

Aurora Plomer

Aurora Plomer, LLB, BA, MA, PhD
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RESUME

My research interests and publications are on the ethical and legal dimensions of research in the biosciences, IP and innovation. I was the PI and lead author of the FP6 funded project and report 'Stem Cell Patents: European Law and Ethics' cited in legal proceedings at the Enlarged Board of Appeal of the EPO in the landmark WARF case. My original background and publications were in the philosophy of science/knowledge. I taught moral and applied philosophy at the Open University and the University of Leeds before reading law at the University of Manchester and taking up a post as lecturer in law at the University of Leeds, when I started publishing on the regulation of new technologies and conducted research commissioned by the Council of Europe. My book 'The Law and Ethics of Medical Research: International Bioethics and Human Rights' has become an international point of reference in the field. The role of human rights in IP including jurisdictional problems in Europe, legal and philosophical questions on patent scope boundaries and balancing of private and public interests in IP have been the focus of my research in recent years. I am a member of the newly created AAAS' Science and Human Rights Coalition subcommittee on 'Science, Ethics and Human Rights', a member of the ESRC Impact Committee on the Stem Cell Initiative and an advisor to the Stem Cell and Society Programme at the University of Stanford. I have extensive collaborative research links with scholars and international organizations in Europe, Canada and the US and I am frequent invited speaker at conferences and workshops all over the world.

Career History

Chair in Law and Bioethics, Director of SIBLE, School of Law, University of Sheffield (from 1st January 2007 - present). Previously Reader and Lecturer in Law at the University of Nottingham (2003– 2006), Lecturer in Law at the University of Leeds (1993 -2003), Philosophy Tutor (P/T) Open University (1988-1992).

Education

Ph.D, Philosophy (1988), University of Lancaster (funded by British Academy)
LLB, Hons (1993), University of Manchester (Lawson-Markesinis Prize)
M.A., Philosophy (1982), University of Lancaster (Distinction, Senate Award)
B.A., Hons Philosophy (1981), University of Lancaster (Peel Award)

Publications

Books

Stem Cell Patents: European Law and Ethics (ed.) OUP – forthcoming 2009 (with P. Torremans).

The Law and Ethics of Medical Research: International Bioethics and Human Rights, London: Routledge-Cavendish, 158pp, February 2005. ISBN 1-85941-687-X

Book Reviews (8):

http://www.law.dept.shef.ac.uk/cms/staffprofiles/ap/Plomer_The_Law_and_Ethics_Medical_%20Research_%20International_%20Bioethics.pdf

Recent Cites:

- US Department of Energy: Office of Biological and Environmental Research, *Protecting Human Subjects*, Issue no. 16, November 2008. Recommended in the list of key publications:
<http://humansubjects.energy.gov/doe-resources/newsletter/HS16final.pdf>
- AHRC & NESTA, *Arts and Humanities Research and Innovation*, November 2008 – Cited as an example of research in the humanities informing policy on science and innovation.
- American Society for the Advancement of Science, *Science & Human Rights Newsletter*, April 2008. Featured publication.

Phenomenology, Geometry & Vision, Aldershot: Avebury, pp 156. ISBN 1-85628-218-X.

Articles & Chapters in Books

‘Fundamental Disjunctions in the EU Legal Order on Human tissue and Cells’ *Maastricht Law Journal* (2009) vol. 1 (in press). With Marcella Favale.

‘The European Group on Ethics: Law, Politics and the Limits of Moral Integration in Europe’ *European Law Journal* (2008) 15(6) 639-659.

‘Constitutional Limits on Moral Exemptions to Biotechnological Patents’ in A. Bakardjieva Engelbrekt & al. (eds.) *Festschrift to Marianne Levin*, Norstedts Juridik (2008) 487-502.

Plomer, A, Taymor, K, Thomas-Scott, C, ‘Challenges to human embryonic stem cell patents’ *CellStemCell* (2008) 1.2 (1): 13-17.

‘Patents on Human Embryonic Stem Cells’ *Chartered Institute of Patent Attorneys Journal*, Sept. 2006, 594-598.

‘The patentability of human embryonic stem cells in Europe. *Nature Biotechnology*’ (2006) 24 (6): 653-655 (with Porter, G, Denning, C, Sinden, J and Torremans, P).

'A Foetal Right to Life?: The case of *Vo v France*' *Human Rights Law Review* 2005 5(2):311-338.

'European Patent Law & Ethics' *Drug Discovery Today*, July 2005, 3-6.

'Rights, Principles & Political Values in Medical Research : the ACHRE Report and the Convention on Human Rights & Biomedicine' in F. Adams (ed.) *Ethical Issues for the 21st Century*, special issue of the *Journal of Philosophical Research*, pp. 283-296, Philosophy Documentation Centre (2004) Delaware, USA.

'Derecho, Etica y Politica en Relacion a la Investigacion con Celulas Troncales en el Reino Unido y los Estados Unidos' in *Celulas Troncales Humanas* (ed. Julio Luis Martinex), Desclee de Brower (2003) 121-145.

'Stem cell research in the UK: from Parliament to the Courts' *Revista de Derecho y Genoma Humano*, 2002 (2) 181-196.

'Beyond the HFE Act 1990: The regulation of stem cell research in the UK' *Medical Law Review* (2002) 10:2 132-164.

'Medical Research, Consent and the Convention on Human Rights and Biomedicine' in *Health Care Law & Practice: The Impact of the Human Rights Act 1998* (eds. Garwood-Gowers, Tingle & Lewis), Cavendish (2001) 313-330.

'Protecting the Rights of Human Subjects in Emergency Research' *European Journal of Health Law* (2001) 9:4 333-352.

'Principles Underlying the Regulation of Clinical Trials with Children: International Bioethics or Moral Bankruptcy?' in *European Neonatal Research: Consent, Ethics Committees and Law* (eds. Mason & Megone) Ashgate (2001) 191-206.

'The Regulation of Neonatal Research in the UK' in *European Neonatal Research: Consent, Ethics Committees and Law* (eds. Mason & Megone) Ashgate (2001) 185-190.

'Overview of European Legislation on Informed Consent in Neonatal Research' in *European Neonatal Research: Consent, Ethics Committees and Law* (eds. Mason & Megone) Ashgate (2001) 107-121 with Dalla-Vorgia, Mason, Megone, Allmark, Bratlid, Gill, Morrogh, Eiter-Theil.

'Overview of European Legislation on Informed Consent for Neonatal Research' *Arch Dis Child Fetal Neonatal Ed* (2001) 84 70-73 (with Dalla-Vorgia & others).

'The Regulation of Clinical Research Trials on Children: UK, International and European Perspectives' *Medical Law International* (2000) 5:1 1-24.

'Rationing Policies on Access to IVF in the NHS, UK' in "Access to IVF: A Matter of Distributive Justice" *Reproductive Health Matters* (1999) 7:14 60-71 (with I. Smith & N. Martin-Clement).

'Judicially Enforced Caesareans and the Sanctity of Life' *Anglo-Am.L.R.* (1997) 26:2 235-271.

'Parental Consent and Children's Medical Treatment' *Family Law* (1996) 26 739-741.

'The Limits of Beneficence: Egg Donation under the HFE Act 1990' *Legal Studies* (1995) 15:3 434-454 (with N. Martin-Clement).

'Le Marche Interne dans le NHS' in '*L'Europe de la Sante : entre Service Publique et Service d'Interet Economique General*' CERDES, Nantes, (1996) 23-28.

'HFEA: Donated Ovarian Tissue in Embryo Research & Assisted Conception: Public Consultation Document & Report' *J.Soc.Welfare & Family Law* (1995) 17:1 97-100 (with N. Martin-Clement).

'Merleau-Ponty on Sensations' *Journal of the British Society for Phenomenology* (1990) 21:2 153-163.

Reports

Plomer & al, *Stem Cell Patents: European Law and Ethics*, European Commission (July 2006). <http://www.nottingham.ac.uk/law/StemCellProject/reports.htm>

Digest of UK Cases in Medical Law (1998) 80 pp. Commissioned by the Council of Europe.

Legal Controls on IVF in Technologically Advanced Countries (1997) 200 pp. Commissioned by Garretts Solicitors (Leeds).

Invited Papers & Presentations

'The Future of Stem Cell Patents in Europe after WARF' *NESCI Legal Workshop*, Clifford Chance, London, 13th February 2009

'Stem Cells and the European Patent System' Berkeley Centre for Business, Law and Ethics, University of California at Berkeley, 27th January 2009 (video link: <http://www.law.berkeley.edu/2579.htm>)

'Foundational Stem Cell Patents in the UK and the US', University of California at Berkeley, 23rd January 2009.

'Moral Exclusions on Stem Cell Patents: European Perspectives' School of Law, University of Stanford, 22nd January 2009.

'The European Group on Ethics: Law and Politics', Stanford Centre for Biomedical Ethics, University of Stanford, 20th January 2009.

'Patently Complex: Emerging Questions on Patents on Biotechnological Inventions', LSE ESRC Complexity Seminar Series Workshop, London, 26th November 2008 (with Peter Taylor).

'Towards Open-Access to Patent Data', *2020 Vision: The Impact of Science on Society*, Genome Canada International Conference, Vancouver, 22nd-24th October 2008.

‘The role of morality in patent law’, UK Intellectual Property Office, Newport, 15th October 2008.

‘Fundamental Disjunctions in the European Normative Order on Human Tissue and Cells’, *Biotechnology, European Law and Citizens* workshop, Queen’s University, Belfast, 9th September 2008 (with Marcella Favale).

‘Stem Cell Patents in the UK: Emerging Questions’, UK Stem Cell Bank, London, 4th September 2008.

Research Ethics, Property Rights and Innovation in the Biosciences’, University of Sheffield Research Ethics Workshop, 24th July 2008.

‘Intellectual Property, Law, Ethics & Innovation’, ‘*Who Owns Science?*’, Manchester Interdisciplinary Bioscience Inaugural Conference, University of Manchester, 5th July 2008.

‘Ethics, Human Rights and the Responsible conduct of research in the biosciences’ *Jerusalem Research Ethics Conference*, 27th- 29th May 2008, Hebrew University, Jerusalem.

‘What Role for the EGE in a pluralistic and morally diverse Europe?’ *Bioethics and the reconciliation of cultural difference*, 16th May 2008, King’s College, London

‘Patent Ethics in Europe’ – *School of Law* – University of Manchester, 23rd April 2008.

‘Ethical Controls on Patents & Biotechnological Research in Europe ‘*Is there a future for patent ethics committees?*’ workshop, Wellcome Trust funded project, Manchester, 13th April 2008 (with Marcella Favale).

‘UK Stem Cell Patents & Access to Patent Data’ – *UK Stem Cell Network Inaugural Conference*- Edinburgh, 9th-11th April 2008.

‘Stem Cell Patents, Morality and Human Rights in Europe’ – *Pharmaceutical Patent Litigation Strategies*- IP Institute, London, 31st March – 1st April 2008.

‘Stem Cells: the interface between Intellectual Property Rights and Human Rights’ – National Institute of Industrial Property (INPI), 17th March 2008, Rio de Janeiro, Brazil.

‘Businesses: The Contribution of Industry to Social Innovation’ Chair, *Science, Social Innovation and New Humanity, Embedding Science in Society Workshop*, 2-5th December 2007, Brussels.

DGEmap, 1st Scientific Advisory Committee, Chair, Newcastle, 18th October 2007.

‘*EU Ethical Controls on Biological Research*’ Promet Symposium – 26-27th June 2007, Sheffield.

‘*The Scope of Moral Exclusions on hESC patents in Europe*’ Commercial Opportunities & Legal Issues in Stem Cells - Conference, 10th May 2007, NESCI, Newcastle.

‘*Recent EPO Decisions and the Pompidou Statement*’ Ethical Aspects of Stem Cell Research in Europe Joint EuroStemCell – ESTOOLS workshop, Berlin, 19–20 April 2007

‘*Human Tissue & Cells: The Regulatory Maze*’ Developing Governance – DGE Map Symposium: 28th Feb-1st March 2007, Newcastle.

‘Stem Cell Patents and the Morality Clause’ *Biotechnology Patents and Policy: What’s the Evidence*, Banff, Alberta, Canada: May 25-27, 2006

‘The Construction of Moral Exclusions in the Directive on Biotechnological Inventions’ experts meeting on *Ethics of commercialization of stem cell research* (by invitation of Chair of European Group on Ethics) Lund., 13th-14th March 2006.

‘Moral Constraints on Patents in Medical Research: European Perspectives’ IMLAB, Liverpool. 6th March 2006

‘Human Dignity & the Rights of the Embryo’ ‘*Embedding Science in Ethics*’ Budapest, 7th-8th Nov. 2005.

‘Beyond Negligence: Violation of Human Rights at Porton Down’ King’s College London, *Centre for Medical Law & Ethics: Lent Lecture Series* (11 March 2004).

‘Regulation of human tissue from a human rights perspective’ *Sheffield Institute of Biotechnological Law and Ethics* (April 2003)

‘Derecho, Etica y Politica en relacion a la investigacion con celulas troncales en Reino Unido y Estado Unidos’ *Celulas Troncales Humanas: Aspectos cientificos, eticos y juridicos*, 25th- 27th April 2003, University of Comillas, Madrid (Spain)

Keynote Speaker “El embrion ante la Legislatura y los Jueces, *IX Jornadas sobre Derecho Genoma Humano*, 22nd – 23rd April 2002, University of Deusto, Bilbao (Spain).

Expert Participant at the Symposium on “Stem Cells: Therapies for the Future?” Brussels 18th-19th December 2001 organized by the European Commission under the aegis of the High Level Life Sciences Group – Research Directorate.

Expert participant at ‘A European Conference on Clinical Research in Children’, *European Forum on Good Clinical Practice*, Annual Conference, 24th-25th January 2002, Brussels.

‘The regulation of stem cell research in the UK’ *Brandeis School of Law*, University of Louisville (USA), August 2001.

‘The conjoined twins case and the spectre of murder’ *Joint Meeting of Leeds and Birmingham Health Care Ethics Masters Programs*, Leeds, January 2001.

‘Ethics and the Private Law Regulation of Medicine’ *Association of Legal & Social Philosophy*, University of Cambridge, April 1999.

'Regulation of Clinical Research Trials on Children in the UK' BIOMED 2nd Symposium of Euricon, Cork (Eire) July 1997.

Guest seminars on biomedical ethics and law, *Masters in European Legal Theory*, Academie Europeenne de Theorie du Droit, Facultes Universitaires, Saint Louis, KUB, Brussels, Jan. 1994, Feb. 1995 and 1996).

'Clinical Research Trials: English and European law' *Yorkshire Trials Unit Annual National Forum*, Leeds, November 1996.

Keynote speaker on 'Le Marche Interne dans le NHS' at the *Centre de Recherche du Droit Europeen de la Sante*, Nantes, January 1996.

'Regulating IVF: Is a legal and ethical consensus possible?' *SLSA Conference: Value and Commitment in Diversity*, University of Leeds, March 1995.

Keynote speaker on 'Use of Foetal Ovarian Tissue: Legal Aspects' *Human Fertilisation and Embryology Authority's Public Consultation Meeting*, Sheffield, May 1994.

Keynote speaker on 'Recent Advances in the Law of Consent', Medical Protection Society, Leeds, April 1994.

International Conferences* (*invited)

'Towards Open-Access to Patent Data', *2020 Vision: The Impact of Science on Society*, Genome Canada International Conference, Vancouver, 22nd-24th October 2008.*

'Ethics, Human Rights and the Responsible conduct of research in the biosciences' *Jerusalem Research Ethics Conference*, 27th- 29th May 2008, Hebrew University, Jerusalem. *

'Stem Cell Patents, Morality and Human Rights in Europe' – *Pharmaceutical Patent Litigation Strategies*- IP Institute, London, 31st March – 1st April 2008. *

'Medical Research & the Legal Scope of Protection of the Convention on Human Rights & Biomedicine' in M. Peled-Raz (ed) *Science, Law, Ethics* (29th May-2nd June 2005) Haifa. *

'Ethical Guidelines On Research In Developing Countries: A Licence For Exploitation?' (Full paper was refereed) *15th World Congress in Medical Law*, Sydney 1st-5th August 2004. Selected for publication in *Journal of Medicine & Law* (World Association of Medical Law)

'In Search of Universals: Rights, Principles and Political Values in Medical Research' (refereed) *American Philosophical Association*, 100th Anniversary Conference: Morality in the 21st Century, 27th 29th October 2001, University of Delaware (USA). Selected for publication in conference collection.

'Principles Underlying the Legal Status of the Embryo in English Law' in Council of Europe, *Symposium on the Status of the Embryo and Medically Assisted Procreation*, Conference Proceedings, 16th-18th December 1996, Strasbourg.

'Life in the Balance: Conflict of Foetal and Maternal Rights' *3rd International Conference on Philosophical Ethics in Reproductive Medicine*, University of Leeds, April 1994.

Organized Workshops (2008)

Is there a future for patent ethics committees?, Wellcome Trust funded project, Manchester, 13th April 2008.

‘IP rights on stem cells’ – at the invitation of the *UK National Stem Cell Network*, Inaugural Conference- Edinburgh, 9th-11th April 2008.

‘Stem Cells: Emerging Legal and Ethical Challenges’ – *Stem Cell Research under the Microscope* – University of Sheffield, 7th December 2007.

Book Reviews

‘Lee and Morgan’s *Human Fertilization and Embryology* (Blackstone, 2000) Book Review, *Medical Law Review* (2002) 10:1 105-107.

‘Dworkin’s Life Dominion’ (Book Review) *Modern Law Review* (1996) 59:3 479-482.

Advisory Posts/Consultancy

Member of the UK’s Medical Research Council’s expert committee on *Human Developmental Biology Resource* (HDBR).

Member of the AAAS Science and Human Rights Coalition

Member of the AAAS Science and Human Rights committee on Science, Ethics and Human Rights

Member of the ESRC Policy Impact Group for the Stem Cell Initiative.

Advisor to the Stem Cell & Society Programme (University of Stanford, US)

Advisor to DGEMap (University of Newcastle)

Consultant to the UK Stem Cell Bank and the Wisconsin Alumni Research Foundation (WARF),

Consultant to the *Retained Organs Commission* (England).

Research Awards/Grants/Contracts

White Rose, (£13,350) – Sheffield PI. ‘White Rose IPBio Project’. (2009-2010)

The aim is to raise the international standing of the Universities of Leeds, York and Sheffield on IPR and the biosciences, in the first instance via linkage with the newly created IPBio Network (including Harvard, Yale, MPI, CERMES (Paris) recently established by Dr Radick (Leeds) and to explore opportunities for further collaborative research.

ESRC (UK Stem Cell Initiative) £3000 – International Visiting Fellowship (2008-2009), University of Berkeley, Centre for Business, Law and the Economy and University of Stanford, Stem Cell & Society Programme.

Wellcome Trust, £29,000, PI ‘Is there a future for patent ethics committees?’ (1st February 2007 – May 2008) This pilot project builds on the results of FP6 funded project on European law and ethics of human embryonic stem cell research (1st January 2005 – June

2006), whose preliminary findings have highlighted a possible tension between the proposal to create an ethics review committee attached to the European Patent Office and the existing system of ethical review of biomedical research in Europe. There is as yet no other international precedent and no systematic analysis of the ambit of operation of such committees or the nature of their possible relationship to existing national and supranational research ethics committees (RECs). The aim of the pilot project is to identify the potential synergies and tensions, conflicts, duplication or disjunctions that the creation of such committees may generate between the ethical regulatory controls on research and the additional ethical controls on patents, with a view to providing a map to chart future collaborative research with other leading partners internationally

European Commission, euros: 250,000. (PI) FP6 program, *Stem Cell Patents: European Law & Ethics* Contract no. 005251. January 2005-June 2006. The aim of the project was to provide a lead in the resolution of the legal uncertainty concerning the scope of exclusion of the moral clauses in the EU Directive on Biotechnological Inventions. The report for this project was published by the European Commission and is available free from: giancarlo.oriolo@ec.europa.eu.

Society of Public Teachers of Law ((April 2001): £560 visit to the Council of Europe in Strasbourg to conduct research relating to a book.

European Union, Biomed Program euros: 350.000 partner in *Euricon*, an interdisciplinary study on consent to the inclusion of neonates in clinical research trials (BMH4 – CT95 – 1069 (DG 12-SSMA)) 1995-1998.

Council of Europe (1998): £800 Principal Investigator. to lead coordination of analytical compendium of *UK Cases in Medical Law* (1992-1998). Commissioned by the Secretary of the Bioethics Committee at the Council of Europe.

Garretts Solicitors (1997) £21,000: Principal Investigator to lead analysis of *Legal controls on IVF in Technologically Advanced Countries* (May 1997).

University of Leeds: Staff Development Fund (1997): £10,000 Principal Investigator to lead coordination of the first empirical survey of the rationing policies on IVF of all the Health Authorities in England and Wales. Ms. Norma Martin-Clement (Dept of Law, University of Leeds) and Dr. Iain Smith (Nuffield Institute, University of Leeds) collaborated in this project.

British Academy (1982-1985) Major Award (PhD).

University of Lancaster (1979-81) *Peel Award*, (1982) *Senate Award*.

Collaborative funded research with international scholars

March 2008-2011, partner in MATEs, PIs P. Wright and R. Poole, BBSRC Synthetic Biology Research Network Initiative.

August 2007-2012, partner (with Bartha Knoppers) in REGULOME, funded by Canadian Stem Cell Network

September 2005-2008, partner in 'Ethical, Legal and Social Issues Relevant to Emerging Stem Cell Therapies' (ELSI) PI, Prof. T. Caulfield (Canada Research Chair in Health Law &

Policy, University of Alberta). This a major multidisciplinary international project funded by the Canadian Stem Cell Network involving 19 partners from Canada, NZ and the US. The project will examine the issues associated with the integration of stem cell research and technologies into clinical research.

International Visiting Fellowships

- ESRC funded international visiting scholarship (UK SCI), University of Standord and University of California at Berkeley, January 2009.
- Louis Brandeis School of Law – University of Louisville – Kentucky (USA) – August 2001
- Academie Europeenne de Theorie du Droit – KUB University (Brussels) 1995 and 1996.

TEACHING

- M.A.B.L.E PROGRAMME (Regulation in the Biosciences, Principles of Bioethics & Biolaw, Regulation of Human Tissue & Cells).
- M.A. in Law (Torts)
- PhDs

ASSOCIATIONS

- Member of the Society of Legal Scholars (UK)
- Member of the AAAS Science and Human Rights Coalition

ADMINISTRATION

- Director of SIBLE
 - Director of MABLE
 - Chair of the University Bio-science and Ethics Forum
 - Member of Senate
 - Member of Sheffield University High-Level Research Leadership Strategy Committee.
 - Member of the University Research Ethics Committee
 - Member of the University of Sheffield's WUN's strategic committee
 - Member of Sheffield University Emergency Task-Force
 - Member of the School of Law Executive Committee and Research Committee.
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