



Intellectual property in health research and commercialization of research results

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Overview of Presentation

- **Introduction**
- **Applicable IPR in R&D Process**
- **Commercialization of R& D Results**
- **Contractual Agreements**



Introduction

- **Concept of IP has assumed enhanced importance**
- **Wealth no longer based on capital investment *per se***
- **Wealth depends on ability to create and brain power**



Introduction (Contd.)

- **Health care –fundamental human rights (Universal Dec. & ICESCR) – Country need for economic growth**
- **Impact of IPR (TRIPS Agreement) on health esp. in developing countries (Doha Declaration)**
- **Need for striking a balance (Health Innovations & access to good health)**



TRIPS Agreement

- The most comprehensive agreement in IP
- Sets minimum standard of protection to be provided by each member
- Lays down general principals applicable to all IPR enforcement procedures
- Incorporates dispute settlement mechanism
- Apply equally to all member countries (LDC given longer time to phase them in)



TRIPS Agreement

- Offers several options such as:
 - Compulsory licensing & government use order
 - Parallel importation & exceptions to rights
- Which could be used for meeting the health challenges of developing countries
- Many of these countries have not used these opportunities
- Those who tried faced some problems including court litigation from MNC (e.g. SA)



Applicable IP in the R&D Process

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Research & Development Process

Research Planning



Research



Research Breakthrough



Development Phase



Marketing

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Phase One: Research Planning

A search of patent documentation is undertaken to:

- ✓ **Identify potential competitors**
- ✓ **Determine the state of the art in the existing research field**
- ✓ **Find niche opportunities**
- ✓ **Avoid duplication of research efforts**
- ✓ **Locate potential or commercial partners**



Phase Two: Research

Confidentiality and the law of trade secrets becomes important to safeguard:

- ✓ Research directions and outcomes of RD project
- ✓ Agreements with research partners
- ✓ Confidentiality within the enterprise or institution
- ✓ Patent law considerations are also essential in relation to:
 - ✓ Publications by those working on the Project
 - ✓ Participation in trade fairs and scientific conferences



Phase Three:

Research Breakthrough

- ✓ Any outcome must be kept confidential at least until patent applications are filed
- ✓ A patent filing strategy needs to be adopted including a possible choice to keep outcome as a trade secret and not pursue patent at all
- ✓ Associated developments may be protected as industrial designs
- ✓ Associated software and documentation might be protected through copyright



Phase Four: Development Phase

- ✓ **An IPR licensing strategy is required**
- ✓ **Trademarks may need to be developed**
- ✓ **An international patent strategy is required, underpinned by a commercial strategy**
- ✓ **Patents may be required on improvements to the original breakthrough**
- ✓ **Cross-licensing or other “freedom to operate” strategies to gain access to overlapping IP owned by others if needed to allow the product to be commercially developed and put on the market**



Phase Five: Marketing Phase

- ✓ **The marketing strategy will need to consider effective strategies for protecting and promoting trade marks and designs**
- ✓ **It is necessary to monitor the market place for possible infringement and enforcement actions**
- ✓ **The portfolio of registered patents, trademarks and designs will need careful management**
- ✓ **There will be the issue of licensing and evaluation of the IP assets from the project**



Commercialization of Research Results

Experiences from R&D and S&T institutions from developed countries has shown that a significant income could be generated through commercialization of R&D results



Stakeholders



✓ Stakeholders in commercialization of innovations and research findings are:

- R&D or S&T institution
- Researcher or creator of IP
- Industry or licensee
- Government or sponsor
- IP management Unit

✓ All have conflicting interests and expectations



An instrument to guide all stakeholders involved in commercialization process

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Issues to be addressed by the policy

- ✓ Disclosure of innovations/inventions- IP product
- ✓ Ownership/ Distribution of income
- ✓ Contract/Sponsored projects/research
- ✓ IP products from joint R&D
- ✓ Rights of invention by research assistant, student & fellows
- ✓ Marketing and choice of licensee
- ✓ Patent processing costs
- ✓ Commercialization of innovations
- ✓ Responsibilities of the creator



Example: The apportionment of IPR derived revenue- SUA

Distribution proportions	Receiving Unit	Remarks on the apportionment share
50%	Inventor(s)/ Creators	Personal income
20%	Department	Development of R&D Capacity
10%	Faculty/ Institute	Development of R&D Capacity
15%	DRPGS	<ul style="list-style-type: none">•Development of R&D Capacity•Administration of IP and Funds
5%	Central Administration	General Administration and Utilities



Institutional IP-Policy

- ✓ Should not be made in isolation from existing policies and frameworks
- ✓ Identify/establish a unit to manage the policy
 - Research and Postgraduate directories
 - R&D Directorates



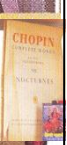
Expected Challenges

- ✓ Lack of national IP-Policy
- ✓ Funding constraints
- ✓ Waiting period
- ✓ Lack of qualified Human Resource in IP



Proposed Approach

- ✓ Institutional IP Policy formulation is a process
- ✓ There is a need to learn from experiences of others
- ✓ Different approaches can be followed



Examples of Institutional IP-Policies

- ✓ -University of Cape Town Web Site, <http://www.uct.ac.za>
- ✓ -Cleveland State University Web Site, <http://www.csuohio.edu/nored/POLICIES/patent.html>
- ✓ -Rice University Research Policy No. 303-90 at <http://www.ruf.rice.edu>
- ✓ -Duke University: Policy on Copyrightable Intellectual Property at <http://www.ors.duke.edu>
- ✓ -Cornell University Patent Policy at <http://www.research.cornell.edu>
- ✓ -



Conclusion & Recommendations

- ✓ IPR are of **increasing significance** to research
- ✓ Commercialization of innovations & research finding involving stakeholders with **conflicting** interest & expectations
- ✓ Necessitates the need for **instrument to guide** the stakeholders i.e the Institutional IP Policy
- ✓ IP Policy creates **conductive environment** for innovations& inventions
- ✓ Recommend that it is high time that each R&D and S&T **must formulate its inst. IP- policy**



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Why Have Agreements?

- ✓ **Allows all parties to know what is happening, under specific conditions, for a certain length of time, at a certain cost, for specific uses, etc.**
- ✓ **Prevents misunderstandings, fights, reserves ownership, etc.**
- ✓ **Provides a base for penalty assessment for not following agreement conditions**



Why Have Agreements?

- ✓ **Protect intellectual properties – especially those not protected by federal governments or where protection is limited**
 - **Retain ownership**
 - **Define how the intellectual property is to be used**
 - **Commercialization restrictions**



Types of Agreements

- ✓ **Confidential Disclosure Agreement**
- ✓ **Material Transfer Agreement**
- ✓ **Research Agreement**
- ✓ **Cooperative/Inter-institutional Agreement**



Common Points

- ✓ **Effective or starting date**
- ✓ **Listing of what government's laws govern the terms of the agreement**
- ✓ **Listing of parties involved**
- ✓ **Signatures by those authorized by organization to sign such documents**



Confidential Disclosure Agreement (CDA)

- ✓ **Importance – allows researchers to exchange information under defined terms**
- ✓ **Terms**
 - **Exceptions**
 - **Term Limitation**
 - **Commercialization Limitation**



Material Transfer Agreement (MTA)

- ✓ **Importance – allows researchers to exchange research materials under defined terms**
- ✓ **Terms**
 - **Parties**
 - **Obligations/restrictions**
 - **Term**
 - **Commercialization restrictions**



Research Agreement

- ✓ **Importance – allows researchers to conduct research under defined terms**
- ✓ **Terms**
 - **Parties**
 - **Project**
 - **Budget**
 - **Ownership**
 - **Publication**
 - **Deliverables**



Cooperative/Inter-institutional Agreement

- ✓ **Importance – allows researchers from two or more institutions to work together on a project under defined intellectual property terms. Usually no financial obligations.**
- ✓ **Terms**
 - **Parties**
 - **Intellectual Property**
 - **Ownership**
 - **Exchange**
 - **Management**



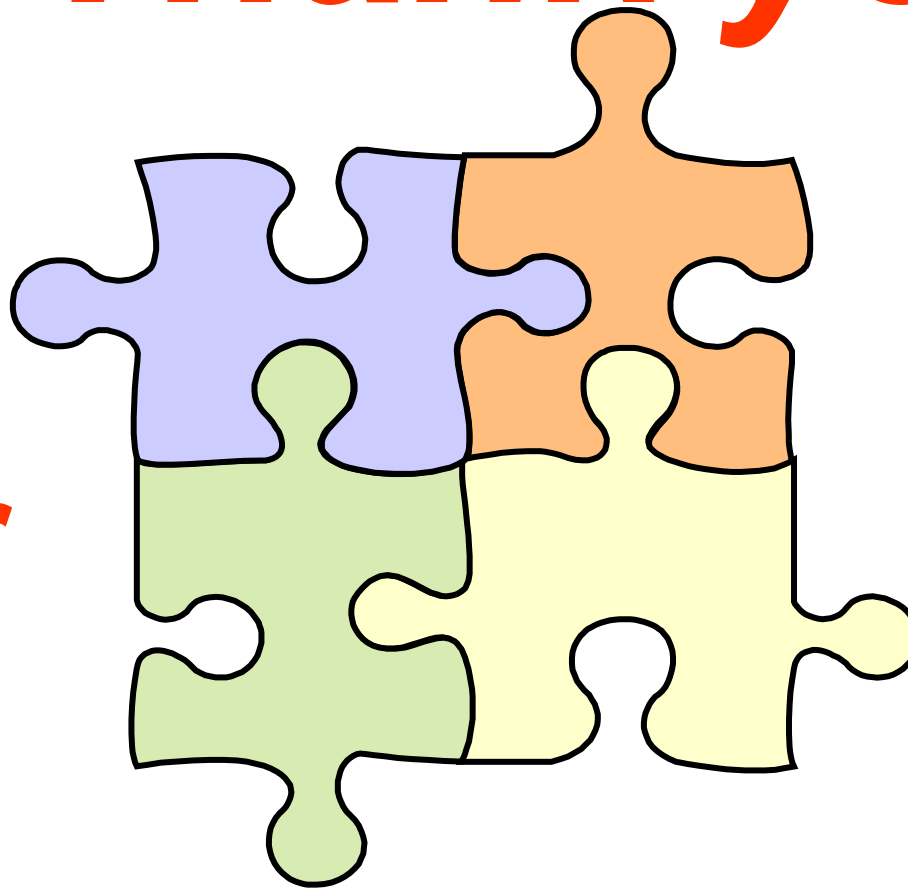
Summary

- ✓ **Agreements are important and very necessary**
- ✓ **Agreements must be read by one skilled in contract review**
- ✓ **Agreements must be negotiated to get proper terms**
- ✓ **Agreements must be signed by authorized representatives**



Thank you

for



your

attention

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