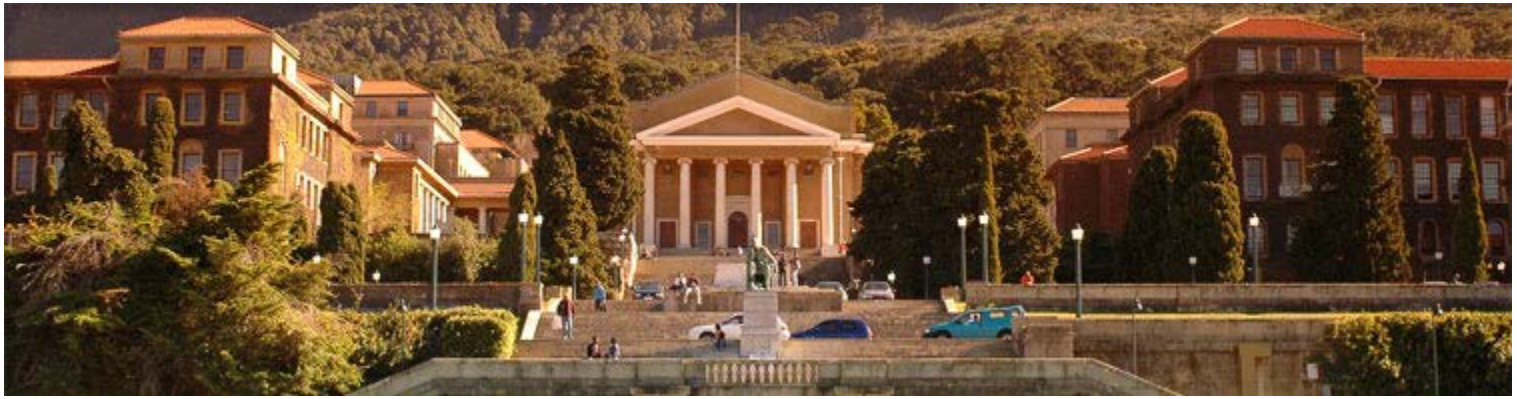
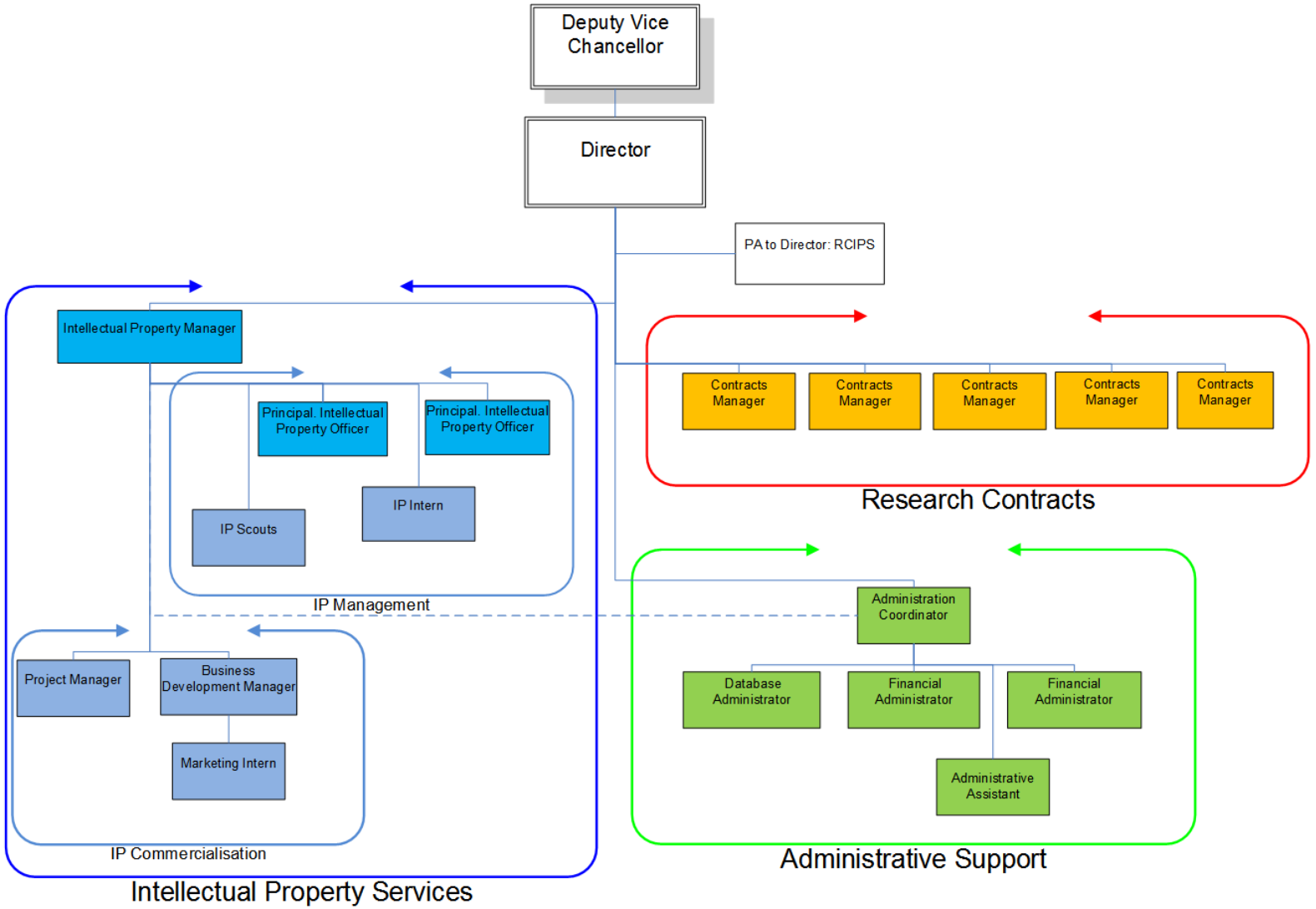
Research Contracts and IP Services

IP System: Challenges and Approaches for UCT

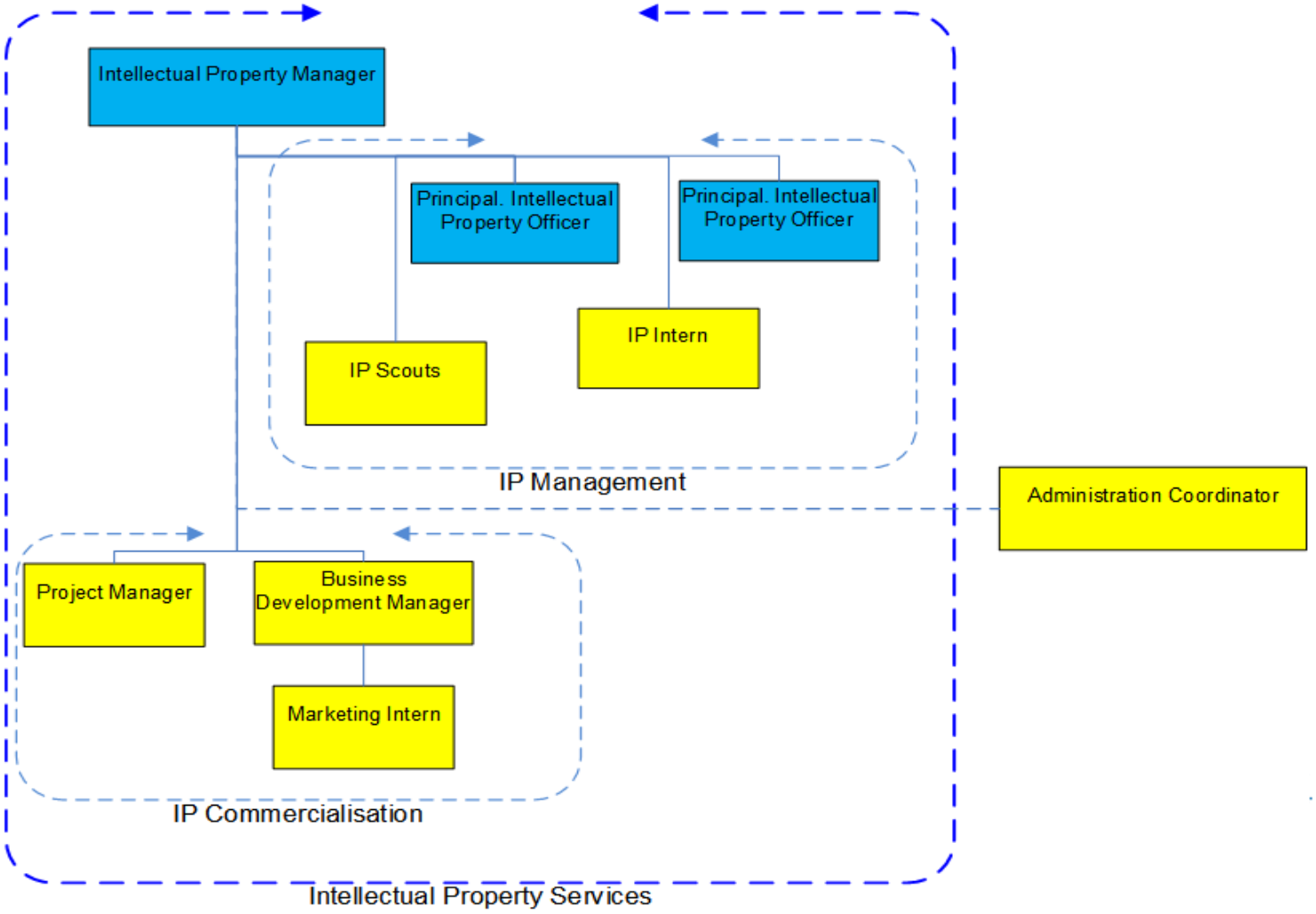


Dr Andrew Bailey, IP Manager
Research Contracts & IP Services

Research Contracts and IP Services



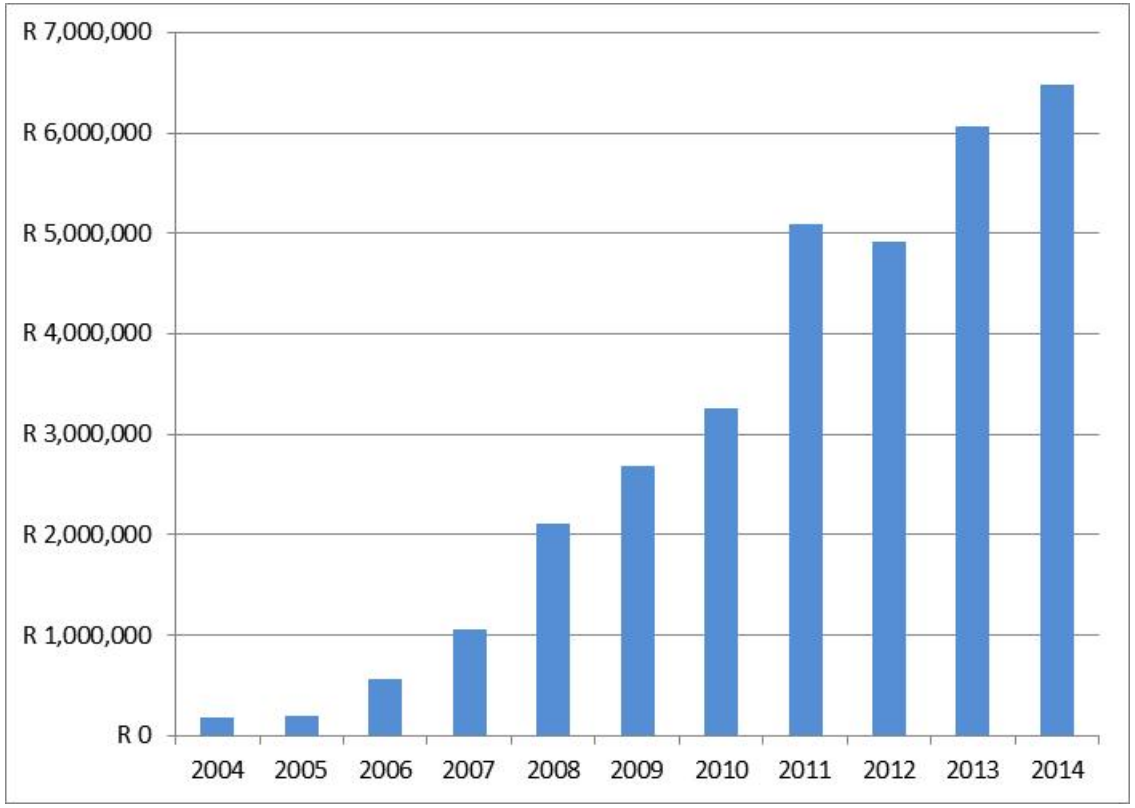
IP Services


Intellectual Property Manager
Principal. Intellectual Property Officer
Principal. Intellectual Property Officer
IP Intern
IP Scouts
IP Management
Administration Coordinator
Project Manager
Business Development Manager
Marketing Intern
IP Commercialisation
Intellectual Property 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

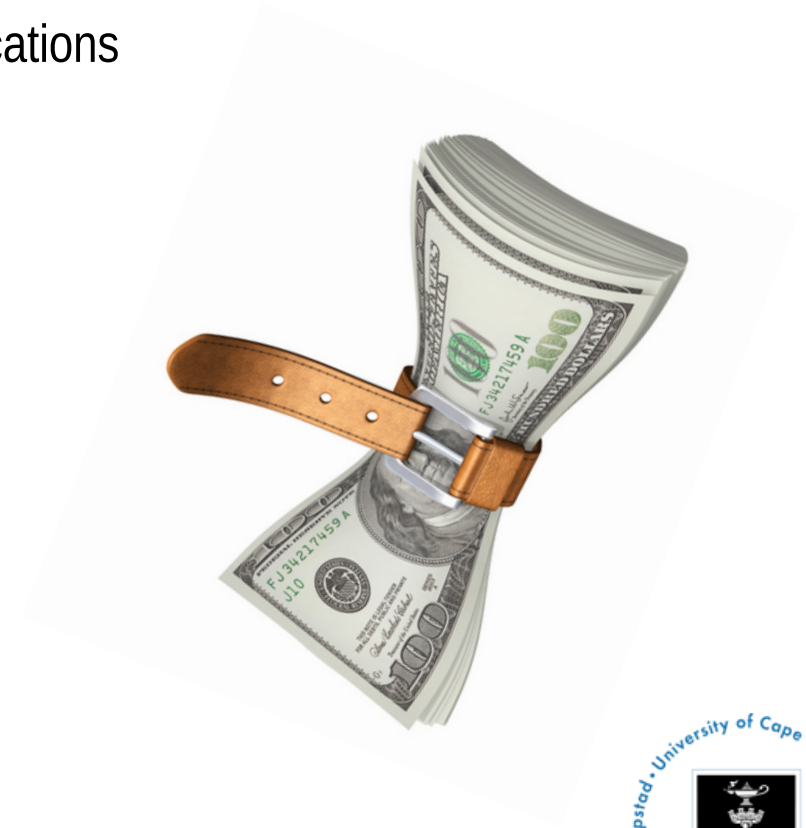
- Preference to partner at PCT stage:
  - insight of commercial partner in terms of filing
  - aligned with their business strategy
  - commercial partner supports national phase patenting

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

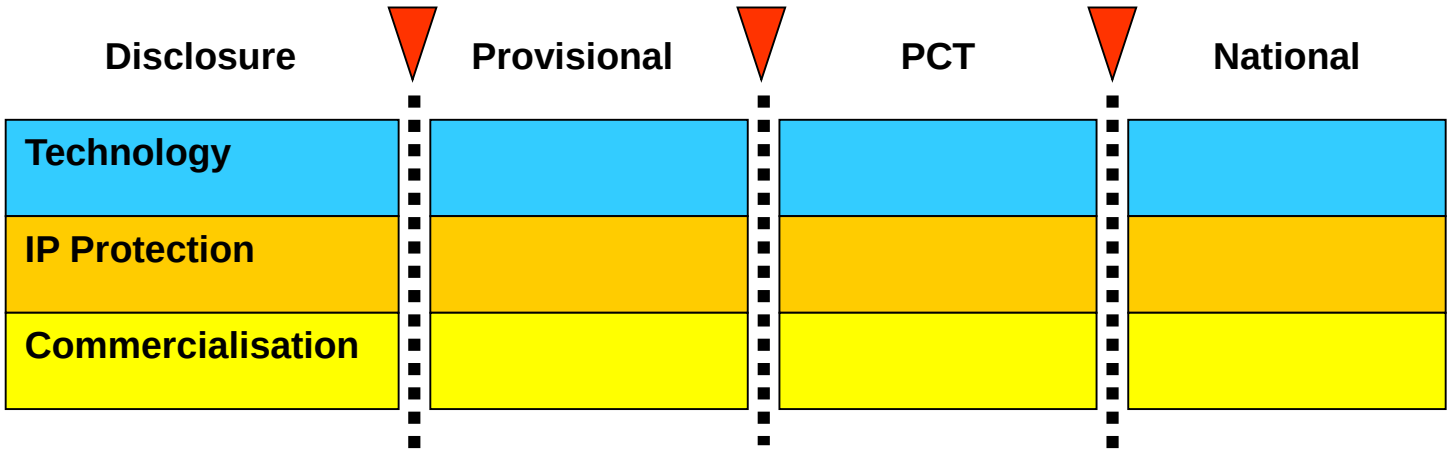
Patent Budget

- Prior reserves depleted
- Pressure from national phase applications

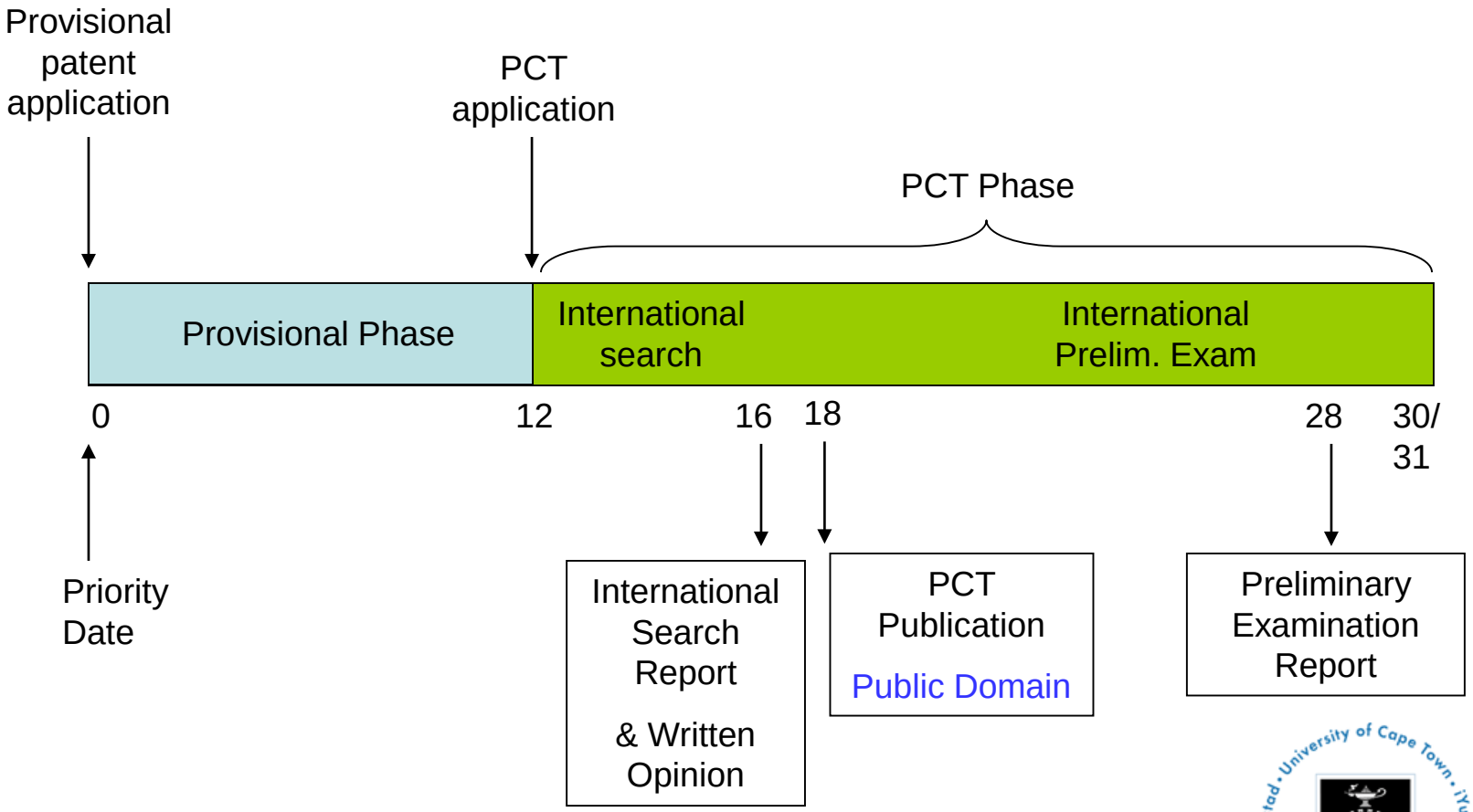
- Adopted a number of strategies to:
  - spend prudently
  - commercialise earlier



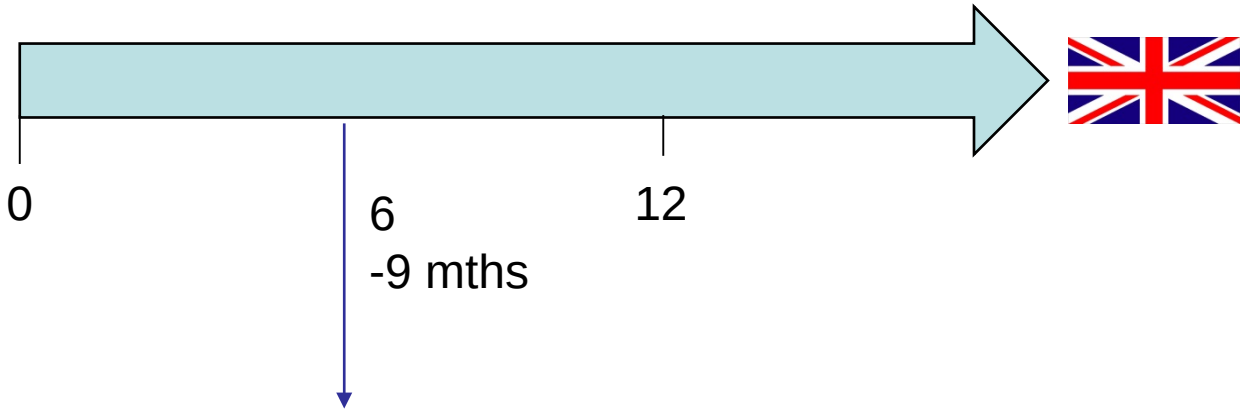
Stage-Gate Process



Patenting Process



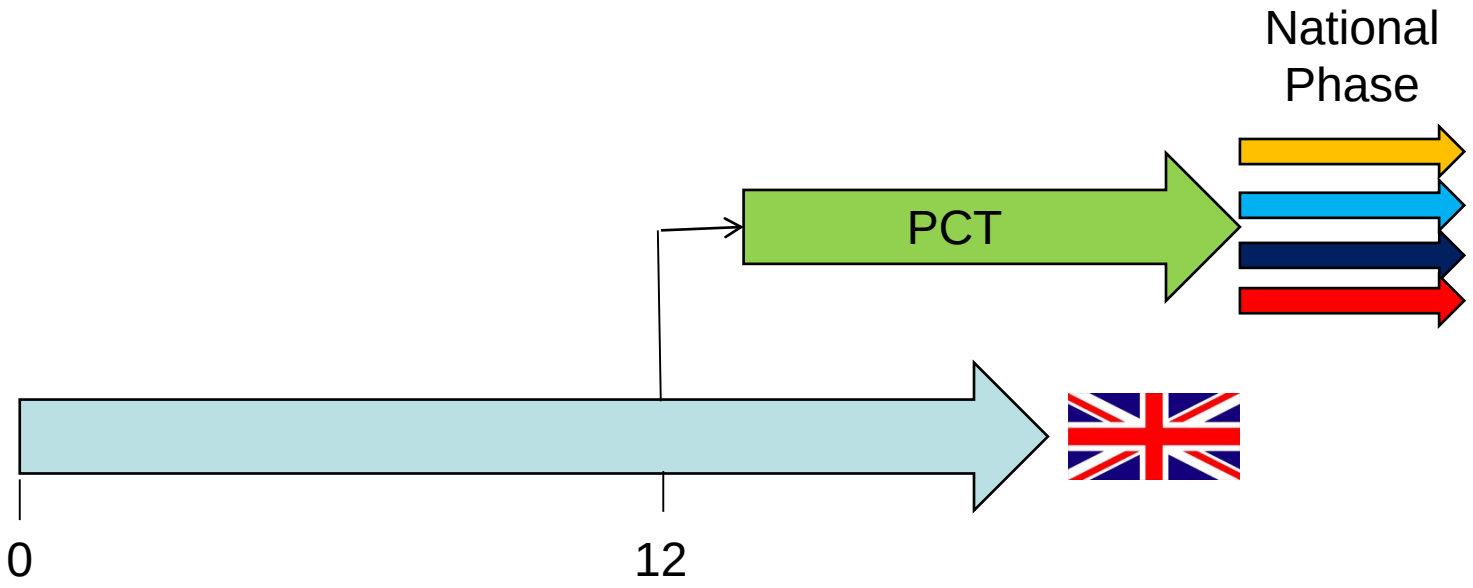
UK Route



Preliminary Search Report

Examination Report

UK Route



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

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

Europe vs USA

Europe vs USA

Europe: 739.2 million
U.S.: 313.9 million

2.3 X

Europe vs USA

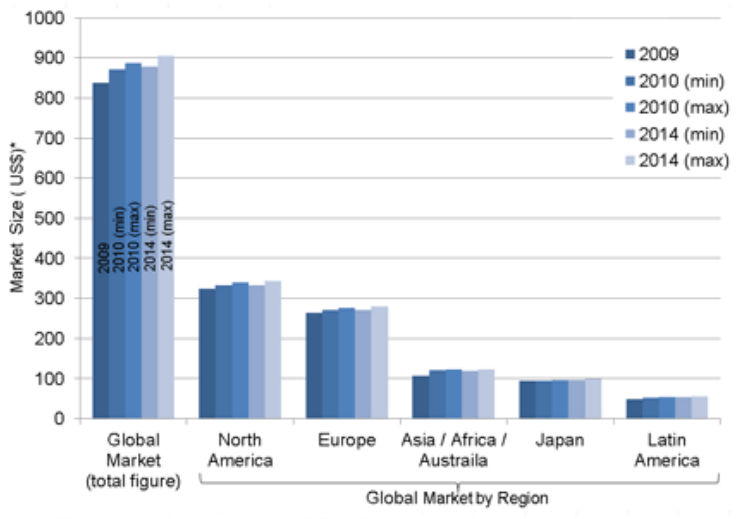
Europe: 739.2 million
U.S.: 313.9 million

2.3 X

Europe Area: 10,180,000 km^2
(3,930,000 SQ MI)

USA Area: 9,629,091 km^2
(3,717,813 SQ MI)

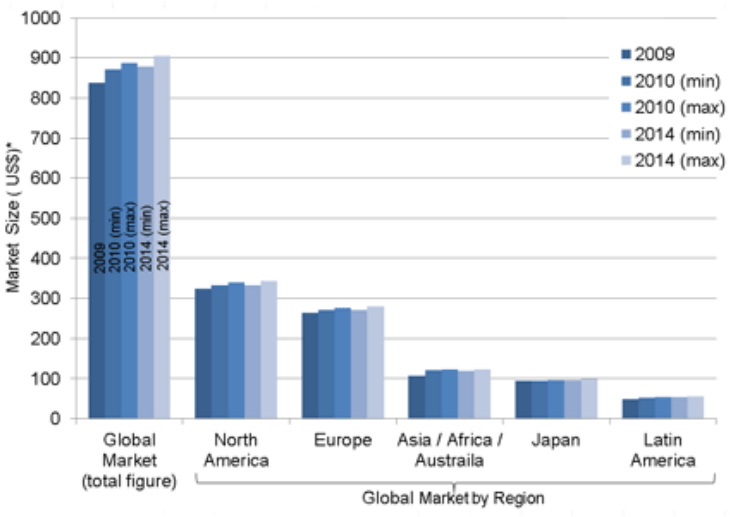
Pharma Market Size



Source: IMS Health Market Prognoses, March 2010

www.imshealth.com/portal/site/imshealth

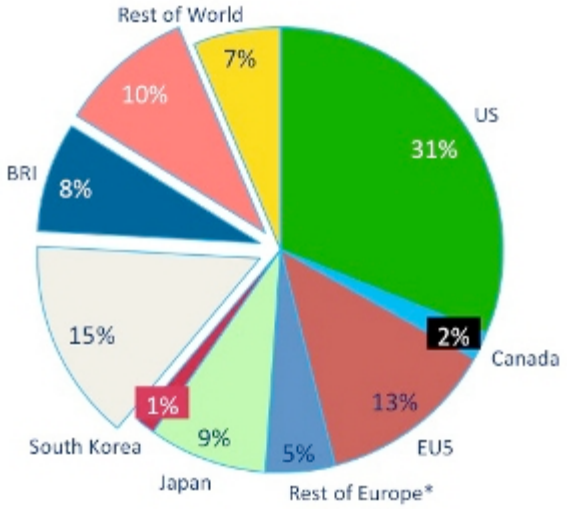
Pharma Market Size



Source: IMS Health Market Prognoses, March 2010

www.imshealth.com/portal/site/imshealth

2017 forecast



IMS Market Prognosis, Sept. 2013

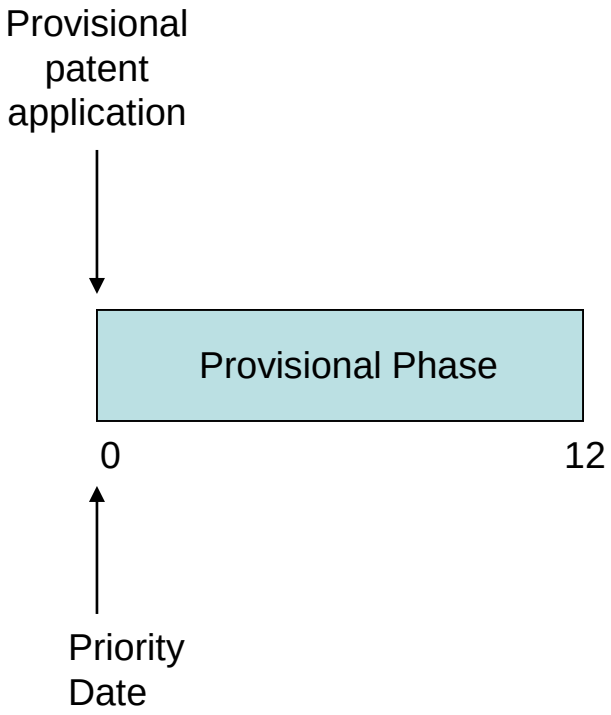
EU5 - France, Germany, Italy, Spain, UK

Europe vs USA

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

- Unitary patent a solution?

Publishing!



Research Contracts and IP Services

5 000 to 10 000 compounds — 250 — 5 — 1 FDA APPROVED PRODUCT

Best timeline assuming availability of adequate funding and skilled resources. Not necessarily representative of current SA situation	1 TO 2 YEARS		2 YEARS	3 YEARS	6 TO 7 YEARS			0.5 TO 2 YEARS	
IDENTIFY DISEASE Scientists and clinicians work on understanding the characteristics of the disease and its causes as the basis for drug discovery.	**IDENTIFY AND VALIDATE DRUG TARGET** Selection of a suitable target for the new drug to act on. Need to validate that it is indeed involved in the disease.	**COMPOUND SCREENING-IDENTIFY HITS** In vitro activity and selectivity is monitored to identify compounds that show promise.	**LEAD IDENTIFICATION** *In vivo* activity & selectivity.	**LEAD OPTIMISATION:** *in vitro* and *in vivo* activity. Physical properties LEAD Selectivity TOXICITY ASSAYS *in vitro + in vivo* absorption, distribution metabolism and excretion Optimised lead or development candidate	**PRE-CLINICAL TRIALS** Laboratory and animal testing to check safety ahead of human trials.	**PHASE 1 CLINICAL TRIAL** Drug is tested on small group (20 to 100) of healthy volunteers. Establish human safety and side effects.	**PHASE 2 CLINICAL TRIAL** Drug is tested on a small group of patients (100 to 500). Short-term side effects, risks and efficacy are assessed.	**PHASE 3 CLINICAL TRIAL** Large group of patients (1 000 to 5 000) are administered the drug to generate statistically significant safety and efficacy data.	**FDA REVIEW AND APPROVAL**	**LARGE-SCALE MANUFACTURING. POST-MARKET SURVEILLANCE.**
IIDMM Groote Schuur Hospital Health Sciences Faculty	IIDMM Dept. Chemistry	IIDMM Dept. Chemistry	Dept. Chemistry IIDMM Division of Pharmacology	IIDMM Division of Pharmacology	IIDMM Division of Pharmacology Dept Medicine UCT Lung Institute	IIDMM Dept. Medicine UCT Lung Institute	IIDMM	Industry partner	Industry partner

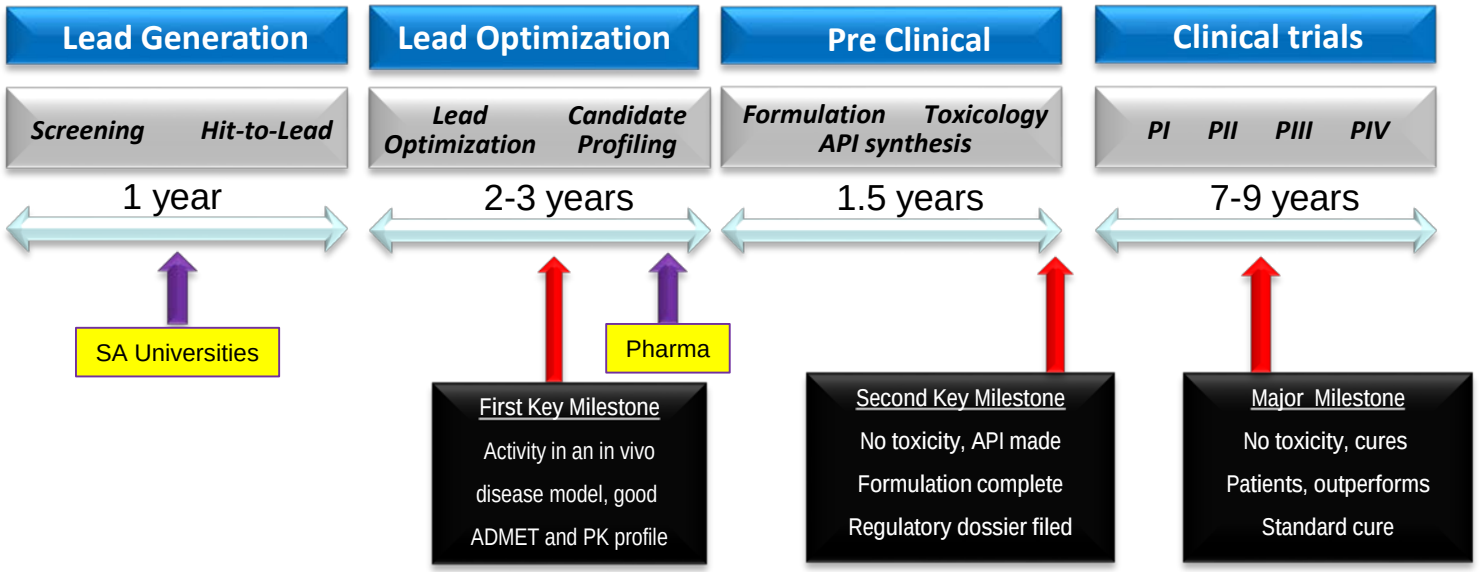
Publishing!

- 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

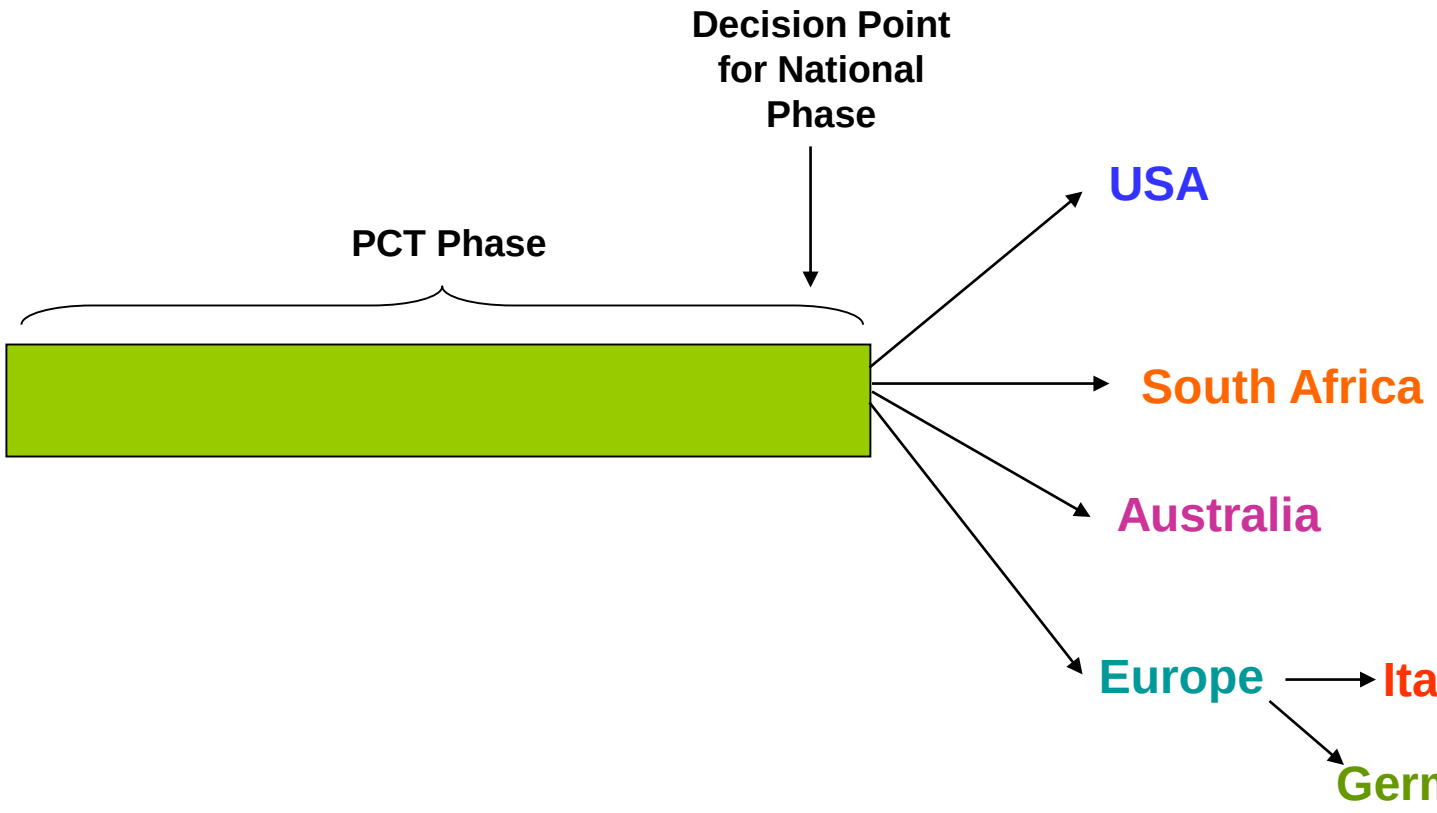
UCT vs Pharma Patenting



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!



Research Contracts and IP Services

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