# Building a “Cottage Industry” for Health (and Wealth):

## The New Framework for IP Management in India [1]

***R Saha***
*Director, Patent Facilitating Centre*
*Technology Information, Forecasting and Assessment Council*
*Technology Bhawan,, New Mehrauli Road,*
*New Delhi-110 016, India*

***Kanikaram Satyanarayana***
*Deputy Director General and Director*
*Intellectual Property Rights Unit*
*Indian Council of Medical Research*
*New Delhi-110, 029, India*

***Charles A. Gardner***[2]
*Associate Director for Health Equity*
*The Rockefeller Foundation*
*420 Fifth Avenue, New York, NY, USA*

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[1] Saha R, K Satyanarayana and CA Gardner. 2004. Building a “Cottage Industry” for Health (and Wealth): The New Framework for IP Management in India. *IP Strategy Today* No. 10-2004. Pp. 23-58. www.bioDevelopments.org/ip

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# Executive Summary

*It is plausible that by 2010,*
*the center of gravity of innovation in drugs and vaccines*
*will have moved noticeably towards developing countries.*

Richard Feachem (2001). Editorial, *WHO Bulletin* 79:8.

By the standards of any developing country, India's government has invested heavily in health research. About two thirds of the country's total health research infrastructure remains in the public sector, responding to national health priorities such as HIV/AIDS, malaria, tuberculosis, leprosy and cholera. Indian institutions are quite capable of contributing solutions to these global problems. To do so effectively, however, they must first bridge a gaping chasm between India's public and private sectors, a cultural divide that limits the potential of any public investment. The government has moved forward with policy changes to begin to address this problem, but much more effort is required.[3]

In North America, most health innovations arise from small- and medium-sized biotechnology companies. These companies tend to cluster tightly around academic research centers to harness the critical mass of brainpower they find there. Technologies licensed from U.S. universities have stimulated the creation of thousands of new companies, tens of thousands of new jobs, and billions of dollars in new wealth, as well as countless new products to improve human health.[4]

Thus, a significant portion of U.S. economic growth derives from innovations that arise out of a "cottage industry" of university spin-offs and small biotech companies linked to university laboratories. Because of the modest scale on which most university-industry partnerships take place, this model could be applied to at least a handful of developing countries that, like India, have significant research and manufacturing infrastructure of their own.

Significant cost advantages have already allowed India to become a major provider of low-cost drugs and vaccines for the world's least developed countries. India can also become an important engine of innovation when its universities and national laboratories become adept at establishing sound public-private R&D partnerships.[5] We believe this could help address a critical global health need for better tools: e.g., vaccines against HIV, malaria and TB; shorter TB drug treatment; microbicides against HIV and STDs; new antibiotics and antimalarials to overcome drug resistance.

Bridging the deep divide between public and private sectors in "Innovating Developing Countries" (IDCs) like India could lead not only to new health technologies that help address national health priorities but also to greater export income and economic growth as other technologies are commercialized for more lucrative markets. This opportunity exists right now. Capacity building of this kind is inexpensive. It is sustainable as it helps to maximize the multi-billion dollar annual investment that developing

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3 After ruling for five years, a BJP-led coalition fell on May 13 2004. Most observers believe the new ruling coalition, led by the Congress Party, will continue the economic reform policies of its predecessor. However, the new coalition may include several far-left leaning parties. It is difficult to predict what impact this may have on science, technology and innovation policies affecting public-private partnerships and IP.

4 We do not mean to argue that this model is an unqualified success in the North. Many question the high cost of products arising from tax-payer funded research, and technology managers in Northern research institutions are only now beginning to consider the impact of their licensing practices on developing countries.

5 Public-private partnerships (PPPs) in this context refers to project-based partnerships within IDCs. These should be seen as complementary to the dozen-or-so non-profit global PPP catalysts, such as the International AIDS Vaccine Initiative (IAVI) and Global Alliance for TB Drug Development (TB Alliance), who's own portfolios of candidate products are actually collections of local PPPs based in both North and South.

countries themselves already make in health research. For the field of international development, this would appear to be a true win-win situation.

There is at least one more important reason for the developed world to consider this approach. Technical and development agencies from the North now support a variety of world-class research centers in IDCs as well as in some of the least developed countries. We believe such funders have a moral responsibility to ensure that their partners in developing countries can negotiate intellectual property rights on a level playing field. Moreover, when new inventions have applications in global health, both partners should strive to manage the IP to achieve the widest possible access.

Technology managers at public research institutions are the key players in this model. There is now a small but growing cadre of such professionals in India and a few in other IDCs, but they often work in isolation and have limited training. Like their colleagues in the North, they need critical skills, networking to share experiences, and sound, supportive institutional and national policies to be effective and promote the public good.

The process of technology management involves: 1) working with academic or government researchers to identify inventions "at the bench"; 2) development of a patent strategy around each unique invention, identifying company partners and negotiating fair licensing agreements, and 3) follow-up to ensure due diligence on the part of the licensee. Technology managers may also negotiate industry sponsored research agreements with public institutions. All these activities need to take place under clear institutional policies on IP and equally clear national policies on IP and public-private partnerships.

Ideally, IDCs could benefit from the past quarter-century of experience in the North. Technology managers in industrialized countries are adepts in a largely apprenticeship-based learn-by-doing "craft industry." As their profession has matured, some have begun to realize that the ultimate goal of their licensing practices is not to make money for their institution, but rather to maximize the public investment in a way that is consistent with their academic mission (e.g., to educate the next generation, expand and share knowledge, and even to make the world a better place).

In 2003, a new group called Technology Managers for Global Health (TMGH) formed within the North American professional society for technology managers (AUTM). Two new global organizations (MIHR, see page 48, and PIPRA) are developing "tool kits" of best practices for technology managers to address technology needs in developing countries. These efforts show that it is possible to adopt technology management practices that are consistent with global needs and the public interest without sacrificing institutional or national priorities. Technology managers, their institutional directors, and policy makers in developing countries can all learn from this experience, and perhaps avoid some common mistakes.

Building capacity and raising the stature of technology managers in IDCs could help build bridges, engage the gears and give traction to billions of dollars per year in local health research investment. The simplicity, strategic impact and cost-effectiveness of this approach is not yet widely appreciated. To be sure, it may be a necessary but still insufficient means to deliver affordable essential goods to the poor. Nevertheless, it represents an opportunity to simultaneously stimulate the development of affordable and locally relevant technologies as well as to create jobs and stimulate economic growth.

The Government of India has moved quickly to grasp this opportunity. Over the past ten years, it has developed a variety of programs, policies, and incentives to stimulate public-private research partnerships. Much more remains to be done, but India's drive and momentum could illuminate the path for other IDCs. It could also be an example for industrialized countries that are currently working to improve health and economic outcomes in the developing world by more traditional means.

# 1. Introduction

Despite its reputation as a "poor country," India has invested heavily over the past half Century to develop national laboratories and academic research centers. The chief architect of this effort was India's first Prime Minister, Jawaharlal Nehru. He believed that new scientific and industrial research institutions "laid a solid foundation of science on which to build a splendid edifice of New India," and he charged these "modern temples of science" to address his country's most pressing health, agricultural and industrial challenges.

Today, most of India's research infrastructure remains in the public sector (Figure 1). The Government supports at least two thirds of all health and biotechnology research in the country, and nearly 75 percent of research and development on agriculture, energy, engineering and defense[6]. This substantial public sector investment sustains many world-class government and academic research centers throughout the nation, institutions that are capable of making significant contributions to global science and innovation as well as to India's own economic development.

Of particular relevance for global health and increasing health equity, Indian health research institutions are capable of developing new drugs, diagnostics and vaccines to address "neglected" diseases such as tuberculosis, malaria, and cholera that disproportionately afflict the poor. They could develop the next generation of anti-retrovirals to combat drug resistant HIV (Chaturvedi 2002) as multinational companies may be reluctant to work on such drugs because of international controversy and pressure on pricing[7]. They are also capable of modifying indigenous crops to enhance nutrition and increase resistance to abiotic stress (Chaturvedi 2002). The trick will be to translate such technologies out of the ivory towers of academia and into products for public good.

Indian companies are just beginning to invest in original research. Member companies in the Organization of Pharmaceutical Producers of India (OPPI) invest only 2 percent of sales in R&D compared to 18% for multinationals[8]. As India moves to fulfill its obligations under the international agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) to provide product patent protection for pharmaceuticals and agricultural chemicals after 2005, the survival of its vibrant drug and biotechnology industries will depend on their ability to bring new and original products to market by forging strong research partnerships with the public sector.

Recognizing this inter-dependency, and its relevance to India's survival in the face of global competition, the Government has developed innovative grant and soft loan programs to stimulate public-private partnerships. From the mid-1990s, India's technical agencies began to establish "Patent Cells" to protect and commercialize their inventions. A few universities have also moved in this direction.

In 2000, Indian research institutions were given rights of ownership over some of their inventions, and the Government began to co-sponsor exchanges and workshops focused on intellectual property (IP) management in collaboration with the US Department of Health and Human Services. Both the Indian Government and industry now support IP awareness programs for Indian scientists.

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[6] The estimate for health research based on an analysis of budget lines for relevant technical agencies from the Government of India annual budget report, and personal communication with the Organization of Pharmaceutical Producers of India (OPPI); the overall R&D estimate is from the UNESCO Institute of Statistics (est. 83% of all R&D is funded by the public sector); and "Science & Technology Data Book," Government of India, September 2000, p.1, (est. 74.3% of all R&D&S&T is public sector).

[7] Carl Dieffenbach, Associate Director, Division of AIDS, US National Institutes of Health, personal communication.

[8] Data from the Organization of Pharmaceutical Producers of India (OPPI), and Pharmaceutical Research and Manufacturers' Association (PhRMA).

In January, 2003, the Government announced new plans to establish "autonomous technology transfer organizations at universities and national laboratories to facilitate the transfer of know-how generated to industry," and to develop a "comprehensive and well-orchestrated program for training in technology management."[9] On April 26, 2003, the Council of Scientific and Industrial Research announced formation of an "Intellectual Property Managers' Association of India" (IPMAI)[10].

These bold new efforts to leverage greater public benefit from public funds are built upon a solid foundation of practical experience gained by India's agencies and institutions over the past 10 years.

## 2. Global Policy Perspective

The restructuring now underway represents dramatic change—change that has gone largely unnoticed outside India, or indeed outside of a small circle of policy makers who understand such arcane issues, and an equally small collection of the very professionals who cement the process: technology managers.[11] India is just beginning to build its capacity to form effective public-private R&D partnerships. It still has a long way to go, yet other countries with comparable R&D and manufacturing capability may have even less experience in this arena.

Beyond India, several other innovating developing countries (IDCs) have substantial or increasing public sector investments in health research (e.g., Brazil, South Africa and China) collectively totaling well over a billion US dollars per year.[12] Private sector research support is also likely to increase as domestic industries grow, and as multinational pharmaceutical companies and the larger biotechnology companies seek to reduce costs. Comparable R&D may be conducted in India at less than half the cost of the same work in the US or Europe; the manufacturing cost advantage is nearly as significant, and labor costs are less than one tenth the Northern levels. Contract research and contract manufacturing in developing countries are both likely to grow over the next five years.

In response to the vast health disparities that exist between wealthy and poor countries, some foundations and government development agencies have recently created and begun to support a group of non-profit "companies," often referred to as Public-Private Partnerships (PPPs), to accelerate the development of drugs, vaccines and diagnostics for diseases that afflict the poor in developing countries. These organizations include the International AIDS Vaccine Initiative (IAVI), Medicines for Malaria Venture (MMV), Global Alliance for TB Drug Development (GATB), and International Partnership for Microbicides (IPM).

Such PPPs support R&D wherever the science is best. Capacity building in developing countries would be a happy byproduct, but is not their primary focus. However, many of these international PPPs do support research in developing countries, as well as preparations for and active clinical trials. Many will also be drawn toward manufacture in developing countries to ensure that their products are affordable.

Northern technical agencies are also key players in support for health research in less wealthy countries. The largest, the US National Institutes of Health (NIH), now supports over 830 research projects in low- and middle-income countries, and this number has more than doubled in just the past five

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9 www.tifac.org.in/news/policy.htm and dst.gov.in/doc/STP2003.doc. All web links were last accessed on 19 August 2004.

10 R.A. Mashelkar, Director-General, Council of Scientific and Industrial Research, personal communication, see also *Innovation*Matters 1(2):3.

11 Specifically, technology managers who work in India's publicly funded research institutions.

12 Global Forum for Health Research; OECD

years.[13] NIH awards involving scientists in India rose from 17 in 1998 to more than 60 in 2003. Most of these are "domestic awards with a foreign component," usually grants to US universities for collaboration with a foreign partner. Some of these projects will lead to new inventions. Yet such collaborations, funded by the NIHs, MRCs and EUs of the world, necessarily match one institution that has an experienced technology management office with another in the developing world where knowledge of IP and technology management are limited.

The Rockefeller Foundation recently launched an independent international organization called "MIHR"[14] (see also "Box: MIHR" on page 48) to build the capacity of publicly funded health research institutions in developing countries to manage their own IP, and to enter into sound, viable and accountable public-private partnerships of their own. Based on the authors' recent positive experience with a similar but smaller program in India,[15] we applaud this exciting new approach to promote both economic development and the production of locally relevant new technologies to improve health equity through indigenous public-private partnerships.[16]

"Technology management" is a key process in any public-private partnership. As seen from the perspective of a publicly funded research institution, it entails at least five steps:

1. development of an institution's IP policy and establishment of a technology management office;
2. education and outreach to researchers, and identification of bench-level inventions;
3. deciding where, what, when, why and how to file for patent protection, and knowing what not to protect, i.e., research tools;
4. identifying appropriate companies and negotiating license arrangements that are consistent with the institution's mission and the public interest; and finally
5. follow-up to ensure that licensees invest and develop the technology so it will reach the people who need it most.

We believe that capacity building in this area is a fundamental lever of change for public good for the simple reason that publicly funded R&D in developing countries tends to focus on relevant local needs.[17] Here is a golden opportunity for India and some other developing countries to amplify the outcome of their own investments in R&D, to make their own decisions about their own technologies. And here is a golden opportunity for donors to help harness the creative energies of a few key developing countries, requiring only modest investment in the very keystone of modern R&D: technology management.

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13 NIH Fogarty International Center, Division of International Relations, personal communication. Note that NIH international awards represent roughly 2% of that agency's total budget, and most of that international investment goes to institutions in developed countries, especially Canada and Europe. NIH's mission is to support the best science, wherever that is, to advance knowledge of health.

14 MIHR: Center for **M**anagement of **I**ntellectual Property in **H**ealth **R**esearch and Development (www.mihr.org). See Box on page 48. The Rockefeller Foundation has also launched the Public Intellectual Property Resource for Agriculture (PIPRA; www.pipra.org) to make agricultural technologies more easily available for development and distribution of subsistence crops for humanitarian purposes in the developing world. Where appropriate, MIHR and PIPRA will collaborate on joint capacity building efforts in developing countries.

15 The Indo-US Technology Management Program.

16 Note: As an Officer of The Rockefeller Foundation, one of the authors, CA Gardner, has a direct concern for the success and sustainability of MIHR.

17 Whereas the 2% of sales that Indian companies invest in R&D tends to focus on developing products for the wealthy markets in Europe and the United States.

## 3. The Indian Context

### *3.1 Introduction*

Ever since India gained its independence in 1947, science and technology have received considerable attention and occupied a notable position in the management structure at the highest levels of the new government. A government policy resolution on science, piloted by Pandit Nehru and adopted by Parliament in 1958, was one of the first such official statements in the world. From a humble start, with just 20 universities, 60 national laboratories and negligible industry-based research, India has built over 200 universities, 400 national laboratories, and 1,300 industry-based R&D units.[18]

Total national spending on science and technology is just $2.5 billion per year. Yet firm commitment and a strong R&D cost advantage have allowed the country to develop world-class facilities and expertise in a few vital areas and select institutions. The development of hepatitis B vaccine through indigenous R&D independently by two small private biotechnology companies in India has demonstrated that it is possible to translate the newfound scientific strength into low-cost products for the public health system. Both products were developed through public-private partnerships involving companies, Indian research universities and national laboratories, and venture capital from the Technology Development Board of the Government of India.

Significant changes now underway in India affecting public-private partnerships and IP management are all the more extraordinary given the country's past adherence to Nehruvian Socialism, general distrust of the profit motive, prohibition (until recently) of foreign direct investment, and staunch support for and bias toward "cottage industries" and "indigenous" manufacture.

The Government of the Indian State of Kerala defines cottages industries as "Artisans or small industrial activities (viz., manufacturing, processing, preservation and servicing), involving utilisation of locally available natural resources and/or human skills"[19] In this context, research partnerships involving industry and government laboratories or academic institutions represent on the one hand a revolutionary new approach, while on the other hand they remain consistent with a deep rooted national bias toward small scale industry.

### *3.2 Economic Blueprint: Health and Wealth from a "Cottage Industry"?*

In developed countries, the benefits of technology management are weighted heavily toward the life sciences, especially health. According to the Association of University Technology Managers (AUTM), life science inventions account for 70 percent of US university licenses and 87 percent of university royalties (AUTM 1997 and T Young, pers. com.). Over 4,300 companies have been formed since 1980 as a direct result of licensing inventions from American universities (AUTM 2002). The vast majority are small- and medium-sized biotech companies, all clustering tightly around the academic research institutions that provide their intellectual nourishment (Zucker, Brewer and Darby 1998).

Nearly three-quarters of those companies focus on human health applications,[20] and they collectively encompass most of the innovation in that field. Two thirds of all new chemical entities are currently under development by small- and medium sized biotechnology companies; the remainder are in big

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[18] Science and Technology System in India, Vigyan Prasar www.vigyanprasar.com/stindia/about.htm.

[19] www.keralaindustry.org/schemes/Schemes_Refinance.htm

[20] *A Survey of the Use of Biotechnology in U.S. Industry*, U.S. Department of Commerce, Technology Administration, October 2003, found that "Almost three-quarters of firms (72%) indicated that human health applications are their primary area of biotechnology-related activity."

pharma and the top 25 biotechnology comapnies (analysis by the Boston Consulting Group, prepared for The Rockefeller Foundation). Increasingly, university research, small companies and the venture capital that supports them, have come to insulate the pharmaceutical industry from the risks of new product development.Many hope to partner with (or be bought up by) large pharmaceutical companies once they prove their technology. Recent examples[21] of products arising from North American public research institutions and developed through public-private partnerships include:

- a "photodynamic" anti-cancer treatment developed at Queen's University in Ontario, Canada, and licensed to DUSA Pharmaceuticals, now approved by the FDA and in use;
- an oral rinse to prevent tooth decay, and a broad-spectrum new antibiotic, developed at the University of Florida and licensed to a Florida-based biotechnology company called Oragenics Inc.;
- an FDA-approved implant that stimulates regeneration after injury of the shoulder joint, developed at Purdue University and licensed to a small company that was later purchased by Johnson & Johnson;
- a breakthrough in 3-D x-ray that increases comfort and accuracy of mammography, developed at Wake Forest University and licensed to a company in Helsinki, Finland;
- a diagnostic to determine the correct dosage of chemotherapeutic agents (thiopurines) used to treat childhood acute lymphoblastic leukemia (ALL) to help reach a five-year event free survival rate of 80 percent, developed at St. Jude Children's Research Hospital and licensed to PPGx Inc., which was acquired by DNA Sciences Laboratories, which sublicensed the technology to Prometheus Laboratories;
- a novel anti-sense chemotherapy developed at McGill University in Montreal, Canada, and licensed to a small Montreal-based biotechnology company called MethylGene Inc.;
- a acoustically customizable hearing aid developed at Brigham Young University and licensed to Sonic Innovations which has since sold over 200,000 units;
- an inexpensive method to synthesize the anti-cancer drug Taxol® from renewable starting materials, developed at Florida State University and licensed to Bristol-Myers Squibb where the drug reached worldwide sales of over $1 billion dollars in 1998; and
- an FDA-approved topical treatment for AIDS-related Kaposi's sarcoma, developed at the Salk Institute which spun-out a new biotechnology company called Ligand Therapeutics to produce the product.

Technology transfer from academia to industry, that is, project-level local public-private partnerships, can occur on a scale that is appropriate for India as well as other developing countries that have a comparable R&D and industrial base (IDCs). Nearly 60 percent of US biotechnology companies have fewer than 50 employees (AUTM 2002). University spin-off companies may be even smaller; many have less than 10 employees. Yet this is where the innovation lies. According to the Biotechnology Industry Organization (BIO), this "cottage industry" in the United States generates over 400,000 jobs, nearly $50 billion in sales, and $10 billion in annual tax revenues (Earnst & Young 2000).

Predictably (and unfortunately for global health), in the United States and Europe the growth and success of the health biotech industry is weighted heavily toward high-cost solutions to the chronic diseases and lifestyle concerns of people in the United States and Europe. Of the 1,393 new chemical enti-

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21 www.autm.net/pubs/survey/storylist.html

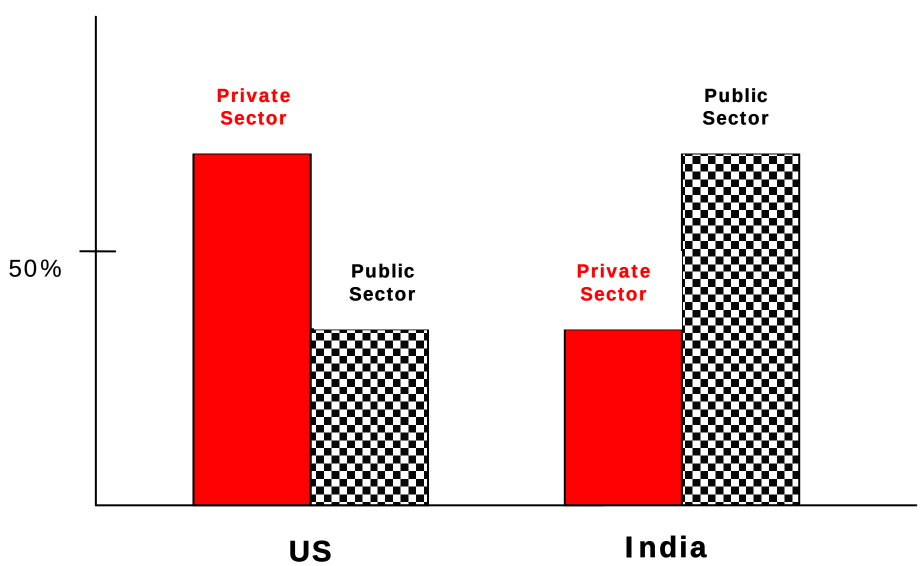
ties marketed around the world between 1975 and 1999, only 16 were developed to combat tropical diseases and tuberculosis (Trouiller and Olliaro 1999 and Trouiller *et al*. 2002).

So far, most of the benefits of biotechnology have accrued to the developed world. But if it can be applied in developing countries as well—many of which enjoy significant research and manufacturing cost advantages—it could lead not only to new jobs and export income but also to greater health equity. This seemingly improbable outcome follows from the fact that public sector research investments in any country tend to focus on local health priorities. Therefore, products arising out of publicly funded laboratories, developed through public-private partnerships in developing countries, will be weighted heavily toward lower cost interventions against the greatest local burdens of disease.

India's public-sector investment is not insubstantial. The budget of the Indian Council of Medical Research ($40 million/year) is spent almost entirely on R&D relating to India's national health priorities.[22] Other public sector funding agencies also support health research, as well as non-health initiatives, including India's Department of Biotechnology ($52 million/year, about half of which goes to health), the Council of Scientific and Industrial Research ($104 million/year, about a third of which goes to health), Department of Science and Technology ($160 million/year), University Grants Commission ($326 million/year) and Department of Atomic Energy ($821 million/year).[23] Overall, India's R&D spending in health is approximately one third by the private sector and two-thirds by the public sector (Figure 1); a ratio that is just in reverse in the US.

In contrast, of course, India's private sector must respond to the same bottom-line pressures that its US or European counterparts face. Indian companies will therefore tend to focus in-house R&D efforts on the development of products that would find a ready market. Such a goal may overlap poorly—if at all—with a country's national health research priorities.

**Figure 1: Health R&D Profile of the US and India**
(percent of total, 2000)




[22] This budget is supplied directly by the Indian Council of Medical Research.

[23] Union Budget of India, 2003-2004: indiabudget.nic.in/ub2003-04/eb/vol2.htm

In India's case, the official national health research priorities include: "communicable diseases, fertility control, maternal and child health, nutritional disorders, strategies for health care delivery, environ mental and occupational health problems, cancer, cardiovascular diseases, blindness, diabetes and other metabolic and haematological disorders, mental health and drug research (including traditional remedies)."[24]

These factors highlight an opportunity to forge stronger links between the public and private sectors to ensure that innovations arising from India's relatively strong public sector health R&D investment are translated into products that reach the public through sound public-private partnerships. This opportunity is not unique to India. Over the coming decade, India and a handful of other innovating developing countries (IDCs) could become powerful engines of innovation, generating new products to combat diseases that have caused the greatest suffering to their own people (see "Box: Innovating Developing Countries" below).

### ***3.3 Wealth from Public-Private Partnerships in India? Wealth from IP?***

#### *3.3.1 Case Study I: Technology Licensing from a Public Laboratory to Industry*

Central Drug Research Institute (CDRI), under the Council for Scientific and Industrial Research (CSIR), has developed a drug to treat cerebral malaria, now licensed to Indian company which "sells it under

**Box: Innovating Developing Countries**

Many of these considerations were anticipated in a 2002 report of U.K. Commission on Intellectual Property Rights (www.iprcommission.org), which recommended "a network of public-private partnerships in developing countries, taking advantage of the concentration of research resources in public sector institutions but also the opportunity to build research capacity in the private sector" (p. 34). The report cautioned that "the arrangements for intellectual property arising from such research need to be such that access by the poor to the products of research is ensured as much as possible" (ibid.). The UK Commission report also considered the impact of technology management practices in the United States, and their relevance for developing countries (pp. 123-125). It emphasized that there is continuing debate over the economic impact of university-industry technology transfer in the United States, yet made the following recommendations with which we wholeheartedly agree (p. 125):

Based on the above, we believe that there is a role for IP in public research institutions in developing countries to promote the transfer and application of technologies. But it is important that:

- generating alternative sources of funding is not seen as the principal goal, which is rather to promote technology transfer.
- care be taken to ensure that research priorities, particularly as regards the technology requirements of the poor, be it in agriculture or health, are not distorted by the search for a larger licensing income.
- patenting and licensing should only be undertaken where it is judged necessary to encourage private sector development and the application of technologies.
- careful consideration be given to the need to take out "defensive" patents on important inventions, particularly for use as a bargaining tool where complementary technologies are owned by private sector entities and cross-licensing may be required to access those technologies.
- expertise in IP is developed in public sector institutions which traditionally have had none, but without losing sight of the objectives of public policy for research.

[24] ICMR Public Document: icmr.nic.in/abouticmr.htm

the brand name E-mal to 48 countries at affordable prices" (R.A. Mashelkar, Director-General of the CSIR, pers. com.). The following is from the CDRI's website (www.cdriindia.org/Arteether.htm):

“Arteether is a semi synthetic derivative of artemisinine, the active constituent of the plant, *Artemisia annua*. CDRI conducted extensive preclinical, toxicological and other regulatory studies in which the drug was not only found to be very safe but also proved to be a fast acting, blood schizontocidal agent which attacks at the erythrocytic stage of malaria in blood. Extensive clinical trials were conducted at 7 centres in malaria prone areas of India. Over 500 patients showed excellent response and the recrudescent rate was very low. Arteether has been developed by CDRI and is being prescribed to the patients as second line of treatment for chloroquine-resistant *P. falciparim* malaria including cerebral malaria.

Though choloroquine has been and still remain one of the most extensively used first line drug for malaria, resistance against this drug is quite frequent. Search for a drug which could be more effective than chloroquine and which could minimize the chance of resistance development has been going on the world over. CDRI has always been quite in the forefront in searching for natural or synthetic drug that could be used as a weapon to fight malaria since it is causing so much of devastation in tropical countries, especially India. Many plants used by traditional systems of medicine have been tried and many of the leads are being pursued.

CDRI got a major success when it developed Arteether from the plant Artemisia annua while working in collaboration with, Central Institute of Medicinal and Aromatic plants (CIMAP), the other CSIR laboratory based at Lucknow. The Drugs Controller General (India) has allowed the drug exclusively for use in hospitals and nursing homes.

Being a new drug, it is indicated for use only in severe *P. falciparum* malaria including cerebral malaria as a second line treatment for chloroquine resistant cases. It is not recommended to be used as a first line treatment for malaria to avoid its overuse which may lead to the emergence of resistance against this drug once again.

CDRI has licensed the drug to Themis Chemicals Ltd., Mumbai which is marketing it under the trade name E-Mal as an injectable formulation.

Post marketing surveillance data on 400 patients received from clinicians from 6 states has validated the efficacy and safety of Arteether in uncomplicated/complicated cases of *P.falciparum* malaria. No drug related side effects have been observed so far.”

### *3.3.2 Case Study II: A Public-Private Partnership within India*[25]

The Central Salt and Marine Chemicals Research Institute (CSMCRI) developed a new process to manufacture Zeolite A (used as an intermediate for making eco-friendly detergents). The CSMCRI is, a laboratory of the Council of Scientific and Industrial Research (CSIR), and the Government of India. The process was patented in India and then licensed to Nalco, the National Aluminum Company.

There were four partners in the deal:

1. CSMCRI, a public sector laboratory that generated the know-how
2. the National Research Development Corporation (NRDC), a public sector technology transfer organization, evaluated the technology, filed for protection and then negotiated the license,
3. Engineers India Ltd., fine tuned of pilot plant trials to generated data for design of a commercial size plant, provided detail design and engineering advice, and
4. a company, Nalco, that invested in manufacturing capacity to scale up to 10,000 tons per year.

[25] Source: NRDC, 2003.

Terms of the license included the following points: commercial use of the technology would be owned jointly by all four partners; all royalty or other revenues would be shared equally; each party was free to charge reasonable fees for their respective services; and all expenses relating to the management of the IP would be shared equally by the NRDC and the CSMCRI.

### *3.3.3 Case Study III: Rice Husk Particle Board*[26]

Indian Plywood Research Institute developed the technology. The Indian patent rights were assigned to the NRDC. NRDC assigned the rights and transferred the know-how to M/s. Padmavati Panel Boards (PPBL), a relatively new company. The company developed some specific products (laminated boards) based on the know-how. The up scaling outlay was jointly funded by PPBL and NRDC. (data on revenue generated not available).

NRDC licensed the technology to a Malaysian client (MHES) with an up front payment of $50,000 and a royalty of 2.5% on sales for 10 years. Technology has also been licensed to an Indonesian client with an up front payment of $90,000.

### *3.3.4 Case Study IV: Other Private Initiatives in India*

Shantha Biotechnics, a small but rapidly growing biotech company in Hyderabad, got its start at Osmania University in that city, incubated further at the Center for Cellular and Molecular Biology (CCMB), and then scaled up to manufacture hepatitis B vaccine in its own new facility. This was the first recombinant vaccine in India. Slightly later, another Hyderabad company, Bharat Biotech, leased 10,000 square feet of laboratory space at the Indian Institute of Science (IISc) in Bangalore to develop its own hepatitis B vaccine before scaling up in its own facilities. Bharat maintains the lease agreement with IISc to access brainpower and equipment and continue a research program.

Clinical trials to demonstrate product safety for both companies have been conducted in collaboration with local public sector medical colleges. Shantha sponsored preclinical testing at the National Institute of Nutrition in Hyderabad, which is part of the Indian Council of Medical Research (and has a large primate facility).

Scientists from the Indian Institute of Science (IISc) recently spun out a company called Metahelix Life Sciences to do contract research in genomics, molecular markers and bioinformatics. They have raised $1.5 million in venture capital, employ more than 30 professionals and support staff, and are working to build a sustainable contract research business (Chaturvedi 2002).

### *3.3.5 Case Study V: Examples of IP Protection Leading to Wealth Creation*

The National Chemical Laboratory in Pune (NCL) is a national laboratory under the CSIR. CSIR's Director-General, Dr. R.A. Mashelkar, is a polymer chemist, and prior to assuming the Director-Generalship of CSIR he directed the NCL in Pune. While there, his laboratory developed a polymer that now coats one third of all the compact discs in the world (RA Mashelkar, pers. com.). The polymer was patented worldwide by CSIR. Significant royalties have flowed back to CSIR and the Government of India.

India's pharma industry also has examples of wealth generation from IP protection. Several years ago, Ranbaxy licensed an oral antibiotic formulation that was developed in its own laboratories to the Bayer Corporation in Germany for $50-60 million. Dr. Reddy's Laboratory has licensed numerous compounds with anti-diabetic properties to Novartis.

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[26] Source: NRDC.

# 4. From Ivory Tower to Engagement: the Birth of IP Management in India

### *4.1 A Brief History of IP Laws in India*

The past decade has seen significant changes in policies and laws relating to public-private partnerships and IP management in India, but these are just the latest steps in a long journey. India passed its first patent laws in 1856, one year before its first war of independence. Under British rule, these laws were modified over time, culminating in stable patent and design laws by 1911. These laws were similar to those followed in England, and therefore comparable to most advanced countries of that time.

After independence in 1947, some Indian leaders felt that the patent laws should be revisited. Changes were proposed to reflect the social and economic needs of a country with a large population of poor people who did not have easy access to medicines and other advancements of science. At the same time, there was a strong emphasis on self-reliance in many areas of technology. This emphasis led to serious efforts to nurture "indigenous" science and technology (so called self-reliance) following economic policies that have sometimes been called "Nehruvian socialism."

After lengthy debate, the patent laws were finally revised through the Patent Act of 1970. The new law did not recognize patenting of substances that result from chemical reactions, and it did not allow product patent protection for drugs. Only process patents were allowed for pharmaceuticals and agricultural chemicals. During the 1970s and 1980s, India's pharmaceutical industry grew rapidly as it focused on the manufacture of generic drugs and "reverse engineering" of products that had been developed in the West.

Other IP laws have been enacted or modified in the post-independence period. The Indian Copyearight Act, first passed in 1957 and amended in 1983, 1984, 1992, 1994 and 1998, is comparable to laws in developed countries. A Geographical Indication of Goods (Registration and Protection) Act and a new Trademark Act were passed in 1999, and a new Design Act in 2000. A new act for the protection of integrated circuit layout design, "The Semiconductor Integrated Circuit Layout Design Act 2000," has been promulgated. A new act for protection of new plant varieties and farmers' rights is also in place. Both the Contract Act of 1872 (modified in 1932), which protect trade secrets, and the Design Act of 1911, have been left unchanged. These changes were intended to bring Indian law in line with international standards in a way that was consistent with Indian priorities.

As a developing country that had not previously followed an open market model, India was allowed a transition time of 10 years to bring her laws into agreement with TRIPS. Following its signing of the WTO Agreement in 1995, India took many steps to develop new laws regarding various forms of IP rights. The immediate post WTO-entry period also saw a large number of policy and program initiatives undertaken by government, industry and R&D institutions to prepare for new challenges emerging from the multi-lateral trade regime. India is now a member of Paris Convention, the Patent Cooperation Treaty and Budapest Treaty.

India is the largest democracy of the world. As with any democracy, it must evolve a political and social consensus before bringing in major new legal changes. The process of negotiating passage of bills through both houses of Parliament has been time consuming, and there have been some set-backs. India's patent laws were amended in 1999, and then again in 2002, to make them TRIPS compliant. However, some authorities believe the new laws are not yet fully compliant.

There has been stiff opposition in India to the General Agreement on Tariffs and Trade (GATT), and a growing feeling among some authorities that trade negotiations are being used to coerce developing countries to amend their domestic laws in a non-transparent way. Patent law amendments imposed by the World Trade Organization (WTO) have been opposed by public in both developed and developing countries with increasingly noisy demonstrations from Seattle to Davos. Not surprisingly, it is taking time to build consensus within India to change patent laws to make them TRIPS-complaint.

### 4.2 Legacy of Government Economic Controls

While science has received continued strong support from the Government since Independence, the stress was on building basic research infrastructure and the generation of new knowledge with the implicit assumption that innovations would automatically lead to applications. Industrial policy emphasized self-reliance and "indigenization" of materials and products to reduce imports. The result was a dramatic increase in the number of trained scientists and published papers, but a failure to bridge the gap between bench-research and the translation of new knowledge into usable products for local use and export.

The domestic industry was protected, and foreign investment was actively discouraged. Many Indian companies acquired dated technology for the local market, and precious time was lost—technological progress remained near-dormant while the heavily protected domestic industry had no incentive and therefore failed to invest in original R&D.

India's first hesitant steps towards liberalizing the economy began under Prime Minister Narasimha Rao and Finance Minister Manmohan Singh in the early 1990s. These changes triggered a debate on globalization, awareness of and the need to generate and protect IP. Technology generation, the "knowledge society" and global competitiveness all entered the vocabulary of policy makers. Various steps were taken to begin to educate scientists and science managers about the generation and management of new technology,[27] sometimes with support from experienced technology mangers from abroad.

Despite recent progress, the legacy of earlier government policies remains and may take serious effort to overcome. During a series of workshops on technology management in the spring of 2001, held in New Delhi, Pune and Hyderabad, Indian participants highlighted the following challenges to the nascent local biotechnology industry: conflicting and confusing regulations by different Government ministries; longer product development time and higher capital requirements compared to information and communication technology (ICT); lack of understanding among Indian venture capitalists; naiveté and lack of business acumen among Indian Government and university scientists; and a strong undercurrent of distrust between industry on the one hand, and Government and academia on the other.

The Director of one major research center noted that "most Indian research institutions are still IPR illiterate." A faculty member from a research university expressed his frustration because of a lack of administrative support on IP rights at his institution. He had an invention and a potential partner in the private sector, but no idea how to negotiate a fair deal. These anecdotal stories are telling. Despite the fact that IP laws have been in place for nearly 150 years, until very recently leaders in industry, government, and the scientific community were not aware of, nor conversant with, the fundamentals of IP rights and IP management. This is beginning to change.

### 4.3 India's Private Sector

If the Indian government supports 75 percent of all R&D in the country now, it is safe to say industry's share was even lower during the first decades after independence. The bulk of the government's investment went to energy, defense and space industries under focused programs intended for just one consumer: the Government. Though many of India's "modern temples of science" had been specifically established to conduct research to support the industrial sector, the country's emphasis on self reliance

[27] E.g., training courses sponsored by the Patent Facilitation Center, TIFAC/DST, under the directorship of one of the authors (R. Saha).

had often led to research that did not reflect local or international market needs. R&D in these institutions rarely led to marketable products or processes.[28]

Some elements of Indian industry have been a bit more patent-savvy, especially those with links to foreign companies, including Indian subsidiaries of multinational companies (e.g, Hoechst and Hindustan Lever). Since the 1950s, such companies have developed strong IP divisions to manage their own inventions. In contrast, most wholly-owned Indian companies remained unfamiliar with the protection of IP, especially patents. Faced with government price controls on thousands of products and an almost impenetrable thicket of licensing requirements for newly developed products, industry was reluctant to support R&D on its own. This reluctance was all the stronger because of the ease with which any real innovation might be copied by competitors who could then benefit from sales without having had to make the original investment in R&D.

In the 1990s, the tide began to turn, driven by economic reform from the Central Government as well as real success stories in the private sector. Some Indian companies began to reap immense benefits from their own and foreign R&D investments in information technology. Pharmaceutical companies and the new biotech industry also began to invest in research. While pharmaceutical R&D in 2000 remained relatively low by international standards, at just 2 percent of sales, this still represents a doubling from 1990, and the top five companies invest far more, putting an average of 7 percent of sales into R&D (A Dangi, pers. com. OPPI Director-General). Over the past few years, a few Indian companies have negotiated multi-million dollar licensing arrangements with European companies for product formulations that were developed in their own laboratories.

The Director-General of the Organization of Pharmaceutical Producers of India (OPPI) estimates that as many as 35 Indian companies have (or could develop) a capacity for original research. The number of patent applications from Indian industry, while still small, is growing (*Business India* 2004; see also Figure 2).

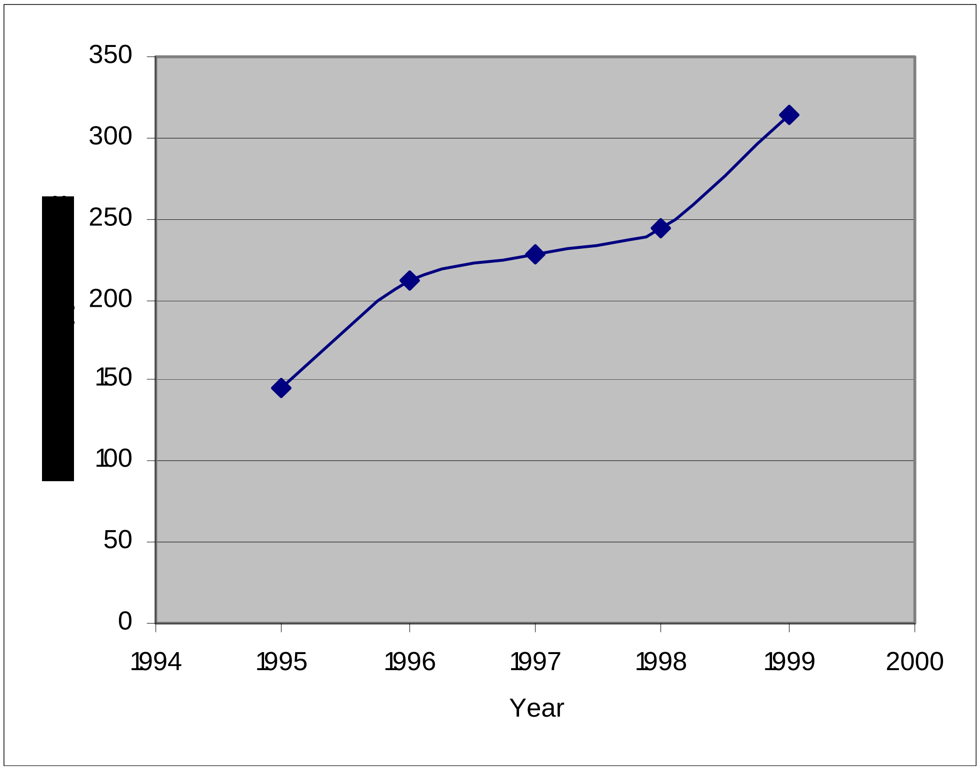
But critical realities within the country still make it difficult for Indian companies to invest heavily in R&D for health technologies. Government is, of course, the largest buyer of drugs for public sector distribution. It has imposed longstanding (though recently relaxed) price controls. This, along with the inherent price sensitivity of the local market, guarantees comparatively low profit margins. Companies have little surplus to invest in research.

Despite these impediments, India's pharmaceutical industry is growing at a healthy pace, expanding at about 10 percent each year, largely due to the export potential of bulk drugs at very competitive prices (A Dangi, pers. com.). While annual sales are just $4.4 billion (out of a current global market of about $400 billion), India's pharmaceutical industry is the fifth largest in the world by volume, and the sector has become a powerhouse for the generation of jobs and export income. Over 30 Indian manufacturing plants have been approved by the US Food and Drug Administration for export to the United States (A Dangi, pers. com.).

While most of those plants manufacture generics, the future may look very different. Some observers put India's R&D and manufacturing cost advantage at more than 1-to-10 over the West. Certainly, labor cost differentials are in that range. With a rapid growth in sales, a large cost advantage over the North, and TRIPS looming on the horizon, India's pharmaceutical and biotechnology industries are likely to increase their R&D investments over the coming years.

[28] This is beginning to change, as we describe below. The largest public sector R&D agencies—Space, Defense and Atomic Energy—have all initiated steps to translate the technologies they generated into products for the civilian sector. Interestingly, Defense now has very strong public-private partnerships and has established substantial in-house R&D management skills. The Space, Atomic Energy and Defense Departments have all set up IP Units to commercialize their products.

**Figure 2: Patent applications filed by Recognized R&D units and Public Sector Undertakings**




Unfortunately, HIV/AIDS, TB, nutrition, water borne diseases, and malaria are not high on their agenda. India's private sector alone cannot be expected to solve India's most pressing public health problems. Like their counterparts elsewhere in the world, Indian companies are in business to maximize a return to their shareholders, and this will drive their choice of targets for product development. During a symposium on "Managing Intellectual Property in Public-Private Partnerships" held in New Delhi, in 2002, one executive stated clearly—if resignedly—that his company was pursuing the same strategy as its multinational counterparts, developing high-profit-margin treatments for chronic diseases such as cancer, Alzheimer's and other neurological disorders for wealthy markets around the world.

Whatever road Indian industry follows, most of the country's research infrastructure still lies in the public sector, in academic and national laboratories scattered throughout the subcontinent. Some companies have already taken advantage of this. Shantha Biotechnics Pvt. Ltd. got its start at Osmania University, scaled up at a national laboratory, the Center for Cellular and Molecular Biology (CCMB), and then shifted to its own laboratories and manufacturing facilities to produce India's first recombinant product: hepatitis-B vaccine. Bharat Biotech International Ltd. leased over 10,000 square feet of laboratory space from the Indian Institute of Science in Bangalore to develop its own version of the hepatitis-B vaccine. Such arrangements are common in the United States and Europe, but relatively new to India.

According to press reports in December of 2000, several of India's larger pharmaceutical companies, including Dabur, Ranbaxy, Zydus, and Cadila, planned to establish a "Technology Transfer Deck" involving publicly-funded scientists and institutions in biotechnology and bioinformatics. The "Deck" would be coordinated by the Confederation of Indian Industries (CII), and monitored by the Department of Biotechnology. Its goal is to promote innovation and commercialization of IP rights for drugs and vaccines. Larger pharmaceutical companies such as Ranbaxy, Dr Reddy's Laboratory, Cadila, Sun Pharma and Wockhardt have very active patent divisions.

CII, the Federation of Indian Chambers of Commerce and Industries (FICCI), the Associated Chambers of Commerce and Industry of India (ASSOCHAM), and other industry associations have been active in creating IP awareness among their members through workshops, seminars and training programs with the help of Indian and foreign experts. FICCI has established an IPR institute,[29] and an Indian law firm, Lall, Lahiri and Salhotra, has established an Institute of Intellectual Property Practices and Research.

Thus, despite financial constraints, some Indian pharmaceutical and biotechnology companies are beginning to support original research. They are actively seeking to protect IP that arises from that research, and are increasingly eager to partner with experts and facilities in India's public sector to carry out original research.

Is the public sector ready to work with these companies? Historically (with some exceptions), the gulf between India's technical agencies, national laboratories and universities on the one hand, and the private sector on the other, has been large. Again, this appears to be changing.

### *4.4 India's Technical Agencies*

While most of India's universities have been slow to adapt, the country's technical departments and agencies have been moving toward indigenous public-private partnerships for some time. Since 1995, almost all have established offices to manage and protect IP arising from their own laboratories. These offices are often staffed with tremendous enthusiasm, though with varying levels of expertise. As yet they are linked only informally with each other, and rarely to their international counterparts.[30]

The following pages contain a selective survey of IP Management Offices among India's technical departments and agencies. Websites of are included when possible. The discussion resumes on page 44 with a summary of recent policy changes initiated by the Government of India affecting technology management.

#### *4.4.1 NRDC (www.nrdcindia.com/index.html)*

The National Research and Development Corporation was established by the Indian Government in 1953 as a central technology transfer office to commercialize technologies developed by government funded agencies. It acts "as a link between scientific laboratories and industrial establishments for transferring technologies," and is "wholly dedicated to transfer of technologies from R&D laboratories to industry [covering] the entire spectrum of industrial technologies ranging from chemical to metallurgy, mechanical engineering, electrical engineering, electronics, biotechnology, etc."

The NRDC used to provide patenting services as well, but many government agencies have now begun to handle IP on their own. The NRDC still provides financial assistance to individuals and institutions for patent filing in India, but does not provide funds for patent maintenance. It will assist with foreign filing as well, but only if the patent is assigned to the NRDC and if 50 percent of the filing costs are borne by the inventor/institution. The NRDC will assist inventors and institutions in the search for potential licensees, and will facilitate legal and other tasks associated with negotiating licensing agreements and technology transfer (see "Box: Brief History of NRDC" on next page for additional information on NRDC).

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[29] www.iprindia.net/newiprindia/index.htm

[30] In contrast, from a small founding group of 51 in 1975, the U.S.-based professional society AUTM has grown to nearly 3,000 members, publishes its own journal, has regular meetings, and is reaching out to its counterparts in other countries through the establishment of a Global Network of Technology Transfer Societies.

**_Box: Brief History of NRDC_**

The National Research Development Corporation (NRDC) was established as early as in 1953 under the Department of Science and Technology, Ministry of Science and Technology, under Section 25 of the Companies Act (as non-dividend paying company), on the pattern of NRDC of UK to promote, develop and commercialise indigenously developed technologies primarily of the Council of Scientific and Industrial Research (CSIR) with the prime objective of smooth, effective and efficient flow of technology from R&D centers and individual inventors to the industry and to bring the fruits of science and technology to the people. Pt. Jawaharlal Nehru, the great visionary and Dr. S.S. Bhatnagar, the celebrated scientist became the founding scribers of the Corporation and signed as being the President of Council of Scientific & Industrial Research and on behalf of the President of India respectively. Since then many eminent Indians had been the chair-persons of the Corporation - Shri R. Venkataraman (ex-President) of India and noted scientists like Dr S.H. Zaheer and Dr. G.S. Sidhu are from amongst them.

The Corporation commercialised CSIR technologies exclusively till 1986. After that CSIR laboratories were given the freedom to license the know-how developed by them directly to industry and since then the CSIR technologies were commercialised by both NRDC and CSIR laboratories. Over the last five decades of its existence, the Corporation has tied up with over 300 R&D Institutes/Universities/IITs[spell out]/Industries for assignment of technologies, and over 2500 technologies were assigned. The Corporation executed more than 4,500 licence agreements for commercialization of wide variety of technologies.

The Corporation has been carrying out several promotional programs under which the Corporation undertakes the following major activities:

- Awarding meritorious inventions ["providing award for meritorious inventions?"]
- Publication of Invention Intelligence (English) and Awishkar (Hindi)
- Providing technical, legal and financial support to the inventors for filing patents in India and abroad
- Promotion and development of Rural & Household technologies
- Providing Techno Commercial [can you use a non-jargon phrase?] support to its licencees

The Corporation has diversified its activities from transfer of technology to provide knowledge-based information. The Corporation has initiated the project for setting up technology e-channel on the Internet for providing information on technologies. The Corporation has also developed Interactive Multimedia Training Package on Intellectual Property Rights (IPRs) for disseminating information and giving training on IPR related issues.

Source: Courtesy of S.K.Sakhuja, NRDC Company Secretary.

#### *4.4.2 CSIR (www.csir.res.in)*

The Council for Scientific and Industrial Research – with 42 laboratories scattered around the country conducting research ranging from aeronautics to ceramics to molecular biology – has always had a strong orientation toward private and State owned industry. Most CSIR laboratories were specifically created during Nehru's time to assist industry. The CSIR itself was established in 1947. However, up to the 1980s they focused more on basic research and filed few patent applications. In the early 1980s, negative criticism grew as journalists and policy makers pointed out how few CSIR technologies were ever taken up by the Indian industry. In response, the CSIR began to increase its thrust and focus on the 'industrial' component of its work. CSIR laboratories that had focused primarily on generating new knowledge were now required to create new policies and facilities for converting that knowledge into products.

They began to establish and strengthening in-house facilities for industrial liaison and technology transfer of bench level inventions to the pilot plant level of manufacture. Today, the CSIR model is unique among Indian technical agencies. Each of the 42 CSIR laboratories has its own IP coordinator (other technical agencies have numerous national and regional laboratories throughout the country but still manage IP centrally, in New Delhi). The CSIR also has a strong IP division in its headquarters, which coordinates the work of individual CSIR laboratories. The CSIR shares revenues from technology transfer with its scientists.

In 1995, the CSIR filed 58 patent applications, and in 1999 it filed 112 (many in India alone). In 2003, the CSIR filed a record 100 US patents. As noted earlier, one recent CSIR success from the laboratory of the current Director-General, Dr. R.A. Mashelkar, is a polymer that now coats one-out-of-three compact discs in the world, and is bringing significant royalties back to CSIR. This and other success stories have raised eyebrows on Rajpath (the Government corridors of power), highlighting how IP can work in India's favor.

CSIR laboratories in fields with a strong industry focus such as synthetic chemistry, chemical technology and engineering generally have strong technology transfer units. However, two premier CSIR research centers, the Center for Cellular and Molecular Biology (CCMB) in Hyderabad, and the Central Drug Research Institute (CDRI) in Lucknow, still file only a few patent applications per year. In contrast, the Center for Biochemical Technology in Delhi, recently renamed the Institute of Genomics, has increased its technology transfer activities dramatically over the past few years, developing a healthy portfolio of US patents, and has entered into several public-private partnerships with significant co-funding from industry.

### *4.4.3 DST Patent Facilitation Center (www.tifac.org.in/do/pfc/pfc.htm)*

The Department of Science and Technology (DST), the Federal nodal agency for science and technology, responded quickly to the changing IP and technology transfer scenario. A first step in this direction was to create awareness among Indian scientists, technologists, academicians and policy makers from universities, R&D institutions, industries and government departments. The DST established its Patent Facilitation Center (PFC) under the Technology Information Forecasting and Assessment Council (TIFAC) in June of 1995.

The PFC's goal is "to spread IPR knowledge and encourage and help scientists to commercialize their technologies," with objectives to introduce the culture of using patent information as an input for the development of research programs, providing technical and financial assistance to Indian scientists, especially from universities, to protect their inventive work in India and elsewhere, and to create IPR awareness among the Indian scientists, technologists, policy makers and students.

Since 1995, the PFC has assisted researchers to file over 125 patent applications (including 23 outside of India). While the numbers remain modest, the PFC is unique in one particular way. It takes all comers. Anyone in the country who thinks he or she has an invention can come to the PFC for advice and assistance. Even the quintessential backyard inventor can get help from the PFC. Other technical agencies have established offices with more circumscribed missions, to transfer technologies only from their own laboratories into the private sector. See Appendix A for a full description of the PFC.

PFC has been conducting patent awareness workshops all over the country and has conducted over 200 workshops sensitizing about 20,000 scientists, students and policy makers from about 110 universities, more than 350 industries and 200 R&D institutions. Its monthly IPR Bulletin is circulated to about 10,000 readers and has a large membership on the net. PFC has filed 205 patent applications on behalf of universities, government departments and ministries in India and elsewhere. Many foreign patents have been granted for these inventions; these results show the expertise developed by PFC in conducting patent searches and assessment of novelty and inventiveness.

In order to reach out to many scientists, PFC has set up Patent Information Centers (PIC) in the states of Andhra Pradesh, Gujarat, Kerala, Madhya Pradesh, Manipur, Punjab, Rajasthan, Sikkim, Tirpura, Uttar Pradesh, Uttranchal, and West Bengal. The PICs are performing the role of the PFC at the state level. The PFC Model has caught the attention of, and received delegations from, many other developing countries. Over the years, the PFC has developed considerable expertise in the negotiation of IP agreements.

The Government of India, through the DST, has taken major strides at the international level by signing IP rights agreements with the European Union and Russian Federation in respect of their joint S&T programs. The first such agreement was put in place for the Indo-French Center, set up for promoting joint research among Indian and French institutions.

#### 4.4.4 DBT Biotechnology Patent Facilitation Cell (dbtindia.nic.in/programmes/patent/patentmain.html)

The Department of Biotechnology (DBT), DST and CSIR all fall under the umbrella of the Ministry of Science and Technology. Following the PFC model, the DBT established a Biotechnology Patent Facilitation Cell (BPFC) in 1999. To date, the BPFC has filed over 72 patent applications, most in India, but a few in the United States and Europe. For the identification of companies to work with, and negotiating licenses, the DBT had established an autonomous technology transfer office, the Biotechnology Consortium of India, Ltd. (BCIL).

One top-level DBT Advisor has observed a dramatic shift in the attitude of Indian companies. He now receives visitors from the private sector almost every day—Indian companies seeking him out to explore potential partnership opportunities with the DBT. The DBT has now has well-established linkages with Indian industry (and some foreign biotechnology companies, notably in the United States) to develop vaccines against HIV and other diseases.

#### 4.4.5 ICMR IP Rights Unit (www.icmr.nic.in/ipr.htm)

The Indian Council of Medical Research is an autonomous body funded by the Ministry of Health and Family Welfare. The ICMR created its Intellectual Property Rights Unit (IPRU) in 1999 to provide technical and legal support to its scientists. During the summer of 2002, the Indo-U.S. Technology Management Program supported training for the Director of the IPRC at Michigan State University and with the Office of Technology Transfer, National Institutes of Health (NIH). The Indo-US program also supported a consultant from NIH who spent two weeks with the IPRC and subsidiary ICMR institutes to review their IP policies. For ICMR's IP policy, see Appendix II.

#### 4.4.6 ICAR Intellectual Property Rights Cell (www.icar.org.in)[31]

The Indian Council of Agricultural Research established its Intellectual Property Rights Cell in 1998. Its Director received training on Technology Management and IPR at Michigan State University in 1999.

#### 4.4.7 India's Academic Institutions

Universities receive the bulk of their funding from the University Grants Commission, but are also among the largest recipients of extramural research funding from India's technical agencies. Few, if any, autonomous research centers or State Government-based universities have developed skills in IP management. Aside from faculty who have participated in PFC training programs (noted above), most students and faculty have little knowledge of basic IP principles.

Many of India's institutions of higher learning, including the well-known Indian Institutes of Technology (IITs), were established with the help of more developed countries during the first three decades after

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[31] This is the agency's homepage; no website is available for the IP office.

independence. The IITs, among India's most prestigious academic institutions, were also the first Indian institutions of higher education to establish industrial liaison and technology transfer offices.

The IITs have not traditionally been involved in health or molecular biology research, despite that one of the models of the IIT system, the Massachusetts Institute of Technology, moved into the life sciences nearly 40 years ago. However, most IITs have bioengineering centers, and most have or are now developing biotechnology centers, and making a shift to consider life sciences research and development as part of their core missions.

In no particular order, these institutions include the IIT New Delhi, IIT Bombay, IIT Kharagpur, IIT Kanpur, IIT Guwahati, IIT Roorkee, and IIT Chennai. Most of the IITs have offices that handle IP and technology transfer issues. One knowledgeable observer of the technology management landscape in India has noted that these offices are not very busy or productive compared to their foreign counterparts. Nevertheless, they are developing experience and a deeper understanding of the issues involved.

### *4.4.8 Foundation for Innovation and Technology Transfer (www.fitt-iitd.org/fittdisplay.html)*

IIT Delhi maintains a Foundation for Innovation and Technology Transfer (FITT). It was established in 1992, and its mission is "To be an effective interface with the industry to foster, promote and sustain commercialization of Science & Technology in the Institute for mutual benefits." The Foundation has held workshops on IP awareness.

### *4.4.9 Industrial Research and Consultancy Center (www.ircc.iitb.ac.in)*

IIT Bombay now provides a course for students on intellectual property. IIT Bombay's Industrial Research and Consultancy Center (IRCC) coordinates, facilitates and manages externally funded research and development projects, including IIT-Industry interaction. The IRCC "handles not only aspects related to intellectual property protection and technology transfer but also the complete financial management and recruitment of research scientists and engineers to work on funded projects."

### *4.4.10 Office of Sponsored Research and Industrial Consultancy (www.iitkgp.ernet.in/sric)*

IIT Kharagpur has an "IPR and Industrial Relations Cell," created recently within its office of Sponsored Research and Industrial Consultancy (SRIC). The SRIC is a "special R&D Cell established in 1982 as an interface between funding agencies and the Institute to handle sponsored research projects and industrial consultancy assignments." Since its creation, the SRIC has handled over 1,200 research projects worth over $20 million US dollars. The center currently manages over 450 sponsored projects from national and international clients worth more than $8 million dollars. Clients include both Indian companies and ministries, as well as companies from Germany and the United States.

### *4.4.11 Office of Sponsored Research and Industrial Consultancy (www.rurkiu.ernet.in/sric)*

IIT Roorkee has an Office of Sponsored Research and Industrial Consultancy (SRIC), and "encourages its faculty, scientists, technicians and students to interact with industry in all possible ways with the spirit of deriving mutual benefit." An IP Rights Cell was established in September 2000 within the SRIC to assist faculty who are involved with the creation of intellectual property. The Cell organizes lectures, conferences, and workshops to increase awareness of patents, copyrights and other IP rights.

### *4.4.12 Center for Industrial Consultancy and Sponsored Research (www.iitm.ac.in/ICSR)*

IIT Chennai's Center for Industrial Consultancy and Sponsored Research (IC&SR) was established in the early seventies to promote interaction between the Industry and the Institute. Today, the center for

IC&SR is an independent section of the Institute, headed by a Dean. Over the years, this center has played a vital role in bringing together the people from the Industry and the faculty of the Institute resulting in important contributions to design and development in the country.

#### *4.4.13 Innovation and Incubation Center (www.iitk.ac.in/siic/about1.html)*

IIT Kanpur: In 2001, with funding from the Small Industries Development Bank of India (SIDBI), the IIT Kanpur established an Innovation and Incubation Center to "foster successful entrepreneurs and develop industry," with a special focus on information technology and biotechnology.

#### *4.4.14 IISc Center for Scientific Industrial Consultancy (www.csic.iisc.ernet.in)*

The Indian Institute of Science (IISc) established its Center for Scientific Industrial Consultancy (CSIC) in 1975. The Center was "vested with the responsibility of further promoting the already existing institute-industry relationship for mutual benefits and advancement." It negotiates leasing of IISc facilities, consulting by IISc faculty in product and process development, as well as technology transfer from IISc laboratories to the private sector. The CSIC has succeeded in launching companies with equity participation by faculty members (a novel approach in India).

#### *4.4.15 The Small but Growing Cadre of Indian Technology Managers*

Universities with similar technology management centers include Delhi University, G B Pant Nagar University, Pant Nagar, Bidhan Chandra Krishi Vishwavidyalaya, Kalyani (West Bengal) and Jadavpur University, Kolkata. Many more such centers will soon come up depending on the need of each institution.

Yet the IITs and IISc are the exception. India has about 250 universities and close to 700 engineering and medical colleges. Only a handful have IP cells. University management often fails to appreciate the need, and often lack resources to support work in this area. Finally, there is a shortage of faculty volunteers who understand and are willing to take the responsibility for an IP management office.

Despite these impediments, organizers of the March 2002 All India Technology Managers Workshop/Retreat were able to identify individuals who focused on IP management (at least part time) from the following Indian institutions: National Center for Cell Sciences, Pune; Bidhan Chandra Krishi Viswavidyalaya, Nadia District; Department of Atomic Energy, Mumbai; Defense Research and Development Office, New Delhi; Agarkar Research Institute, Pune; International Center for Genetic Engineering and Biotechnology, New Delhi; Punjab Agricultural University, Ludhiana; GB Pant University of Agricultural and Technology, Pantnagar; IIT Bombay; IIT New Delhi; IIT Kharagpur; Indian Space Research Organization, Bangalore; MS University, Baroda; Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram; National Institute of Pharmaceutical Education and Research, Punjab; Center for Cellular and Molecular Biology, Hyderabad; Central Drug Research Institute, Lucknow; Center for DNA Finger Printing and Diagnostics, Hyderabad; Center for Biochemical Technology, Delhi; National Institute of Immunology, New Delhi; IISc, Bangalore; Bose Institute, Kolkatta.

### ***4.5 Indian Policy Breakthroughs***

As in many other countries, ownership of inventions arising from government-funded research has historically resided with the government of India, which retained the right to transfer such technologies for commercialization. However, the government had little expertise to guide it in this process. The concerned research institutions had a role in negotiating technology transfer and also in helping industry overcome problems arising during scale-up.

One of the arguments supporting this arrangement was that it would not be fair for one institution or a few individuals (inventors) to enjoy the fruits of R&D that was funded at the taxpayers' expense. The government was thought to be the only organization capable of ensuring that the benefits of research would be distributed equitably. Government financial rules did not allow for the collection of assets generated through R&D.

With the coming of the WTO, the Government of India recognized that scientific inventions would have an increasingly important role. In the knowledge society, conducive environments and circumstances should be created to increase the number of scientific inventions leading to the generation of IP. Since India signed TRIPS in 1995, with the help of WIPO and the WTO, the Ministry of Commerce and Industries (which sets the country's rules for patents, designs, trademarks and geographical indications) has conducted many workshops and seminars, both national and international. Similarly, the Ministry of Human Resource Development, the rule making body for copyrights, has taken many initiatives in spreading IPR knowledge.

Unless scientists and institutions capable of generating new knowledge are adequately motivated, no society could expect to benefit from a growing research portfolio. Against this backdrop, injecting a new paradigm is not an easy task. Many people enter this debate over the relative advantages and disadvantages of public goods and private property without realizing that a property, duly owned, can be used for public good (rather than profit) if the owner so desires.

### *4.6 New Government Ruling*

Based on the positive experiences of individual agencies and institutions since 1995, and following the advice of top officials from the Ministry of Science and Technology, in March 2000 the Ministry of Science and Technology issued an Official Notice to "encourage institutions to file patent applications on their innovations, motivate them to transfer their technologies for commercialization, and facilitate them to reward their inventors." The ruling gives ownership of inventions to any research institutions that receive funding from the Ministry of S&T. It also requires research centers to direct 25 percent of IPR-derived income into a "Patent Facilitating Fund" to cover the cost of patent applications, protect against infringement, and to create awareness and build competency on IPR. One of the results of this policy has been a significant rise in patent applications by academic institutions (Figure 3).

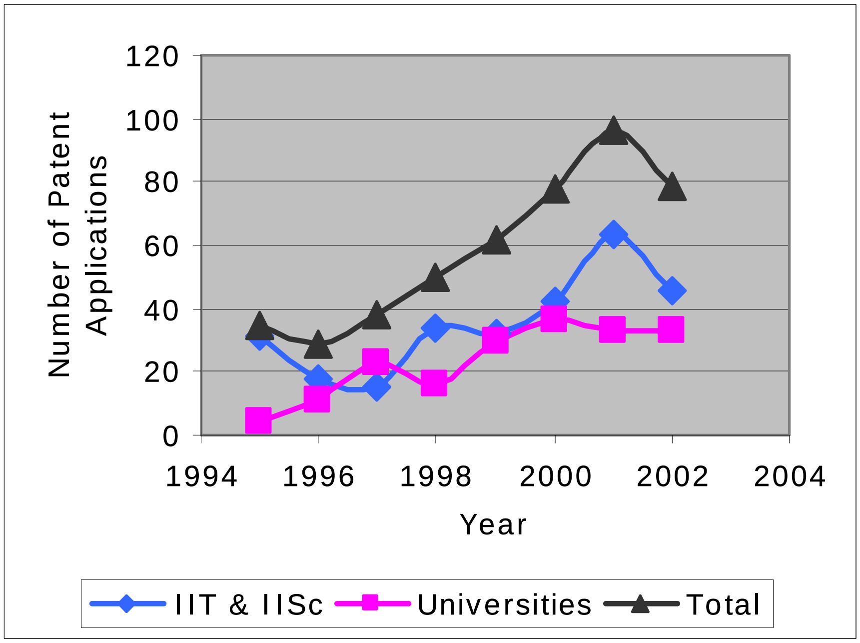
These guidelines were intended to enhance the motivation of scientists, research institutions and universities in projects funded by the Department of Science and Technology, Department of Biotechnology, Department of Scientific and Industrial Research and Department of Ocean Development. The salient features of the guidelines are:

1. Institutions shall be encouraged to seek protection of intellectual property rights in respect of the results of R&D. They may retain the ownership of such IPR. "Institutions" mean any technical, scientific or academic establishment where research is carried out through funding by the central or state government.

2. The institutions shall take necessary steps to commercially exploit patents on a exclusive or non-exclusive basis.

3. The owner institution is permitted to retain the benefits and earnings generated out of the IPR. The institution may determine the share for inventor(s) and other persons from such actual earnings. However, such share shall be limited to one third of the actual earning.

**Figure 3: Patent Applications from Academic Institutions**




Source: Data collected by R. Saha, Patent Facilitation Center, TIFAC/DST

4. IPR generated through joint research by institution(s) and industrial concern(s) through joint efforts can be owned jointly by them as may be mutually agreed by them through a written agreement. The institution and industrial concern may transfer the technology to a third party for commercialization on an exclusive or non-exclusive basis. The third party, exclusively licensed to market the innovation in India, must manufacture the product in India. The joint owners may share the benefits and earnings arising out of commercial exploitation of the IPR. The institution may determine the share for the inventor(s) and other persons from such actual earnings. Such share shall not exceed one third of the actual earning.

5. The owner institution shall set apart not less than 25% of the revenue generated from IPR to create a Patent Facilitating Fund which shall be utilized by the institution for updating inventions, filing new patent applications and protecting IP rights against infringement and for building competency in the area of IPR and related issues.

6. The Government shall have a royalty free license for the use of the intellectual property for the purposes of the Government of India.

This represents a major departure for one government ministry. Unfortunately, implementation has been uneven. Other departments and government agencies follow different rules. Many of India's research centers were established under a socialist banner with prohibitions against ownership of inventions etched into their founding charters. Many institutions simply have not received the message from the Ministry of Finance, or haven't noticed it, or do not have sufficient expertise to understand and implement the ruling. In order to have a more uniform policy, new legislation may be required.

The Ministry of Science and Technology ruling was a radical departure from past practice, yet it went largely unnoticed in the local press. Twenty years ago, a similar law in the United States (the Bayh-Dole Act) sparked considerable controversy with charges that American consumers would be forced to pay twice: first through taxes to support research, and second to purchase the products of research. Twenty years later, the consensus is that Bayh-Dole has been a net positive factor helping to build the nexus of public-private interaction and venture capital that drive innovation, high-tech job creation and wealth formation in the United States. (However, Bayh-Dole has done little to address specific health needs of the poor, especially in developing countries.)

### *4.7 Incentives for Public-Private Partnerships and for Research*

Former Prime Minister Vajpayee had announced plans to double national R&D spending (both public and private) by 2005 through a combination of increased public investment and incentives. The Government of India now encourages pharmaceutical and biotechnology research and promotes public-private partnerships through a range of tax concessions, soft loans and grants to Industry.

Research incentives include a 10-year tax holiday on income arising from R&D, a 3-year Excise Duty waiver on goods developed by Indian companies and patented in the United States, Japan, or any two or more countries of the European Union. Bulk drugs, produced in India through a manufacturing process developed from Indian R&D, are exempt from Drug Price Controls for up to 5 years, and novel drugs developed through indigenous R&D will remain outside price controls for up to 10 years from the date of commercial production.

The Department of Science and Technology supports soft loans and grants to promote public-private partnerships through an Industry R&D Partnership Program and the DST's Drug Discovery Program, while the Drugs and Pharmaceuticals Research Program supports joint research projects between academic or national laboratories and industry. Both the Indian Council of Medical Research and the Department of Biotechnology have also begun to develop partnerships with Indian industry to develop vaccines and diagnostics, however current Government of India restrictions still make it difficult for them to support Indian companies directly.

### *4.8 International Exchanges and Experience*

The Indo-US Technology Management Program (IUTMP) is a first-of-its-kind effort to raise local capacity for public-private R&D partnerships in a developing country. Its goal is "To create linkages between Indian and American technology management experts to highlight the benefits of public-private partnerships and intellectual property protection for India, and to stimulate local research and innovation to address India's own public health, agricultural and environmental needs." One lesson for Indian institutions is that patents are just a tool in the much larger process of technology management, of which the end result is new technologies, job creation and economic development.

The IUTMP was created in 2000 with funding from the US Embassy Public Affairs Office. It is managed by the Health Office of the US Department of Health and Human Services (HHS) in the Science Section of the US Embassy. In 2001, in collaboration with India's Council of Scientific and Industrial Research (CSIR), this program supported a series of multi-sectoral Symposia in New Delhi, Pune and Hyderabad, as well as training exchanges with Michigan State University. In 2002, the program collaborated with the Patent Facilitating Center of the Technology Information Forecasting and Assessment Council (TIFAC), under the Department of Science and Technology, to support a Workshop/Retreat for Indian technology managers as well as a multi-sectoral Symposium on "Managing Intellectual Property in Public-Private Partnerships."

IUTMP Events focused on case studies to highlight lessons learned from successes and failures over the past 20 years in the United States, and more recently in India. Agendas were typically divided into five areas, highlighting the perspective of public-sector research institutions:

1. developing your institution's IP policy;
2. how to identify an invention in the laboratory, and how to educate researchers about IP;
3. where, when, how and why to file a patent application;

4. how to identify company partners and negotiate fair license agreements with them;
5. follow up to ensure the company invests sufficient resources to commercialize the technology.

Recommendations from the March 2002 All India Technology Managers' Workshop/Retreat are included in Appendix C (page 55). They are consistent with, and appear to be largely incorporated into the Indian Government's 2003 S&T Policy.

Symposium participants included Government policy makers, research administrators, scientists, industry representatives and venture capitalists. These events generated significant enthusiasm from participants, were highly successful in the view of the Indian technical agencies involved, and included a recommendation from the 2002 All India Technology Managers Retreat/Workshop to establish an "Indian professional society for technology managers" which was subsequently endorsed, in the presence of the US Ambassador, by the Secretary of the Department of Science and Technology Dr. V.S. Ramamurthy, and the Principal Scientific Advisor to the Government of India, Dr. R. Chidambaram

As this new association gets started, every effort should be made to link it to its counterparts in other developing countries, as well as to the U.S.-based Association of University Technology Managers (AUTM), and to European counterparts such as the Association of European Science and Technology Transfer Professionals (ASTP) and the Public Research Organisations' Technology Offices Network (ProTon-Europe). No such organizations yet exist in the developing world, though MIHR (see "Box: MIHR" below) is working to create supportive conditions for professional associations to form.

India's head start in technology management (among developing countries) also makes it an ideal partner for developed countries in many areas of research. Sharing experience in technology management only strengthens the relationship. Northern technology managers gain an understanding of the needs and capabilities of Indian institutional partners, and when an invention arises from joint research both sides can negotiate from the same frame of reference. India's private sector will also benefit as it reaches out to the public sector, and as Northern technology managers enable the transfer of technologies that are available in the United States (presentations by US technology managers through the IUTMP led serendipitously to the transfer of several health technologies from NIH to Indian companies).

### *4.9 The 2003 Science and Technology Policy*[32]

During the annual Indian Science Congress in January of 2003, the Prime Minister announced a radical new science and technology policy (Appendix D). One of the Policy objectives is:

> To establish an IPR regime which maximizes the incentive for generation and protection of IP by all types of inventors. The regime will also provide a strong, supportive and comprehensive policy environment for speedy and effective domestic commercialization of such inventions so as to be maximal in the public interest.

***Box: MIHR***

In 2002, The Rockefeller Foundation launched MIHR, the Center for the Management of Intellectual Property in Health Research and Development (www.mihr.org), to help build technology management capacity in developing countries, as well as to conduct research and share best practices in the management of IP to promote global health. The organization is international in scope, based in Oxford UK, with linkages and activities throughout the world. Though young, MIHR has already developed a handbook of best practices, conducted workshops in South Africa, Egypt and India, and is now exploring partnerships with the ICMR, South Africa's Medical Research Council and other technical agencies in developing countries. One of MIHR's primary goals is to raise the stature and build capacity of technology managers and technology management offices in publicly funded health research institutions in developing countries – so they can enter into sound, viable "indigenous" public-private partnerships that are accountable to the public interest.

[32] See also dst.gov.in/doc/STP2003.doc

The Policy further states:

> Intellectual Property Rights have to be viewed, not as a self contained and distinct domain, but rather as an effective policy instrument that would be relevant to wide ranging socio-economic, technological and political concepts. The generation and fullest protection of competitive intellectual property from Indian R&D programs will be encouraged and promoted.

In order to enhance the synergy between industry, scientific organizations and universities, the new policy includes plans to develop a comprehensive program on technology management training, and to create autonomous technology transfer offices at research institutions throughout the country. This represents the culmination of ten years of experience by India's technical agencies and institutions. It also points the way toward a future in which technology management in publicly funded research institutions will play a central role in the country's economic development, and in the development of new locally relevant technologies.

It is also a significant shift away from a focus on what were once called "Patent Cells" in the technical agencies. The new policy now recognizes the full spectrum of interactions in technology management from invention disclosures to patents, licensing and follow-up, scale up and manufacturing. In this context, IPR and patents can be seen as necessary – though never sufficient – tools in a larger process to create incentives that bring private sector know-how to address public sector goals. See Appendix E for selected highlights of the new policy.

## 5. Conclusions

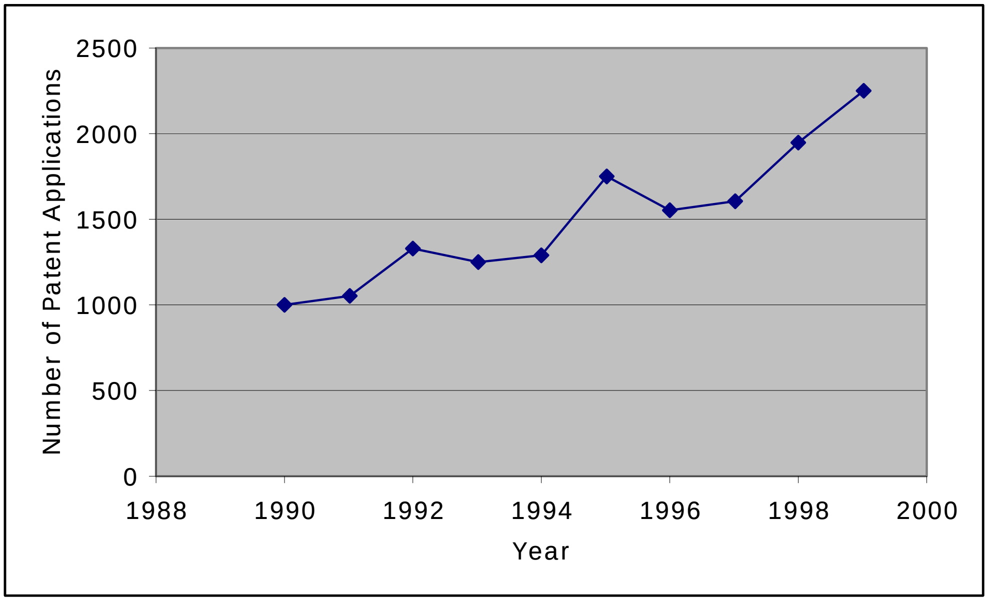
It is difficult to bridge the gap between public and private sectors in any country. In many ways, these two cultures are more distinct than any two communities in the world. Models for public-private partnerships and the management of IP in such partnerships are being tested, but are still only tentatively established in India, still less in other developing countries (they are also relatively new in the United States, Europe and Japan). Patent filings by Indian academia, national laboratories and industry are low, but growing. Government policy and the move toward stronger product patent protection are encouraging greater investment in R&D by the pharmaceutical and biotechnology industries. The trend lines all are positive, even impressive (Figure 4).

In contrast to the United States and other developed countries, the lion's share of India's health research infrastructure is in the public sector. The country's rapidly growing pharmaceutical and biotechnology industries are hungry for new technologies, yet the historical chasm between public- and private sectors has prevented effective technology transfer in the past. The engine was running, but the gears were not engaged.

Now, and at least for the next several years, there would appear to be a unique window of opportunity for India and, by analogy, other countries at a similar stage of development. Raising the capacity of publicly funded health research institutions so they can transfer their own innovations to their own private sector could give traction to a very significant public investment that is based on national health priorities rather than profit.

Technology transfer from such institutions would include a high proportion of diagnostics, drugs and vaccines against diseases of the poor. As technology management offices become more experienced, they will help move other technologies as well, from cancer drugs to advances in engineering and chemical synthesis (most research institutions don't just work on health). Capacity building in health technology management, therefore, could be a key factor in overall economic development.

**Figure 4: Total Patent Applications Filed by Indians in India**




Source: Patent Facilitation Centre, TIFAC/DST

The authors have had some experience and success in establishing technology management linkages and information exchanges between India and a more developed country. Still, we feel that Indian IP managers may have as much or more to learn from each other, and from their counterparts in other developing countries, than they do from Northern technology managers (similarly, U.S. technology managers have much to learn about Indian conditions and capabilities). Networks, including professional societies, are sorely needed to create these linkages among technology managers throughout the developing world. We are delighted that MIHR is working to meet this need.

There is still much to do, but India appears well on the way toward the construction of a substantial and comprehensive platform to support IP management and public-private partnerships. We believe this structure could be a model for other developing countries.

The positive impact of a small Indo-US program to share information and experience with Indian technology managers (IP managers) highlights a lever of change that has gone largely unnoticed by many development agencies. This seems strange; the role of innovation in economic growth in "wealthy" countries is generally acknowledged. Why should it be any different in less wealthy countries such as India?

Northern technical agencies should also take note, particularly health research organizations. NIH has become increasingly involved in a new approach to capacity building in developing countries, incorporating management training (e.g., project management, financial management, data management, ethical review management, and clinical trial management) into large research awards in addition to the more traditional technical training and provision of equipment that usually come under the heading of "research capacity building." So far, however, this new emphasis does not include capacity building in technology management.

The NIH Office of Technology Transfer (OTT) provided significant intellectual input into the design and execution of the Indo-US Technology Management Program. Unfortunately, no current mechanism exists for that office or its counterparts in individual institutes to become more actively involved in this area. Yet NIH currently supports over 80 collaborative research projects in India, and nearly ten times that number in other low- and middle-income countries around the world.

We believe NIH has a moral responsibility to build capacity in technology management in developing countries where it supports research. If an invention arises from that research, the developing country institution needs to be on a level playing field in negotiating ownership and licensing arrangements consistent with its own institutional and national interests. OTT understands this, and is exploring creative ways to support such capacity building wherever possible.

Capacity building in technology management represents a tremendous opportunity for donors and local governments alike to simultaneously stimulate the development of locally relevant technologies, create jobs and wealth, and improve the lives of people throughout the developing world (as the least developed countries import low cost products made in IDCs like India). With the right support, local technology managers themselves can shoulder the hard work to build a sound cottage industry for health and wealth. India is showing us how.

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## Appendices

### *A. Patent Facilitation Center*

Technology Information Forecasting and Assessment Council

Intellectual property protection plays a key role in gaining an advantageous position in the competitive technological game for achieving economic growth. India enjoys a large asset of R&D personnel and infrastructure. Scientists would need information, orientation and facilities for protecting the products of their intellectual prowess. As a first step in this direction a Patent Facilitating Cell now called Center (PFC) was set up by the Department of Science and Technology under the Technology Information Forecasting and Assessment Council (TIFAC) in 1995. Major Indian Scientific establishments have in-house facilities to provide patent support to their scientists. However, such facilities are not available to most of the academic sector and smaller scientific institutions whether in the Central or the State sector. PFC was created as a single window facility to service this large ALL INDIA clientele with a smile and "may we help you" approach. This helpful and human approach has helped PFC reach out to remote universities and R&D centers. Scientists thus have a direct and easy access to PFC's complete coverage.

Objectives

- Introducing patent information as a vital input in the process of promotion of R&D programs.
- Providing patenting facilities to scientists and technologists in the country for Indian and foreign patents on a sustained basis.
- Keeping a watch on development in the area of IPR and make important issues known to policy-makers, scientists, industry, etc.
- Creating awareness and under standing relating to patents and the challenges and opportunities in this area including arranging workshops, seminars, conferences etc.

Services and Conditions

- PFC provides technical, legal and financial support for obtaining patents and also for post patent actions in respect of patentable inventions emanating from research funded by government and Indian university / educational institution
- Scientists and their institutions are expected to keep track of developments in areas related to patented inventions and inform PFC about possible exploitation and also violation of their patents.
- For patentable inventions funded by a university/ educational institution, applications for patents will be filed in the name of the university/educational institution with the concerned scientist(s) as inventor (s).
- For patentable inventions funded by central / state government department/ agency, applicants for patents will be decided by the term and conditions mutually agreed between the funding agency and the research agency.
- Request for patent search are entertained from scientists, universities/educational institutions, government industry, attorneys and PSUs, with a levy of nominal change.
- Scientists concerned or their institutions, requesting PFC's help in patenting or patent search should send a list of key word, a brief technical description of the invention and names and addresses (if possible ) of agencies and scientist engaged in similar R&D work. This would ensure more extensive data search and saving in time. Information so furnished by inventors will be kept confidential.
- Queries on IPRs from individuals, government, university, industry, PSUs, R&D institutions and other agencies are quickly responded to.
- Advisory services are available to all.

Facilities

- Patent search facilities
- Databases on Indian patent applications filed and applications accepted.
- These are now available on-line (www.indianpatents.org.in) and on CDs entitled Ekaswa A & Ekaswa B.
- Mechanism for obtaining full text patent documents and patent searching elsewhere.
- Panel of patent attorneys drawn from all over the country for helping PFC in patenting activities
- Panel of expert faculty for patent awareness workshops
- Free of cost bulletin on IPR

### B. *ICMR Intellectual Property Rights Policy*[33]

Preamble

The Indian Council of Medical Research (ICMR) is the premier autonomous organization of the Government of India for the planning, promoting, co-ordinating and conducting biomedical research in India. The objectives of the ICMR are in consonance with the national health policy and aim towards improving the health of the people of India through biomedical research.

The ICMR (established in 1911) is one of the oldest medical research organizations in the world with a broad mandate to acquire new knowledge through the conduct and support of biomedical research in all areas of biomedical research that would have a bearing on improving the health of Indian people. The Council carries out its mandate through its network of 27 permanent Institutes/Centers and extramural research support system to investigators in various institutes and medical colleges in India and active international collaboration.

Over the past nine decades, scientists working within and with support from the Council have been carrying out high quality research to achieve the objectives. Any new information/data generated in the laboratory are immediately published for its widest dissemination and application for public good.

Of late, scientists of the Council are becoming increasingly conscious of the need and importance of protecting such new knowledge generated through appropriate IPR systems before publication. Such an awareness has largely been triggered by changes like liberalization and globalization of economy and the encouraging participation of industry in the increasingly technology-driven medical research, and health care.

In addition, the realization that in the present context, public-private partnership could well be an important means of achieving the goal of providing affordable health care to the needy has reinforced the thinking that such joint ventures could help health care products reach the needy public more efficiently and quickly. For such partnerships to be viable and successful, it is essential that the Council has appropriate IPR, technology transfer and licensing policies in place.

Mission

ICMR thus recognizes and supports new intellectual property development and technology transfer as integral components of its mission and asserts that the guiding principle governing the conduct of these activities shall be the prompt and efficient availability of the products developed for the service of its mission.

Policy

To meet its objectives of improving public health through research, the ICMR will pursue an active policy of ensuring the most rapid and efficient development of new medical technologies developed by its scientists through seeking IP rights in India and abroad. The Council, as an agency of the Indian government, will ensure that its basic mission will not be compromised by its efforts to commercialize new technologies. Further, where research and development is not necessary to realize the technology's primary use and future therapeutic, diagnostic or preventive uses, IP protection may not be sought and instead those technologies can be commercialized through non-patent licensing.

The Intellectual Property Rights Unit in the ICMR Headquarters Office will help scientists in their efforts to identify, protect and commercially exploit all new knowledge generated with ICMR support. The IPR Unit would provide technical, legal and other support needed for IP protection, technology transfer, licensing and commercialization issues.

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33 See also www.icmr.nic.in/ipr.htm

Major objectives

- To make scientists aware of the need and responsibility to protect new knowledge generated through IP rights, ownership of biological and other materials and data generated using ICMR funds and facilities.
- To develop procedures at ICMR institutions to capture, assess and protect new intellectual property generated.
- To provide ICMR scientists information on demand relating to patents in their areas of interest by maintaining appropriate national and international databases.
- To provide appropriate technological, professional and legal expertise and services to assist ICMR scientists to file patents in India and abroad.
- To encourage and provide all support to universities and other institutions for protecting and commercializing new knowledge generated with ICMR support.
- To develop a licensing policy that ensures the maximal public health benefit and a fair return on investment from ICMR research.
- To develop and implement a royalty policy at ICMR institutions that encourages innovative scientists and technology generators through a system of royalty sharing, and reward system.
- To serve in an advisory capacity to the Indian government on IP related issues concerning public health.
- To forge appropriate strategic alliances with national and international S&T agencies and industry to market its new inventions and develop professional knowledge networks for ICMR's technology management professionals.

Strategy

- Some steps to achieve the objectives are as follows:
- Appropriate internal and external systems would be set up at various ICMR Institutes/Centers for the identification of new IP before publication.
- Innovation-driven research would be encouraged through a IPR-friendly climate. Scientists would be made aware of need for prompt IP protection before public disclosure, through personal contacts, regular training workshops, seminars, etc.
- To help promote a sound IPR system, some basic and essential practices like record keeping, appropriate recording of data, maintenance of laboratory handbooks etc. will be encouraged at various ICMR Institutes.
- The IPR Unit would be engaged in regular monitoring of the Indian and global patent scenario to keep track innovations of the world.
- The advice of experts would be sought for furthering the objectives.

### *C. Recommendations from the First All India Technology Managers' Workshop & Retreat*

March 11-14, 2002, Neemrana Fort-Palace, Rajasthan

1. Awareness about IPR should be a continuing process
2. IP and technology licensing would be situation, institution and technology specific. Therefore each institution should workout its own policy for valuation, license negotiations and identification of companies

3. There are many groups in the country working in the fields of IPR and technology management in different universities and R&D institutions. There is a need for more interactions among these groups. It is recommended that these group can form a society of IP and technology managers (Indian Society of Technology Managers (ISTM))
4. A portal may be created which should act as a virtual discussion forum through which participants of this workshop could share their experience, case studies, different types of model agreement (licensing, MTA, etc.) and any other topic of benefits to participants. The portal will be available to people from other institutions working in this field.
5. More such workshops should be conducted involving many more institutions and practicing IP and technology managers, occasionally also with research directors from companies in research-intensive industries (Agriculture, Health, electronics, etc.). These may be organized jointly by TIFAC and US Department of State (Subject to availability of funds).
6. IPR culture must be integrated as an essential component of R&D efforts of an institution. Each academic and research institution should create an enabling mechanism for undertaking IPR activities.
7. Identification of inventions in these institutions should be given utmost importance, which would necessitate extensive training of research faculty and professionals involved in IPR and technology management in patent searches. Such expertise should be developed in all institutes.
8. Scientist-scientist and scientist-student contacts were considered- important parameter for facilitating IP and technology licensing. Each academic institution should develop a dynamic database of its alumni, which should be used for identifying licensees.
9. In order to facilitate licensing of IPR and technology from University/R&D institutions to industry, a need for evolving common principles and formats for licensing was strongly felt.

### *D. 2003 Government of India Science and Technology Policy*

Selected Highlights on IP Management

Policy Objectives:

- To encourage research and innovation in areas of relevance for the economy and society, particularly by promoting close and productive interaction between private and public institutions in science and technology.
- To establish an Intellectual Property Rights (IPR) regime which maximises the incentives for the generation and protection of intellectual property by all types of inventors. The regime would also provide a strong, supportive and comprehensive policy environment for speedy and effective domestic commercialization of such inventions so as to be maximal in the public interest.

Implementation Strategy:

- A comprehensive and well-orchestrated program relating to education, R&D and training in all aspects of technology management will be launched.
- Every effort will be made to achieve synergy between industry and scientific research. Autonomous Technology Transfer Organizations will be created as associate organizations of universities and national laboratories to facilitate transfer of the know-how generated to industry. Increased encouragement will be given, and flexible mechanisms will be evolved to help, scientists and technologists to transfer the know-how generated by them to the industry and be a partner in receiving the financial returns.

- Intellectual Property Rights (IPR), have to be viewed, not as a self-contained and distinct domain, but rather as an effective policy instrument that would be relevant to wide ranging socio-economic, technological and political concepts. The generation and fullest protection of competitive intellectual property from Indian R&D programs will be encouraged and promoted.
- The process of globalization is leading to situations where the collective knowledge of societies normally used for common good is converted to proprietary knowledge for commercial profit of a few. Action will be taken to protect our indigenous knowledge systems, primarily through national policies, supplemented by supportive international action.
- For this purpose, IPR systems which specially protect scientific discoveries and technological innovations arising out of such traditional knowledge will be designed and effectively implemented.
- Our legislation with regard to Patents, Copyrights and other forms of Intellectual Property will ensure that maximum incentives are provided for individual inventors, and to our scientific and technological community, to undertake large scale and rapid commercialization, at home and abroad.
- The development of skills and competence to manage IPR and leveraging its influence will be given a major thrust. This is an area calling for significant technological insights and legal expertise and will be handled differently from the present, and with high priority.

### *E. Setting up of the IPR and tech transfer activities at the Indian Council of Medical Research, New Delhi*

The Indian Council of Medical Research (ICMR) is the premier agency in India for the formulation, promotion and conduct of biomedical research in India. The ICMR, established in 1911, is one of the oldest medical research agencies in the world and was set up a year before Medical Research Council (MRC) of the United Kingdom. The ICMR has a network of 27 research institutes spread all over India that address disease-specific and discipline activities.

During its 90 odd years of existence, scientists of ICMR have made several significant contributions to advancing frontiers of medical research and find solutions to serious public health problems. However, in common with other scientists in India ICMR researchers also have traditionally held strong belief that new information and knowledge should be freely and widely disseminated. More so, if the research happens to be supported with public funds and is expected to be of direct or indirect impact on public health. Not surprisingly, the moment there is an exciting finding; it would be immediately published in a learned journal to enable its widest dissemination. That new knowledge generated could be protected through instruments of intellectual property rights has been rather alien to many established scientists in the best of institutes. In addition, having any systems of monopoly over new knowledge which restricts free access to others has been not very palatable, until very recently. In that sense, patents and other forms of protection were never considered as serious options to publication among the scientific community.

But a series of events in the recent past that pushed the world towards a new global economic order triggered new thinking among the society at large including the scientific community. The signing of the GATT treaty by India in 1996 and the eventual membership of the World Trade Organisation is perhaps first event. The signing of the GATT treaty that contained the contentious Trade Related Intellectual Property Rights (TRIPS) set off a fierce national debate on the IP rights. Several non-Governmental organizations in India expressed serious reservations on what is the first step of India's hesitant attempt towards globalization. One of the major concerns was the fear and apprehension that the new IPR regime would drive the drug prices beyond the reach of the common people. Also, the deadline of 2005 for India to become fully WTO compliant with appropriate amendments to the prevailing patent regimes and apprehension that multinational drug companies will monopolize the public health system increased the anxiety levels of the Indian public, and the policy makers. It had an interesting spin-off; enhancing the awareness of the scientific community, including ICMR scientists of the protection of new knowledge and its associated benefits and drawbacks.  There were other events that brought things to a boil of the need to protect indigenous knowledge from being exploited by others. The abortive attempt to patent the wound-healing properties of turmeric by two US-based Indians underlined the need for vigilance to and the urgency to find means of protecting knowledge through legal instruments. The legal battle in the US resulted in the revocation of this patent as it documented evidence was presented to show that turmeric was used for centuries in India for wound healing. The patenting of a plant with proven hepato-protective properties again in the US reinforced the thinking that intellectual property protection is an intrinsic component of doing science in a globalized world and India would perhaps only stands to gain by putting some legal framework on intellectual property rights in place. By late 1990s, there was a favorable climate for initiative steps towards IP protection and new technology generation.

The first step taken by the ICMR was the drafting a policy for working with industry and the transfer of new technology generated on commercial terms – the first attempt towards public-private partnership in its 90 year old history. A policy document was generated which envisaged working with industry. This policy document outlines modalities with which the ICMR scientists could interact with the industry and the terms and conditions on which new knowledge generated by ICMR scientists could transfer to industry, both on an exclusive or non-exclusive basis and the associated licensing issues. As a follow-up of the approval by the Government of India, a Technology Transfer Unit (TTU) was set up in 1996 at the ICMR headquarters to centrally promote, co-ordinate and monitor this first ICMR-industry partnership. In addition, the policy of rewarding inventors through a royalty-sharing policy on the revenue generated helped scientists recognize that new knowledge with potential industrial application can also have commercial value. Simultaneously, steps were taken to sensitize scientists of the need to identify new intellectual property and protect the new knowledge and that disclosure through publication would mean loss of their IP rights. They were made aware of the need to keep appropriate records of data generated as a mandatory protective measure against possible legal challenges and claims of priority. The ICMR researchers realized in a very over a short period that new IP and technology could be major driving forces for the overall development of the country besides benefiting them. A single window approach by the TTU to facilitate smooth transition of laboratory knowledge to industry encouraged many ICMR scientists to protect and exploit their new knowledge.

As a natural extension of the encouraging response to these initiatives, a full-fledged IPR Unit was set-up at the ICMR Headquarters in 2000 to take care of all IP-related activities of the Council. During this period, through the initiative of the Science Office of the US Embassy, services and advice of a senior technology manager of the National Institutes of Health, Bethesda, were made available to the IPR Unit of ICMR. The IPR policy of ICMR then being drafted was finalized. This policy document was released by the federal Minister of Health & Family Welfare, Govt of India. These new policy initiatives were widely appreciated by scientists within and outside the ICMR as it recognizes the importance of new knowledge besides outlining steps towards protection and eventual commercialization.

These new policy initiatives appear to have a snowballing effect on the scientists of the Council. Over a ten year period (1990-99) just 10 patents were filed by the ICMR scientists. But over the last two and a half years (2000-2003) as many as 19 patents including 5 international patents were filed. Over half a dozen technology negotiations were held and some products transferred to the industry. It has been very exciting to both the scientists and the IPR staff to be part of this new and very rewarding experience The new found vigor among ICMR scientists to recognize IPR as a legitimate tool for furthering science goes to show that what it was perhaps knowledge-gap that dissuaded them from exploiting new knowledge. More recent experience with a new HIV/AIDS vaccine initiative with public (India) - Private (US industry partner, Therion) – an international NGO (International AIDS vaccine Initiative, IAVI) showed that it is the generation cutting edge technology that can help a country acquire self-sufficiency in health care besides helping India become truly globally competitive.

In this brief period of less than eight years, there has been a perceptible change in the mind-set of scientists and a lot of skeptics have turned believers. This includes a large number of scientists and a handful of bureaucrats, who were initially rather cool to the setting up of minimal IP infrastructure at the ICMR. No major concessions were made nor serious impediments created. Two significant factors, more by chance helped these new initiatives take off ground smoothly. When the first technology transfer policy document was taken before the Governing Body of ICMR, the highest policy making body in 1996, it was cleared with surprising ease. This was because the then federal Minster of Health & Family Welfare was an industrialist-politician who understood the language of new technology, commercialization and how new knowledge could be converted into money. His unflinching support virtually pre-empted any possible serious and normal bureaucratic road-blocks. The second major significant historical event has been the presence of a dynamic Director-General of ICMR during these exciting times. He virtually guided and strongly supported the IP activities smoothly to its present stage. It is due to his encouragement and unstinted support that the Council which at one time was a publication-oriented agency has become patent savvy and a vibrant technology-generating organization. The DG very strongly supported the policy as he believed that to remain globally competitive, ICMR scientists should not only do research that pushes the frontiers of science but generate create cutting-edge technology and in the bargain generate wealth for the Indian Council of Medical Research and India.