

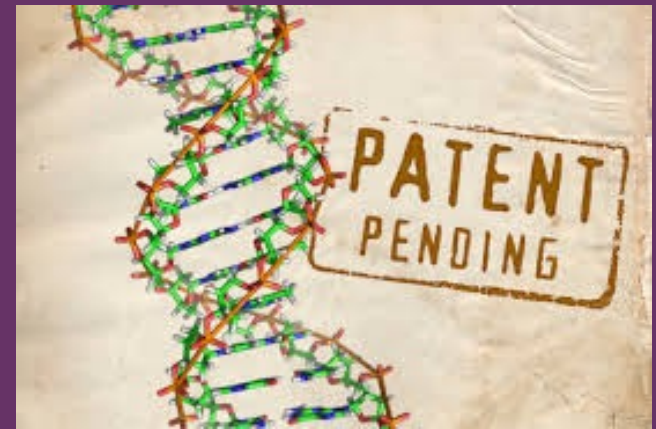
Patents & Emerging Biotechnologies: An Obligation of Ethical Patent Use?

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New Morally significant Technology.**

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Outline

- 1) Context – Nature of Patents
- 2) Patents and Morally Significant Technology – Role of Ethics?
- 3) Patents as a Private Governance Tools?
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 - iii. The Potential for Ugly?
- 4) Lessons for AI and other Morally Significant Technology
- 5) Concluding thoughts



Context: Nature of Patents

- Patent: Limited monopoly right subject to three criteria:
 - novelty, inventive step, industrial application
- Patent entitles owner a right to **exclude others use of an invention**
 - Mechanism of control over uses of an invention during patent - 20 years.
- Patents and Regulation: **Complementary role**
 - Denial of patents - Reduces incentives for a particular area
 - Patents as governmental stamp of approval
- Patents as Private Governance Tools – Licensing controls on use
- A Tale of Caution

I. Patents & Morally Significant Technology – Role of Ethics

- To what extent are moral issues considered in patent grant?
- European context – Art 53(a) EPC and the *Biotechnology Directive 98/44EC*
- Article 6 (1): Biotechnology Directive:
 - Inventions shall be considered unpatentable *where their commercial exploitation would be contrary to ordre public or morality*; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
- General Morality Provision - Very rarely applied in practice
- Threshold set extremely high for application

Marginalisation of Ethical Issues

- Leland Stanford (2002) EPOR 2
 - Transgenic mouse - useful in the study of treatment for HIV and human transplants.
 - Role of the EPO was not to act as a moral censor.
 - Only deny patents where “would be regarded by the public as so abhorrent that the grant of a patent would be inconceivable”
- Howard Florey/Relaxin [1995] EPOR 541
 - Whether “Human genes should be patented is a controversial issue on which many persons have strong opinions... [T]he EPO is not the right institution to decide on fundamental ethical questions”
 - universally be regarded as outrageous

Specific Moral Exclusions

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
 - a) processes for cloning human beings;
 - b) *processes for modifying the germ line genetic identity of human beings;***
 - c) uses of human embryos for industrial or commercial purposes;
 - d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.
- Definitional test – interpretative scope for narrowing provisions
- (c) has been used related to hESC, parthenotes etc
- To date (b) not been used in relation to patents over gene editing technology

Interpretative Gap – Patents & Ethics

- Morally significant technologies ethical issues side-lined – why?
 - Linkage of patents with innovation
 - Patent=Innovation=Economic Success?
 - Necessity of certainty in patent law
 - Resulting marginalisation of ethics – partly, on basis of uncertainty which could be detrimental to innovation.
- Patent Frameworks – Isomorphism (Powell and DiMaggio)
 - Normative isomorphism - groups of professionals which “create a pool of almost interchangeable individuals ...who possess a similarity of orientation and disposition that may override variations in tradition and control that may otherwise shape organizations”

Interpretative Gap - Patents and Ethics

- **Patent Decision-making Frameworks:**
 - Scientific personnel - limited external input
 - Patents and innovation
 - Reluctance to engage with generalist issues
 - Echo chamber effect?
- **Increasing Specialisation within law**
 - Patent law seen as different
 - Limited engagement with other fields
 - Development of insular interpretative community
- **Result - Speaking past but not to each other**
 - **Patents very unlikely to be denied on basis of ethical issues**

II. Patents as Private Governance Tools

- Patents - Mechanism of private governance
 - Can refuse to license or limit this:
 - Monopoly provider of invention – Access issue
 - Attempt to stop use of ‘controversial technology’
 - Can place stipulations on licence – Ethical licensing?
 - Conditions of use or Licence to specific categories
- Double edged sword: Unfettered use of power
- Patent Use: Good, Bad and Potential for Ugly?

i) The Good: Ethical Licencing

- Patents used to ensure license holders meet certain conditions e.g. provide broader access to technology
- **Broad Institute's License to Monsanto for use of CRISPR-Cas9 for agricultural purposes**
 - Condition of use - requirement that Monsanto allows its farmer customers to save and reseed seed from one season to the next.
 - Customers otherwise would have to buy seed from Monsanto each year
- Potential for use in other contexts?
 - Commit not to enforce patent against particular categories

ii) The Bad: Myriad Gene Patents

- Myriad patent over BRCA1 and BRCA2 genes – Genetic Testing
- Enforced patents very aggressively in US context
- Difficulties:
 - Price – issues of access
 - Quality of testing
 - No second medical opinion
- Limited scope for self correction within patent law?
 - ***Association for Molecular Pathology v. Myriad Genetics*, (569 U.S. June 13, 2013)**
 - ***D'Arcy v. Myriad Genetics Inc.* [2015] HCA 35**



iii) The Potential for Ugly?

- Licensing leaves much discretion to patent holders and also to third parties who negotiate licenses with them.
- Limited oversight or control over licensing conditions or over whether patent holder will agree to license
- Patents and licenses have significant influence over downstream research and use of technology
 - Myriad BRCA1 and BRCA2- refusal to licence restricted availability and development of other types of testing
 - WARF patents over hESCs – US context restrictions on licensing
 - Sherkow notes critics view this as “an impermissible walling off of secular research for religious purposes.”

IV. Lessons for AI and other morally significant technology

- Ethical Exclusion of Patents on AI – unlikely based on biotechnology experience
- Exclusions more likely based on application of patent criteria
 - Difficulties – narrow interpretation and can be worked around in future cases
- Licensing – useful but an unfettered use of power?
- White Paper Artificial Intelligence Collides with Patent Law (April 2018) - Core Issues Patents and AI:
 - Subject Matter - Are patents available on AI?
 - Who is the Inventor?
 - How does AI involvement challenge criteria?
 - Liability issues



Patents and Artificial Intelligence

- AI patents granted increased threefold, from 708 in 2012 to 2,888 in 2016
- **AI – Is it suitable patent subject matter?**
 - European context – Inventions must have technical effect
 - Exclusions from patentability – Art 52 EPC - mathematical methods; schemes, rules and methods for performing mental acts or doing business; and presentations of information
 - However – categories expressly excluded under Article 52 EPC, such as mathematical methods or presentations of information can enter the realm of patentability in Europe with the use of technical means
 - Key – Technical function.
- AI and consciousness – Ethically suitable subject matter?

Patents and AI: Future Issues

- **Who is the inventor?**
 - Patent Law framed around and justified by human invention
 - Creativity Machine developed by Stephen Thaler
 - Modelled the neurological processes of the human brain,
 - Machine created new ideas and adapted to different scenarios without human intervention.
 - Research led to Oral-B Cross Action toothbrush
 - Inventor listed as Thaler, Creativity machine not noted.
- Should AI be listed as inventor? Who will control patent use?
 - How would this influence downstream research/development?
- Questions over standards of inventiveness
 - Currently inventive step assessment – ‘person skilled in the art’
 - If AI is used more frequently – should it be AI skilled in the art?

Concluding Thoughts

- Role of patents in technology development and use highly significant
- Ethical Issues tend to be marginalized in patent grant and patent use
 - Need to be engaged with both in terms of patent grant but arguably more even importantly for patent use
- Lessons and mistakes from biotechnology may be useful to learn from in AI context

