

# **Challenges & Opportunities in Licensing Health Technologies: The Perspective of a Practitioner from an African Research Organisation**

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# The CSIR at a glance

The CSIR is a science council, classified as a national government business enterprise

In numbers:



1945 - 2018



2 619

Total staff base



1 850

Total in SET base



546

Publication  
equivalents



348

Staff with PhD



<R150 m

Total investment in HCD



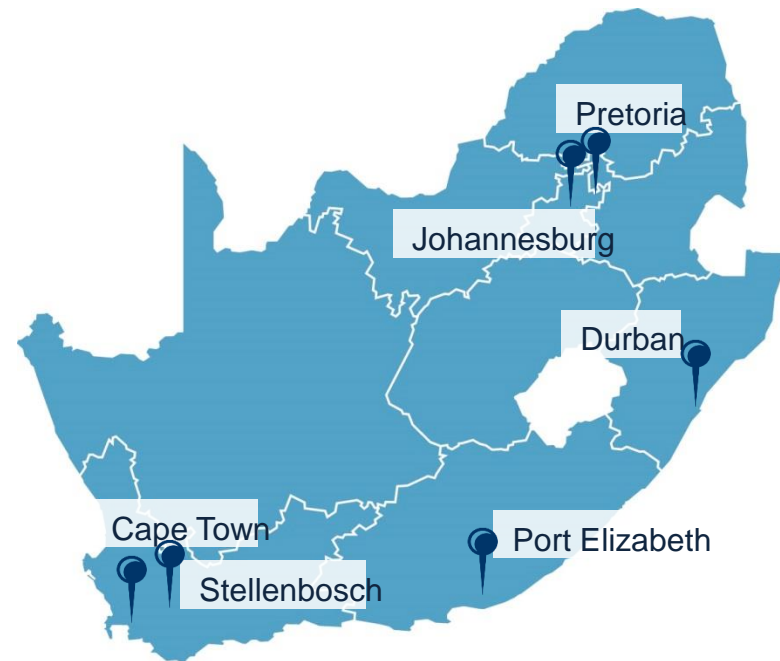
R2.5 bn (~\$180 m)

Total operating income  
(includes parliamentary grant)



R1.8 bn

Contract income



# SA regulatory environment

- IPRs from Publicly Financed R&D Act (2008)
  - ‘SA Bayh-Dole’
    - Borrows heavily from US tech transfer model
  - Requirement for institutions to have a TT function
    - National IP Management Office
      - Support for TTOs (including HR) & patent fee rebate
    - Contains both enabling & prescriptive provisions
      - Conditions for IP ownership in collaborations
      - Conditions for licensing transactions
        - Preferences
        - Approvals required for assignment of IP, exclusive licensing offshore & royalty-free licences
- Public Finance Management Act & SA Reserve Bank Regs
- SA Health Products Regulatory Authority (SAHPRA)
- National Environmental Management Act: Biodiversity
  - Bioprospecting, Access & Benefit-Sharing
- IP Policy

# Building the foundation: Effective R&D

- Carrying out the 'right' R&D
  - Needs-based
  - In order to develop a pipeline of relevant technologies for transfer
  - [Licensing/tech transfer function rarely involved]
- Dedicating necessary resources
  - Accessing large funding available (international)
  - Strong R&D as well as research management capacity required
- Ensuring outputs are appropriately protected and transferred
  - Fit for purpose IP provisions in collaboration & sponsored research agreements
  - Patent strategy
  - Influencing route to market
    - How much reach-through can be justified?

# R&D contracts

- IP terms of R&D contracts can ultimately influence licensing choices
  - Tacitly or explicitly
- IP ownership
  - Understand the needs of each party & unpack accordingly
  - An exclusive licence can give close to full control
  - A non-exclusive royalty-free licence can ensure freedom-to-operate
- Benefit-sharing
- Freedom-to-operate
  - Material transfer agreements
- If terms are unfavourable, weigh up short term benefits against long term costs
  - Bear in mind respective bargaining power

# Academic collaborations

- Equal partners or a more asymmetrical relationship?
  - Who is setting the agenda, conceptualising, funding?
- Joint IP can be challenging to manage
  - Inter-institutional agreements for managing IP
- Cross-border collaborations have to accommodate different regulatory regimes
- Large consortia
  - Tried & tested agreements
  - Difficult to negotiate changes but generally fair
  - Research support capacity needed to ensure eligibility & compliance

# Partnering with the private sector

- Generally want to own/fully control IP
- What background IP is involved?
- Freedom-to-operate (retain R&D licence)
- Publication
- Acknowledgment or future involvement
- Funding of the R&D
  - Benefit-sharing

# Funding organisations

- Public sector
  - Grant funding v loans v investment funding
  - Conditions attached to funding
  - Any return on investment required?
- Charitable organisations & international organisations
  - Some measure of control over the IP to ensure that it can be exploited in advancement of the objectives of the funding – different approaches taken:
    - Requirement to assign rights to consortium lead
    - Requirement to grant agency a non-exclusive royalty-free licence
    - Requirement to own the IP
    - In SA, these all attract the need for regulatory approvals



# Exploring alternative models

- Finding the balance between open & proprietary approaches
- Delinking the cost of R&D from the price of the product
  - WHO health R&D demonstration projects
    - Aimed to close R&D gaps in areas unaddressed due to market failures
    - Funding constraints
- Innovation prizes as an alternative funding mechanism?
- IP pools & clearing houses
- Open source licensing models
- Data sharing via repositories
- Easy access licensing
- Socially responsible licensing

# Socially responsible licensing (SRL)

- IP management strategy and associated business models to attract investment to address situation where the private sector would not otherwise invest in an unmet market need in the developing world
- Way to leverage IP to accelerate solutions for improving access to technologies by populations in need
- Operates in parallel to traditional commercial licensing
- Especially relevant, but not limited, to medical technologies
- Voluntary alternative to compulsory licensing
- Particularly suited to technologies with application in both developed and developing country markets
  - Dual commercialisation strategies can be developed

# Examples of SRL terms

- IP filing strategy
- Market segmentation
  - Different licence terms for developed & developing country markets
  - Undertaking to control pricing in developing countries
  - Differential/tiered pricing – public/private sectors
- Set limits on mark-up – ‘cost-plus’ pricing
- Royalty sacrifice by public research organisation
- Non-assert clauses
- Mandatory sub-licensing
- Walk-in rights (for state or funding agency)
- Tailored performance clauses
  
- But... limited success in practice in trying to incorporate these terms successfully

# TTO guide

## SOCIALLY RESPONSIBLE LICENSING GUIDE FOR TECHNOLOGY TRANSFER OFFICES

Adoption and Implementation of Socially Responsible Licensing Practices

*Co-ordinators: Rabogajane Busang & Rosemary Wolson*



Developed in the  
course of an EU  
Framework  
Programme project on  
Access to  
Pharmaceuticals

# Take home messages

- Critical importance of partnerships to take African health technologies to market
  - Therefore a need to reduce friction in facilitating such partnerships
  - Enabling regulatory environment needed
- Strong R&D (& research support) capacity to develop relevant & necessary outputs & health technology pipeline
- We need to develop creative new models suited to our own respective environments and needs rather than borrowing uncritically from elsewhere
  - Strike the right balance between open & proprietary approaches
  - Calls for participation from all stakeholders
    - PPPs; North-South; South-South
- It's always a negotiation
  - Understand your own & the other party's dealbreakers
  - Be flexible about everything else

***Thank you!***

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