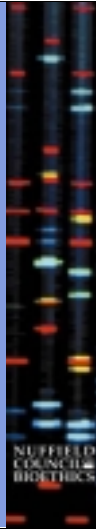


# IP and the diffusion of technology

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28 August 2003

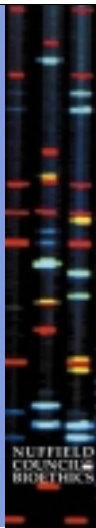
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## IP and diffusion of technology

- Goals – to promote the public interest
- Making available medicines, diagnostics
- Diffusion - diverse paths
- Balance between incentives for investment – require IP protection
- Spread of technology – widely accessible

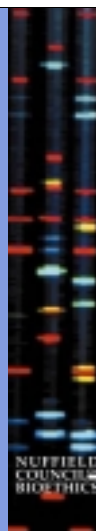
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## Progress in biomedicine

- Increased level of patenting in public sector
- Patenting of biological molecules, animals
- Trend to patent upstream
- Emphasis on protecting information
- May restrict technology diffusion

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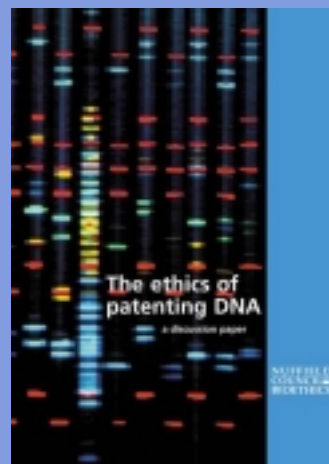
## Progress in biomedicine

### Fundamental tension:

- need to promote sharing of knowledge in research, especially in public sector and developing world and
- need to promote innovation in health by protecting inventions

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## Terms of reference

- To examine ethical and legal issues within current regulatory framework
- To provide an ethical framework and policy recommendations for policy-makers, the courts, patent lawyers and patent offices

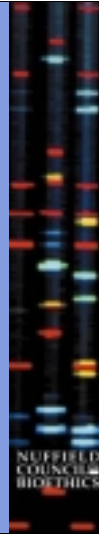
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## Genetic information as technology

- To consider eligibility
- To consider legal criteria for patentability
- To consider the public interest

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## Context

- Well established that patents play a key role in pharmaceutical innovation
- IP in biotechnology and genomics has encouraged investment
- Small companies: assets as IP
- Still relatively few products on the market

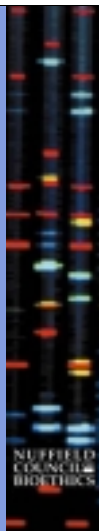
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## Context

- Two key trends:
  - Protection of investment
  - Protection of information
- .....rather than inventions

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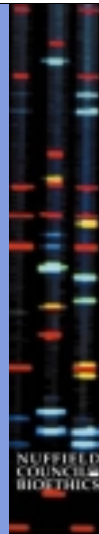
## The patent system

Goals:

- Stimulate innovation for the public good
- To reward people for new and useful ideas and inventions

Are these being achieved?

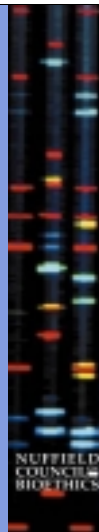
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## Patenting DNA

- Will patenting DNA promote the public good?
- Do patents on DNA unfairly reward inventors?

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## Types of information

- Information about a natural phenomenon
  - Scientific knowledge
  - Discovery
  - Not eligible for patenting
- A natural phenomenon which is itself information
  - Genetic information
  - Encoded in an artificial molecule
  - Eligible for patenting

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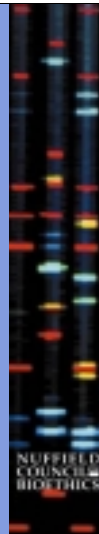


## Inventiveness changes as technology evolves

- New techniques in isolating DNA
- In silico research
- Europe vs US

No longer inventive to identify a gene

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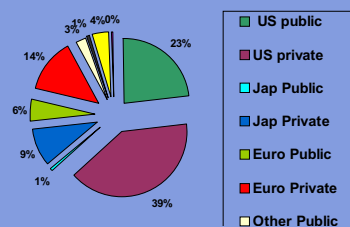
## Patents and diffusion

- Product patents:  
on the DNA sequence itself – restricting new applications of information?
- Use patents:  
on the use of the sequence – other applications possible?

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Patents claiming DNA sequence filed between 1996-1999: by country and sector



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## Diagnostics: BRCA1

- Test for faulty gene associated with a disease, based on knowledge of the structure of the gene
- Both product and use patents can have same effect of powerful monopoly

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## Diagnosis:BRCA1

- Myriad has monopoly on the use of the gene; BRCA1 under opposition
- All diagnostic uses of the gene
- Broad patents would be dominant over other uses
- Cannot 'invent around' the sequences
- High cost of tests: \$2,400 in UK

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## Diagnostic tests

- Do patents on diagnostic tests cause adverse effects?
  - difficulty of 'inventing around'
  - broad patents create a powerful monopoly
- Are they needed?
  - to encourage development of new tests
  - R&D to identify genes for diagnosis

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## Diagnostic tests

- Use patents? Yes, if specific
- Product patents? Rarely

“the **protection by use patents** could provide an effective means of rewarding the inventor while providing an incentive for others to develop alternative tests.”

- Use of compulsory licensing?

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## Research tools

- Product patents? Rarely
- Use patents? Rarely

- Welcome USPTO Utility Guidelines
- Research exemption
- Compulsory licensing

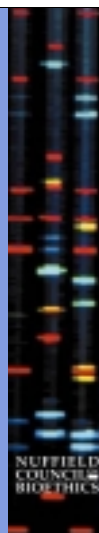
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## Limiting the scope

- One gene often produces more than one product
- If a patent protects all the uses of a sequence, this can give extensive rights, and unjustified rewards
- Scope of protection should be limited to specific defined uses

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## Conclusions

- Grounds for eligibility should be re-examined
- Rigorous application of patenting criteria –exclude majority of patents claiming sequences as research tools and diagnostics
- Use of research exemption and compulsory licensing to encourage diffusion of technology and applications when in the public interest

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