No. 2010-1406

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD, ARUPA GANGULY, PhD, WENDY CHUNG, MD, PhD, HARRY OSTRER, MD, DAVID LEDBETTER, PhD, STEPHEN WARREN, PhD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, and KATHLEEN RAKER,

Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant,

and

MYRIAD GENETICS, INC.,

Defendant-Appellant, and

(caption continued on inside cover)

Appeal from the United States District Court for the Southern District of New York in Case No. 09-CV-4515, Senior Judge Robert W. Sweet

BRIEF FOR CANCER COUNCIL AUSTRALIA AND LUIGI PALOMBI AS AMICI CURIAE SUPPORTING AFFIRMANCE

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(caption, continued)

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, and MICHAEL K. YOUNG, in their official capacity as Directors of the University of Utah Research Foundation,

Defendants-Appellants,

CERTIFICATE OF INTEREST

Counsel for Cancer Council Australia and Luigi Palombi certifies the following:

1. The full names of every party or amicus represented by us are:

   Cancer Council Australia

   Luigi Palombi

2. The name of the real party in interest (if the party names in the caption is not the real party in interest) represented by us is:

   Not applicable

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by us are:

   None

4. The names of all law firms and the partners or associates who appeared for the party or amicus now represented by us in the trial court or agency or are expected to appear in this Court are:

   The Law Office of Larry Frierson (Larry Frierson) is appearing for Cancer Council Australia and Luigi Palombi in this Court.

Dated: December 3, 2010 .....

Larry Frierson

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STATEMENT OF INTEREST

Cancer Council Australia ("CCA") is Australia's peak national non-government cancer control organization. CCA advises the Australian Government and other Australian non-government bodies on practices and policies to help prevent, detect and treat cancer. It also advocates for the rights of cancer patients for best treatment and supportive care. CCA works with its members, the eight Australian state and territory cancer organizations, to undertake and fund cancer research, prevent and control cancer and provide information and support for people affected by cancer.

Luigi Palombi is an adjunct professor of law at the University of Sydney's Law School and a member of the academic staff of the Regulatory Institutions Network at the Australian National University. Prof Palombi is also admitted to the Supreme Courts of the States of South Australia, Victoria, the Northern Territory and New South Wales. And also admitted to the Federal and High Courts of Australia. He was first admitted to the practice of law in Australia in 1982. He is a former law partner of Australia's largest patent attorney firm, Davies Collison Cave. He specialized in patent law in 1986 and in 1993 further specialized by focusing his practice on patents directed to the life sciences. He was the attorney-

of-record in the first Australian case to challenge the validity of an Australian patent containing claims to 'isolated' and 'purified' nucleotides and amino acids, their synthesis by biotechnological processes and their use in medical and scientific applications.[1] He has also advised clients in Australia and in other parts of the world on patents containing such claims. He was awarded a PhD by the University of New South Wales in 2005. His doctoral thesis entitled *The Patenting of Biological Materials in the Context of TRIPS* was examined by Professor Peter Drahos of the Australian National University, Canberra, Australia, Associate Professor Ann Monotti of Monash University, Melbourne, Australia, and Emeritus Professor William Cornish of Cambridge University, Cambridge, United Kingdom. Since 2008 he has acted as a *pro-bono* advisor to CCA during the course of the Australian Senate Community Affairs References Committee's inquiry into the impact of gene patents on medical and scientific research and Australia's healthcare system. He has also been invited to present to Australian Members of Parliament and Senators on issues concerning patents in the life sciences, particularly gene patents. He has made written submissions to a variety of Australian Parliamentary inquiries on matters relevant to the life sciences as well as giving evidence in those

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[1] *Murex Diagnostics Australia Pty Ltd v Chiron Corporation*, Federal Court of Australia, NSW District Registry NG 106 of 1994.

inquires at the request of the relevant committees. He has given numerous interviews on the subject of gene patents on Australian radio and television and is often quoted in leading Australian newspapers on the subject. His book, *Gene Cartels-Biotech Patents in the Age of Free Trade* ("*Gene Cartels*"), has been mentioned in speeches made in the Australian Parliament concerning gene patents. His book, which is about the history of the patent systems of the United Kingdom, Europe and the United States and the patentability of biological materials such as genes and proteins, has also been positively received and reviewed. The foreword to his book was authored by Nobel laureate, Professor Baruch S. Blumberg. He is the author of learned peer-reviewed papers on the subject of gene patents under Australian, United States and European patent law. He has been invited to speak on patent law at international legal and scientific meetings held in Australia, New Zealand, the European Union and the United States.

The issues raised in this appeal are of relevance to CCA and to Prof Palombi, to the extent that he is an advisor to CCA on gene patent law and policy, in that its outcome, and the reasoning employed in reaching an outcome, may be highly influential on developments in contemporary patent law in Australia and, importantly, on how such patent law impacts on medical and scientific research

into cancer in Australia. CCA and Professor Palombi have no commercial interest in the parties to this action. None of the parties have any association with either CCA or Professor Palombi.

All parties have consented to the filing of this brief.

INTRODUCTION

A patent monopoly is a legally enforceable instrument that enables the holder to exercise exclusive control within the jurisdiction of the subject matter which falls within the scope of any of the claims in the patent document ("the patent").

The grant of a patent monopoly, however, is a conditional privilege. It is not an irrevocable right. As a conditional privilege, bestowed by the State on the holder, it can be revoked. Thus the holder of a patent monopoly may exclusively exploit the subject matter of the patent but only within the terms of the grant and only if the grant is lawful.

Since the passage by the British Parliament of the *Statute of Monopolies* in 1623, monopolies, under Anglo-American law, have been restricted. Under section 1 of the *Statute* all monopolies, except for a few specific kinds, were rendered "null and of none effect". One of these exceptions was provided in section 6.[2]

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[2] 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."

Accordingly a "manner of new manufacture" was patentable subject matter with respect to which the grant of a patent monopoly was lawful, provided, the grant (a) did not exceed 14 years and (b) its effect did not transgress on the proviso in the section.

British law was received by the North American colonies and although they broke away from Great Britain and reorganized themselves as the United States of America under its own Constitution in 1787, the *Patents Act, 1790* clearly borrowed from British patent law[3] and the subsequent *Patents Acts, 1793*, *1836* and *1952* retained the same association. True it may be that in 1790 the United States patent system differed from the British patent system in that it required examination of the patent application but, as explained in Professor Palombi's book[4], the patentability thresholds were undoubtedly of British legal heritage.

Thus, it has been a long accepted principle of the Anglo-American patent system that the grant of a patent monopoly is only lawful if the subject matter of the patent is an 'invention'. Professor P. J. Federico noted:

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[3] Prager, Frank D., *Standards of Patentable Invention from 1472 to 1952*, The University of Chicago Law Review, 20(1), 69-95, 70.

[4] Palombi, L., *Gene Cartels-Biotech Patents in the Age of Free Trade*, (Edward Elgar, Cheltenham, UK, 2009), 9-16.

> "There must be a fundamental principle or axiom in patent law which might be similar to the axioms or fundamental elements of geometry which are stated to be incapable of proof or definition. This axiom is that anything new is *not necessarily* capable of being patented; ..."[5]

Indeed, this principle is the bedrock of Anglo-American patent law. And today is contained in the *Agreement on Trade Related Aspects of Intellectual Property Rights*[6] ("TRIPS") which governs intellectual property within the World Trade Organization ("WTO"). The WTO's membership consists of 153 countries and includes the United States and Australia, both of which have been members since its inception on January 1, 1995.

In addition, the number of international agreements governing free trade incorporating aspects of intellectual property law have proliferated since the formation of the WTO, with the result that today how patent law is interpreted and applied in the United States can have a corresponding influence on patent law in other countries. Thus, it is reasonable to suggest that since the formation of the WTO, and the policy of free trade which it stands for, common legal principles in the field of intellectual property law are necessary to strengthen the matrix which

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[5] Federico P. J., *The Concept of Patentable Invention*, Journal of the Patent Office Society, 32, 118-122, 120 (emphasis added).

[6] Article 27.1 of the *Agreement on Trade Related Aspects of Intellectual Property Rights* states: "... patents shall be available for any inventions ...."

brings countries closer together, both economically and politically. To do otherwise serves only to undermine the objectives of the WTO. Likewise, there is a growing international expectation for the members of the United States Congress and Judiciary to acquaint themselves with the intellectual property laws of other countries and their development and to take both into account in terms of the interpretation and development of the corresponding law of the United States.

ARGUMENT

I. A BRIEF OVERVIEW OF PATENTABLE SUBJECT MATTER UNDER AUSTRALIAN PATENT LAW

The relevant statute under Australian patent law is the *Patents Act, 1990*. The *Patents Act, 1990* is a Commonwealth Act passed by the Australian Parliament in Canberra. The Commonwealth's power to make laws for "patents of invention" is reserved to the Australian Parliament under section 51(xviii) of the *Commonwealth of Australia Constitution Act, 1901*.

The *Patents Act, 1990* superseded the *Patents Act, 1952* which superseded the *Patents Act, 1903*, being the first of such legislation after Federation in 1901. Prior to Federation, Australia consisted of a number of British colonies. The colony of New South Wales was the first in 1788.

British and Australian patent law was directly linked to section 6 of the *Statute of Monopolies, 1623*. Accordingly, either the subject matter of a patent was a "manner of new manufacture" or the patent was void *ab initio*.

The "manner of new manufacture" or 'invention' threshold first appeared in a British patent statute with the passage of the *Patent Law Amendment Act, 1852*. The threshold was retained in the *Patents, Designs and Trade Marks Act, 1883*, the *Patents Act, 1902*, the *Patents and Designs Act, 1919* and the *Patents Act, 1949*. It was not until 1977, with the passage of the *Patents Act, 1977* (which was a consequence of the United Kingdom ratifying the *European Patent Convention, 1973)* that a different test of patentability was adopted by the United Kingdom, and even so, the threshold of 'invention' is retained, albeit differently expressed.

The Australian 1903 legislation was modeled on the United Kingdom's *Patents Act, 1902*. Likewise, the Australian 1952 legislation was modeled on the United Kingdom's *Patents Act, 1949*.

The first change to the conditions of patentability as originally provided by section 6 of the *Statute* occurred in 1919 when (a) the term of a British (and subsequently an Australian) patent monopoly was extended from 14 years to 16 years (section 17) and (b) chemical substances *per se* were expressly excluded

from patentability (section 38A). The ban on the patenting of chemical substances did not, however, prevent the patenting of processes for the production of chemical substances. In this way, British patent law was brought into line with German patent law.[7] The British government believed this policy to be necessary in order to encourage the establishment of a British chemical industry which, with the severe shortages of chemicals common place in the United Kingdom throughout the First World War, was needed to guard against the reemergent dominance in the British market of German chemical companies.[8]

The only other change to the conditions of patentability as originally provided by section 6 of the *Statute* occurred in the Australia in 1995 when the

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[7] The German patent law of 1877 did not permit the patenting of chemical substances *per se*. This only changed in 1968.

[8] The United States government instead confiscated German-owned US chemical and other patents, trademarks and copyrights and established the American Chemical Foundation ("ACF"). The ACF then either licensed or sold the US patents to US-owned companies. One of the major beneficiaries of this policy was the Sterling Drug Co., which acquired the famous 'Bayer' trademark as well as Bayer's US patents and factories. See Vaughan, F.W. (1919), *Suppression and Non-working of Patents, With Special Reference to the Dye and Chemical Industries*, The American Economic Review, 9 (4), 693–700. Also Steen, K. (2001), *Patents, Patriotism, and "Skilled in the Art": USA v The Chemical Foundation*, 1923–1926', Isis, 92, 91–122.

term of a Australian patent was extended from 16 years to 20 years by effect of Australia's membership of the WTO.[9]

What can be deduced from this brief history of Australian patent law is that the bedrock of patentability is 'invention'. Over a period of nearly 400 years the only significant change in the operation of this principle as it was originally written (apart from briefly banning chemical substances from patentability between 1919 and 1949 in the United Kingdom) has been to increase the patent term from 14 years to 20 years. As such it can be stated with confidence that unless the subject of a patent is truly an invention, the grant of a patent monopoly is unlawful.[10]

Although the ban on patenting of chemical substances was repealed by the *Patents Act, 1949 UK,* the same legislation reemphasized the overriding of importance of this principle by expressly prohibiting the grant of a patent monopoly over any substance as "found in nature".[11]

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[9] The term of a British patent changed to 20 years with the passage of the *Patents Act, 1977* (UK).

[10] Section 18(1)(a) *Patents Act, 1990* (AU) states: "… an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim: (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies".

[11] Section 4(7) *Patents Act, 1949* (UK) states: "Where a complete specification claims a new substance, the claim shall be construed as not extending to that substance when found in nature."

The crucial question, of course, is: what is an 'invention'? and in the context of section 18(1)(a) *Patents Act, 1990* (being the current subject matter provision) the correct inquiry for answering this question, according to the High Court of Australia (equivalent to the US Supreme Court) in *National Research Development Corporation v The Commissioner of Patents* ("NRDC"), is this:

> "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?"

II. ARE 'ISOLATED' BIOLOGICAL MATERIALS 'INVENTIONS'?

As Professor Palombi points out in his book *Gene Cartels,* the bedrock principle of 'invention' binds the patent laws of Britain, the United States and Australia together through a common heritage. True it is that today each has its own patents legislation and within each of these the thresholds of patentability are expressed in their own way, such that it cannot be said that the legislations are the same. However, regardless of the language used, the intent is the same. At its most fundamental, a patent, regardless of jurisdiction, concerns, and only concerns, an invention. Thus, although the courts in each jurisdiction have developed their own unique jurisprudence on the issue of invention, what emerges from a study of them are similarities in approaches. One of these is that the discovery of a naturally

occurring thing, a natural phenomenon, in the parlance of the U.S. Supreme Court, is excluded from patentability because it is not an invention.

The distinction between discovery on the one hand and invention on the other has, however, been problematic. And this is true in each of these three common law jurisdictions. Clearly, there have been significant technological developments since 1623 when the phrase 'manner of new manufacture' was first coined and, with respect to each of these developments, the courts in each jurisdiction has had to apply their respective patent laws in the context of these developments, while at the same time ensuring that the original intent encapsulated within the meaning of this phrase was maintained. These technological developments have, at times, caused considerable controversy over precisely where to draw the line and how to draw the line between 'discovery' on the one hand and 'invention' on the other.

The High Court of Australia in *NRDC*, a celebrated judicial authority in Australia, New Zealand and the United Kingdom, attempted to do this in the context of an Australian patent application which claimed, as an invention, a process that used a well known herbicide in a new way so as to produce a new and useful result, namely, the herbicide killed certain weeds but not the crops over

which the herbicide was applied. The Court was asked to consider whether such a result, being an 'effect' (in the field of agriculture) and not a tangible physical product was, at law, capable of satisfying the patentable subject matter test of 'manner of new manufacture'. The Court answered that question in the affirmative. In doing so the Court made some pertinent statements about the distinction between discovery and invention. The most relevant, in the context of the issues raised in this appeal, is this:

> "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". But where a person finds out that a useful result may be produced by doing something which has not been done by that procedure before, his claim for a patent is not validly answered by telling him that although there was ingenuity in his discovery that the materials used in the process would produce the useful result no ingenuity was involved in showing how the discovery, once it had been made, might be applied."

This decision remains, despite having been handed down in 1959, the leading authority on patentable subject matter in Australian jurisprudence.

What is noteworthy about this passage is the distinction which the Court draws between the "discovery of materials" on the one hand and the use of those

materials "in the process" on the other. The first, in the opinion of the Court, is not an invention. The latter, however, is.

This distinction is central to this appeal on the issue of the patentability of the composition claims in issue.

The composition claims are to biological materials derived from human beings. No one invented them. They are not, therefore, the product of humankind. That they have been identified and linked to specific human forms of cancer, namely, breast and ovarian cancers, is not an act of invention. It is an act of discovery. Likewise, that they have been the subject of human manipulation through the application of scientific processes leading to their isolation from the human body or their synthetic production via some biotechnological process does not transform either what they are or what they do. Neither in an isolated form, nor as cDNA, nor even as purified nor synthesized proteins are these materials in any way, shape or form significantly different in structure or function to the corresponding materials as found in nature. However, that they may be used as components in a process, method or product is, as the Court pointed out in *NRDC*, another issue entirely. So long as the patent claim is to a specific and well defined

process (as opposed to a claim to 'any' process[12]) or method[13] that meets the patentability criteria of novelty, inventive step and utility then, according to *NRDC*, the process or method is patentable subject matter even if the end product is 'an effect' and not a tangible physical product.

NRDC has been often cited by IP Australia (the Australian Patent Office) as supportive of its policy of allowing patent claims over "isolated and purified gene sequences".[14] Indeed, throughout the course of a two year inquiry[15] conducted by the Australian Senate over the impact of gene patents on Australia's healthcare system,[16] IP Australia cited *NRDC,* arguing that its reasoning sanctioned a "broad scope of the expression Manner of Manufacture".[17] The line of argument used by IP Australia is similar to a line of argument used by proponents of similar patent

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[12] It is arguable that a claim to 'any' process, method or product is a de facto claim to the biological materials themselves.

[13] This Amicus brief does not address the method claims in issue in this appeal.

[14] Submission by IP Australia to the Australian Senate Community Affairs References Committee's Inquiry into Gene Patents: http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents/submissions/sub19.pdf

[15] The Inquiry was ordered on November 11, 2008. The Senate Community Affairs References Committee undertook the Inquiry. The Committee's Report was presented to the Australian Senate on November 26, 2010.

[16] http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents_43/index.htm

[17] Op cit 14 at page 13.

claims in the United States. The difference being that they cite the U.S. Supreme Court's decision in *Diamond v Chakrabarty* instead.

However, neither *NRDC* nor *Chakrabarty* is supportive of the patentability of the composition claims in issue.

First, although *NRDC* approved the patentability of new and useful processes that produced a beneficial 'effect' in the field of agriculture, it expressly disapproved of the patentability of the "fruit" grown with the benefit of that effect. As the High Court of Australia held: "However advantageously man may alter the conditions of growth, the fruit is still not produced by his action."

Secondly, while *Chakrabarty* sanctioned a "broad construction" of section 101 (*Patents Act, 1952 US*), it also emphasized the limits on that construction by endorsing the well established principle that "laws of nature, physical phenomena and abstract ideas" are not patentable subject matter. It also provided guidance on how that limitation should be applied in the context of patents concerning biological materials derived from natural sources. Importantly, the Court found that the genetic modification performed on the naturally occurring bacterium "produced a new bacterium with *markedly different characteristics from any found in nature*" (emphasis added). Moreover, the Court found that the new bacterium had

the "potential for *significant* utility". The Court cited (with approval) the U.S. Supreme Court's decision in *Funk Brothers Seed Co. v. Kalo Inoculant Co* so as to make the point that where there is no difference between the artificial biological material and its naturally occurring equivalent, either in what the biological material is or the function it performs, then the artificial biological material is unpatentable subject matter because it is structurally and functional indistinguishable from the thing from which it was derived.

The 'isolation' of a naturally occurring biological material does not change either the structure or function of that material. It does not lead to the creation of a new biological material which exhibits *markedly different characteristics from anything found in nature*. Quite to the contrary, while it may be 'new' in the sense that it has been removed from its natural environment and modified during the process of its isolation, the end result is something which is structurally and functionally equivalent.[18] This fact, as was shown in *Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc*, has been long known. After an extensive investigation into the nature of the claimed invention, in that case

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[18] *Amgen, Inc v Chugai Pharmaceutical Co and Genetics Institute, Inc* 13 U.S.P.Q.2D 1737 (1989).

erythropoietin, a human made protein, and the biotechnological processes used in synthesising it, the presiding Federal Magistrate held:

> "…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)"

It is noteworthy that the Appellate Committee of the House of Lords (which served as the court of last resort in the United Kingdom until the establishment of the Supreme Court in 2009) in *Kirin-Amgen, Inc v Hoechst Marion Roussel Ltd* held invalid patent claims to the synthetic erythropoietin precisely because it was

identical in structure and function and, therefore, indistinguishable from erythropoietin as produced by the human body.[19]

It is also noteworthy that in its Gene Patent Report (presented to the Australian Parliament on November 26, 2010) the Australian Senate Committee stated:

> "While the Committee acknowledges IP Australia's defence of the current approach as being analogous to other classes of patents, such as chemical products, the Committee *strongly rejects* the reasoning which says that, for the purposes of the Patents Act 1990 (the Act), genetic information that is 'isolated' from its naturally occurring state in the human body may be classed as an invention, and therefore properly be the subject of a patent (where the other requirements of patentability are satisfied)."[20]

The forceful rejection of IP Australia's reasoning is significant. It supports the view that 'isolation' is insufficient, under Australian patent law, to transform a product of nature into patentable subject matter.

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[19] *Kirin-Amgen, Inc v Hoechst Marion Roussel Ltd* [2005] 1 All *ER 667*.

[20] Australian Senate's Gene Patent Report: http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents_43/report/index.htm (at page xii, emphasis added).

III. ARE SYNTHETICALLY MADE BIOLOGICAL MATERIALS 'INVENTIONS'?

In their original form and in their natural environments there can be no question that the materials in issue in this appeal are naturally occurring biological materials. That these same materials can be isolated, that is, removed from their natural environment and modified as a result of the process employed in their isolation, does not change what they are nor what they do. Therefore, they are not sufficiently changed in either their structure or function to distinguish them from their naturally occurring origins in any material way, shape or form.

However, in an isolated form and so modified by the process of isolation, these biological materials are, in this state, artificial. But artificiality is not and has never been the sole criterion of patentability. Rather, it is but one of a number of criteria used to assess whether the 'invention' threshold has been reached. *Chakrabarty* makes this clear. And the reasoning applied in *Chakrabarty* (and in a consistent line of U.S. Supreme Court authority both before and since) is equally applicable to biological materials derived from a natural source but synthetically made.

cDNA is a biological material but it does not exist in nature. And it is synthetically made. Yet, are the composition claims in issue here, to the extent that

they might apply to cDNAs, patentable subject matter? *Amicus* United States argues they are. Plaintiff-Appellees argue the issue is immaterial. However, putting this point to one side, for the sake of completeness, and since the issue has been raised by *Amicus* United States, the question is addressed below.

While cDNAs are artificial, in the context of the composition claims in issue, it is argued here that they are not patentable subject matter for a number of reasons.

First, the genetic information contained in the cDNA is identical to the corresponding genetic information contained in the DNA of the human gene from which it has been sourced. There is, in fact, no point of structural or informational distinction.

Secondly, unlike the genetically modified bacterium in *Chakrabarty* which was, as a result of those modifications, able to degrade crude oil, a function unprecedented anywhere in nature, a cDNA containing the same corresponding genetic information as contained in a human gene (or a fragment of that gene) cannot be said to perform an unprecedented function from any found in nature. There is, in fact, no point of functional distinction.

A Bill, the *Patents Amendment (Human Genes and Biological Materials) Bill 2010*, to amend the Australian *Patents Act, 1990* was introduced in the Australian

Parliament on November 24, 2010. The Bill seeks to apply the reasoning in *Chakrabarty* so as to expressly preclude, among other things, such biological materials as these from patentability.

Specifically, the Bill proposes to amend subsection 18(2).

Currently the subsection reads as follows:

> "Section 18(2) Human beings, and the biological processes for their generation, are not patentable inventions."

The amended subsection as proposed in the Bill reads as follows:

> "Section 18(2) The following are not patentable inventions:
>
> (a) human beings, and the biological processes for their generation; and
>
> (b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

The Explanatory Memorandum to the Bill states:

> "The purpose of this Bill is to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature. These biological materials even if they have been isolated, purified or synthetically made have not been transformed from products of nature into products of humankind."

The Bill does not seek to change Australian patent law. Rather, it seeks to see it properly applied as it was originally intended.

IV. INTERNATIONAL IMPLICATIONS

Throughout the course of the Australian Senate's Inquiry into Gene Patents, IP Australia, the chief defender of the patent policy under the Committee's scrutiny, argued that a legislative amendment to Australia's *Patents Act, 1990* of the kind proposed in the *Patents Amendment (Human Genes and Biological Materials) Bill 2010* could possibly contravene both TRIPS and the Australia-United States Free Trade Agreement ("AUSFTA").[21]

In its submission to the Inquiry, on TRIPS, it stated:

> "IP Australia assesses applications for gene patents by applying the same patentability requirements as for all other applications, irrespective of their technological field. Introducing a limited term of protection, higher thresholds of patentability or a general exclusion specifically for gene technologies may breach obligations under the TRIPS agreement."

In its submission to the Inquiry, on AUSFTA, it stated:

> "AUSFTA is a major bilateral trade agreement with the United States that Australia entered into in 2004 ... AUSFTA does not expand the exclusions from patentability allowed under the

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[21] Op cit 14 at page 24.

> TRIPS Agreement. The agreement does require both parties to seek to reduce differences in law and practices between their respective systems and participate in international patent harmonisation [sic] efforts."

In response to these statements the Committee stated in the Gene Patents Report:

> "In relation to potential barriers to creating an express prohibition on gene patents, despite the possible difficulty of fashioning legislative provisions that would be sufficiently precise, effective and of enduring effect, the Committee does not agree with the view that it is not feasible or necessarily possible to expressly prohibit gene patents, as the ALRC concluded in its 2004 report. Nor did the Committee regard the need for compliance with international agreements such as TRIPS to be insurmountable if Australia were to seek to enact a prudent exclusion for gene patents. The Committee believes that Government should not feel prevented from enacting express exemptions of certain subject matter in future where this is justified by sufficient evidence."

The Report did not, however, contain a recommendation to the effect proposed in the Bill. Part of the reasoning given in the Report for not doing so was the Committee's recognition that:

> " ... the introduction of the Bill to the Senate will provide a further, and much-needed, opportunity for the arguments and questions around the impacts and effectiveness of an express prohibition on gene patents to be considered."

The Committee was aware of the litigation which has given rise to this Appeal and of the views expressed by *Amicus* United States. Indeed the uncertainty

felt over the outcome of this Appeal and the potential for a further appeal to the U.S. Supreme Court was of importance to the Committee.[22]

Given that TRIPS and AUSFTA are binding on Australia and the United States, it is appropriate for Australian patent law and pertinent developments in that law to be taken into account with respect to the issues raised in this Appeal.

CONCLUSION

The judgement of the district court should be affirmed.

Dated: December 3, 2010.

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[22] The Committee stated: "The Committee understands that, in the event that this ruling [of the US District Court] is mirrored in the judgement of a higher court, it will become binding on the practices of the USPTO. In such circumstances, and assuming there was no change to the Act in the meantime, the Committee would expect that the Government and IP Australia will act quickly to update Australian patent law and practice to conform with the US approach, particularly given evidence concerning the importance that IP Australia places on international harmonisation [sic] of patent systems and Australia's obligations under AUSFTA."

CERTIFICATE OF SERVICE

I hereby certify that on this 3 day of December, 2010, I caused twelve true and correct copies of the foregoing Brief for Amici Curiae Cancer Council Australia and Luigi Palombi to be sent to the Court by overnight commercial carrier and for two true and correct copies of the Brief to be served upon the following counsel of record listed below by mail.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B), because it contains 5,722 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of the Federal Rule of Appellate Procedure 32(a)(6), because it has been prepared in a proportionally spaced typeface using Apple Pages 2009 in Times 14 point font.

Dated: December 3, 2010

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