

CURRICULUM VITAE

NAME: Luigi Palombi

EDUCATION: LL.B., 1981, University of Adelaide, Adelaide, SA, Australia

B.Ec., 1986, University of Adelaide, Adelaide, SA, Australia

Ph.D., 2005, University of New South Wales, Sydney, NSW, Australia
The Patenting of Biological Materials in the Context of TRIPS

CURRENT POSITIONS:

2006-Present. Director: Genetic Sequence Right Project; Chief Investigator, Traditional Knowledge and Intellectual Property, Australian Research Council Project (2008-2011), Australian National University, Canberra, Australia;

Consultant to Macquarie Bank; Intellectual Property and Emerging Technologies

POSITIONS HELD:

2005, Consultant Counsel in Biotechnology & International Patent Law, Minter Ellison, Lawyers, Sydney, NSW, Australia.

2001-2004, PhD candidate; Faculty of Law, University of New South Wales, Sydney, NSW, Australia: Consultant Counsel in Biotechnology & International Patent Law to various companies in the US, UK and EU (Subject to Confidentiality Agreements)

1997-2001, Consultant Counsel in International Patent Law and Hepatitis C Virus Patents to various companies in the US, UK and EU (Subject to Confidentiality Agreements).

1993-1996, Partner; Banki Palombi Haddock & Fiora, Sydney, NSW, Australia.

1991-1992, Partner, Mitchell Sillar, Sydney, NSW, Australia.

1986-1990, Partner, Davies & Collison, Melbourne, Vic, Australia.

1981-1985, Attorney, Ouwens Wagnitz, Adelaide, SA, Australia

LEGAL PROFESSIONAL:

1986, Admitted to the Supreme Court of Victoria as a Barrister and Solicitor.

1984, Admitted to the Supreme Court of the Northern Territory as a Barrister and Solicitor.

Admitted to the Supreme Court of New South Wales as a Solicitor.

1982, Admitted to the Supreme Court of South Australia as a Barrister and Solicitor; Admitted to the Federal and High Courts of Australia as a Barrister and Solicitor.

CAREER SUMMARY:

Dr Palombi has already made a significant contribution to legal scholarship in this research field. As a practicing barrister and solicitor in Australia, he commenced his specialisation in the field of genetic patents in 1993, having been the senior litigation partner at Davies Collison Caves (Australia's largest IP firm) between 1986 and 1990. In 1993 he led an Australian legal team (which included Justice Annabelle Bennett SC AO as she is today) that brought the first genetic patent revocation action to the Federal Court of Australia. In the *Murex v Chiron* litigation, he instructed counsel, developed legal argument and wrote pleadings and submissions for a case that concerned the validity of a patent that claimed the hepatitis C virus as an 'invention'. He also arranged expert witnesses that included Prof Baruch Blumberg (Nobel Prize for Physiology or Medicine, 1976) and Dr Lynn Dalgarno (one of Australia's leading molecular virologists), drafting their affidavits in the case. Other notable Australian scientists that were involved in that case were Prof Sir Gustav Nossal and Prof John Shine. The litigation was settled during the Federal Court hearing and resulted in significant improvements to Australian

health by providing Australian hospitals and virology laboratories with HCV immunoassays that were not produced under license from Chiron Corporation. This was a crucial step to ensuring the purity of the Australian blood supply and in halting the unnecessary spread of HCV through blood transfusion.

Between 1997 and 2001 he delivered invited lectures at UNSW and travelled and lived in the United States, Switzerland, France, Belgium and England at the invitation of a number of significant organisations that required advice on gene patents, particularly those relating to HCV.

In 2001 he commenced his PhD candidature at UNSW in this field of research. He completed his candidature in September 2004 and was awarded his doctorate in September 2005. During this period he was instrumental in having the President of the ALRC ask the Attorney-General for a separate reference into Gene Patents. This was a separate reference to the reference to the *Use of Genetic Information*. He wrote three substantial and lengthy submissions for these inquiries and participated in meetings with the ALRC. His contributions were cited by the ALRC in its final reports. In addition he was invited to teach undergraduate law students in intellectual property law by Prof Jill McKeough (now Dean of Law, UTS) and taught Masters in Intellectual Property Law course on the topic of gene patents and biotechnology.

During this time a number of his peer-reviewed papers were published and he was invited to speak at University of Tasmania, UNSW and ANU on the subject of gene patents and biotechnology. He also made submissions (both oral and in writing) to the Advisory Council on Intellectual Property (ACIP) regarding a proposal for an *Experimental Use Defence* in the Patents Act, 1990. He also gave invited lectures in biotechnology and patent law at UTS in its US law student summer program with Santa Clara University.

In 2005 he was engaged full-time by Minter Ellison in Sydney to advise it on the development of a biotechnology practice as part of its extensive international intellectual property law practice. This involved giving in-house seminars on developments in intellectual property law and biotechnology in Australia and the United States. He was also invited by the Rockefeller Foundation in September 2005 to attend a closed workshop on biotechnology and open source held in Belagio, Italy. He was also an invited speaker at the *Patenting Lives Conference* held in London in December 2005 and organised by the Queen Mary Intellectual Property Law Institute, at the University of London.

During 2006, as a visiting fellow at the ANU (invited by Prof Drahos on the basis of Dr. Palombi's PhD thesis) his work has involved written communications with the Minister for Industry, Mr. Ian Macfarlane on the impact of gene patents on the Australian biotechnology industry; an invitation to advise a Federal Government Committee on certain aspects of gene patents in Australia; an invitation to participate in the 11th International Congress of Human Genetics and was invited to speak in a closed high level workshop on gene patents and policy held at the Catholic University of Leuven in Belgium by the *European Society of Human Genetics*. He also was invited to present his research on the ABC National radio program *Perspective*.

In March 2007 he was an invited speaker at the MINDS Network Workshop, hosted by the Federal University of Rio de Janeiro, as a result of which, was invited to join the Editorial Board of Electronic Journal in Communication, Information, and Innovation in Health, of Oswaldo Cruz Foundation (Fiocruz).

In July 2007 he was invited to speak at the University of the State of Amazonia in Manaus, Brazil as a consequence of his paper delivered in Rio de Janeiro.

In September 2007 the Australian Research Council awarded Prof Drahos and Dr Palombi a Discovery grant for three years commencing in 2008 for their project: *The Sustainable Use of Australia's Biodiversity: Transfer of Traditional Knowledge and Intellectual Property*.

In May 2008 he was invited to participate in an international workshop by Professor Thomas Pogge on his *Health Impact Fund* and the *Improvement of Access to Medicines for Developing Countries* at the ANU, Canberra and was an invited speaker at the Victoria University of Wellington (at which Professor Daniel Gervais and Professor Rochelle Dreyfuss also spoke) regarding *Patent Law Reform and Innovation*.

In August 2008 he was quoted in various Australian newspapers over the enforcement of patents

controlling the diagnosis of the BRCA 1 and 2 human gene mutation that is associated with breast and ovarian cancer; met with the Shadow Minister for Health, the Hon. Joe Hockey MP and as invited by the National Board of the Cancer Council of Australia (chaired by Prof Ian Fraser) to address it on the issue of the patenting of the BRCA 1 and 2 human genes.

In September 2008 he made submission to the Advisory Council of Intellectual Property's inquiry into patentable subject matter and filed a response to the Innovation Green Paper, *venturousaustralia*, regarding the role of the Australian patent system and its role in encouraging or repressing innovation in Australia.

In November 2008 he played a major role in assisting Senator Heffernan bring to the Senate's attention the impact that patents over isolated biological materials were having on the Australian health care system, particularly as a result of the patenting of the BRCA 1 and BRCA 2 genes. The Australian Senate then ordered an Inquiry into Gene Patents and their impact on Australia. The terms of reference for the Inquiry were principally drafted by him.

He also presented at a 2 day workshop in Broome at the invitation of the WA Department of Agriculture. The focus of the workshop was the development of an indigenous industry involving 'Gubinge', a fruit that is native to northern Australia and which grows mainly on land that belongs to indigenous Australians. This fruit is the richest source of natural vitamin C known and has been part of the diet of indigenous Australians for thousands of years. His presentation dealt with the various patents that have been applied for and granted over the exploitation of Gubinge – patents that interfere with the ability of these indigenous people from being able to fully exploit the economic benefit of this fruit.

His focus during 2009 was divided into two streams. The first, gene patents, through the Senate Inquiry which commenced in March, and the US Health Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) release of a draft consultation paper, also in March, in which submissions were invited from the public. Dr Palombi gave evidence to the Senate during the opening session, which was otherwise reserved for IP Australia, the National Health & Medical Research Council and the Federal Department of Health & Aging. In response he prepared substantial submissions for the Senate Committee and also for the SACGHS. The second, traditional knowledge and intellectual property, involved numerous field trips to remote parts of Australia to meet with indigenous communities. His fieldwork has also involved meeting with State and Federal government agencies and the CEOs of companies involved in the commercialization of products derived from traditional knowledge as well as a presentation to the CEO of the Fair Trade Labeling Organization (FLO) to encourage the application of the fair trade movement into developed countries which have indigenous people that have been marginalized through colonialization

In July 2009 his book, *Gene Cartels: Biotech Patents in the Age of Free Trade* was published as a hardcover (Edward Elgar) internationally and as a paperback (Scribe) in Australia and New Zealand. The foreword was written by Prof Baruch Blumberg, winner of the Nobel prize in physiology and medicine and Dr Cutler, a leading Australian economist, after reading the book wrote:

Gene Cartels is a truly magisterial and important book. It shows how we need to bring together the discrete threads around intellectual property law (ie patent, copyright, etc) so there can be a clear spotlight on the important public policy issues.

He also delivered invited lectures and papers at Murdoch University, the University of New South Wales, the Australian National University and at the Licensing Executive Society's Australian Conference.

PUBLICATIONS, PRESENTATIONS & MEDIA

Books

Palombi L., *Gene Cartels: Biotech Patents in the Age of Free Trade*, Edward Elgar, London & New York, 2009 (hardcover)

Palombi L., *Gene Cartels: Biotech Patents in the Age of Free Trade*, Scribe, Melbourne, 2009 (paperback)

Book chapters

Intellectual Property Law Issues in Asia, National University of Singapore, 2004

Patenting Lives: Life Patents, Development and Culture, Ashgate Publishing, London, 2008

Journal articles

Palombi, L. *Patenting Human Genetic Information and the Appropriateness of the International Patent System*, Centre for Law and Genetics, (2002) 1-15.

Palombi, L. *Patentable Subject Matter, TRIPS and the European Biotechnology Directive: Australia and Patenting Human Genes*, UNSWLJ (2003) 26(3) 782-792.

Palombi, L. *The Impact Of TRIPS On The Validity Of The European Biotechnology Directive*, Journal of International Biotechnology Law, (2005) Journal of International Biotechnology Law, Vol 2, 15-23.

Palombi, L. *TRIPS, Bilateralism And Patents: How They Are Failing Both the Developed And The Developing World and What To Do About It*. Journal in Communication, Information, and Innovation in Health, Vol 1, No 1, 71-81, June 2007

Palombi, L. *Beyond Recombinant Technology: Synthetic Biology and Patentable Subject Matter*, Journal of World Intellectual Property (accepted: forthcoming), 2009.

Submissions to Governmental Inquiries

Palombi, L. Submissions to the Australian Law reform Commission (ALRC) Inquiry concerning *Protection Of Human Genetic Information*, 2002 and 2003.

Palombi, L. Submissions to the ALRC Inquiry concerning *Intellectual Property Rights Over Genetic Materials And Genetic And Related Technologies*, 2003 and 2004.

Palombi, L. Submissions to Australian Senate Inquiry into *Hepatitis C Virus and the Australian Red Cross*, 2004.

Palombi, L. Submissions to the Advisory Council on Intellectual Property (ACIP) Inquiry concerning *Patents and Experimental Use*, 2004 and 2005.

Palombi, L. Submission to ACIP Inquiry concerning post-grant patent enforcement, 2007.

Palombi, L. Submission to ACIP Inquiry concerning patentable subject matter, 2008.

Palombi, L. Submission to Innovation ("Cutler") Inquiry concerning the role of the patent system in innovation, 2008.

Palombi, L. Submission to Australian Senate Inquiry into *The Impact of Gene Patents on Healthcare in Australia*, 2009

Palombi, L. Submission to IP Australia's review of Australia's Patent System – *Getting the Balance Right*, 2009.

Palombi, L. Submission to IP Australia's review of Australia's Patent System – *Experimental Use Proposal*, 2009

Palombi, L. Submission to US Government Inquiry into Genetic Tests: *Response to the SACGHS Draft Report*.

Presented Papers

Palombi L. *Hepatitis C Virus patents and the Murex case*, Australian National University, 2003

Palombi L. *Genetic Sequence Patents*, University of New South Wales, 2003.

Palombi L. *Review of the House of Lords in Kirin-Amgen and its impact on the patentability of biological materials*, Australian Intellectual Property Law Teachers National Conference, University of Tasmania, 2005

Palombi, L. *The Implications of Recent US Supreme Court Decisions on Experimental Use in Biotechnology*, Minter Ellisons, 2005

Palombi, L. *The Genetic Sequence Right: A Sui Generis Alternative to the Patenting of Biological Materials*, Queen Mary Intellectual Property Law Institute, University of London, 2005

Palombi, L. *The Genetic Sequence Right*, 11th International Congress of Human Genetics, Brisbane, 2006

Palombi, L. *Alternative Models to the Patent System*, European Society of Human Genetics, Leuven, Belgium, 2006

Palombi, L. *The Genetic Sequence Right and its Application in the Developing World*, Rio de Janeiro, Brazil, 2007.

Palombi, L. *Equity For Traditional Owners, The Developing World And Intellectual Property*, Manaus, Brazil, 2007

Palombi, L. *Improving Access to Medicines Doesn't Not Have To Mean More Patents*, Australian National University 'Workshop on Access to Medicines for Developing Countries', Canberra, Australia, 2008

Palombi, L. *Beyond Recombinant Technology: Synthetic Biology and Patentable Subject Matter*, Conference: 'Patent Law Reform: Getting it Right', Victoria University, Wellington, New Zealand, 2008.

Palombi, L. Making Traditional Knowledge Available for Commercialisation, Licensing Executive Society, National Meeting, Canberra, Australia, April 2009.

Palombi, L. *The Role of Patent Law in Regulating Restricting Access to Medicines*, University of New South Wales, Sydney, Australia, May 2009.

Palombi, L. *The Senate Inquiry into Gene Patents: Implications for Geneticists*, Genes for Health Conference, Human Genetics Society of Australia with Genome-based Research and Population Health International Network, Fremantle, Australia, May 2009.

Palombi, L. *Patenting the Unpatentable*, Murdoch University (invited), Perth, Australia, May 2009.

TV and Radio Media Presentations

Palombi L. ABC TV, *Lateline*, August 1994.

Palombi L. Channel 9, *Sunday*, August 1994.

Palombi L. ABC TV, *Quantum*, June 1996.

Palombi L. ABC TV, *7.30 Report*, August 1996.

Palombi L. ABC Radio National, Interview, September 1996.

Palombi L. ABC Radio National, *Perspective*, November 2006 (script) [<http://www.abc.net.au/rn/perspective/stories/2006/1765826.htm>].

Palombi, L. ABC Radio National, *Perspective*, August 2008 (script) [<http://www.abc.net.au/rn/perspective/stories/2008/2339000.htm>]

Panel Discussion on Gene Patents with George Negus (mediator): November 2008: Sydney Convention Centre

Palombi, L. ABC TV, *7.30 Report*, May 2009

Palombi, L. ABC National Radio, *Background Briefing*, June 2009.