Workshop Cum Retreat on IP Management and Public Private Partnership

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Licensing of IPR

an Indian experience – CSIR

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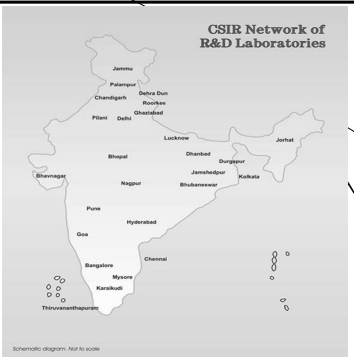
CSIR, India

- **The largest network of publicly funded Research Labs in the India having 38 labs/institutes**
- **19000 highly qualified Scientists, Engineers and Auxiliary staff**
- **Annual Budget USD 260 million**
- **R&D in Aerospace, Biological Sciences, Chemicals, Pharmaceuticals, Drugs, Earth Resources, Food, construction, minerals, metals, environment, leather, information products etc**

CSIR Network of R&D Laboratories



CSIR Mission

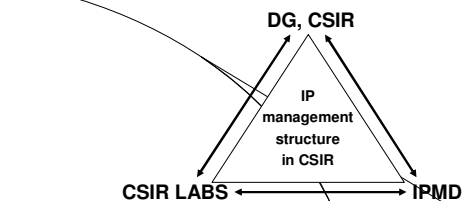
"To provide scientific industrial R&D that maximizes the economic, environmental & societal benefits for the people of India"

Serve the Nation

IP Management in CSIR - Genesis

- **Patenting activity in CSIR - instituted since its very inception and looked after by its Patent Cell at CSIR HQ. (filings as and when scientists desired to protect)**
- **Enactment of Patents Act, 1970 - the Patent Cell upgraded to the Patents Unit (sporadic filings and virtually no protection to drug, pharma, agrochemicals, food because of shorter term),.**
- **India joins WTO in 1995 – the Patents Unit upgraded as a Division named Intellectual Property Management Division (IPMD) in 1995 (boost in patenting of drug, pharma and biologicals)**

IP Management Structure in CSIR



Meeting post WTO challenges

- **To meet the challenges under new IP regime, CSIR announced its IP Policy in 1996 which envisaged:**

  "The maximization of the benefits to CSIR from its intellectual property by stimulating higher levels of innovation through a judicious system of rewards, ensuring timely and effective legal protection for its IP and leveraging and forging strategies alliances for enhancing the value of its IP."

- **CSIR sets up its own targets of developing a portfolio of 1000 Indian and 500 Foreign patents by 2001.**

Meeting post WTO challenges

Goals of the IP Policy

- stimulate and encourage increased creativity and innovation in CSIR to gain economic advantage;
- develop skills amongst the scientists to understand, interpret and analyze the techno-legal and business information contained in patents and other IP documents;
- use the information acquired from analysis of IP documents to direct and mount strategic R&D programmes;
- establish a globally acceptable system of recording and documentation of experimental results and data;
- evolve appropriate systems to capture and assess the intellectual property generated in the CSIR system;
- provide the highest level of professional techno-legal services for securing and protecting the IP generated;
- manage the portfolio of IP as a business activity;
- manipu1ate the patent portfolio, defensively / and aggressively, to forge strategic alliances / international S&T collaborations, to gain business advantage / and ward of competition;

Capacity Building (1995-2005)

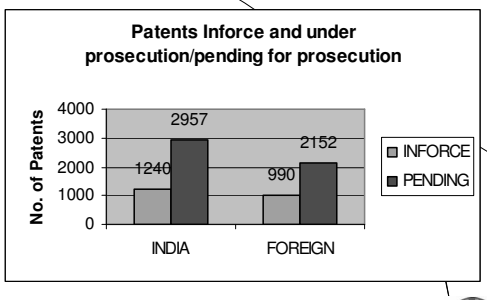
- IP Management
- Information & Documentation
- Patent Search & Analysis
- Techno-Legal Drafting
- Patent Litigation
- Licensing, Valuation and negotiating IP licensing deals

Patent Portfolio Development

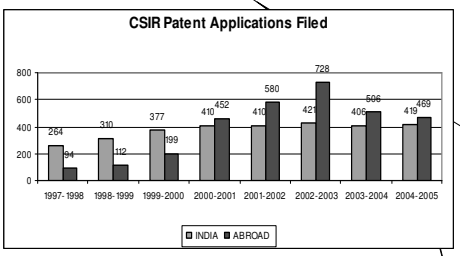
- Expansion of Patent Coverage (Improvement Patents)
- Protection of New Uses/Combinations
- Protection of Plant Varieties/Software
- Creation of Buffer Zone Surrounding Patents

LICENSABLE IP

Current Status of CSIR's IP



CSIR Patent filing



Top PCT applicants in 2002

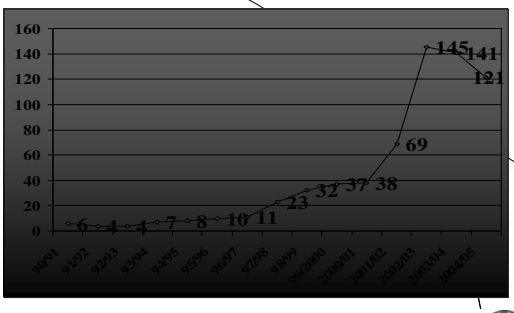
Rank	Applicant	Country	No
1	**Council of Scientific & Industrial Research**	**India**	**186**
2	Samsung Electronic Co.	Rep of Korea	184
3	Biowindow Gene Development Inc	China	136
4	LG electronics Inc	China	125
5	Huawaei Technologies Co.	China	84
6	Ranbaxy Laboratories Ltd.	India	56
7	LG Chem Ltd.	Rep of Korea	47
8	SAE Magnetics (H.K.) Ltd.	China	31
9	The National University of Singapore	Singapore	28
10	Philips Electronics Singapore PTE Ltd.	Singapore	24

Top PCT applicants in 2003

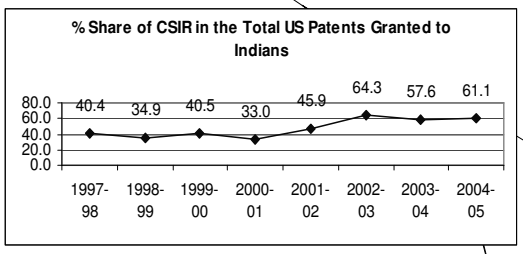
Position	Organisation
1	LG Electronics (Republic of Korea)
2	Samsung Electronics Co. Ltd. (Republic of Korea)
3	Council of Scientific and Industrial Research (CSIR) (India)

*CSIR filed 213 PCT applications in 2003

US patents granted to CSIR



% Share of CSIR in the total US Patents granted to Resident Indians



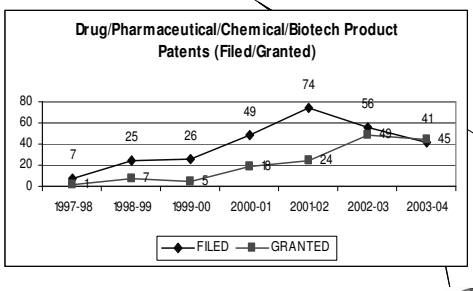
LICENSABLE IP - Some key portfolios

- **Bio-enhancers**
- **Herbal Formulations**
  - **anti-diabetic**
  - **anti-oxidants**
  - **Hepatoprotective**
  - **Immunomodulators**
  - **Weight Reduction**
- **Standardization of herbal products**
- **Anti-malarials and anti-cancer compounds and formulations**
- **Food products and processes**

LICENSABLE IP - Some key portfolios

- Bio-informatics Products
- Leather
- Optical Fibre
- Drugs & Pharmaceuticals
- Nanotechnology
- Polymers
- chemicals

LICENSABLE IP - CSIR Patents on Drugs/Pharmaceuticals/Chemicals/ Biotechnology



Licensable IP - Herbal Medicine Patents (Source: Nature Biotech)

Herbal Medicine Patents — Top 5 Organisations

ASSIGNEE	US Patent Grant (1976-2003)
Council of Scientific and Industrial Research	33**
The Procter & Gamble Company	30
Societe LOreal S.A.	23
Indena S.p.A.	16
The Bio Balance Corporation	12

* Grant Status upto Dec. 2003 as updated on 30-01-2004.

** Patents Granted during 1998-2003

Licensable IP - Copyright

Year	Software	Others
2000-2001	20	11
2001-2002	36	13
2002-2003	31	05
2003-2004	14	02
2004-2005	42	13
2005-2006*	08	09
TOTAL	**151**	**53**

IP Ownership & Valorisation Models in CSIR

Ownership of IP

- CSIR Employees/Visiting Scientists
- Assignment of rights to CSIR

Copyrights

Copyrights in respect of papers/books with author

Copyrights in Software

Stand transferred to CSIR

Government funded/Collaborative/Sponsored Research/International Agreements

- Govt. funded projects: Joint Ownership
- Collaborative Research: Joint sharing of ownership on mutually agreed terms and based on contribution
- Sponsored Research: IP Rights generally with CSIR (negotiable)
- IP in International Agreements: As per MOUs

Use, Distribution and Ownership of Biological Materials

- Material Transfer Agreements (MTAs)

Licensing of IP

- Direct Licensing by the Laboratory
- Licensing of Intellectual Property through TTAs / Business Consultants / Attorneys / Foreign Licensing Firms
- Through NRDC

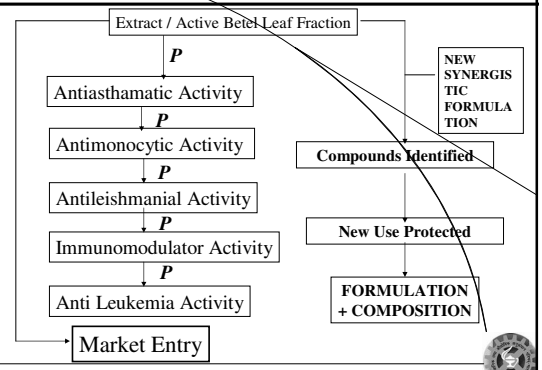
Royalty Distribution

Share of	Monies realized from licensing	
	Through NRDC	Direct by Laboratory
NRDC	30%	-
CSIR (Lab)	30%	60%
Investigators	40%	40%

Models Used for valorization of IP in CSIR – Some Examples

Model Used – bringing product to the market using a small player

Betel Leaf Extract



Creating a Market share in a Established Market and Attracting Large Players

Success Stories in Licensing - I

- Increasing No. of people suffering from heart diseases worldwide and specially in India
- Cause of death – development of a blood clot causing vascular blockage
- Prevention by timely intravenous administration of a thrombolytic agent
- Non availability of affordable thrombolytic agent within six hours of the onset of heart attack
- Drugs commonly used are tissue plasminogen activator, urokinase and streptokinase
- Market demand for thrombolytics Rs. 1 bn
- Streptokinase - 80% of the demand
- Growth in demand - 20% annualy

Success Stories in Licensing - I

- IMTECH developed first indigenous clot buster drug 'STPase' and it was launched in market in 2000 through Cadila Pharma
- IMPACT – crash down of the price from Rs. 3,500 to Rs. 2,000 per dose
- Milestone payments based on the demonstration of the technology i.e 98% purity at 20/100 L scales
- Royalties started from the date of commercial production

Success Stories in Licensing - I

- Further R&D work by the lab for the production of recombinant natural type SK at a level nearly 10 times of natural SK
- The product is licensed and regulatory testing for rDNA based theraupatics has been completed and this drug is likely to be available at most affordable cost.
- Licensing model - milestone payments/royalties

Model Used: Licesning & R&D Co-operation -Licensing to the Largest Global Player and Entering into R&D Collaboration

Success Stories in Licensing - II

- NCL-GE Alliance – originated in 1993.
- GE supporting the R&D at NCL
- Alliance operating for over 9 years successfully and emerged as a paradigm in "relationship" management in R&D.
- Cash flow to NCL from GE of around USD 8.5 m over the period 1994-1995 to 2003-2004
- Exposure to and training of NCL scientists to world class R&D management practices.

Success Stories in Licensing - II

- Building up of world class facilities and resources in NCL
- Attracting and hiring of talented young scientists
- New contract research opportunities with multinational companies
- Diffusion of ideas and generic methods developed to Indian industries
- Half a dozen patents assigned to GE
- CSIR owns several patents based on generic ideas developed while interacting with GE having relevance to systems other than polycarbonates

Success Stories in Licensing - II

- Ushering into NCL the understanding, importance and culture of IPR.
- Spin off: THPE [1,1',1"-Tris(4'-hydroxyphenyl) ethane] is a branching agent used in the synthesis of high grade polycarbonates with properties of high transparency, good mechanical and high parison strength.
- Hoechst Celanese USA, was the only supplier of THPE to the global market. In 1994, NCL initiated a program, funded by GE aimed at developing a proprietary process for THPE.

Success Stories in Licensing - II

- Patents were filed in India and abroad
- Excel has exported THPE valued at around Rs. 30 Crore over the three year period 2001-03
- NCL has received US $ 50,000 as license fee and royalty payment of around US $ 1,00,000.
- NCL's endeavour has led to an Indian firm challenging and breaking global monopoly of a single supplier.

Model Used : Aiming earnings and societal benefits - licensing to a Multinational but still generating rural employment

Success Stories in Licensing - III

United States Patent 6,893,479 (CSMCRI)

Integrated method for production of carrageenan and liquid fertilizer from fresh seaweeds

"An integrated method is developed to utilize to a maximum extent the fresh biomass of seaweeds such as *Kappaphycus alvarezii* that can be crushed to release sap and where the sap is useful as a potent ***liquid fertilizer*** after suitable treatment with additives and dilution while the residue is a superior raw material for extraction of κ-carrageenan, thereby enhancing the value of the seaweed. Other advantages of the invention include a reduced drying time and drying area to obtain the raw material for κ-carrageenan production in dry and storable form, a reduced cost of transporting and storing this raw material because of its lesser bulk, easier handling due to its free flowing granular nature, and its direct use for gel preparation in certain applications"

Success Stories in Licensing - III

- CSIR licenses Sea Weed Technology to Pepsico
- A plant growth harmone and regulator is derived from fresh Sea Weed grown along the shoreline.
- Liquid Sea Weed Fertilizer increases yields from same seed by 10% for wheat, 30% for peddy, 20-30% for fruits and vegetables to 35% for corn and chana, BT cotton 20%, Banana for 19%.
- Patent application fined in India and abroad

Success Stories in Licensing - III

- Trials in Punjab, Andhra Pradesh and Gujarat.
- Realizing the employment generation potential of aqua-agriculture, DBT, ICAR other government deptts. are now pushing sea weed cultivation as a promising money spinner for rural population
- **Social Impact:** Hundreds of women along the shoreline can look forward to earning more than Rs. 12,000 a month as pepsi suppliers.

Different Models at different stage of IP Development – from Plant Varieties to New Molecules – achieving manifold benefits

Success Stories in Licensing - IV

- Mint oil is used mainly for producing menthol and the by-product dementholised oil (DMO) also finds uses in pharmaceutical and cosmetic industry.
- Menthol has a cooling, refreshing aroma and antiseptic properties.
- The current world-wide consumption of natural and synthetic *l*-menthol in the cosmeticeutical and cigarette industries is estimated at about 15,000 and 3,000 metric tons, respectively.

Success Stories in Licensing - IV

- About 15 years ago bulk of l-menthol rich essential oil of M. arvensis for international use came from Brazil and China in the order.
- China and India became the main exporters.
- In the last few years India has come to occupy 1st position in the trade of M. arvensis essential oil and its products.

Success Stories in Licensing - IV

Social Impact:

Estimated area and production of menthol mint during 1994-2002

Year	Area (ha)	Production of oil (t)
1994	45000	5000
1996	120000	9000
1998	133000	12000
2000	150000	14000
2002	150000	14000

Employment Generation
Enhancement in rural earning

Success Stories in Licensing - IV

- A new and distinct variety **"Himalaya"** of *Mentha arvensis,* (US Patent No. PP10,935) has been developed by CIMAP
- characterized by its higher yield of oil which is rich in menthol; improved regeneration potential; tolerance to rust, alternaria leaf blight, corynespora leaf spot, and powdery mildew; vigorous growth; deep green broad thick leaves; and pinkish white flowers.

Success Stories in Licensing - IV

- CIMAP developed another novel mint plant **"Kosi"** (US Patent No. PP12,426)
- Characterized by its high biomass and high oil yield with synchronous branching giving globular shape to the canopy for equal distribution of sunlight to the lower leaves

Success Stories in Licensing - IV

- Another novel high menthol producing plant **"Saksham"** (US Patent No. PP13,279) developed by CMIAP obtained through metabolic engineering, a unique method of screening of the somaclones in poison agar medium containing toxic level of menthol.
- Tolerant to high concentration of menthol in cultures and hence possesses property of accumulating more menthol per unit leaf mass

Success Stories in Licensing - IV

- A new and distinct interspecific mint hybrid **"Neerkalka"** (US Patent No. 12,030) developed by CIMAP through sexual crossing between improved Mother plant *Mentha arvensis* (cv Kalka) and pollen plant *Mentha spicata* (cv Neera).
- The hybrid is propagated vegetatively by suckers or stem cuttings and is stable for commercial cultivation.

Model Used for Solving Basic Problems of the Poor – bringing product to the market

Success Stories in Licensing - V

United States Patent 6,858,141 (NCL)

Process for the preparation of ultrafiltration membranes of polyacrylonitrile, using malic acid as an additive

"A process for the preparation of ultrafiltration membranes from polyacrylonitrile using malic acid as additives, with said ***membrane*** of molecular weight ranging between 80 to 180K, showing high purification and water permeating ability."

Cost of wtare purification (Bacteria + Virus free) 6 paise per litre as compared to Rs. 10 per litre of mineral water

Licensed to the industry recently

Model Used: Licensing to a Research Firm

Licensing of Anticancer IP Portfolio

Recently, CSIR licensed portfolio of 4 US granted patents and one patent application relating to anticancer compounds to a US Biotech research firm.

International Co-operation

Encouraging Technopreneurship amongst Scientists under Indo-US Program

Other Success Stories from CSIR

- Each lab has several such success stories
- Licensing was possible because of IP protection
- Value realization is a long term process
- Several proposals for IP licensing the pipeline – all because of IP protection internationally.

Valorization of IP: Efforts being made

- Portfolio formation
- Forging Strategic Alliance
- Licensing
- Public-Private Partnership
- Regulating Access in the area of public health
- Strengthening Linkages with Industry
- Attracting Venture Capitalists
- Public/Social Good/Pvt returns
- Capacity building in strategic areas

THANKS