Growing the Value of your Intellectual Property

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14 November 2014
smartphones as diagnostic tools

“The app will see you now”

MC10/Biostamp
All those products include some or multiple forms of IP

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Apps</th>
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<tr>
<td>– New molecule</td>
<td>– Copyright</td>
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<td>– Formulation/excipient</td>
<td>– Algorithms</td>
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<td>– Know-how</td>
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<td>– Trademark</td>
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<th>Medical Devices</th>
<th>Diagnostics</th>
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<td>– Design</td>
<td>– Composition</td>
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<tr>
<td>– Materials</td>
<td>– Use</td>
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<tr>
<td>– Way in which it works &amp; is used; know-how</td>
<td>– Know-how</td>
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Focus for this presentation

Types of IP
&
Why we care about IP
&
How to manage IP to increase its value
What is IP

• “The application of the mind to develop something new or original.”
• A new invention, brand, design or artistic creation
• Patent, design, copyright, trademark, know-how, trade secret & more
• Protection depends on the form of the IP – some registered, some unregistered

Gardasil

• Product composition → patent
• Product formulation → patent
• Product name → trademark
• Product logo → trademark
• Company name & logo → trademark
• Syringe → design
• Insert/instructions → copyright
• Trade secrets
Do you have to register IP? Yes & No

YES! Registered Rights
- Patents
- Trade Marks
- Designs
- Plant Breeders Rights

NO! Non-Registered Rights
- Copyright
- Trade Secrets
- Know-how
- Confidential Information
- Circuit Layout Rights
Technical Matters – Patents

What it is

• Protects how an invention works or functions
• A patent is a right that can be granted for any device, substance, method or process
• Must have 3 attributes: New, inventive and useful
  
  – *Novelty*: has not been publicly disclosed in any form, anywhere in the world before priority date
  
  – *Inventive step*: invention must not be obvious for someone with knowledge & experience in the technological field of the invention
Other Forms of IP

- **Copyright – not registered:**
  - Literature, drawings, computer programs, music, film, art, photographs
  - The owner’s *original expression of the ideas* is protected, but not the ideas themselves eg. poster presentations & published papers

- **Registered design:**
  - Protects the visual appearance but not how the product works eg medical devices

- **Registered Trade Mark:**
  - Logos, words, letters, numbers, a phrase, sound, scent, shape, colours
  - Identifies the particular goods or services of a trader that are distinct from those provided by others eg. Coca Cola vs Pepsi
Technical Matters - Patents

**Patent Types**

**Provisional application**
- Not a granted patent, but sets priority date (date first filed) & starts process; gives you time to complete studies before Standard application.

**Standard patent**
- Protection & rights for 20yrs/25yrs for pharmaceuticals.
- Examined by IP Australia (6 months – years) or another patent office.
- Published by IP Australia 18 months after priority date.

- File one international patent app that can lead to protection in 148 countries.

**Innovation patent**
- For up to 8 years; to protect inventions that do not meet inventive threshold required for Standard patents.
- Not examined; granted within 1 month; apply separately for other countries.
- Lower cost; lower standard; therefore lower value.
Typical Application Process

**Step 1:** file Provisional patent application to establish priority date
- Application has priority over applications filed by competitors after this date
- Lasts 12 months; published after 18 months
- Priority date recognised by other countries

**Step 2:** complete Standard application within 12 months of filing provisional
- Claims/specification based on the Provisional; can include modifications, developments & improvements to the original invention, but no new material

**Step 3 v1:** International filing in each country of interest.
- Cost effective if <4 countries identified within 12 months of priority date

**Step 3 v2:** single PCT application
- Delays decision & incurring expenses for 18 months
- Reserves right to file in individual countries (entering National Phase)
Why we care about IP

Why would a company go to the expense of using these forms of protection?

BECAUSE IP HAS VALUE

• It can be traded – sold, licensed
• It can be protected to exclude others from using it for a period
• If someone infringes your IP, you have rights to recover costs
• If protected by patent, can provide exclusive period 25 yrs for pharmaceuticals, for you & your licensees to develop, commercialise & sell
• Governments around the world enable these monopoly rights
Growing IP Value

**Invention**
- Researcher: ID novel compounds, early data, novelty & FTO identified
- Risk

**Early Stage Commercialisation**
- Likely with Partner &/or funds from AC:
  - Evidence that it does as is, or will be described in patent

**Commercialisation**
- Partner/Licensee: Payment for licensee to have access to develop & use IP

**Growth**
- Product sales

TIME

VALUE & RISK

IP Value

RISK
“The Race” for pharma cos: balance patent life, development costs, competitors, cost recovery, income

Invention

Early Stage Commercialisation

Commercialisation

Growth

TIME

VALUE & RISK

RISK

>5 YEARS R&D SPEND $M’s

+5 YEARS DEVELOPMENT SPEND $10’sM

+3-5 YEARS DEVELOPMENT SPEND $100’sM

PRODUCT SALES = REVENUES!!

IP Value
Why we care about IP

Considerations during the early stages

• We’ve established that IP
  – has value
  – this value is time-limited due to competition, limits on protection, timing
• To ensure IP retains its initial value & grows, be aware of how value can be undermined
  – Be aware of timing for patents & other IP protection
  – Early disclosure of an invention may reduce the scope of any patent eventually granted, or may lead to that patent being invalid
    • Disclosure: the spoken word, drawings, written description, exhibition (poster presentations)*, use or sale
• It is essential to keep an invention secret before a patent application is filed.

*Some limited confidential disclosure might not prejudice your rights
What not to do

- Never write your own patent specification
- Never rely solely on your own IP searches. Allow costs for IP attorneys to do searches to ensure your IP does not infringe others
- Never assume that you have Freedom to Operate (FTO)
  - You might need other technology to “enable” yours (e.g., patented formulations, excipients or someone’s technology for devices)
  - This can often be licensed
  - An extensive search is needed – best to never state that you “know you have FTO”
- Never assume that a potential partner will help you – do your own due diligence
**IP Strategy**

### What to do

- Get advice *early* from a registered IP attorney
- Understand what options are available for your product
  - Type/s of protection & timing & cost for this
- Build the IP strategy into your commercialisation strategy
- Find out whether you have Freedom to Operate (FTO)
- Be careful with what is disclosed
  - non-disclosure agreements & materials transfer agreements can have hidden consequences for your IP
  - advise your staff of their obligations
- Be aware that discussions with potential partners:
  - can/should be *non-confidential*
  - you do not need to disclose all details up front
Publish or Patent

Ultimately it’s your decision … unless there is an agreement in place

- Publishing early can
  - Impact granting of a patent
  - Alert competitors
  - Unnerve potential biotech/pharma partners & investors
- Patent then publish
  - Partners will want you to publish when the time is right – it’s a valuable & important marketing tool
  - Your partners might want to have a say in how much is described publicly
- Publish non-confidential information
  - Must be “non-enabling”
Non Disclosure & Materials Transfer Agreements

Always read an agreement before signing. Never assume that it’s ok. Obtain a legal view if unsure

• NDAs (1-way/2-way):
  – Starting point for negotiation
  – Disclosure can be staged – no need for all up front
  – Watch for requirements of disclosure (eg providing signed/dated information in writing following verbal disclosure)
  – Who can sign on behalf of your organisation
• MTAs:
  – Access to results vs ownership of data – should this be a research agreement?
• Companies often want non-confidential information first – to determine if there is a conflict of interest
Some useful links

ALWAYS WORK WITH YOUR TTO

IP Australia
- www.ipaustralia.gov.au

Knowledge Transfer Ireland

IP Attorneys
- Most websites describe processes & provide other valuable information
Department of Industry | Business

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Provisional (priority date)

- File complete apps in other countries
  - Overseas applications

- File Australian complete application

- File international (PCT)
  - National phase in Aust within 31 mnths of priority date
  - National phase entry other countries within 30/31 months of priority date
  - Overseas applications

12 months

Examination process

Patent granted

Patent term is from filing standard or PCT