Second WIPO Inter-Regional Meeting on South-South Cooperation on Patents, Trademarks, Geographical Indications, Industrial Designs and Enforcement

Supporting Innovation, Technology Transfer, Patent Information and Knowledge Dissemination. National and Regional Experiences

IP for Development – Indian Approach

Zakir Thomas
Project Director, Open Source Drug Discovery (OSDD) Unit
Council of Scientific & Industrial Research, New Delhi, India
Innovation is Market Driven

Technology: Push and Pull Factors

Most Developing Nations need Technology Push as local demand for technology is not there in all sectors; Need to support Technology Push
Innovation Ecosystem

Components/Requirements

• Market Forces
• Skilled Human Resource
• R&D Infrastructure and capability
• Legal System supporting innovation, including regulatory and IP framework
• Availability of venture capital
• Policy Environment
Converting Valley of Death into a Risk-Opportunity Pool

Handholding Required to help out of the Valley of Death

http://www.erc-assoc.org/best_practices/53-building-innovation-ecosystem
Who is Innovating?

580+ Pharmaceutical Deals were struck in 2011 involving Academic Institutions / Governmental Agencies

Source: Thomson Reuters
Total No. of Laboratories/Institutes: 37
Outreach Centres: 39

CSIR Society formed in 1942

Scientists ~ 4,600
S &T Support ~ 8,000
Total manpower ~ 17,000
PhD Students ~ 3,300
Research Asst ~ 7,000
Annual Budgetary Support ~ 600 Million US $
External Earning ~ 100 Million US $
Utilization of CSIR’s Inventions

Total Patents in force (India) 2350
Total patents in force (abroad) 3250
Total Patent granted (India)* 1507
Total patents granted (abroad) 1282

* Figures for 11th FYP only

<table>
<thead>
<tr>
<th>US Patents Granted (till September 2011)</th>
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<tbody>
<tr>
<td>Organisation</td>
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<tr>
<td>---------------</td>
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<tr>
<td>CSIR</td>
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<tr>
<td>IITs + IISc</td>
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<td>Others</td>
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Source: USPTO

Utilization of CSIR’s Patents in Force: 9%
Worldwide Rate of Patent Utilization: 3-5%
Increasing Technology Depth in MSME Sector

Developing Economies Need to Support MSME sector for Job Creation

Preferred Mode of licensing adopted by CSIR: Non Exclusive transfer of technology without motive of financial returns
CSIR–NML New Lacquer Product Innovation:

- 2-4x less time (15min) to dry. No baking oven needed
- 50x more storage time (2 years) for lacquer formulation
- 25-30% less cost of lacquer
- Low gloss (natural metal) finish rather than high gloss finish (plastic-like)

- Moradabad products now compete in global market
Agartala Bamboo Cluster

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Before Intervention</th>
<th>After Intervention</th>
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<tbody>
<tr>
<td>Minimising use of Jiget</td>
<td>100% Jiget dependency</td>
<td>Minimised the use of Jiget by about 30% through Formulation-A and about 60% through Formulation-B</td>
</tr>
<tr>
<td>Availability of raw material used as adhesive</td>
<td>Litsea glutinosa Tree (Source of Jiget) take 5-6 years to mature)</td>
<td>Aromatic plant used in the improved Formulation-B is a short duration crop of 4-5 months and easily cultivable</td>
</tr>
<tr>
<td>Use of other floral bioresource or aromatic plants</td>
<td>Only coal powder used with Jiget powder in Agartala</td>
<td>Use of bioresources available in Agartala such as Bamboo, saw dust powder and easily cultivable aromatic plants can be used</td>
</tr>
<tr>
<td>Burning time of Agarbattis</td>
<td>25-30 minutes</td>
<td>40-45 minutes</td>
</tr>
</tbody>
</table>

Envisaged Impact of CSIR-CIMAP Technology

- 2.5x increase in production
- Increase in livelihood opportunities
- 13-20% reduction in cost
- 100-120% increase in turnover
- 20-30% increment in monthly family income

Litsea glutinosa - Jiget plant; Bark (in set)  
Floral bioresource  
Aromatic plant seeds  
Technology demonstrated to the women artisans
Innovating where Markets do not Exist

Open Source Drug Discovery
A World Map Based on TB Incidence
TB Drug Discovery

1940
1943
Streptomycin
1952
Isoniazid
1954
Pyrazinamide
1955
Cycloserine
1957
Kanamycin
1960
Ethionamide
1961
Ethambutol
1963
Capreomycin
1963
Rifampicin

1948
PAS

1970
1980
1990
2000
2010

47 Years

Malaria Transmission, 2011

Boundaries of Malaria Transmission By Country

2011
- Transmission
- No transmission
- Planning for elimination or eliminating

Source: Malaria Elimination Initiative (2011) UCSF Global Health Group
Neglected Diseases Drug Discovery: Issue with the Funnel

Issue with the Innovation Model

- Breakthrough Science
- Investment
- Patent Protection
- New product
- Investment
- Market

Virtuous Cycle

- Increased Investment in R & D
- Return on Investment from Market
Issue with the Innovation Model

Virtuous Cycle

Breakthrough Science

Investment

New product

Investment

Market

Increased Investment in R & D

Return on Investment from Market

Patent Protection
Assignment of TB Related Patents

Categories of patent assignees and their share in total patents
- Research Institutes/universities: 33%
- Individuals: 24%
- Companies: 43%

Category of patent assignee and their share in India
- Companies: 39%
- Research Institute/Universities: 33%
- Individuals: 28%
More Patents….but drying pipeline of drugs / diagnostics

Math Just Doesn’t Add Up!
Global TB Market ~ $ 300-400 Mn
Limitations of the Classical Model

Do Patents ‘per se’ spur the components of an Innovation Ecosystem?

How to get medicines at the bedside in the absence of market forces?
First-Line Treatment of TB for Drug-Sensitive TB

- **standardized 6 month short-course chemotherapy requires direct supervision**
- hepatotoxicity and substantial side effects in subsets of treatment populations
- **not compatible with most common antiretroviral therapies (ART) used to treat HIV/AIDS**

Needed: A shorter therapy with novel mechanism of action that are affordable and better manageable

[Figure courtesy: NIH website]
An Innovative Approach to Drug Discovery: A New Paradigm

Innovation Funnel

- Biology/ Genomics
- Target Identification
- Target Validation
- Hit(s)
- Validated/ Quality Lead
- Optimised Candidate Drug
- Clinical Trials
- Registered Drug

Drugs to be available without IP encumbrances; use generic industry business model

High Risk, Innovation Driven Sphere

Strategy-> Open collaboration with best minds from academia/ industry

Process Oriented –

Strategy-> Industry/ CRO’s Participation

Strategy-> Conduct clinical trials in publicly funded institutions
Make the data available to industry
OSDD: Approach to Patents

- Two patent applied molecules in hit to lead phase

- Patent to ensure that:
  - Quality assurance in downstream processes
  - Subsequent innovations remain in open source
  - Affordability: through non exclusive licenses
“When it comes to health, we need to have a balanced view between *health as a right* and *health as a business*”

Prof Samir Brahmachari
Director General, CSIR and
Chief Mentor, OSDD

(Ref: Cell (2008) v.133, pp. 201-203)
Open Source Drug Discovery
A New Paradigm of Innovation for Neglected Diseases

• First Target: Tuberculosis launched in Sept 2008; extended to Malaria in 2012
• A Global Community - More than 7000 members from over 130 countries
• Actively working on all areas of Drug Discovery; several publications
• First time Clinical Trial in India of novel TB drug combinations in collaboration with Global Alliance for Tuberculosis – Protocol developed, trials to start by end 2012

OSDD Innovation Model Recognised Globally...

www.osdd.net
Does Exclusivity have Relevance in the Absence of Market Forces?
Thank You