The genome editing innovation landscape Setting the scene with biomedical innovation

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The CLG's biomedical innovation pool team

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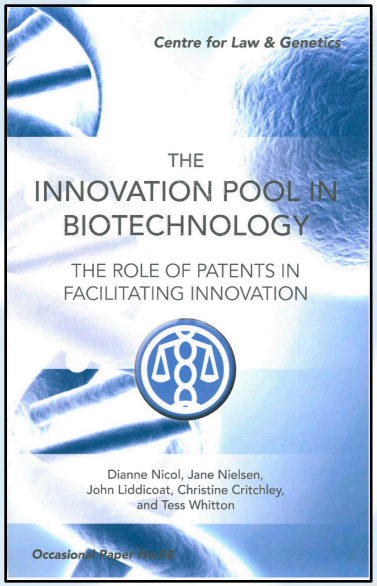

Lessons from biomedical innovation – the vital role of the SME

- Mostly spin outs from universities/research labs
- Ongoing collaborations – virtual model
- Tools, diagnostics, platforms and products
- Drug development - value add and move on or out
- Many promising innovations, no products as such

Facilitative role of patents

- Patents seen as vital – chief asset
- Encourage innovation and product development
  - Exclusion of competitors
  - Disclosure
  - Revenue raising
  - Signalling
  - Collaboration and sharing
    - Exclusive, non-exclusive, mixed licensing
    - Pooling, aggregation
    - Dispute settlement

Some negative consequences of patents on innovation

- Blocking
  - Refusals to licence
  - Reach through terms
- Thickets
  - Negotiation costs
  - Royalty stacking
- Anticompetitive conduct
- Trolling

Empirical analysis in Australian drug discovery and diagnostics

- Australian biomedical SMEs
  - Highly competitive environment
  - Yet white spaces, work arounds, aggregation
  - Live and die by patent length and strength
- Australian public labs and clinics (different from US and EU?)
  - Little enforcement exposure
    - Deterrents from enforcing – uncertain validity, negative publicity, uncertain financial benefit, threat of compulsory licensing
    - Relevant patents not always filed or granted, lapsed
  - Lab experience
    - Rely on experimental use
    - Problems with research tools, materials, data?
    - Commercialisation - can be sophisticated and nuanced, but not always

Yet

- None of this is easy
- Patents are but one issue
  - Regulatory requirements, funding, revenue, business acumen, partnering, bad luck
- Many promising innovations are lost
- What then of genome editing?

Genome editing innovation – progressing wisely

- What should be propertised?
- What should be shared?
- Are the two incompatible?
- Is anything different here from the broader biomedical experience?

Complexities in the evolving genome editing landscape

- Even more demanding regulatory and governance environment
- Inflated expectations (over $3,500 million by 2019 – IP Pragmatics 2016 report)
- Global disharmony of patent laws
- Changing IP strategies - trade secrecy
- Increasingly competitive and aggressive research environment
- Conditional/open sharing
- Changing industry milieu