IP System: Challenges and Approaches for UCT

Dr Andrew Bailey, IP Manager
Research Contracts & IP Services
Patent Fund

- UCT provided RCIPS with a fund to support patenting activities in 2003
- Prior to that:
  - funded from research projects / departments – challenging!
  - patenting not managed centrally
- Need to have “reserves” – budgeting difficult, patent expenditure erratic
- Budget based on an “event horizon”
- Up to 10 years, before expenses recouped
UCT Annual Patent Expenses
Supporting National Phase Patenting

- 2008 signalled a change where commercial partners sought granted patents
- UCT compelled to maintain national phase patent portfolios

- Preference to partner at PCT stage:
  - insight of commercial partner in terms of filing
  - aligned with their business strategy
  - commercial partner supports national phase patenting

- Delay in raising start-up funding = UCT continuing to maintain spin-off company IP portfolios
Patent Budget

- Prior reserves depleted
- Pressure from national phase applications

- Adopted a number of strategies to:
  - spend prudently
  - commercialise earlier
Stage-Gate Process

Disclosure  Provisional  PCT  National

Technology

IP Protection

Commercialisation
Patenting Process

Provisional patent application

PCT application

International search

International Prelim. Exam

0  12  16  18  28  30/31

PCT Phase

Priority Date

Provisional Phase

International Search Report & Written Opinion

PCT Publication Public Domain

Preliminary Examination Report
UK Route

0
6
-9 mths
12

Preliminary Search Report
Examination Report
UK Route

0 12

National Phase

PCT
Advantages of UK Route

- Early examination to guide Seed investment / future patenting
- Enrich information available for PCT Gate Review
- Cost effective
  - SA Prov (R20k) + PCT (R80k) = R100k
  - UK = R50k
- Can treat it as a usual provisional ("priority founding document")
  - Include new examples, etc. ahead of PCT
  - If specification changed will not reflect for UK application
Advantages of UK Route

- Amend specification to provide basis for claim amendment going into PCT
  - E.g. STI Biomarkers where all prior art related to pregnant women
- Amend deficiencies in claim construction ahead of PCT
- Get second bite at “UK cherry” by going via PCT, Europe and validating in UK
- May obtain an early granted patent
  - Whilst PCT is still in progress, so country selection still open
  - Useful for commercialisation
## Outcomes

<table>
<thead>
<tr>
<th>Case</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>TB Biomarkers</td>
<td>• Unity of invention – only one invention searched</td>
</tr>
<tr>
<td></td>
<td>• Abandoned UK application and continued into PCT</td>
</tr>
<tr>
<td></td>
<td>• Filed in Australia PCT, less objection to unity of invention</td>
</tr>
<tr>
<td></td>
<td>• Suggestion of only doing search, if multiple inventions then pay</td>
</tr>
<tr>
<td></td>
<td>for additional searches. Issue is need examination outcome.</td>
</tr>
<tr>
<td>STI Biomarkers</td>
<td>• Amend specification to overcome prior art (&quot;pregnant women&quot;)</td>
</tr>
<tr>
<td></td>
<td>• Abandoned UK application, will file a PCT</td>
</tr>
<tr>
<td>Hydraulic Pruner</td>
<td>• Poor prior art outcome. 7 X’s</td>
</tr>
<tr>
<td></td>
<td>• Abandoned entirely</td>
</tr>
<tr>
<td>Power Injection</td>
<td>• Good search outcome – all A’s</td>
</tr>
<tr>
<td></td>
<td>• Issues relating to claim construction and “excluded matter” – need</td>
</tr>
<tr>
<td></td>
<td>more implementation steps</td>
</tr>
<tr>
<td></td>
<td>• Likely to include more info for PCT (cannot form part of UK application)</td>
</tr>
</tbody>
</table>
Europe vs USA

Europe: 739.2 million
U.S.: 313.9 million

2.3 X
Europe vs USA

Europe: 739.2 million
U.S.: 313.9 million

2.3 X

Europe Area: 10,180,000 km²
(3,930,000 SQ MI)

USA Area: 9,629,091 km²
(3,717,813 SQ MI)
Pharma Market Size

Source: IMS Health Market Prognoses, March 2010
www.imshealth.com/portal/site/imshealth
Pharma Market Size

Source: IMS Health Market Prognoses, March 2010
www.imshealth.com/portal/site/imshealth

EU5 - France, Germany, Italy, Spain, UK

IMS Market Prognosis, Sept. 2013
Europe vs USA

- Patent expenses
- Europe = 10x more than USA
- EU5 = double USA

- Unitary patent a solution?
Publishing!

Provisional patent application

Provisional Phase

Priority Date

Can disclose publicly after filing
Research Contracts and IP Services

5000 to 10000 compounds

1 to 2 years
- Compound Screening
- Identify and Validate Drug Target

2 years
- Lead Identification
- Lead Optimisation
- Laboratory and animal testing to check safety and efficacy

3 years
- Pre-Clinical Trials
- Phase 1 Clinical Trial

6 to 7 years
- Phase 2 Clinical Trial
- Phase 3 Clinical Trial

0.5 to 2 years
- FDA Review and Approval
- Large-scale Manufacturing

1 FDA APPROVED PRODUCT

Best timeline assuming availability of adequate funding and skilled resources. Not necessarily representative of current SAA situation.
Publishing!

- Senior academics may delay publication
- Generally though patenting early goes with the territory
- Having a commercialisation team is important as well as seed funding to ensure that there is no delay in commercialising new IP
- Early patenting is particularly problematic in the pharmaceutical sector where time to market is long – this can severely limit the revenue potential of a new drug
Dr Richard Gordon, UCT Pharma IP Portfolio Review, NIPMO Funded Project
Pharma Patenting Strategy

- Developing “guidelines” to:
  - Improve awareness of drug discovery steps
  - Encourage outsourcing of key ADMET tests
  - Encourage use of H3-D platform
  - Manage publication & optimise patenting – maximise reward to UCT
Once Off Decision!

PCT Phase → Decision Point for National Phase →

- USA
- South Africa
- Australia
- Europe → Italy
- Germany
Contact RCIPS

Andrew Bailey

Andrew.Bailey@uct.ac.za
+27 (0)21 650 2425

Allan Cormack House
Research Contracts & IP Services
2 Rhodes Ave
Mowbray

www.rcips.uct.ac.za