Discussion Paper: The Interplay between Patents & Trade Secrets in Medical Technologies

Tanya Aplin & John Liddicoat | WIPO Headquarters, Geneva, Switzerland | 18 October 2023

Today's Plan

1. **Background** (Tanya Aplin)
2. **Specific interplay issues** (John Liddicoat)
3. **The interplay and public policy goals** (Tanya Aplin)
4. **Summary and future issues**

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Background

Innovation cycles

- **Main characteristics of innovation cycles for pharmaceutical drugs**
  - Discovery and development -> pre-clinical research -> clinical research -> regulatory review -> post market safety monitoring
  - Differences between small molecules v biologics?
  - Differences when it comes to drug repurposing?
- **Main characteristics of innovation cycles for medical diagnostics**
  - Device discovery and concept -> pre-clinical research & prototype - > pathway to approval -> regulatory review -> post market safety monitoring
  - Difference with drugs is that there is building of prototypes tested in controlled lab settings; also, the pathway to approval depends on the risks associated with the device. Cf LDTs

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Justifications for patents

- Incentive to invent
- Inventive to disclose (and to avoid relying on secrecy, with its downsides)
- Way of managing prospects – i.e. patents reduce wasteful duplication of inventive activities
- Rewarding the labour or personality of the inventor, especially through naming him/her
- *NB there is significant scepticism about the incentive function of patent protection*

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Justifications for trade secrets

- Incentive to innovate
- Encourages limited sharing of information
- Saves on wasteful expenditure of maintaining secrecy
- Promoting national economic interests (e.g. US Economic Espionage Act)
- Promoting fair competition (art.10bis Paris Convention)
- *NB there are significant criticisms of these justifications*
- ***What about choosing between patents and trade secrets?***

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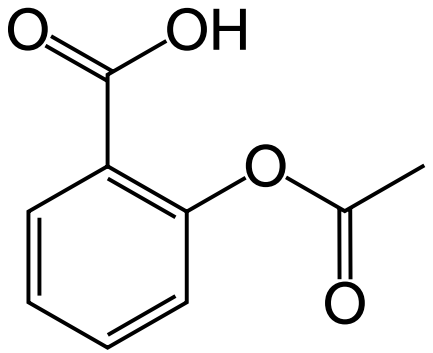
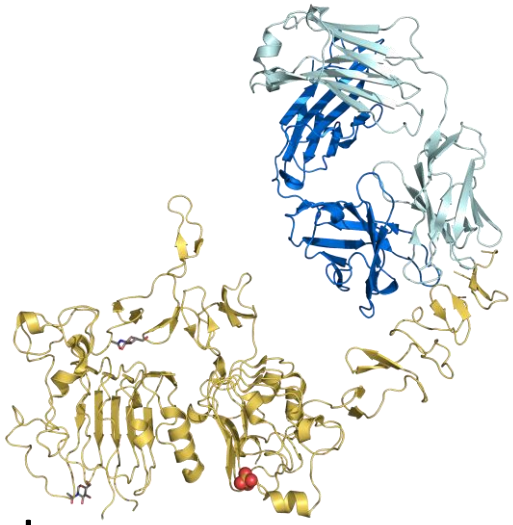
Specific Interplay Issues

Pharmaceuticals #1



- Small molecules and generics (Aspirin and acetylsalicylic acid)
  - Generally working well, in particular, new molecules and cheap generics
  - But, note acceleration of analytical chemistry in the 1960s and 70s
    - Paved path for generics



- Biologics and biosimilars (Herceptin and trastuzumab)
  - Similar relationship as small molecules and generics
  - Hard to understand exact chemistry (due to complexity)
  - Hard to know manufacturing (due to variety of methods)
  - Chemistry and, particularly, manufacturing can be kept secrets
  - These trade secrets *could* prevent or delay biosimilars, costing $€£₣ millions

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Pharmaceuticals #2

- Do trade secrets prevent or delay biosimilars?
  - There are examples (e.g., Premarin from 1942)
  - But no cogent, industry-wide evidence (e.g., how often companies chose not to pursue biosimilars due to trade secrets or how much longer biosimilars take to reach markets)
  - Current evidence indicates that 'patent thickets' are more profound (in the US!)

- A second problem for small molecules AND biosimilars: secrets on clinical trial data and protocols
  - There's a complex interface between: a) authorisation of trials; b) obligations to publish trial protocols and results (different practice around the world); and c) publications by regulators.
  - But often protocols and data are not published, e.g., Piller et al. found 1 in 3 trials failed to publish data despite a legal obligation in a certain time
  - Can adversely affect: a) third party reviews of data; b) insurance calculations; c) follow-on innovators (including rescuing and repurposing)
  - No estimates on quantum of effects

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Drug manufacturing & Pricing

- Drug manufacturing
  - Argument in short: ineffective incentives for improvements in manufacturing
  - Why? A. Patents disclose inventions and are hard to enforce; B. Trade secrets are hard to enforce and, even if used, prevent cumulative innovation
  - Argument is supported by anecdotes (c.f., chocolate) and survey studies (confirming companies predominantly use trade secrets to extract value from new processes)
  - But no cogent evidence on breadth and scale. And some evidence to contrary (e.g., thickets of manufacturing patents!)
- Drug pricing
  - Many prices are kept secret
  - Can be kept secret due to complex arrangements for selling, distribution, prescribing and dispensing
  - Secret prices prevent market forces and allow opportunistic pricing
  - Several governments have begun transparency initiatives, but the effects of the initiatives are inconclusive

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Medical diagnostics

- First issue: Patentees & 'data generating patents'
  - Often not considered a problem, except in medical diagnostics
  - Problem: there's a concern that secret databases could provide long, *de facto* extensions of patent periods
  - Famous example: Myriad and *BRCA1 & 2* genes
  - Evidence of the problem?
    - Very little beyond Myriad

USAMRUK Malaria Diagnostics and Control Center of Excellence microscopy training - Nigeria, Africa 09200

- Second issue: Narrowing of patentable subject matter in the US
  - Three key cases *Myriad*, *Mayo* and *Alice*
  - Commentators argued innovators would use trade secrets instead of patents
  - Or, not innovate at all
  - One interview study (n=19), found one US company relying on trade secrets and four universities stopping development. But didn't affect Europeans (n=18)
  - But no industry-wide evidence

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Surgical methods and other technology

- Surgical methods often do not attract patent protection
  - E.g., Exclusion from subject matter (EPC) and immunity from infringement (US)
  - Commentators argue forces innovators to keep trade secrets or *not* innovate
  - No systematic empirical evidence. Innovation continues (e.g., journals)
- Other technology
  - E.g., surgical devices, medical imaging, diets, behavioural changes
  - Speculation about *insufficient* incentives (e.g., challenging patent enforcement) or trade secrets providing *de facto* extensions
    - In short, similar arguments to the technologies already discussed
  - But almost no evidence of these effects
  - Less of a problem? Or perhaps commentators focus on 'headline' technology?

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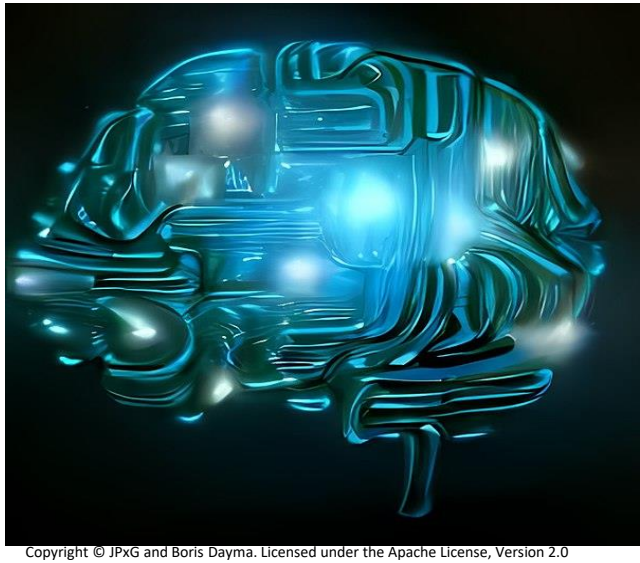
Medical machine learning

- Lots of IP-related issues (e.g., ownership in copyright and patent law)
- One key issue: does patent law provide sufficient incentives? Especially in light of narrowed US law
  - A recent study indicates rapid growth in patents (Aboy et al, 2023)
  - ‘fears [of not] patenting’ are unwarranted’
- Are patents sufficiently well described for PSAs to practice the invention?
  - Open question
- Do trade secrets on training data and algorithms unduly slow follow-on innovation or give large incumbents excessive advantages?
  - Open question; challenging weighing exercise



Policy Goals

Acceleration of new medical technology

- Is a patents/trade secrets overlap in the case of drugs desirable? Especially when there is also regulatory exclusivity protection
  - A key issue is whether disclosure of clinical trial data and protocols is needed – this is consistent with the incentive-to-disclose justification for patents and with the regulatory requirement to provide sufficient information
  - However, trade secret and regulatory exclusivity are seen as 'backup' protection
- Might trade secret protection stimulate innovating around? E.g. generics
- Does non-disclosure of information about medical diagnostics hamper further innovation? Note the differences compared with drugs
- Weak or non-existent incentives for medical diagnostics, surgical techniques and drug manufacturing?

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Access to medical technology

- Restricted access in some key areas
  - Trade secrets on clinical trial protocols and data
  - Trade secrets on drug prices
  - Imperfect patent disclosure and trade secrets on manufacturing and quality control processes for biosimilars
  - Trade secrets on databases for medical diagnostics
- Benefits of greater access
  - E.g. reducing government expenditure on drugs, increasing competition in manufacturing methods for biologics, which could mean lower prices and more treatments
- Role of compulsory licences, government use, etc
  - note the WTO Covid 19 Ministerial Declaration – *do trade secrets and regulatory protection thwart such flexibilities?*

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Building a ‘knowledge commons’

- Shared information resource whose use is not restricted by IPRs – this can facilitate scientific understanding and progress
- Query whether patent law incentivises meaningful disclosure
  - Patent attorneys draft specifications - legalese
  - Incentives to restrict disclosure in order to limit competition
  - Specification drafted at an abstract and wide level that obscures what is actually being practised
- Replicability crisis in scientific research – mirrored in patent law
  - Studies show that there the methodological quality of patent specifications was worse than in scientific papers
  - Unlikely to publish negative data – i.e. something does not work – but to protect as a trade secret

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Future issues

Areas for further research and policy debate

I. The desirability & impact of increased disclosure of clinical trial data and protocols for drugs
II. Whether there are sufficient incentives for medical diagnostics, surgical treatment methods and drug manufacturing processes
III. The extent to which drug prices are kept secret and the impacts of this
IV. Do data generating patents (diagostics and medical ML) affect follow on innovation?
V. Are medical ML patents sufficiently incentivised by patents or trade secrets?
VI. Can the disclosure mechanisms under patent law be improved?
VII. Desirability, nature and form of compelled disclosure of trade secrets by regulatory authorities
VIII. Further analysis of TRIPs (esp. Art 39) and the circumstances in which compelled disclosure of trade secrets and regulatory data is permitted

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Thank you

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