

IP Auditan imperative

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Does Intellectual Property Bring
in value?

Where are the Intellectual Assets?

Tracking IP Portfolio

Sample Questions:

What does IP Audit involve?

How to create IP Portfolio?

How to create an inventory of IP?

Who owns what?

What is the scope and status of the IPR?

**Is anyone using the intellectual assets in an
unauthorized manner?**

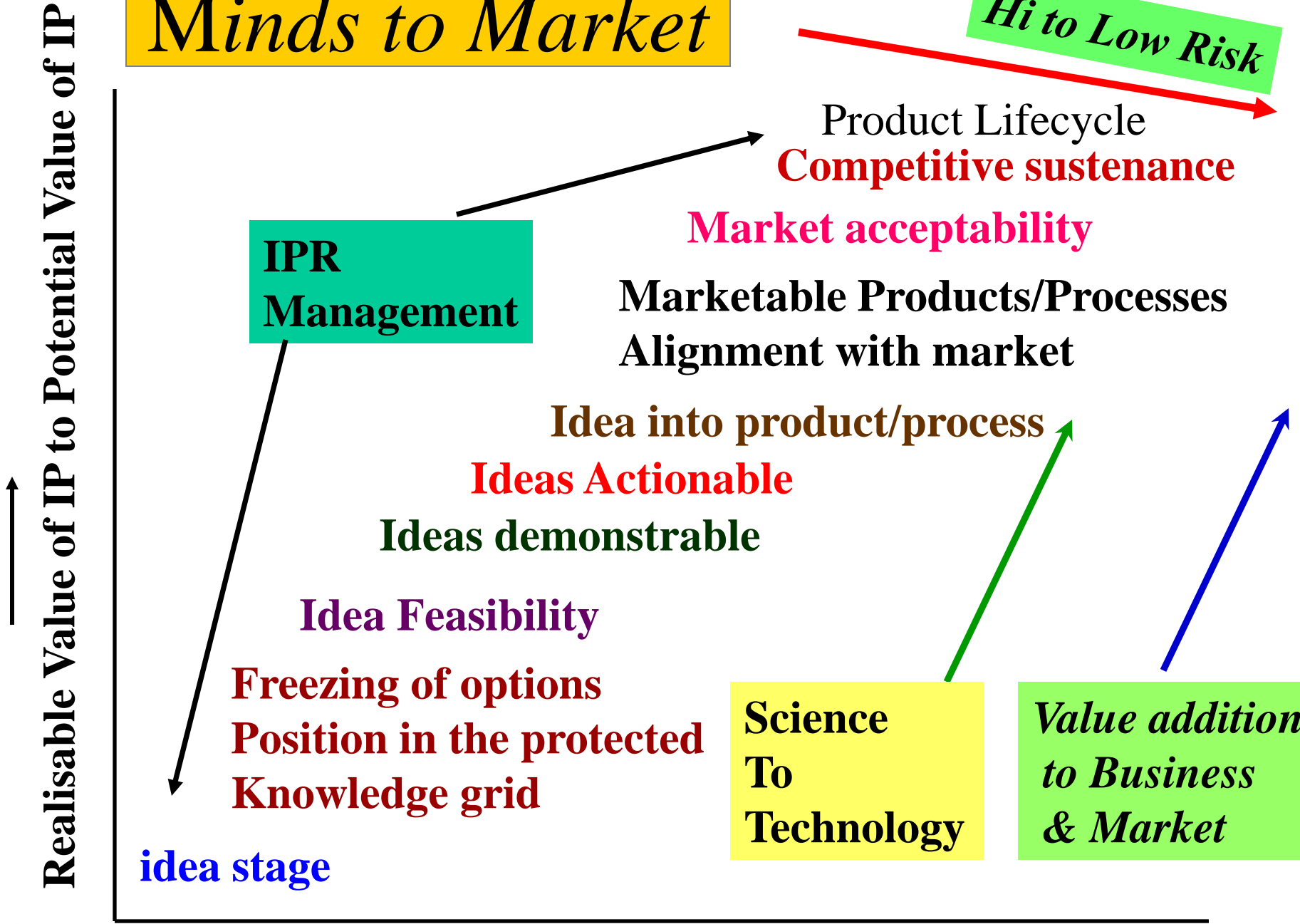
Who should get involved in IP audit?

What does IP Audit Involve?

- Evaluation and Quantification of the value of Intellectual Assets based on its techno-legal strength
- Like all audit, the process provides a means of evaluating the strengths and weaknesses of the asset, the procedures being followed, recommending changes in processes of creating and managing the assets.
- Further it helps to avoid unnecessary litigations
- Working out strategies for enhancing the value of the IP assets.

Minds to Market

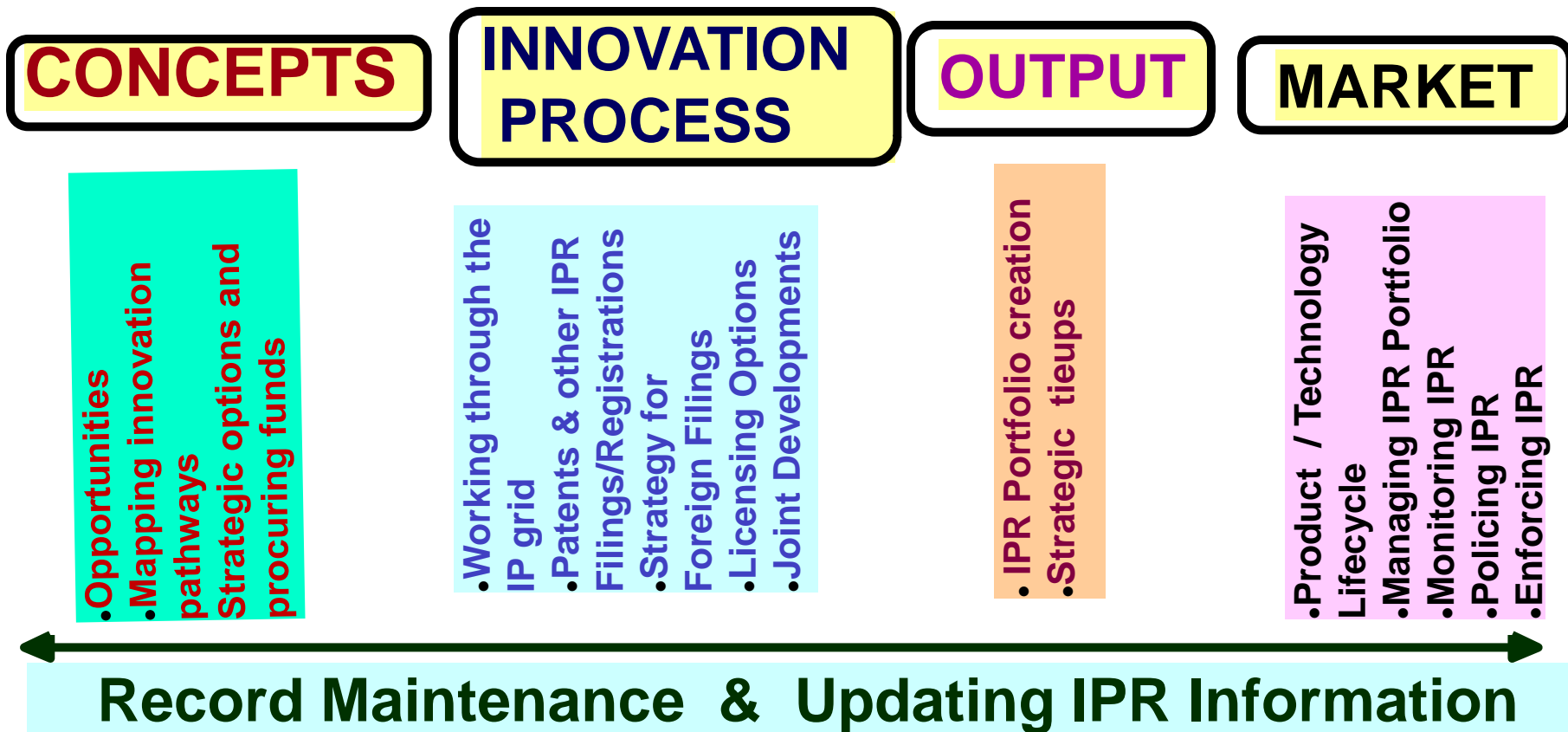
Hi to Low Risk



Internalise Intellectual Property and Strategic Management of IPR

Ref: Intellectual Property Rights.. Unleashing the Knowledge Economy

P. Ganguli (Tata McGraw Hill, New Delhi 2001)



Managing IPR ... A framework

Business Mission

Product and Services Portfolio Strategic Intent

Market and Competitor Positioning

Protection needed

vis-a-vis

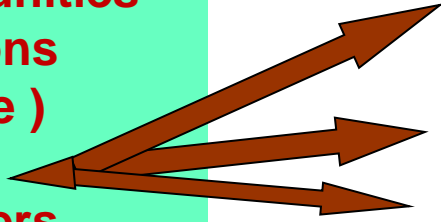
existing Intellectual Assets

Innovation Strategy and IPR plan

Vision-IPR

Managing IPR ... Concept Phase

- Business Opportunities
- Technology Options
(mapping exercise)
- Strategic Options
- Possible Customers



Acquire Externally ?

Generate Internally ?

PART INTERNALLY/EXTERNALLY ?

Use Patent Information

Generate IP Grid Maps

Formulate Business & Innovation plan

Managing IPR

... Innovation Phase

- Working through the IP grid
- Decisions on Patents & other IPR Filings/Registrations

Project Implementation

- Strategy for Foreign Filings
- Litigation Strategy (clearing IPR mine fields)
- Licensing Options
- Joint Developments

**Business driven
Decisions**

*Signing of NDAs/IPR assignments with employees/contractors,
MOUs with possible partners, Trade Secrets,*

milestone payments, royalty and other benefit sharing arrangements

Managing IPR

... Output Phase

- Fit in IPR Portfolio
- Marketing tie-ups

Valuation of the IPR

Evaluate fit
with business strategy
and growth plans

Evaluate Licensing Options

Options for IPR
value extraction

(e.g. venture capital,
business incubators, etc.)

Technology life cycle
analysis

WHO NEEDS AN INTELLECTUAL PROPERTY AUDIT?

- ACQUIRING A TECHNOLOGY / MANUFACTURING OR SERVICE ORGANISATION
- WHAT TO DO AT CRITICAL JUNCTURE OF A PRODUCT LIFECYCLE
- PURCHASING A COMPANY PRIMARILY TO GET RIGHTS TO ITS TECHNOLOGY
- PURCHASING / LICENSING / DISTRIBUTION RIGHTS
- LICENSING TO MAKE, USE, OR SELL A PRODUCT OR PROCESS.
- PURCHASING RIGHTS TO A “UNDER DEVELOPMENT PRODUCT”
- ASSESSING FREEDOM TO OPERATE
- ASSESSING POSSIBILITIES OF INFRINGEMENT BY OTHERS

WHO NEEDS AN INTELLECTUAL PROPERTY AUDIT?

- SETTING UP JVs,
PLANNING M&A
- STRATEGISING FOR IPOs
- INTERACTING WITH INVESTORS, FINANCIAL INSTITUTIONS, BANKS ETC.
- DESIGNING COLATERALS
- TAX PLANNING TO DERIVE THE MAXIMUM BENEFITS FROM STATE / FEDERAL LAWS
- ASSESSING MANAGEMENT OF ORGANISATIONAL TRADE SECRETS
- MANAGING CONTRACTS INVOLVING EMPLOYEES, SUPPLIERS, FUNDING COLLABOTATIVE RESEARCH / JOINT DEVELOPMENT S
- OUTSOURCING R&D, MANUFACTURING

WHO NEEDS AN INTELLECTUAL PROPERTY AUDIT?

- LICENSING IP ASSETS TO OTHERS WITH INDEMNITIES FACING POSSIBLE LITIGATION INVOLVING IP
- EXPERIENCING MARKET SHARE EROSION FROM KNOCKOFFS OR PIRACY.
- SELLING A MANUFACTURING OR SERVICE ORGANISATION

- SELLING IP ASSETS IN WHICH ONE IS A PARTY TO TO :
 AMBIGUOUS LICENSING
 MANAGING IP OF SUBSIDIARIES OR AFFILIATES
- IP INSURANCE
- IS THE WEBSITE OF THE COMPANY BEING MANAGED PROPERLY?

Audit Process

- Getting the appropriate team in place
 - Information gathering on the assets...background research, data gathering, etc
 - Consolidation of Ownerships also evaluate packaging of the products?
 - Valuation
 - Assessing Infringement of own and 3P's IPs
- Evaluating trade secrets
 - Personnel and contractual issues, including NDAs
 - Policy matters on intellectual assets prior and post any mergers, acquisitions, JVs, etc.
 - Assignment /Transfer of key rights
 - Portfolio pruning
 - Educating the stakeholders

Example of a Small Indian
Pharmaceutical Company which
gained enormously from early IP
audit Process as part of the
Enterprise IP Management System

AUDIT of R&D and Patenting Strategy

- Selecting a drug (substance), for which the patent has or is near expiry in a set of countries
- Conduct search on patents that use this drug in formulations
- Design non-infringing and patentable strategy for new formulations
- File patents for the developed new formulations
- Ensure Bioequivalence / bioavailability of the new formulations
- Prepare complete dossier for Regulatory Submission
- Offer the developed bioequivalent / bio-available patented products to innovator companies who either have the patented drug and/or original formulations for their brand extensions
- Assign or license the patent and the technology to innovator companies
- Negotiate manufacturing rights for the Company's assigned or licensed formulation from the innovator company.

A Business Synergy

Create a mutually win-win situation for both the companies

The company commercially benefits from its developments through licensing and technology transfer deal

Enhancement of company image as a technology developer/transferor/ reliable manufacturer

The Innovator Company Benefits as acquiring the patents allowing them to create brand extensions and retaining their market leadership even after their own patents have expired

The Company's R&D, Patenting and Business Strategy

- One of the patents has been assigned to A Multinational Pharmaceutical Company. The deal also ensures that the company becomes a contract manufacturer for the Multinational; for two formulations covered by the Company's patent.
- The business deal between the two companies is such that the Multinational has allowed The Company to commercialise the other formulations covered in the Company's patent without any further involvement of the Multinational Company.
- The Company has also licensed two other products to another company for countries other than India. The company enjoys the manufacturing rights for these products in India.

"The technology transfer agreement with The Company enabled the Multinational Company to introduce their Products with Brand Extensions in India to give doctors and patients access to top-quality combination products with indigenously developed patented technology of The company. This widened their portfolio of drugs to manage Type 2 diabetes at various disease progression points .