Case Study: ITL Corporation

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I N N O V A T I O N L A W
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ITL Corporation Pty Limited

- An Australian Company
- Commenced operations in 1994
- My pleasure to have been its lawyer since 1995
- I have seen it grow
  - from the two founders with no other staff, to
  - over 150 staff in four countries
- Rarely does a lawyer have an opportunity to speak about the affairs of his successful clients given duties of confidentiality, and other ethical duties
- This is an occasion where I can speak about ITL, which was kind enough to permit me to use it as a case study at this workshop

Snapshot in 2003

- Innovator, designer, manufacturer, and commercialiser of medical devices and health care products
- 25 + staff in Australia
- 130 + staff in Ipoh, Malaysia
- Small team of marketing staff in United Staff and United Kingdom
- Export to over 30 countries
- 12 patent families
- Over 100 granted patents worldwide
- 11 Trademarks registered in over 25 countries
- Case study is about how ITL used its IP Assets to grow from 2 founders with no staff to over 150 staff, in 8 years

Company's name

- ITL stands for
  - Innovation
  - Technology
  - Licensing
- ITL's name itself indicates that IP Assets are a major focus of its attention
- And as its name suggests, IP Assets have been of critical importance to the company's success.

Company beginnings

- Joint Managing Directors
  - Bill Mobbs (computer consultant)
  - Jag Dillon (research scientist and then TGA (FDA) official)
- Both decided to undertake a Masters of Business Administration and met at University
- At the time were aged in early 30s
- They both decided that the business that the wanted to form needed to be
  - niche
  - global
  - innovative
  - protectable

Identifying the need

- In 1993 - 1994 the risk of AIDS infection was receiving global attention, as was Hepatitis C infection
- Healthcare professionals (doctors, nurses, etc) were particularly concerned about the risk of accidental infection, given that they daily dealt with patient's blood
- At about this time a retractable syringe entered the market
- The blood collection agencies (Red Cross and others) were particularly concerned about accidental needle stick injury to their staff
- Bill and Jag identified the need for a product into which blood collection needles could safely be contained, upon exit from the blood donor, in that way minimising the risk of needle stick injury

Developing the IP

- With the idea of a vessel into which needles could be safely housed, they engaged a designer to implement their design concepts
- The designer was an independent contractor
- Independent contractor, not being employee, owns IP that he creates
- If ITL had done nothing about IP at this stage:
  - The design of the product would be owned by the designer
  - The patent over the new product would have been jointly owned by ITL and the designer
- Consequences of
  - designer sole ownership
  - Joint ownership with designer

    impedes ITL's commercialisation efforts

IP Strategy #1

- Critical that ITL own the IP that its business relies on
- IP Policy:
- Independent contractors:
  - A written agreement between ITL and the contractor ensured that ITL owned the intellectual property crated by the contractor in the course of the contractor's engagement by ITL
  - Confidentiality obligations upon contractors
- Employees
  - Clear provision about ownership of IP created by staff
  - Confidentiality obligations upon staff
  - Restraints upon competition in staff contracts

First patent

- In 1994 ITL applied for a utility patent or petty patent (in Australia now called an innovation patent) over the first product, the DonorCare
- Later converted to a standard patent
- Has a unique design
- Needle retracts into the vessel

IP Strategy #2

- The four essential characteristics of their business:
  - Niche, global, innovative, protectable
- These objective could not be achieved unless there was a patent
- IP Strategy #2 was to protect new products by patents

Niche	A product that was sought after, would be in high demand, and which had no competitors
Global	Patents in every high population country where blood is regularly collected
Innovative	A new product
Protectable	Patent was granted in each key country

First trade mark

- DonorCare was also the first trade mark

DonorCare

- Trade Mark was sought at an early time
- ITL identified the need to achieve product recognition at an early date
- It needed its potential customers to be aware of its product, and to recognise ITL's products, over any competing product

Capital Needs

- Capital needs of the company:
  - Founder's equity
  - Investor's equity
  - Concessional grants (no repayment) and loans (repay with generous repayment terms)
- Govt policy to encourage new innovative businesses
  - Particularly where protectable IP + export earning potential
  - Not dissimilar to schemes in other countries, aimed at promoting economic activity, including creation new employment, earning export income, reducing imports and improving balance of payments
- ITL, with protectable IP and export potential easily fit into the criteria for loans and grants
- Loans mostly employed for international marketing and promotion activity

Competitors

- Other players entered the market with their own products
- But they had to ensure that their products did not infringe ITL's patent
- Result was that products made by competitors were inferior to ITL's product. If they were to adopt the DonorCare's unique characteristic as a retractable vessel, they would be exposed to infringement action.
- ITL created a high profile to discourage infringers
- There have not been any infringers
- There are competitors, but the competing products are inferior, because of ITL's patent position

Beating competitors

- The key to ITL staying ahead and beating competitors has been:
- A patent position, and
- A trade mark position
- Patent position
  - Copy cats are eliminated – there are no copy cats trying to copy the DonorCare
  - It acts as a deterrent to infringers
  - It is a myth that a patent owner spends considerable amounts in pursuing infringers – the fact that there is a patent acts to deter copy cat producers

Beating competitors

- A trade mark
  - Product is recognised
  - Potential customers do not confuse ITL's products with those of a competitor
  - Customers are loyal to ITL's products
  - Pressure upon blood collection agencies to use ITL's products, and that is only possible because of brand recognition
  - New customers prefer the superior ITL product over inferior products, and that has been achieved by the brand recognition that has been made possible by the trade mark

Other products

- Platypus
  - Similar to DonorCare, but designed specifically for AV Fistula Needle sets
  - Also designed to prevent needle stick injury
- Key to its success has also been
  - Patent protection
    - (Niche, global, innovative, Protectable)
  - Trade Mark
    - Market recognition and loyalty

Other Products

- Blade Guard
  - Stitch cutter, reducing risk of injury

- Flipper Stripper
  - Strips blood tubing

- Samplock
  - Vacuum tube for blood collection

- All protected by patents in some countries
- All protected by trade marks in more countries

Strategic use of patents & trade marks – IP Strategy #3

- If ITL patented every product in every country, and registered every trade mark in every country, it would be a prohibitively expensive process
- Strategy:
  - Patent in major countries for product protection
  - Trade mark in a greater number of countries for product recognition, in that way leveraging off the patent protection in other countries
- Achieves: avoiding extensive patenting expenditure
- Clever use of two different IP Assets to leverage off each other

Manufacturing

- Original intention of ITL was not to be a manufacturer
- Focus was to be a creator of good ideas:
  - Create good ideas
  - Outsource designers to perfect it
  - Outsource patent attorneys to protect it
  - Outsource lawyers to make deals with it
  - Outsource manufacturers
  - Co-ordinate all the above

Evolution to Manufacturing

- Unreliable manufacturers prompted ITL to expand to become a manufacturer itself
- Now has 4 buildings in Ipoh, Malaysia
- Manufactures all products on own premises
- Makes it own tools

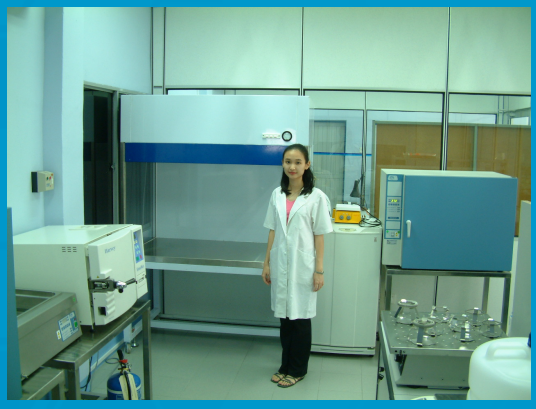
Evolution to manufacturing

- Engages own staff
- From staff of 2 to 150
- Clean room certified

Evolution to Licensing in

- Having established own manufacturing facility, it has licensed in other people's technology to add to its product range
- That is, has licensed in other people's unique patents or designs to produce and sell
- Leuko Cart
  - A portable cart for blood bags
- Baby Leuko Cart
  - A smaller version

Evolution to Biological testing



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Evolution to Biological testing

- Hemolysis, ISO 10993

  measures the amount of lysis caused to erythrocytes by an extract of the medical device which is under evaluation. Lysis causes release of hemoglobin from the erythrocytes which can be measured spectrophotometrically.

- Medical Device Bioburden: Total (Heterotrophic) Plate Count

  enumerates the total (aerobic) bioburden. Can be expanded to include fungus counts.

- Microbial Limit Tests

  performs general bacteria and fungus counts on raw materials. Can be expanded to include USP indicator microorganisms such as *Escherichia. coli*, *Salmonella*, and *Staphylococcus aureus*.

- Method 1 Sterilization Validation , ISO 11737

  validates the selected irradiation dose (gamma) for a product and validates this dose using the method predicated in ISO 11137.

Lab Capabilities

- Environmental Monitoring (Airborne and Surface)

  enumerates the total number of aerobic microorganisms present in the air in one unit volume of air sampled using the MQS automatic air sampler .

  quantifies the surface bioburden on work areas (Surface Contact Plate Method)

- Process water testing (Total Plate Count & Coliforms)

  reports the number of bacteria present in water as the Total Plate Count

  detects for total and fecal coliforms in water samples

- Microbial identification, Gram staining

  Profiles the type of microorganisms isolated following product bioburden or environmental monitoring using the Gram reaction. Single colonies are Gram stained and examined microscopically.

- Statistical evaluation of microbial data

  Microbial count data can be processed and given suitable statistical address to derive distributions, goodness-of-fit testing and control limits using statistical software.

Evolution to Procedure Kits

- Evolved to assembling procedure kits for specific medical procedures

Foley

Insertion Tray

Evolution to Procedure Kits

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Ulcer Wound Care Tray

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Procedure Kits

Dressing change tray

Procedure Kits

Incision and Drainage Tray

ITL's lessons

- Ensuring that you own the intellectual property that your business relies on
- Ensuring that independent contractors assign to you the intellectual property that you pay for
- Seeking out public grants and concessional loan schemes that will help your business
- Ensuring that your staff maintain confidentiality, and will not compete with you
- Taking out patents to protect your unique products
- Registering trade marks to create market recognition for your products
- Leveraging off your patents and trade marks.

Awards

Winner 2002 ACT R&D Award

Winner 2000 Australian Design Mark - Platypus® Needle Guard

Winner 1999 ACT OH&S Overall Outstanding Award - Platypus® Needle Guard

Winner 1998 ACT "Emerging Exporter" Award.

National Finalist 1998 Australian Export Award.

Runner Up 1998/99 Australian Design Award -LeeSpec® Disposable Speculum.

Winner 1997 Australian Design Award - DonorCare® Needle Guard.

Winner 1997 ACT OH&S Prevention Award - DonorCare® Needle Guard.

Who is ITL

Bill Mobbs and Jag Dillon.