Current IP Management Issues for Health and Agriculture in India

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ABSTRACT

This chapter describes the current status of IP (intellectual property) management in the areas of health and agriculture in India with a focus on post-2005, at which time India became fully complaint with the Agreement on TRIPS (Trade-Related Aspects of Intellectual Property Rights). The major policy trends existing in India include (1) public sector expenditure for R&D is on the rise and is currently about US$5.0 billion (one US$ equals about 4 Rs); (2) pharma industry R&D expenditures were on the rise and had reached Rs 15.0 billion, or close to 4.0% of their turnover; (3) several major policy initiatives had been undertaken by the government, including the National Health Policy (2002), National Policy on Indian Systems of Medicine and Homeopathy (2002), and National Biotechnology Policy (2005). Other major initiatives to promote IP generation include the creation of a Central Drug Administration, a new national body for the registration of medical devices, a National Registry for Clinical Trials, and a law similar to the Bayh-Dole Act that provides for the sharing of IP with inventors. The Departments of Science and Technology and Biotechnology, the Council of Scientific & Industrial Research, the Indian Council of Medical Research, the Indian Council of Agricultural Research, and so forth, have initiated large R&D programs in the health sector for the generation of new diagnostics, vaccines, and drugs largely focused on current health problems of India. A few indigenous products are being tested for safety and efficacy before use in the public health system. A new thrust and focus are being given for public–private partnerships involving both national and international partners. In agriculture, besides a substantial allocation of funds for R&D, two new initiatives—the National Agricultural Innovation Project (NAIP) and the Indo-U.S. Agricultural Knowledge Initiative (AKI) were started in 2005. The NAIP is a World Bank-supported project worth approximately Rs 11.7 billion that is expected to strengthen basic and strategic research in agriculture in India. The AKI is expected to address a large number of issues including education, research services, and commercial linkages in agriculture.

1. INTRODUCTION

Compared to many developing countries, India has a strong science and technology base. When India gained its independence in 1947, many science and technology institutions already existed there. Moreover, during the past 50 years, India has made rapid strides in science through a series of policy initiatives promoting high-quality research. This chapter focuses on developments in the last few years, especially since 2005, when India became fully complaint with the Agreement on TRIPS (Trade-Related Aspects of Intellectual Property Rights).

The past five years have seen an important change in science and technology primarily due to the anticipated impact of the TRIPS agreement on IP regimes in India. Globalization and liberalization, which have primarily affected the economy and business, also have triggered innovative R&D, as Indian companies have realized that unless they learn to become globally competitive, they may not survive. The pharmaceutical

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and biotechnology industries have been among the first to understand the implications of the new patent regime and the need to carry out innovative R&D. Some companies have increased their research budgets to as much as 10% of their total budgets. Even public sector institutions have realized that there is a need to reconsider their IP policies. Agencies like the Indian Council of Medical Research (ICMR) have adopted IP polices to promote innovative R&D, encourage partnerships with industry, create incentives for patent filing and systems of royalty sharing with inventors, and so on. In the more recent past there have been attempts to create, through partnerships of the ICMR with agencies such as the National Institutes of Health (NIH) and MIHR (the Centre for the Management of Intellectual Property in Health Research and Development), a strong force of technology transfer professionals. The formation in 2005 of the Society for Technology Managers (STEM), accomplished with the help and cooperation of AUTM (the Association of University Technology Managers) is a watershed in IP management in India.

2. EXPENDITURE ON R&D

2.1 *Government sector*

Publicly funded biomedical research and development (R&D) in federal laboratories in India is carried out by the ICMR, the Council of Scientific and Industrial Research (CSIR), the Department of Biotechnology (DBT), and a few institutes of the Department of Atomic Energy (DAE). The ICMR has 21 research institutes and six regional medical research centers. There are at least six laboratories of the CSIR, four DBT institutions, two DAE centers, six autonomous institutes that carry out significant medical research, and approximately 25 medical colleges, a few of which belong to the private sector. The colleges are supported by nongovernmental scientific research organizations (perhaps about a hundred) that are registered with the Government. Still, a significant chunk of biomedical research is carried out with only government support. The public-sector R&D effort primarily focuses on mapping disease burdens, profiling infectious diseases, carrying out preventive and/or therapeutic interventions, testing the efficacy of available new therapeutic interventions (such as drugs and diagnostics), finding new drugs and diagnostics for more cost-effective interventions, and carrying out basic research to improve understanding of biological systems.

No reliable data exists with regard to total expenditures for health and biomedical R&D. Estimates by one researcher, based on expenditures on R&D by major agencies, suggest that total expenditures (excluding expenditures by the pharma sector) about US$5.0 billion (one US$ equals approximately 4 rupees [Rs]), or approximately 2.5% of the estimated direct government expenditure on health.

2.2 *Research and development in the pharma industry*

In the private sector, the pharma industry spends the majority of its R&D funds on biomedical research. This started a few years ago, primarily because India's impending globalization and TRIPS-compliance spurred the pharma industry to carry out more innovative research to create new molecules in order to remain globally competitive. Recently, technologically competent small and mid-sized firms collaborating with multinational corporations and Indian generic companies have emerged. Some Indian pharma companies have already reoriented their R&D strategy from business-driven research (generic manufacture) to research-driven business (developing new molecules, novel drug-delivery systems, and so on). From 1999 to 2003, the number of U.S. patents granted for drugs and pharmaceuticals to India grew significantly. In 2003, India filed the most drug master files (DMF) applications (126) with the U.S. Food and Drug Administration (FDA), which was more applications than had been submitted by China, Italy, Spain, and Israel combined. India has the largest number of FDA-approved manufacturing facilities (more than 60) outside of the United States. R&D investment inside India is on the rise. For the year 2003–2004, the top-ten pharma companies spent more than Rs

9.7 billion on R&D (greater than 6.0% of their turnover). The pharma sector spent more than Rs 13.0 billion (almost 4.0 % of its turnover), which was the highest R&D investment of any Indian industry sector.

In addition, publicly funded institutions like the DST, CSIR, and DBT, support research in pharmaceutical R&D (including biopharmaceuticals) through various schemes, such as the New Millennium Indian Technology Leadership Initiative (NMITLI) and the Pharmaceutical Research & Development Support Fund (PRDSF).

3. POLICY INITIATIVES

The Government of India recently implemented a series of policy initiatives that have energized and focused R&D on generating new knowledge that could lead to new products and processes of public-health importance.

3.1 *National Health Policy in* 2002

Recognizing changing demographics, altered disease patterns, the health needs of its diverse populations, and the intensification of technology interventions in delivering health care, the Government of India announced the National Health Policy (NHP-2002). This initiative seeks to: (1) expand and improve primary healthcare facilities; (2) meet the health needs of disadvantaged sections of the population (women, children, elderly, and tribals) through special programs; and (3) mount programs to eradicate polio, yaws, leprosy, kala-azar, and filiarasis and to control diseases like HIV/AIDS, TB, and malaria within specified time periods. To achieve these objectives, the Government has committed to raising public spending on health to 2–3% of GDP (gross domestic product). Although the NHP-2002 does not explicitly state it, there has been a focus on generating new drugs, diagnostics, and vaccines for diseases of public-health importance like TB, HIV/AIDS, and so on. This attention is evident from the new initiatives to generate new diagnostics and vaccines through various public–private partnerships with national and international partners.

3.2 *Biotechnology Policy*

The new Biotechnology Policy of the Government of India (2005) draws a clear roadmap for developing biotechnology R&D in India. Some of the major initiatives proposed include encouraging R&D in academia, entering into partnerships with industry and support to industry per se, granting tax breaks and other incentives to biotechnology companies, and setting up biotechnology parks, special economic zones, and so forth. To help industry quickly bring products to market, the regulatory framework is being streamlined through a new set of simplified guidelines for the approval of all recombinant DNA products. Also, a single biotechnology regulatory authority (BRA) for clearing biotechnology products is being created. A series of bioclusters will be developed around existing biotechnology centers and some identified institutes of excellence. A strong focus on human resources development is evident from new programs, such as a new M.D.-Ph.D. program, an Asian-level United Nations Educational, Scientific and Cultural Organization (UNESCO) Center for teaching and training in biotechnology, and training fellowships abroad for cutting-edge areas like stem-cell technology and nanobiotechnology. The National Jai Vigyan Science and Technology Mission also provides support for developing new products and processes. Finally, the new Small Business Innovation Research Initiative (SBIRI) aims to provide early-stage funding to scientists in private industries for high-risk, innovative, or commercializable product proposals.

3.3 *Policy on traditional medicine*

Traditional systems of medicine have always figured prominently in India's healthcare delivery system because the practitioners of Indian Systems of Medicine and Homeopathy (ISM&H), comprising Ayurveda, Unani, Siddha, and Homeopathy, have a significant presence in India's rural areas. Recognizing the importance of Indian systems of medicine (ISM) in healthcare, in 1995 the Indian Government established a full-fledged Department of ISM&H, not only to promote curative aspects of ISM but also to energize R&D in this area. In 2002, the Government

announced its National Policy on ISM&H to address inadequacies in existing mechanisms, initiating new strategies to (1) improve the quality of teaching in ISM courses, (2) ensure the availability of quality raw materials for therapeutics, (3) formulate and implement standards (for example, good manufacturing practices), (4) encourage research in ISM&H to generate new drugs, and (5) address IP protection for traditional remedies.

Some steps have already been taken. These include setting up the National Medicinal Plants Board to provide quality material for herbal drugs, as well as establishing drug testing laboratories to ensure quality-assurance standards for bringing out pharmacopoeia in ISM, and so forth. Traditional systems of medicine are important because they offer therapeutic alternatives for some lifestyle, degenerative, and age-related ailments, such as rheumatism, for which other satisfactory therapies are lacking. Industry has been encouraged to carry out innovative research to bring traditional-medicine formulations to contemporary dosage standards through concentration of the liquids, modifications in the physical forms, developing appropriate delivery formats, increasing shelf life, ensuring stability in storage, enhancing sensorial acceptance, undertaking limited clinical trials for validating drug safety resulting from new forms and procedures for preparations, standardizing formulations based on active markers and fingerprint profiles, and, most importantly, adapting, modifying, and designing processing equipment to handle the botanical materials at appropriate processing conditions. A dynamic, continuing process, the initiative is spearheaded by about a dozen large, leading Indian pharma companies and a few publicly funded R&D and academic institutions. As an example of the work that's being done, a recent innovation by CSIR provides quantitative scientific representations of various Ayurvedic concepts using three-dimensional high-throughput liquid chromatography (HPLC) techniques. This invention has been patented in the United States and other countries. The Golden Triangle program (see below) is an example of how traditional systems of medicine and modern research and medical systems can work together to bring new drugs to the market.

3.4 *New IP rights regime*

In 1970, India enacted the Indian Patents Act, which came into force in 1972. Some significant features of the Patent Act include restricting to process patents these products in the areas of food, drugs, and agrochemicals; limiting patent life to seven years; and providing more liberal compulsory licensing provisions. The act's primary objective was to promote the development of the domestic pharma industry. Without product patents, it was hoped that the Indian public could get affordable drugs, and indeed the act encouraged industry to manufacture and distribute generics. The policy helped build a strong domestic industry that tapped India's scientific strength, especially in chemistry, to churn out generic equivalents that not only catered to local needs but also built a formidable bulk-drug export market. The act triggered significant growth and revenues through the export of bulk drugs. In the bargain, it also created a demand for testing and evaluation technologies and quality-control systems in the pharma industry. More importantly, this growth created opportunities for the industry to invest in reverse engineering R&D, which created a world-class generic industry. The Patent Act fully served its purpose of providing affordable medicines to the poor.

As a founder-member of the World Trade Organization and signatory to the TRIPS Agreement, India was expected to make its patent laws fully TRIPS compliant by January 2005. Accordingly, the Patents Act was amended three times to become TRIPS compliant. It now provides for product patents in all fields of technology and for other provisions stipulated under the Agreement. Due to these changes, multinational pharma companies have started to consider investing in India for R&D and manufacturing facilities. The companies see the ready availability of qualified people, infrastructure, and the advanced regulatory environment. These policy changes have been received very positively by the pharma industry, as is evident from the increased

Abbreviated New Drug Application (ANDA) filings over the past four years by the top-ten Indian companies. In the short period of six years beginning in 1995, patent filing in the drug industry nearly quadrupled. Today, some pharma multinational companies have started to expand their presence: their share in the Indian market is expected to double in the next five years.

3.5 *Regulatory environment—creation of the Central Drug Administration*

R&D in the pharma sector can be promoted only if an appropriate and reliable regulatory system is in place. India's disorganized drug-control administration has been seriously criticized, especially regarding spurious drugs. Manufacturing licenses for drug formulations are being issued by the drug controllers of various states and Union territories, with no coordination between them or the drug controller general of India (the regulator of the federal Ministry of Health & Family Welfare). Often, the drug controllers of various states were violating their authority by issuing licenses for drugs that were banned by the federal government. As a result, thousands of irrational and harmful combinations are on the market.

A committee under the chairmanship of Dr. R. A. Mashelkar, director general, CSIR, was formed to examine this problem and suggest how to revamp India's drug-regulatory system. The committee's recommendations focused on how to bring central monitoring and intervention activity to bear on the actions of state drug-control agencies in order to uniformly implement the Drugs & Cosmetics Act. The committee proposed elevating the Central Drugs Standard Control Organisation to the level of a Central Drug Administration (CDA), a federal body reporting directly to the federal health ministry that would, among other things, have complete control over the licensing of manufacturing units in the country—a power that was earlier vested with drug departments at the state level. The committee called for the creation of a specific medical-devices division to properly manage the approval, certification, and quality assurance of medical devices in India. The committee underscored the need to globally harmonize regulatory and scientific requirements. It also addressed regulating the activities of healthcare providers and the Indian systems of medicine and food supplements. The report recommends that drug regulatory administration be system based, with every activity justified within a clear policy framework and supervised for uniform implementation and the timely, transparent disposal of license applications, renewals, and so on. Finally, the committee recommended upgrading the present Central Drugs Standard Control Organisation (CDSCO) to the level of a Central Drug Administration (CDA), a federal body reporting directly to the federal Health Ministry, somewhat like the U.S. FDA.

3.6 *Medical devices registry*

More than 80% of the estimated amount spent on medical devices and other critical-care equipment purchased in India (about US$1.5 billion) is now made up of products that are imported. Several academic and research organizations, as well as private entrepreneurs, have started taking an active interest in the development and production of medical devices. Important devices, such as heart valves, orbital implants, coronary stents, oxygenators, cardiac catheters, eye lasers, external cardiac pacemakers, and critical-care ventilators, have emerged from high-technology research spinouts of the research laboratories of CSIR, the Defense Research and Development Organization (DRDO), DST, and others. Many products are also at advanced stages of development/clinical evaluation. Successes in this field—especially when sustained—are impressive.

Biomedical devices are technology based and have a shorter market life span. Unlike drugs, biomedical devices do not work via chemical action within or on the body by pharmacological/chemical/immunological means or by being metabolized within the body. Regulations of biomedical devices with regard to safety, health protection and performance, characteristics, and authorization differ from country to country.

In the United States, the FDA has a separate department to evaluate and regulate medical and radiological devices; in Europe, the safety and efficacy of a product and its quality assurance are

the responsibility of the manufacturers themselves. Avoiding the pitfalls and drawbacks of the U.S. FDA system, the European regulatory model has evolved into one of the most effective, efficient systems in the world today. Although expensive for the manufacturer, the onus of quality assurance is on the producers; any infringement in quality control leads to judicial penalties (as with the U.S. FDA). Indian officials recognize that the country acutely needs a regulatory body to control biomedical devices and ensure that the public is protected from poor-quality products—both indigenous and imported. In addition, a regulatory body could help the various segments of the developmental chain: the R&D groups, the manufacturers, the clinicians, and finally the patients.

To address this issue, the ICMR, New Delhi, and the Society of Biomedical Technology (SBMT) of the DRDO jointly worked to find a suitable structure for regulating medical devices. The proposal was made available on a Web site for comments, and suggestions were invited from a representative group of physicians, surgeons, and other experts using medical devices. A draft report was discussed with a group of experts. In the end, the proposal for an Indian medical devices regulatory authority (IMDRA) was submitted to the Government of India. The IMDRA will be responsible for implementing the country's regulations for medical devices. The proposal remains with the Government for implementation.

3.7 *Clinical-trial registry*

Attempts to register clinical trials being conducted in India have been minimal, because not many trials are carried out, and even the few that are carried out are not reported. But given the availability of large numbers of patients, qualified professionals, and hospitals with infrastructure that can perform clinical trials in accordance with global standards of good clinical practices, India is expected to become a global clinical trial hub. In fact, several contract research organizations have already set up their offices in India. There is, however, serious concern about a lack of transparency for trial data, especially in light of the conduct of unethical trials that the media has uncovered. The flouting of ethical guidelines has been on the rise, and so the Government of India is seriously considering bringing all clinical trials under strict regulatory control through a trial registry. Mandatory trial registration is bound to positively affect the quality of clinical trials conducted in both private and government sectors. So far, the government has entrusted the ICMR with the responsibility of setting up a clinical-trials registry. Efforts are already underway to establish a registry at ICMR, New Delhi.

3.8 *Awards*

There are more than 15 different awards established by Indian Government agencies like the CSIR, DSIR, National Research Development Corporation (NRDC), and DBT. Significantly, the nature of these awards has been changing. The thrust and focus of earlier awards was on import substitution and/or the indigenization of a technology. Recent instituted awards, however, emphasize the generation of innovative technology. For example, the CSIR Diamond Jubilee Technology Award (Rs 1.0 million) is given for the "most outstanding technological innovation that has brought prestige to the nation." Moreover, the CSIR Diamond Jubilee Invention Awards for School Children encourage a culture of innovation at a young age.

3.9 *Innovation and IP ownership*

A major portion of innovative R&D carried out in Indian universities is not IP protected. This is partly because India's university system lacks technology transfer offices that could help university researchers protect and exploit new innovations. In addition, as a matter of policy, most government agencies own all of the IP generated through research funded to the universities extramurally. Therefore, little incentive exists in terms of inventors sharing the royalties of new IP. This situation is widely considered to be the crippling factor that explains both why little innovative work takes place in the university sector and why enthusiasm is lacking to commercialize the few innovations that are IP protected. To address

this issue, the Government of India is seriously considering enacting legislation modeled after the Bayh-Dole Act in the United States, which would allow university inventors to own IP generated from federally funded projects.

3.10 *Entrepreneurship development-new policy on contract research*

The policy of contract research, a system through which public sector R&D institutes collaborate with industry, has been in existence in India for more than 20 years in major scientific organizations like the CSIR and the ICMR. This scheme has recently been liberalized to allow scientists and institutes to work with industry on projects of mutual interest. The time scientists could spend on R&D projects with industry (person days/year) and the amount of honoraria they could earn from such projects per year has been increased. Scientists are encouraged to take up R&D projects from industrial partners from India and abroad that would create products and processes for industrial application. In addition, some institutes have also made provisions for scientists to be entrepreneurs while holding their regular position within the organization (for example, the CSIR and the Indian Institute of Science, Bangalore). The impact of these initiatives has been positive. Some scientist-entrepreneurs from the institutes are already pursuing spinout companies.

4. STRATEGIES AND OUTCOMES

4.1 *Policy initiatives*

Infrastructure–Creation of new institutes of excellence: National Institutes of Sciences. If India hopes to become a global leader in science and technology, it must raise science education standards. A good science education is available in only a few institutes of excellence, such as the Indian Institutes of Technology, the Indian Institute of Science, Bangalore, and a few federally supported universities. Many population centers in India have no institute of excellence nearby, which discourages bright students from taking up science. Accordingly, four new centers of excellence in science education are being set up in different parts of the country. These institutes would be established at Allahabad near Allahabad University (in northern India), at Chennai near Anna University (in southern India), at Pune near Pune University (in western India), and at Bhuvaneswar near Utkal University (in eastern India). The centers primarily would offer an integrated, five-year basic and applied program in sciences leading to a master's degree. Linked with national research labs, science agencies, and industry right from their inception, these institutes will be "incubated" within the existing premier universities. But, although they will be connected to the universities, the institutes will enjoy complete academic, administrative, and financial autonomy. The corresponding university will initially award educational and research degrees to an institute's scholars and students, but the institute will have complete, total freedom to set out its academic programs, frame suitable course structures, and establish its own methods of teaching and evaluation. This organic link with the universities will be crucial in the initial phases. Administrative and financial details have been worked out and the proposal is in the approval process.

4.2 *National Biotechnology Development Strategy*

Ever since the full-fledged Department of Biotechnology (DBT) was set up in 1986 under the Ministry of Science & Technology, the DBT has played a pivotal role in R&D, education, technology management, and support to nascent industry. Both health and agri-biotechnology have received considerable support, and now there is a vibrant industry, a growing number of competent biotechnologists, and a regulatory framework that helps put products on the market.

The DBT has drawn up a ten-year strategy to put India on the global-biotechnology map. This National Biotechnology Development Strategy was unveiled by the Minister for Science and Technology, Kapil Sibal, on March 31, 2005. Highlights of the strategy include 100% of biotechnology units funded by foreign direct investments (FDI), priority sector lending tags, tax credits for money spent on international patent

filings, and the creation of ten biotechnology parks with special economic zone status, among others.

The DBT and the Ministry of Environment and Forests have released a set of guidelines for the approval of all recombinant DNA products. This is expected to give a huge boost to the biotechnology industry, because about 90% of the organisms used by biotechnology companies will be outside the purview of the Genetic Engineering Approval Committee (GEAC). For recombinant pharma products derived from living modified organisms (LMOs) but for which the end product is not an LMO, applications can be submitted for approval directly to the drug controller general of India (DCGI).

The Government is setting up a single biotechnology regulatory authority for clearing biotechnology products, and a high-level committee is figuring out how to create such an authority and rationalize the legislative and regulatory regime. Presently, several agencies under federal Ministries—Agriculture, Health and Family Welfare, Environment and Forests, Science and Technology, and Biotechnology—are involved in clearing biotechnology products.

Another important step being taken by the DBT to build the biotechnology industry is that of fostering bioclusters. Developed around existing biotechnology centers, a series of bioclusters will be formed by strengthening research in medical colleges (both translational biology and clinical research in the cities of Bangalore, Hyderabad, and other centers that have potential). The National Center for Biological Studies (NCBS), Bangalore, and the Christian Medical College, Vellore, are working to strengthen and transform CMC Vellore into a molecular medicine, translational, and clinical-research center. Likewise, a translational research institute is planned in Gurgoan with links to the National Brain Research Centre (NBRC) there. Biotech parks are being planned also on the Delhi-Gurgoan belt with the purpose of attracting industry. In Hyderabad, the DBT is creating a stem-cell R&D cluster (in addition to the one in Bangalore) and an agri-biotechnology corridor is being developed in Punjab.

Support to industry would be extended through (1) a quick, responsive regulatory framework; (2) support for late-stage development; 3) training in clinical validation; (4) a third-party associate for technology transfer projects with international companies/scientists; (5) encouraging industry participation in international science meetings; 6) creating an industry research support cell; and 7) direct industry funding for SMEs. The institutional sector will be strengthened by:

- expanding existing support for science education and training
- supporting the creation of new innovation centers and centers of excellence
- increasing contact and engagement between cross-disciplinary professionals through special grants and interdisciplinary centers of excellence
- a niche-area overseas training program
- large infrastructure grants
- five-year grants for translational research

The DBT has also funded the creation of "good manufacturing practice" facilities at several institutions and is working with Reliance and two other companies to support clinical research on DBT's products. On the international front, various collaborative programs are being considered that emphasize building strategic partnerships. A major program for animal vaccines and immunostimulants in aquaculture has been firmed up with the government of Norway, and another agreement was signed with Australia. Strategic partnership agreements have also been signed with Denmark in the area of agriculture and food biotechnology, with the UK in relation to cutting-edge biology, and with Finland in diagnostics.

Other new initiatives include:

- consolidating support services for regulations relevant to trade
- partnering with the Ministry of Health on GM food testing
- introducing biotechnology methods into the judiciary through a DNA academy funded at the Center for DNA fingerprinting
- improving the capacity for clinical trials in the country

- setting up new life-sciences institutions (like the translational health-science institute in Faridabad and the UNESCO center for training and education in Delhi)
- creating an animal biotechnology institute
- creating two policy centers (a center for health technology policy and a center of agriculture and allied areas).

Furthermore, the DBT is launching the Small Business Innovation Research Initiative (SBIRI), which provides early-stage funding to scientists in private industries for high-risk, innovative, or commercializable product proposals.

Some initiatives in human resources include identifying an Asian-level UNESCO Center for teaching and training in biotechnology. There is also a proposal to award 25 special overseas fellowships to students doing research in stem-cell technology and nanobiotechnology, as well as a plan to support 20 undergraduate colleges across the country (one per state) focusing on high-quality teaching in the life sciences (this is in addition to summer project support for students and skill-enhancing training for teachers). Further efforts to develop quality human resources include:

- a masters program begun in 2007 in health and clinical sciences, as well as a Ph.D. program in health sciences
- initiating similar educational programs for the environment, agriculture, marine, and other sectors
- providing summer project support in diverse life-science fields
- upgrading teachers' skills by developing one high-quality life-science college in every city
- launching an institutional innovation grants scheme
- substantially increasing the number of Ph.D. and postdoctoral fellowships
- creating a national pool of jobs.

4.3 *DBT's technology-mission programs*

Recognizing India's native intellectual capacity, the Ministry of Science and Technology has identified 21 technology missions for integrated technical development that would benefit rural people. The mission covers the areas of plant genetic-resource conservation, the development of new-generation vaccines, biotechnological approaches to herbal product development, genomic research, the development of light transport aircraft, and ocean-thermal-energy conservation. The basic aim of these technology-mission programs is "*Science in the service of common man*." Of the 21 National Jai Vigyan Missions initiated by various departments, four were launched by the DBT to generate new vaccines, develop herbal products, improve coffee, and establish mirror sites of genomic databases in India.

4.4 *Developing new-generation vaccines and diagnostics*

The main objective of DBT's mission has been to develop candidate vaccines for cholera, rabies, Japanese encephalitis, tuberculosis, malaria, and HIV infections using novel strategies. Such strategies include recombinant proteins; DNA vaccines; recombinant/peptide vaccines for cholera, malaria, tuberculosis, Japanese encephalitis, rabies (for animals and humans); and preventive/therapeutic DNA candidate vaccines for HIV infection.

Current work in support of this mission includes:

- **cholera vaccine.** An indigenous recombinant oral vaccine based on the VA 1.3 strain of Vibrio cholerae was jointly developed and tested by the National Institute of Cholera and Enteric Diseases, Kolkata (NICED); the Institute of Microbial Technology, Chandigarh (IMTECH); SAS, Kolkata; SGPGIMS, Lucknow; and PGIMER, Chandigarh. Phase I clinical trial results indicate that the vaccine is safe, and an extended Phase I/Phase IIa study is currently underway in about 1,000 volunteers. Simultaneously, site preparation work in Kolkata for Phase III clinical trials has been initiated by determining the baseline antibody levels in a cohort. The IMTECH Chandigarh is also scaling up the production of the VA 1.3 strain of V. cholerae.

- **DNA rabies vaccine.** Rabies continues to be a serious public-health problem in many countries, especially poorer ones. An indigenous, unique, low-cost antirabies vaccine has been jointly developed by the Indian Institute of Science (IISc) and Indian Immunologicals Ltd (IIL). The world's first combination rabies vaccine, it contains DNA vaccine and a low dose of cell-culture vaccine. Costing much less than the existing vaccine (Rs 300-400), this new vaccine will be affordable for India's people. In addition, it may be stable at room temperature, which would make refrigeration unnecessary. Human trials are being initiated.
- **Japanese encephalitis (JE).** This candidate DNA vaccine for JE virus was developed by the National Institute of Immunology, New Delhi. The tissue-cultured vaccine could provide about 70% protection in animals following intracereberal challenge. This new vaccine will be able to replace the existing Japanese encephalitis vaccine.

4.5 *Public–private partnerships*

The New Millennium Indian Technology Leadership Initiative (NMITLI) is an innovative public–private partnership started by CSIR in 2000 to make India a global leader in the field of science and technology. The strategy of the NMITLI is to catalyze innovation centered in scientific and technological developments in order to allow Indian industry to attain a global leadership position in selected niche areas. The Initiative seeks to identify and synchronize the strengths of publicly funded R&D institutions, academia, and industry. NMITLI supports two types of projects: those initiated by the program and those initiated by industry. In both types of projects, the best public institutions and industry are identified and a joint project formulated. To date, more than 40 projects in various fields (biotechnology, bioinformatics, agriculture and plant biotechnology, drugs and pharmaceuticals, and so on), with more 400 groups in R&D labs, academia, and industry, have been supported.

Some areas that have received support include:

- new targets, drug-delivery systems, bio-enhancers, and therapeutics for latent Mycobacterium tuberculosis
- novel herbal therapeutics for degenerative disorders
- osteoarthritis and rheumatoid arthritis
- diabetes mellitus type II (NIDDM)
- hepatic disorders and hepato-protective agents
- development of an oral, herbal formulation for the treatment of psoriasis
- a new process for manufacturing Tamiflu® (a drug for avian influenza)
- the oral delivery of insulin
- the development of Lysostaphin (a novel biotechnology therapeutic molecule)

One major achievement is the development of the new antimycobacterial molecule Sudoterb (LL 4858) by Lupin laboratories in collaboration with other R&D partners. Sudoterb is the first anti-TB drug in the past 40 years. Tests in laboratory animals have shown that, when given in combination with conventional drugs like rifampicin and pyrazinamide, Sudoterb was able to reduce the duration of TB treatment, from the current six to eight months, to three months. The new molecule is undergoing a Phase I clinical trial. Another significant new drug developed through the NMITLI program is LL 4218 (Desoside-P), a single plant-based herbal drug for psoriasis that is undergoing Phase II clinical trials. Currently there is no drug treatment for psoriasis, which affects millions of people the world over. Trials have shown that this Ayurvedic drug was able to reduce psoriasis symptoms by about 70% in 16 weeks. Just Rs 700 million was spent by Lupin Labs to develop this drug. Lupin Labs collaborated on this project with an R&D laboratory (Central Drug Research Institute, Lucknow) and an academic institute (National Institute of Pharmaceutical Education and Research, Chandigarh).

Recognizing the need to support indigenous R&D in the drug and pharma sector, DST initiated the Drugs and Pharmaceuticals Research Program in 1994–95, providing funds of Rs 1,500 million. The program aims to promote R&D collaborations between industry and institutions for

all areas of drug R&D that would help indigenous industry pursue innovative R&D and develop new molecules. Support is available for R&D projects proposed by industry, academic institutions, and laboratories. Funding is also provided to establish state-of-the-art facilities for drug R&D in India. In addition, soft loans at a simple interest rate of 3% per annum are being offered to industry with in-house R&D laboratories and nonprofit industrial research organizations. A drug-development promotion board has been set up to run this program.

Funded by the DSIR, New Delhi, the Technology Development and Innovation Program aims to promote the development and demonstration of indigenous technologies, the development of capital goods, and the absorption of imported technologies by Indian industry. The DSIR provides partial financial support to research, development, design, and engineering projects related to new or improved product and process technologies (including those for specialized capital goods) for both domestic and export markets. The program also supports projects that absorb and upgrade imported technology. The partial financial support by DSIR is primarily meant to cover costs for prototype development and pilot plant work, the testing and evaluation of products flowing from such R&D, user trials, and so on. Industry funds a major portion of the cost for these projects.

4.6 *Golden Triangle*

The Golden Triangle partnership was conceived in 2003, when it was decided to set up and provide special budgetary support for an integrated technology mission focused on the development of Ayurveda and traditional medical knowledge that synthesizes modern medicine, traditional medicine, and modern science. The CSIR and ICMR are working with the Department of Ayurveda, Siddha, and Homeopathy to bring out safe, efficacious, and standardized classical products for identified disease conditions. New Ayurvedic and herbal products for diseases of national/global importance are also being pursued. Innovative technologies are being used to develop single and poly-herbal-mineral products, which have the potential for IP protection and commercial exploitation by national/multinational pharma companies.

Some areas identified include Rasayana (rejuvenators/immunomodulators) for healthy aging, joint disorders, memory disorders, bronchial allergy, fertility/infertility, cardiac disorders (cardio-protective and antiatherosclerotic), sleep disorders, and diabetes. Identifying the strengths and weaknesses of existing modern medical products, the strategy seeks to develop new products to address gaps; formulate an appropriate R&D strategy for standardization, quality control, IP, and other related issues; take up toxicity/efficacy studies in government laboratories, medical colleges, and universities; prepare detailed dossiers of effective formulations; and negotiate with an identified industry partner to begin commercialization after clinical trials are carried out using standard protocols.

This ambitious multiagency program proposes to spend more than Rs 350 million in the next three years. Several areas have already been identified and research is underway.

4.7 *Promoting innovation in traditional knowledge*

The Traditional Knowledge Digital Library (TKDL) is a CSIR initiative aimed at providing easy access to traditional Indian systems like yoga, Ayurveda, and Unani. The initiative also is intended to prevent IP piracy and promote innovation through the use of traditional knowledge. TKDL will publish an encyclopedia with more than 30 million pages in electronic format. The encyclopedia will contain information on traditional medicine, along with exhaustive references, photographs of plants, and scanned images from original texts of traditional systems. Traditional text in the original Persian, Hindi/Sanskrit, or other Indian languages is being translated into English, French, German, Japanese, and Spanish. Ten million pages have already been converted into electronic format, which is a big step towards the TKDL's goal of minimizing the biopiracy of India's indigenous wealth.

The TKDL is expected to be an authentic source for patent examiners in major global

patent offices (like the U.S. Patent Office) to conduct prior art searches. Currently, examiners are often unable to determine the novelty of inventions based on traditional knowledge/plant-based drugs because they have no ready access to authentic sources. Although well documented in various regional languages, the Indian traditional knowledge sources are readily available to patent examiners from other countries; this has resulted in the granting of patents like the patent on haldi granted by the U.S. Patent Office.

The TKDL encyclopedia should help examiners cross-check the validity and originality of patent applications. It should assist examiners in determining whether an invention is already known and recorded in ancient literature. The availability of the TKDL may also help avoid litigation regarding granted patents, thus saving time and money in litigation. This is especially important for India, which has spent almost US$6 million fighting legal battles against just two patents on turmeric and neem. Significantly, as of 2000, the number of patents on plant-based products granted by the U.S. Patent Office was about 5000, of which an estimated 80% were possibly plants of Indian origin.

To conform to international standards, the TKDL follows the International Patent Classification (IPC) system, having considerably expanded the IPC group AK61K35/78 on medicinal plants to incorporate detailed information about traditional knowledge with a new section titled Traditional Knowledge Resource Classification. The IPC Union of WIPO (World Intellectual Property Organization) is closely associated with this project through a multinational task force. More than 36,000 ancient Ayurvedic formulations have been translated into current scientific/medical terminology, classified as per the modified IPC subclass, and put in digital format. The TKDL has made it possible for all traditional knowledge to be brought under IPC, which should significantly help protect the traditional knowledge of India from being unfairly exploited by others.

4.8 *ICMR as Department of Health Research*

To encourage medical and health research and, more importantly, to ensure better coordination and promotion of India's national health programs, the government is considering upgrading the ICMR to the Department of Health Research (DHR). This would put the ICMR on par with other departments in science and technology.

Creation the DHR will help better coordinate such sister scientific departments as the departments of science and technology; biotechnology; scientific and industrial research; agricultural research and education; and space, atomic energy, and ocean development, all of which are headed by secretaries to the Government of India. The ICMR's collaborative health projects with these departments will be further strengthened, and they will be better placed to foster such complementary interagency partnerships. The secretary of the DHR will also be in a better position to articulate the policies of the Ministry of Health and Family Welfare and to further the Government's programs and policies in this area. During national emergencies, when critical science and technology inputs are required from other agencies, the DHR would function more effectively. Technologies and products developed by other science and technology agencies will transition more easily into the healthcare sector. In addition, a coordinated effort with other agencies in cutting-edge science (stem-cell research, functional genomics, molecular medicine, proteomics, and so on) will be vital for identifying and supporting the best scientists with timely and adequate budgetary support. This effort should send better drugs and devices to market more quickly. The DHR could help translate research results into policy through a vibrant health-research system. Unlike ICMR, the DHR could address labor and infrastructure requirements for medical and health research in India because it would be seamlessly linked with other agencies (and thereby avoiding potential duplication of efforts).

4.9 *Small Business Innovation Research Initiative*

The DBT has introduced a new scheme to boost public–private partnership efforts. It supports both high-risk, pre–proof-of-concept research and late-stage development for small and medium companies led by innovators with backgrounds in

science. The Small Business Innovation Research Initiative (SBIRI) has a unique process for generating ideas. Bringing together technology users and producers, it seeks to promote products that could be created only with the help of the private sector. National consultations are to be held every three to six months to generate ideas in different sectors of biotechnology (medical, agriculture, food, industry, and environment).

The SBIRI aims to:

- strengthen private industrial units whose product development is based on in-house innovative R&D
- encourage other smaller businesses to increase their R&D capabilities and capacity
- create opportunities for starting new technology-based or knowledge-based businesses by science entrepreneurs
- use private industries to stimulate innovation and thereby fulfill Government objectives in fostering R&D
- increase private-sector commercialization derived from Government-funded R&D

The scheme covers all areas in biotechnology that are related to healthcare, agriculture, industrial processes, and the environment. This unique scheme, which directly funds industry, is a big boost for small companies. It took off very well: the DBT received 70 proposals in just the first month. In the year 2005–2006, about 12 companies were financed. The DBT is planning to expand the scale of this program to Rs 1000 million per year.

4.10 *National Innovation Foundation*

Created by the Department of Science and Technology, the National Innovation Foundation (NIF) seeks to recognize, respect, and reward grassroots technological innovators and traditional-knowledge experts. Established as an autonomous society in 2000, its mission is to make India an innovative, global leader in sustainable technologies. It was patterned upon the Honey Bee Network established in 1989, which sought to connect creative people across language cultures, acknowledge the contribution of innovators, expand policy and institutional space for local knowledge experts, and ensure the fair sharing of benefits. The honeybee model was chosen for the NIF because it reflects how innovations are collected without making the innovators poorer and how innovators themselves create connections. It provides a platform to foster innovators who have solved a technological problem through their own intellect with little government or industry help. Located at Ahmedabad, Gujarat, the NIF has a corpus fund of about Rs 20 crores, the interest on which is used to fund the activities of NIF.

Similarly, the Gujarat Grassroots Innovations Augmentation Network (GIAN) picks up innovations from the Honey Bee Network database, performs market research, builds links with design, research, and development institutions to improve the technological efficiency of the innovation, helps test the product, and develops business plans and a market-launch strategy. Conceived in 1997 with support from the Government of Gujarat, IIM Ahmedabad and SRISTI, the GIAN helps with filing patents and licensing the innovators' technologies. GIAN now has separate offices in the north (Jaipur), west (Ahmedabad), and northeast (Guwahati) India. Although protecting IP rights still remains difficult, 29 technologies have been licensed since GIAN was launched.

More than 12,000 contemporary innovations and outstanding traditional-knowledge examples/practices have been documented by the network, but none of the innovations documented have led to viable businesses, because the innovators had neither the resources nor the expertise to commercialize their inventions. To address this issue, the NIF was set up in 2000 to help promote these inventions and to build an entire value chain around them. So far, about 37,000 innovations and traditional knowledge examples have been identified from more than 350 country districts. Currently, the NIF database has more than 50,000 innovations from more than 400 districts. The challenge is to incubate these technologies so that they generate commercial and noncommercial opportunities to improve productivity, generate employment, overcome poverty, and conserve the environment.

4.11 *Society of Technology Management*

To steer tech transfer towards a brighter future and promote better tech transfer management, the Society of Technology Management (STEM) was launched at the international workshop on Intellectual Property Rights, Technology Transfer, Licensing, and Commercialization convened by Cornell-in-India and Sathguru Management Consultant on April 17, 2005. The society was conceptualized by a group of visionary professionals to promote best practices among technology management professionals in south Asia.

The objectives of STEM include:

- offering guidance and assistance to inventors and corporations IP matters
- providing learning opportunities to dealing with the real-world aspects of IP law
- increasing the general awareness of IP laws and their increasing importance
- promoting best practices in technology management and engaging in capacity-building among technology management professionals in India and neighboring countries
- catalyzing the professional development of technology managers for the commercial benefits of innovations

STEM hopes to achieve its objectives through a well-formulated strategy that allows genuinely interested Indian researchers and technology experts to network with global technology managers. Annual meetings and seminars will be organized to benefit tech transfer professionals nationwide, and STEM will promote the economic growth of its constituent members and the organizations those professionals represent. STEM has the support of all the major research funding bodies, academic institutions, and private-research enterprises in India. To build links with similar organizations, STEM participated in the Asian tech transfer meeting in Singapore in 2005 and the Association of University Technology Managers (AUTM) meeting in 2006.

The International Federation of Technology Transfer Organizations, the Southern African Research and Innovation Management Association, AUTM, and the Association of European Science and Technology Transfer Professionals have extended their wide support to STEM.

5. INTERNATIONAL COOPERATION FOR CAPACITY BUILDING

India continues to greatly benefit from technical, financial, material, managerial, and human-resource inputs and assistance from international agencies, developed countries, and, more recently, international not-for-profit organizations for capacity building in the healthcare sector. Initially, such assistance was mainly for human-resources development through training, infrastructure development, and financial and material assistance. But as India has advanced in the healthcare sector, the programs have shifted toward capacity building in the community for health delivery and networking, policy frameworks, and so on. These ongoing initiatives encompass a large number of programs and projects (for example, there are more than 30 ongoing programs with more than 700 activities being implemented in collaboration with the World Health Organization [WHO]).

5.1 *International collaboration in promoting technology management*

With the support of the NIH in the United States, the Technology Forecasting and Assessment Council (TIFAC) of the Department of Science & Technology has just initiated a joint program to train young technology managers at the NIH tech transfer system for five weeks. The first batch of two interns was at the NIH in the summer of 2006.

The ICMR, in collaboration with MIHR, organized a very successful joint symposium on TRIPS and Public Health followed by a one-day workshop at the ICMR headquarters, New Delhi. More than 20 young, mid-level scientists and technology transfer professionals participated and shared experiences with Richard Mahoney and Lita Nelson on technology transfer issues. The Government of India has decided to enter into a formal agreement with MIHR to utilize the expertise of U.S. technology managers to train a new cadre of health technology managers.

In agriculture, the major government departments in India engaged in agricultural technology are the Department of Agriculture Research and Education (DARE) and the Department of Biotechnology. DARE coordinates and promotes agricultural research and education. It provides the necessary government links for the Indian Council of Agricultural Research (ICAR), the country's premier research organization with more than 6,000 members and a countrywide network of 47 institutes (four with university status), five national bureaus, 31 national research centers, 12 project directorates, 89 all-India coordinated-research projects, and 38 agriculture universities.

DARE is the nodal agency for international cooperation in the area of agricultural research and education. The department liaises with foreign governments, the United Nations, CGIAR, and other multilateral agencies concerned with agricultural research. DARE coordinates the admission of foreign students in various Indian agricultural universities and ICAR Institutes. Some of its specific activities include:

- international cooperation and assistance in the field of agricultural research and education, including relations with foreign and international agricultural research and educational institutions (It participates in international conferences, associations, and other bodies dealing with agricultural research and education, and follows up on decisions at such international conferences.)
- fundamental, applied, and operational research in higher education, including coordination of such research in agriculture (agroforestry, animal husbandry, dairying and fisheries, agricultural engineering) and horticulture (agricultural statistics, economics, and marketing)
- coordination and determination of food and agricultural standards in higher education, research, and scientific and technical institutions (This includes animal husbandry, dairying, and fisheries.)
- development of human resources in agricultural research/extensions and education
- access for financing to the Indian Council of Agricultural Research, and community research programs other than those relating to tea, coffee, and rubber
- sugarcane research

5.2 *New policy initiatives*

In addition to DARE, recent new policy initiatives include:

- increased allocation for agricultural research
- research program on microorganisms
- one Krishi Vigyan Kendra (KVK) in each district of India
- National Museum on Agricultural Sciences
- National Agricultural Innovation Project (NAIP)
- new intellectual property rights management, that is, new IPR management is being developed to enable the smooth transfer of agricultural technology for benefit sharing with all stake holders.
- Indo-U.S. Agricultural Knowledge Initiative (AKI)
- a range of activities related to human resources and institutional capacity building

With a specific focus on agricultural technology, the following is the proposed work plan under the agreed priority areas:

- **Education, learning resources, curriculum development and training: Building human and institutional capacity and strengthening public–private partnerships.** Private-sector-sponsored chairs in India or the United States will be created for R&D on strategic/niche areas. This will help establish close collaboration between the public and private sectors, which in turn will lead to the commercialization of technologies at a faster pace. In addition, each year, industry scientists and faculty from premier U.S. and Indian business/management schools and agri-business institutions will be invited to a workshop (in India or the United States) to devise synergistic strategies for exploring the emerging trends and needs in the agriculture sectors of both countries. It

will seek to orient education, training, and research to contribute to economic growth. The workshop will inventory, upgrade, and build on existing agri-business programs to match students or professionals with practical internship experiences.

- **Food processing, use of by-products and bio-fuels.** The AKI Board agreed that developing agricultural marketing and processing industries is now a priority for India's increasingly need-based, demand-driven, market-oriented agricultural sector. The following initiatives seek to meet this need:

  Joint research programs. Technology to rapidly detect and control biotoxins, chemical contaminants, and heavy metals in agricultural produce and by-products: Food quality and safety are essential for both domestic and export markets. Developing or acquiring rapid test equipment and protocols to ensure food quality at various points in the value chain would be developed through training and joint-applied research programs.

  Biotechnology. The Initiative recognizes that both partner countries share the common goal of translating lab results into beneficial products delivered to farmers. Subject to funding from the U.S. and Indian governments, and bearing in mind possible private sector engagement, focus will be on transgenic crops, genomic, molecular breeding, diagnostics, and vaccines and training.

  Water management. The improvement of water quality and water-use efficiency will be vital to the continued growth and productivity of the agricultural sector in both India and the United States. The Board agreed to cooperate on capacity building and joint research activities to develop improved technologies and management practices in a framework that incorporates the needs of multiple stakeholders from lab to farm.

6. CONCLUSIONS

The transition of India from a protected economy to be an open, global-economic power has prompted India to take a series of steps to face the new challenges of globalization. All the public sector science and technology agencies have realized the importance of IP and its creative management and have initiated steps toward generation of knowledge that could be IP protected. This is especially important as the health products of diseases of poor countries need to be indigenously developed in view of the lack of interest by large multinational companies that have little interest in the development of such products. Public–private partnerships with both Indian and foreign collaborators is being explored with some measure of success. In addition, active steps are being taken to strengthen IP protection systems and policies and also to create a trained cadre of technology transfer professionals in the areas of health and agriculture. An important means of skill building in the area of IP include international collaboration and networking with agencies abroad. Early experience has shown that it is only through indigenous development that new health products could be developed, introduced, and marketed. Strengthening R&D and establishing policies for the creation and management of IP and public-partnerships are important steps for making available products of public-health importance in all poor countries. ■

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