexisNexis Headnote HN3.

106 Amicus curiae brief on behalf of the Wisconsin Alumni Research Foundation, the American Council On Education, Boston University, the Regents Of The University Of California, Research Corporation Technologies, the Salk Institute For Biological Studies, University Of Alberta and the University Of Oklahoma in Merck KgaA and other v Integra Lifesciences and others filed on March 15, 2005.
108 Freason v Loe (1878) 9 Ch. D. 48.
109 Taking the HCV polypeptide patent claims discussed in Chapter 5 as an example, how does one design around these claims? How does one improve upon such claims? It is simply impossible to do either.
application of such exemptions has been recognised by the Australian Intellectual Property Council.\textsuperscript{110}

However, the GSR impliedly recognises that the use of genetic sequences or biological materials (that are identical to naturally occurring sequences and materials) for whatever purpose should not be controlled nor come under the control of any one organisation or person, in contrast to a patentee’s exclusive right to prevent third party use of a patented invention. It therefore encourages third party use, rather than attempting to control it. It recognises that irrespective of whether a genetic sequence is an ‘invention’ or not, the elucidation of a genetic sequence and the identification of its function is important work that should be encouraged. It therefore enables universities to fund their research projects by becoming GSR holders without incurring any obligation to pay royalties. It enables universities to offset their GSR revenues with commercial organisations, so that commercially funded or directed research that uses the GSR of that university can be taken into account by the parties to that collaboration. It provides a system to record GSR’s and assess the uses to which they are put. The fact that universities are in the business of education or, that today, see themselves as part of a broader commercial world becomes irrelevant because their primary purposes will always be in the provision of education and related-research and the GSR acknowledges this.

Unlike the patent system which creates a form of ‘property’ in the patented invention and one which gives the ‘owner’ the right to deal with that property as the patentee sees fit, the GSR does not. Rather the ‘holder’ of the GSR is simply recognised to be the first to enable the publication of a natural genetic sequence and its function and accordingly the \textit{quid pro quo} for its disclosure is the entitlement to receive a royalty on its use. The more use of that GSR the greater the potential revenue. Whereas with the patent system, the price of the patented invention can be subject to manipulation through the patentee’s ability to control third party use. It is this ability that provides the rationale for the research exemption thereby balancing the needs of the patentee with the needs of society. However, with the GSR there is no further balancing or fine tuning required because whole system is designed to encourage both commercial and non-commercial use equally.

\textsuperscript{110} \textit{Patents And Experimental Use Issues Paper}, February 2004, ACIP, 2-3.
This Thesis has been about the meaning of the word ‘invention’ in the context of art. 27.1\(^1\) TRIPS and its relationship to the technology described in art. 3\(^2\) and art. 5\(^3\) of the Directive. It has demonstrated that the subject matter described by these two articles of the Directive can be identical to biological material that exists in nature. To the extent that it is possible to include biological material that is identical to that which exists in nature, even if that material is ‘artificial’ in the sense of being ‘isolated’, ‘purified’ or ‘produced by means of a technical process’, this Thesis has argued that the Directive and any patent that has been granted by any member of the WTO in respect of such subject matter violates TRIPS and the WTA. This is because the word ‘invention’ in art. 27.1 TRIPS excludes products of nature or natural phenomena and their ‘artificial’ derivatives which do not meet the threshold of artificiality established in Chakrabarty. This meaning of the word is consistent with a fundamental principle of patent law that a patent pertains only to an ‘invention’. Furthermore, it is consistent with the principle that only when that ‘invention’ is also ‘novel’, ‘involves an inventive step’ and is ‘industrially applicable’ that it becomes patentable.

Through a study of patent law in the context of biotechnology in the United States, the United Kingdom, Europe and Australia, as it was both prior to the WTA, TRIPS and the Directive, this Thesis has demonstrated that mere artificiality, in the form of a product or some other manifestation of artificiality, is not enough to transform a product of nature into an ‘invention’. The cases of Chakrabarty in the United States, Genentech in the United Kingdom and NRDC in Australia are consistent with this proposition. Each of these cases are important not only within their own jurisdictions, but also beyond them. This is particularly so with Chakrabarty, which has been recognised throughout the world as possibly the most important precedential authority in the development of patent law and biotechnology in the twentieth century.

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\(^1\) Art. 27.1 “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. (Emphasis added)

\(^2\) Article 3.1 “… a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.”

Article 3.2. “Biological material which is isolated from its natural environment or produced by means of a technical process … even if it previously occurred in nature.”

\(^3\) Article 5.2 “An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.”
As was explained in Chapter 2, Chakrabarty does not stand for the proposition that, “when some human intervention has been necessary to make [the naturally-occurring product] available … in the [form of the] isolation or purification of the naturally-occurring product, and translates in claim language as ‘…essentially pure …’, ‘… biologically pure …’, or ‘… isolated …’. … it is patentable subject matter within s.101 US Act. Rather, it stands for the proposition that for a natural phenomenon or its artificial derivative to be patentable subject matter that the following three criteria must be satisfied:

Firstly, the natural phenomenon or its artificial derivative must be significantly modified. It is not a matter of simply ‘isolating’, ‘purifying’ or ‘replicating’ it through a ‘technical process’.

Secondly, the end result of the modification must display markedly different characteristics from any found in nature; and

Thirdly, the markedly different characteristics must have the potential for significant utility.

What Chakrabarty demonstrates is that the isolation, purification or replication of a natural phenomenon or its function, even if it results in something artificial per se, remains non-patentable subject matter. In other words, it is not an ‘invention’. It explains that the degree of artificiality necessary to transform a natural phenomenon into patentable subject matter within s.101 US Act is significant.  

Daniel Gervais explained that TRIPS is one of the “most significant milestone in the development of intellectual property in the twentieth century” and that “the spark which ignited the work towards the TRIPS Agreement” was the tabling by the European Community and the United States of almost identical versions of drafts of TRIPS in March and May, 1990. These drafts were “eventually adopted and, subject to a few changes, would serve as the basis for the emerging

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5 B. Looney, Should Genes Be Patented? The Gene Patent Controversy: Legal, Ethical, And Olicy Foundations Of An International Agreement, (1994) 26 Law & Policy in International Business 231-272, 253 “The judiciary has interpreted this requirement to mean that an invention in the biotechnological realm must have a significant ‘human innovation’ component, to move the invention from an ‘object of nature’ to ‘patentable subject matter’ status…The Court held [in Chakrabarty] that Dr. Chakrabarty’s oil-eating bacterium, engineered by splicing together several different strains of bacteria, involved sufficient human intervention to be worthy of patent protection under the law.”


7 Ibid, 16 para 1.18.
Agreement. In these circumstances, it is most unlikely that the EC and the United States failed to understand the significance of the language that was proposed in TRIPS. Moreover, it is unlikely that these two countries would have used language in the proposed drafts of TRIPS that was inconsistent with their understanding of their respective patent laws as they were at that time. In this regard, it is important to appreciate that the language of art. 27.1 TRIPS has a direct association with the language of art. 52.1 EPC and s.1(1) UK Act. The conclusion which this Thesis invites is that the word ‘invention’ in art. 27.1 TRIPS is consistent with the patent law as interpreted in Chakrabarty and Genentech, both of which were decided before the proposed transatlantic drafts of TRIPS were tabled.

However, despite these two binding authorities, the development of patent law through the 1990s has witnessed a distortion through the actions of those that have sought to expand the role of the ‘international’ patent system beyond the fundamental principles described at the beginning of this Chapter. The development of the ‘isolation contrivance’ by the ‘patent community’ in 1988 as a devise to achieve the patenting of isolated, purified or technically produced derivatives of natural phenomena mark the official recognition and adoption of this distortion. The ‘isolation contrivance’ has since been used by the EPO through its own appellate process, one which is not subject to any outside or independent scrutiny, to reinforce the relevance of its own policy and Howard Florey Institute (Relaxin) is the result. Beyond this EPO decision, the EPO has adversely influenced the development of patent law within the EPO but also in the United Kingdom, and the decisions of Chiron and Amgen are examples of this. In the United States, the actions of the patent owners in selectively avoiding s.101 US Act in combination with the CAFC has seen the creation of a perception that the US patent system permits the patenting of isolated and purified natural phenomena and the CAFC decisions in Amgen (1991), Bell, Deuel and Amgen (2003) are the results. Moreover, the selective avoidance by biotechnology and pharmaceutical companies in Europe of objections under art. 52.1 EPC has added further weight to the perception that isolated and purified biological material is patentable subject matter under the EPC.

Clearly, it has been in the interests of patent offices and patent organisations, such as the WIPO, to encourage the expansion of the ‘international’ patent system simply because their revenues are directly affected by the fees which they derive from the administration and prosecution of patents. As Susan Sell confirms,

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8 Ibid.
9 “Purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds.” 1988 Joint Statement of USPTO, EPO and JPO. See footnote 9, Nuffield Council of Bioethics Discussion Paper The Ethics of Patenting DNA, 26, 3.14.
Chapter 7: Conclusion

In the 1970s the World Intellectual Property Organisation enjoyed a reputation as a fairly balanced agency that weighed the interests of both OECD and developing countries. These days, many regard it as little more than a tool for promoting the interests of the proponents of the most protectionist intellectual property norms. It has come to reflect the interests of the favoured factions of capital … and indeed its biggest source of income is its Patent Cooperation Treaty service. … Businesses have increased their use of WIPO’s PCT service dramatically since the late 1980s, and now provide 85 percent of WIPO’s operating budget.¹⁰

Moreover, the biotechnology and pharmaceutical industries that have garnered significant political support through the battle for biotechnological supremacy and investment that currently rages around the world have encouraged this expansion. However, what has been lost in the heat of this economic and political battle has been some proper perspective of the impact which it has had and continues to have on those countries that are not the principle beneficiaries of the international investment which is generated through this process, nor on the level of independent scientific research and development that is subjected to the labyrinth of broad patents over biological materials.

The Directive, which was passed by the European Parliament in 1998, is the legislative instrument through which the isolation contrivance has been implemented and consequently the Directive violates TRIPS. Accordingly, the EC and any complying EC member is in violation of the WTA. But the violation of TRIPS is not confined to the EC, but extends to the conduct of the USPTO, the JPO and to any patent office in a WTO country which has granted patents in respect of subject matter that is not an ‘invention’. In this regard, TRIPS requires all member countries to amend their patent laws to ensure that the stipulated minimum standards of patentability are enforced and this must mean, as TRIPS is presently drafted, that the continued actions of patent offices in granting patents regarding isolated, purified or technically produced products that are identical or materially identical to natural phenomena is contrary to and a violation of TRIPS. How this debate will proceed is a matter of conjecture, however, as this Thesis has demonstrated the WTO now provides its members with an opportunity to move this debate forward. There is no doubt that this needs to be done. This Thesis has proposed a solution to the problem that confronts the biotechnology industry and humanity’s right to be able to freely use products of nature. One can only hope that this Thesis moves the debate a step closer to resolution.

STATUTES
Patents Act, 1952 (United States of America)
Patents Act, 1977 (United Kingdom)
Patents Act, 1990 (Australia)

CONVENTIONS, TREATIES AND INTERNATIONAL AGREEMENTS
Agreement on Trade-Related Aspects of Intellectual Property Rights, 1995
European Patent Convention, 1973
Paris Convention for the Protection of Industrial Property, 1883
Patent Cooperation Treaty, 1971
World Trade Agreement, 1995

COMMITTEES OF INQUIRY AND REPORTS
Hearings on H. R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951).

National Health & Medical Research Council, Report On The Epidemiology, Natural History And Control Of Hepatitis C, November 1993.


**Intellectual Property Rights (IPRs) and Genetics**, by Professor William Cornish, Dr Margaret Llewelyn and Dr Michael Adcock, 2003.


**CASE LAW**

**UNITED STATES OF AMERICA**


*Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc* (1991) 927 F.2d 1200 (CAFC)

*Amgen Inc., v Hoechst Marion Roussel, Inc. (now known as Aventis Pharmaceuticals Inc.) and Transkaryotic Therapies, Inc.,* (2003) 314 F.3d 1313 (CAFC)

*Atlantic Thermoplastics Co. v Faytex Corp.,* (1992) 974 F.2d 1279 (CAFC)

*Corona Cord Tire Co. v Dovan Chemical Corp.* (1928) 276 US 358 (US Supreme Court)

*Daniel W. Bradley v Chiron Corporation, William J Rutter, Edward E. Penhoet, Michael Houghton, Qui Lim Choo, Geroge Kuo and Ortho Diagnostics Systems, Inc,* United States District Court for the Northern District of California, before Wilken J. (US District Court) (unreported)


*Diamond, the Commissioner of Patents v Chakrabarty* (1980) 447 U.S. 303 (US Supreme Court)

*Funk Brothers Seed Co. v. Kalo Inoculant Co* (1948) 333 U.S. 127 (US Supreme Court).

*In re Bergstrom* (1970) 427 F.2d 1394 (CCPA)

*In re Bergy* (1977) 563 F.2d 1031 (CCPA)

*In re Bell* (1993) 991 F.2d 781 (CAFC)

*In re Dewel.* (1995) 51 F.3d 1552 (CAFC)


*Merck & Co. v. Olin Mathieson Chemical Corp* (1958) 253 F.2d 156 (US District Court - Appeals)

*Popeil Bros., Inc. v Schick Electric, Inc.* (1974) 181 USPQ 482 (US District Court)
Scripps Clinic & Research Foundation v. Genentech, Inc (1991) 927 F.2d 1565 (CAFC)


Toner v Sobelman (1949) 81 USPQ 304 (US District Court)


UNITED KINGDOM

Biogen Inc v Medeva plc [1997] RPC 1 (House of Lords)

Chiron Corporation v Murex Diagnostics Limited (No 3) [1994] FSR 202 (Patents Court)

Chiron Corporation and Others v Murex Diagnostics Ltd and Others (No 12) [1996] RPC 535 (Court of Appeal)

Fujitsu Limited’s Application [1997] RPC 608 (Court of Appeal)

Genentech Inc’s Patent [1987] RPC 553 (Patents Court)

Genentech Inc’s Patent [1989] RPC 147 (Court of Appeal)

Hickton’s Patent Syndicate v Patents & Machines Improvements Co Ltd (1909) 26 RPC 359 (Court of Appeal)

Improver Corporation v Remington Consumer Products Limited [1990] FSR 181

Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2002] RPC 1 (Patents Court)

Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2003] RPC 31 (Court of Appeal)

Kirin-Amgen Inc v Hoechst Marion Roussel Ltd and others [2004] All ER (D) 286 (House of Lords).

Lane Fox v. Kensington and Knightsbridge Electric Lighting Co (1892) 9 RPC 413 (Court of Appeal)

Merrill Lynch Inc’s Application [1988] RPC 1 (Patents Court)

Merrill Lynch’s Application [1989] RPC 561 (Court of Appeal)

Re Gale’s Application [1991] RPC 305 (Court of Appeal)

AUSTRALIA


National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 252 (High Court of Australia)
NV Philips Gloeilampenfabrieken v Mirabella International Pty Limited (1995) 183 CLR 655 (High Court of Australia)

EUROPEAN PATENT OFFICE

T208/84 Viacom/Computer Related Invention (Technical Board of Appeal)

T717/89 Biogen Inc (Technical Board of Appeal)


T128/92 Ajinomoto Co. v. Hoechst Aktiengesellschaft, Cetus Oncology Corporation (Technical Board of Appeal)


T223/93 Genentech, Inc. v. Roussel Uclaf, Biogen Inc., Bioferon Biochemische Substanzen GmbH & Co (Technical Board of Appeal)


T441/93 Gist-Brocades N.V. v. Rhone-Poulenc Sante (Technical Board of Appeal)

V 8/94 Howard Florey Institute of Experimental Physiology and Medicine v. Fraktion der Gronen im europCischen Parlament, Paul Lannoye – Relaxin (Opposition Division).

T749/94 Genetics Institute, Inc. v. Amgen Inc (Technical Board of Appeal)

T277/95 Genetics Institute, Inc. v. Amgen Inc (Technical Board of Appeal)

T188/97 F. Hoffmann-La Roche & Co AG v Chiron Corporation (Technical Board of Appeal)


TRANSCRIPTS, AFFIDAVITS AND WITNESS STATEMENTS

Transcript of the Patents Court in Chiron Corporation v Murex Diagnostics Limited, July 5 – August 2, 1993
Transcript of the Federal Court of Australia in *Murex Diagnostics Australia Pty Ltd v Chiron Corporation*, June 24 – 28 August, 1996

Transcript of the House of Lords Appeal in *Kirin-Amgen, Inc v TKT*, July 5-15, 2004

Witness statements in *Chiron Corporation v Murex Diagnostics Limited* (UK Patents Court)

Affidavits in *Murex Diagnostics Australia Pty Ltd v Chiron Corporation* (Federal Court of Australia)


**BOOKS**


**JOURNAL ARTICLES**

S Abrignani, M. Houghton, H.H. Hsu, (1999), “*Perspectives for a vaccine against hepatitis C virus,***” J. Hepatol. 31 Suppl 1; 259 – 263


R.S. Eisenberg, *Re-Examining The Role Of Patents In Appropriating The Value Of DNA Sequences*, (2000) 49 Emory L.J. 783-800


M.A. Heller and R.S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, The American Association for the Advancement of Science, Volume 280, Number 5364, 1 May 1998


