Biobanks, Intellectual Property and Commercialisation

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Structure of Talk

- Current situation and changes in research practice
- Types of IP that might apply to biobanks
- Examples of models that have been used
- Ways Forward

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Changes in Research Practice

- Movement from isolated biobanks to networks of biobanks
- Recognition of the need for sharing of data and samples
  - –Tension between recognition of individual contributions and data-sharing
- These changes have been supported by technological advances

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- Convergence of the aims of commercial and non-profit organisations
  - –Human Genome Project; HapMap; 1000 Genomes Project
- Little empirical research on:-
  - – The relationship between data sharing and innovation
  - – How IP effects the translation of research results into clinical practice
- Few biobanks have Intellectual Property policies in place, but all agree that it is necessary

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What are the Intellectual Property Tools for Biobanks?

- Database protection
- Copyright
- Trade Secrets
- Patents

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Database Protection

- Directive 96/9 on the Legal Protection of Databases
  - Europe only
- Protects from unauthorised reproduction of the database
- It is a right that is potentially unlimited, as each time the database is modified, the clock starts again

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Copyright

- Broad international standards (Berne Convention and TRIPs) implemented in national legislation
- Protects the ‘expression of an idea’
  - – the way in which data is presented
  - –Consent forms are written
  - –Compilations of information in some jurisdictions
- Limited application to freely accessible biobanks

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Trade Secrets

- Derives from the breach of confidence doctrine
- Prohibits the unauthorised disclosure of information that is provided in confidence
- Useful when innovations are being developed but also as an alternative to IP rights
  - –e.g Coca Cola recipe

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Patents

- Criteria for patentability:
  - New
  - Useful
  - Non-obvious/inventive step
- Whether an invention is new is assessed against the prior art
  - If someone has done it before, you can't have a patent
  - Therefore, making genomic information public reduces the likelihood of someone else patenting it

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Patents

- Inventor may be owner but this can be modified by other agreements e.g. employer will usually own patents on employee inventions
- Patents are often licensed
  - –e.g. University may licence a patent to a pharmaceutical company
  - – Licences may be non-exclusive or exclusive

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Patents

- Patents are often viewed as problematic in genetics
  - –Liberal granting of patents by Patent Offices in early years
    - •Patents applied for by NIH on ESTs
  - –Concerns about ‘royalty stacking’
  - –Perception that patents reduce patient access to genetic testing
    - •Myriad genetics and breast cancer tests
- However, in practice there is little evidence of enforcement against academic and public sector institutions in Europe at least

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What does IP do?

- Reward for creativity and the inventor is given a monopoly in return for making the invention public
- IP rights are neutral, it depends how you exercise that right
  - –e.g. Cystic Fibrosis
- Patents have been very effective in encouraging innovation in drug development, but doubts about benefits in other areas
- Despite this, push by institutions and funders to apply for patents because of fear of free –riders and restricting data

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Solutions?

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International
HapMap
Project

‘Click and Wrap’

- Could only access raw data if agreed not to take any action that would restrict access to the data
- Superseded by open access policy which put all the data in the public domain
- Not all biobanks would want to put all data in the public domain

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Structural Genomics Consortium (SGC)

- Launched 2008 with a consortium of foundations, research institutions and pharmaceutical companies
- Purpose to identify and describe molecules that inhibit reactions in cells that could be used in industrial and academic biomedical research
- Partners agreed that none of them would commercialise the inhibitors and use patent rights to block others from doing so

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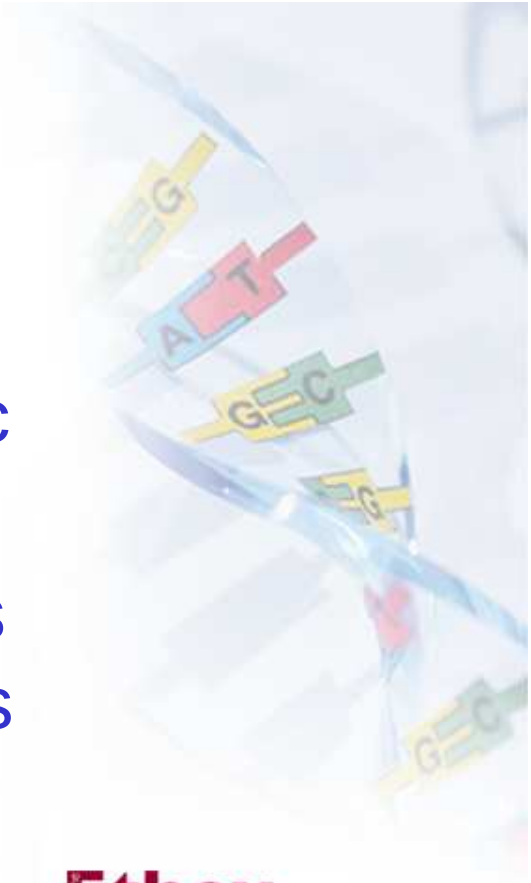
UNITAID

- Established by countries, philantrophic foundations and NGO's
- Purpose to supply essential medicines for HIV/AIDS, malaria and tuberculosis
- Built a patent pool and sponsored a new non-profit agency to manufacture drugs
- Result able to provide essential drugs to those in need in low income countries at a reduced price



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Basic Principles

- IPR are tools and it is *how* we use them and *when* that is important
- IPR must be understood as just one of the drivers for innovation
- Enthusiastic use of IP can stifle sharing which is necessary for further innovation
- IP has a marginal role in encouraging research but a significant role in the dissemination of new products and services

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Ways Forward?

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Option 1 – DO NOT TRY TO CONTROL IP

- Regard biobanks as resources and open to all
- Separates out research and the commercialisation of innovation
- It is unlikely that there will be huge innovations from the raw data in a biobank
- However, this does not recognise the effort in developing the biobank
  - –Publishing recognition e.g.KORAGEN

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The priorities (?)

- Key aim is to carry out research that will improve our knowledge and understanding of the causes of disease and treatment
  - –This is promoted by data sharing
- To ensure the translation of research knowledge into clinical benefits
  - –IP rights are a part of this

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Option 2 – NEW MODELS

- Need to develop models that promote trust and collaboration at the start
- Need to have input from all the stakeholders
  - Funders, participants, users- both non-profit and commercial, regulatory bodies
- Scope for using IP creatively
- Understand innovation as messy and not linear

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In conclusion

- Establish our priorities
- Biobanking networks at a crucial stage
- Recognise that IP is just one tool to encourage innovation
- Develop models that facilitate data sharing and enable innovation, drawing on skills and participation of all stakeholders

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Recommended Reading

- *Toward a New Era of Intellectual Property: From Confrontation to Negotiation* September 2008
  - –International Expert Group on Biotechnology, Innovation and Intellectual Property
  - –Led by Richard Gold at Mc Gill University

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dbGaP

- NIH sets out aspirational principles in access agreements.
- Eg dbGaP:
  - –The data will be pre-competitive and not be protected by IP
  - –Investigators cannot restrict other investigator's use of primary dbGaP data by filing IP
  - –For restricted access data NHGRI discourages the use if patents in a manner that would prevent or block access to any fundamental data that are developed with NHGRI support
- Threat of withdrawal of future funding for failure to comply may be more effective than a legally enforceable agreement

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Memorandum of Understanding

- Basis of collaboration
  - Details expertise bringing to project
  - Distribution of IP benefits
- May have different requirements from different institutions regarding the IP
- Costly and time-consumimg
- Problems of cross-border agreements –conflict of laws

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