



# MOVING FROM RESEARCH TO IP TO BUSINESS

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INTEGRATE



ENABLE



LEAD



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## Moving from research to IP to business

- Traditionally the R&D commercialisation process has been seen as a [roughly] linear process; do your research, develop the results into a product or service, patent it, sell or licence it, (or sell the patent application to a larger business with the capital to go further)
- Long time frames for big pharma and complex biotech tend to reinforce the linear approach – long term product pipelines
- a more “branched” approach is developing, with research results and tools feeding into a wider variety of projects
- pressures to bring in revenue earlier, develop cashflow and/or minimise outgoings create incentives for early commercialisation
- developing revenue streams earlier increases chances of survival, and options for exit strategies



Smaller biotech companies in particular should consider possible “branches”

Potentials:

- new revenue streams
- new partners
- swaps / cross-licensing to access useful products or services
- ‘side’ deals that do not inhibit your main [linear] development path or goals
- unexpected fields of application (and revenue) e.g. Siemens 3D ultrasound technology for expecting parents, a combination of health and entertainment



## Dangers:

- Taking your eyes off the ball
- Time and energy diversion
- Acting outside your fields of competence
- Restricting ability to offer “exclusivity” (may need to focus on “exclusivity in a particular field”)
- Pressures to align your goals to those of another business



## But what IP could I commercialise earlier?

- What IP do you have?
- Conduct an IP audit
- Better still, implement procedures so that you don't need to do a "one off" audit – make it routine so that it is a matter of updating your information on a regular basis
- Require staff producing IP to record it in a place and way accessible and understandable to management



IP your business may possess includes:

- Patents, patent applications, patentable inventions
- Trade Secrets / Confidential Information
- Trade marks, brands, and domain names
- Copyright material including:
  - a wide range of ‘documents’ including manuals, detailed methodologies, reports, articles etc
  - Collections or compilations of documents or information, often in a database (such as a DNA sequence database)
  - Images (such as genetic maps, photographs / micrographs)
  - Software! Probably the most overlooked asset, particularly in the age of “open source”



## “early” IP advantages:

- IP gives something to licence – “commodifies” or “propertises” your R&D output
- Credibility with investors and partners – why should people invest in or deal with you?
- Beachhead to establish markets
- Clear ownership boundaries
- Get in early and marks your territory, areas of expertise, may even signal your potential to currently unknown partners and customers



## Select issues in partnering and commercialising

Beware of allowing other parties to *control* your brand, reputation, website, or confidential information – common problems:

- Other party registers website or brand (trade marks) and refuses to hand over control
- Other party registers trade mark / use brand itself which may mean goodwill attaches to that party, rather than your business
- Other party uses brand in the wrong way with risk of diminishing value or loss of registered brand (eg. allows it to lose distinctiveness / become generic)
- Other party uses brand, website, confidential info to carry on selling your product, or a similar/copied one, without accounting to you
- In short other party does not treat your IP with respect & care



## Agreements / Contracts: the nuts and bolts of business

- We enter into many (dozens) of contracts every day
- Moving from research to 'business' will require you to enter into contracts with a number of other parties, whether you realise it or not
- There will be commercial understandings in the nature of contracts with each party along the value chain, as your product or service 'leaves' your possession –shipping, warehousing, distributors, to purchasers
- Although most of contracts will proceed smoothly, do not assume that will be always be the case
- Allocate time and resources commensurate with the importance of the contract / transaction in question



- Oral agreements are as good as the paper they are not written on
- ALWAYS record an agreement in writing
- any writing is [almost always] better than none
- A good rule of thumb for written agreements:  
*Would a third party (such as a judge) reading this document understand the rights and duties of each party?*
- Preparing a written agreement is an opportunity to establish or strengthen commercial relationships
- Better to disagree now, during negotiation, than later, when you may need to take [expensive] action to regain control of your product or service



- A realistic approach to documentation means using a document which is appropriate and the best you can (afford) in the circumstances
- Documentation may be about many things – including determining what is really agreed to - risk management / allocation
- Risk can almost never be eliminated, but it can be reduced
- Ultimately it is about risk and opportunity management



## Common Agreements:

- Heads of Agreement / MOUs
- Confidentiality Agreements / NDAs
- Joint Venture (JV) Agreements, Joint Development Agreements, Cooperative Research and Development Agreements (CRADAs)
- Material Transfer Agreement
- Licence Agreements
- Outsourcing Agreements (particularly common with software)
- Distribution and Manufacturing Agreements
- Assignments



# A hierarchy of documents

- 1) Formal written agreement (contract) which is drafted and vetted by lawyers for each side
  - Upside
    - likely to be the most robust document
    - Induces each party to explore / consider / determine the 'four corners' of the agreement
    - Minimises chance of dispute via misunderstanding
  - Downside
    - likely to cost more money now (but may save money and grief later)
    - May be more 'confrontational' than feels comfortable – particularly when establishing a new relationship
    - Negotiation and revising several drafts is time consuming when there is pressure to move forward quickly



## 2) 'letter agreement' – a formal letter in which as many details as feasible are recorded

- Good to include numbered paragraphs for the key points or issues agreed, send two signed copies of the letter, ask that the other party sign both and return one (each then having an identical 'original')
- Upside – usually quick and cheap
- Downside – may not cover all areas or be specific enough – omitted areas / details may end up being important



### 3) Even an email is better than nothing

- again include at least the core points or issues
- Use clear and straightforward language ('plain English' ahead of 'ancient lawyer')
- ask for confirmation that the email contains a fair and accurate record of agreement
- Ask for particular points of any disagreement
- "estoppel" (establishing reliance etc)



- Use the best document which is realistic in the circumstances
- A 'letter agreement' is a good option in many circumstances
- Be prepared to “upgrade” documentation as a deal or relationship becomes more important
- try to build on a strong and clear foundation – a good MOU now may become a good set of recitals or ‘background’ to a more complex agreement
- There is no such thing as a ‘standard agreement’
  - *“I can just cut and paste this old agreement and change the party names and everything will be fine”*
- Maybe ... very often not
- A ‘quick and cheap’ solution now may lead to a slow and expensive problem later – thank you for investing in your litigation lawyer’s future



- Select Issues

- Jurisdiction / choice of law
- Specific allocations of risk
  - Insurance
  - Warranties and indemnities
    - Third party IP rights
    - Management of third party disputes
  - Transfer of title to goods
  - IP Rights
    - who has what rights where over what times (e.g. licensing)?
    - i.e. definitions for:
      - » Intellectual Property (of each party and any 'emerging' IP)
      - » Schedules including detail of any IP – lists of registered rights and material in which unregistered rights subsist (e.g. copyright or trade secret material)



- Term – how long does the agreement last – one transaction, many, ‘indefinitely’, until termination?
- Termination – who can terminate, on what grounds, what notice period
- Dispute Resolution – what must each party do in the event of a dispute: written notification, good faith negotiations, mediation, arbitration etc
- Payment Schedules, Royalty rates (gross or net?)
- KPIs, Milestones
- Auditing / verification e.g. sales and payments – rights to inspect books / records



- Each party knows where it stands – what its rights / risks / liabilities are
- Each party is aware of the costs, benefits and opportunities involved
- Neither party feels it has ‘won’
- Rarely do ‘unequal’ or ‘unfair’ agreements last – disputes can and will ‘materialise’ where one party feels exploited or oppressed



- Other issues to consider:
  - Trade Marks Registrations
  - Other aspects of “brands”
  - Domain names
  - Copyright
  - Regulatory issues (HSNO / ERMA, ACVM / NZFSA etc)
  - Confidentiality
    - Particular materials / documents / business information
    - The fact of agreement or specific terms
    - Confidentiality for negotiations; NDAs

