
Why India is on the up and up

India's stock as an innovation centre is at an all-time high. A highly-skilled young workforce, sustained government investment in education, low labour costs and a reverse brain-drain have created an environment where IT, biotech and pharma R&D can all flourish. Full TRIPs compliance, due in 2005, makes the picture even rosier. By Nigel Page

Notwithstanding shock election results in mid-May, when the ruling BJP unexpectedly lost power to the Congress Party, India's commitment to attaining world-class status across its innovation industries looks as strong as ever. Acres of newsprint continue to extol the challenge Silicon Valley faces from Bangalore and Hyderabad (a part of which is now known as Cyberabad). The outsourcing boom, has propelled multinationals, such as Texas Instruments, Cisco, Intel, IBM and Oracle, towards India. According to a December 2003 Morgan Stanley CIO survey, Fortune 1000 companies are now three times as likely to use an India-based, rather than a global, IT service provider. Recently Google announced that it was setting up a development and marketing support centre in Cyberabad, leasing 60,000 square feet of office space in Hitec City.

At the same time, a number of homegrown companies have established themselves globally. During 2003, the country's IT sector grew by 21%, and saw revenues touch Rupees 755.47 billion (US\$16.4 billion), while revenues generated from software exports reached US\$10.4 billion. Generic drugs manufacturers such as Dr Reddy's, Ranbaxy and Sun Pharma, already major players in the US and European markets, now invest significant proportions of their annual income in R&D: this in preparation for the coming of product patents to India in 2005 (see below).

India's investment community too is gearing up in anticipation of expanding international opportunities for the country's pharma and biotech industries: 2003 saw a record number of private equity investments into Indian pharma, which attracted over US\$241.75 million. When Dr RA Mashelkar, director

general of India's Council for Industrial and Scientific Research (CSIR), addressed the Indian Institute of Foreign Trade in April this year, he said: "Goldman Sachs predictions show that by 2050 India will be the third-largest economy after China and the USA. But I strongly believe that by 2025, India has the potential to occupy the first position amongst the world's knowledge-producing centres." Assuming a real commitment from the new government to implementing a robust IPR infrastructure from now on, Dr Mashelkar's words may just come true.

A global R&D hub

India's knowledge economy has been booming for years, buoyed by low R&D costs (the total R&D spend in India last year, at US\$5 billion, was below Pfizer's annual R&D budget), a highly-skilled workforce and the world's largest chain of publicly-funded R&D institutions. This accounts for the country's status as a global R&D hub, with 100-plus companies having located their R&D centres there over the last five years. Currently, the largest of these is General Electric's Bangalore-based facility with 1,600 employees (soon to be increased to 2,400), making it GE's second-largest R&D centre worldwide. Others have followed suit, including Microsoft, IBM and Monsanto, which has set up a research centre dedicated to crop transformation and crop protection.

Speaking from the Bangalore-based centre, company spokeswoman Ranjana Smetacek, says: "India is a logical venue for a large international agricultural company such as Monsanto because it is an agriculture-based economy and the environment is conducive to research, besides the continuity allowed by the time difference with the US." And, says

the CSIR's Dr Mashelkar, others will inevitably follow: "Indian industry itself will benefit in the long run. The researchers who will work in these non-Indian innovation enterprises will acquire insights and skills that would otherwise be impossible to acquire. All such Indians reside abroad today. But in the coming years they will prefer to reside and work in India. There will be enormous benefits that Indian industry can reap out of this supply of superior R&D leadership."

The jewel in the crown

The CSIR has been one of the pioneers of this push towards R&D trans-globalism in India. A publicly-funded institution set up in 1942 to boost the economy via industrial research and R&D, the CSIR now has a total of 38 laboratories across India. With 22,000 employees and an annual research budget of around US\$300m (30% of which is generated by its own licensing/consultancy/training activities), it ranks as the largest such institution worldwide.

The CSIR's Pune-based National Chemical Laboratory (NCL) began to globalise its R&D in 1989 and today numbers various international customers including Du Pont, Dow, Eastman, ICI, GE, Cargill and UoP. Recognising that competitive advantage in high-tech would depend increasingly on the underlying technical skills of an organisation, rather than on particular products, NCL focused on developing in-demand skills, capabilities and technologies.

Other CSIR laboratories followed NCL's example via various routes, including sales of exploitable ideas or concepts, contract research, custom synthesis of low-volume, high-value and high-performance compounds, technology licensing and institutional twinning. Examples of this activity include a Boeing partnership with National Aerospace Laboratories, Mobil's with the Indian Institute of Petroleum and Glaxo India Ltd's with the Indian Institute of Chemical Technology. General Motors, Daimler Chrysler and Procter & Gamble have also linked recently with other CSIR institutions.

Paving the way to commercialisation

CSIR handles IP commercialisation in a number of ways, explains Dr Mashelkar. The first of these is contract research for industry on various breakthrough developments (where CSIR agrees a fee for undertaking research on behalf of the innovator company).

Secondly, when CSIR institutions are themselves architects of scientific innovation, these inventions are licensed to industry. For example, the Lucknow-based Central Drug Research Institute developed a molecule known as centrochroman that had applications as a

family planning pill. The know-how was patented abroad and licensed to two Indian companies. One of which, Hindustan Latex Ltd, markets the product in India under the trade name Saheli and the other, Torrent Pharmaceuticals Ltd, markets it under the trade name Centron. "When Novo Nordisk found the molecule helpful in osteoporosis treatments, we licensed the know-how to them under a technology transfer agreement with built-in milestone payments (to include royalty payments of 5% on bulk sales)," Mashelkar says. Ultimately, however, the product failed in Phase II.

The third route for IP commercialisation is joint development, where industry and CSIR invest side-by-side in the development of a new product, jointly owning the IP. An example of this is the relationship between Lupin Laboratories and NCL in the development of Vitamin B6 – later manufactured by Lupin.

The godfather of Indian R&D

Many credit Dr Mashelkar as one of the prime architects of India's R&D resurgence, having helped to change the mindset of Indian inventors towards greater awareness of IP commercialisation. Formerly, as director of NCL, he was instrumental in changing the policy from, as he puts it, "publish and perish, to patent and profit". He cites the work done by NCL on solid-state polycondensation of polycarbonates as an example of this transition: "We had a breakthrough development there and instead of publishing, we filed a US patent instead. Once that was granted, we published." It was on the back of this development that NCL's relationship with GE began, Mashelkar explains. "GE got interested and we became partners. We later licensed two more patents to them and the partnership grew to such an extent that Jack Welch decided to set up a major R&D facility here. Now, more than 100 such centres exist across India."

Venture capital targets R&D

Not surprisingly, CSIR is the target for a growing number of venture capital firms. Dr Mashelkar confirms that CSIR laboratories are increasingly seen as sources of intellectual capital, pointing to the partnership CSIR has forged with APIDC Venture Capital Company's US\$30m biotech fund, whereby CSIR identifies suitable R&D and APIDC helps to target industry partners, as well as putting up funding for commercialisation.

Sarath Naru is the managing director of the Hyderabad-based venture firm, formerly part of the Andhra Pradesh Industrial Development Corporation Ltd. The early-stage venture firm covers a hybrid range of investments. One fund, in which the World Bank is the largest investor,

Commercialisation of IP in India

Recent legislative, administrative and other changes in the intellectual property rights (IPR) regime in India are likely to boost commercialisation and licensing of IPRs for at least the following three reasons:

- Quantitatively there has been a major increase in the last nine or so years in the filing and grant of patents. Whereas from 1970 to 1995, patent filing remained static at 3,500 to 4,000 applications per year, confidence in the system increased after the TRIPs Agreement and patent filing went up to over 10,000 applications annually from 1995. It is predicted that the product patent regime for pharmaceutical and agricultural chemicals will further increase filing activity to about 25,000 applications per year. Similarly, there has been an upsurge in trademark filing and registration in the past five years, with trademark filing rising from about 46,000 to 90,000 applications per year. This is bound to increase now that the Trade Marks Act 1999 has come into force.
- With increased grant of patents and trademarks, litigation particularly in the field of patents, will go up considerably. At present, it is estimated that there are about 1,500 to 2,000 IPR-linked lawsuits filed throughout the country. This is likely to go up at least five-fold in the next decade or so (although changes to the Code of Civil Procedure mean that the lifespan of litigation will fall from 7 - 10 years to 2 - 4 years).
- With increased grants and lawsuits, India is poised to experience a major change in its damages culture. Some key judges who were formerly averse to the grant of damages and costs have changed their position over the last two years and the last few months of litigation have seen costs awards alone running into lakhs (100,000-plus) of rupees. It is expected that, over the next few years, there will be a sudden spurt in damages awards which in the initial period are likely to be in the range of Rupees 5 to 20 lakhs (Approximately up to say US\$50,000).

A greater preparedness to grant damages would ensure that rights owners did not feel the cost of litigation and their reluctance to sue would reduce. The advent of a damages culture is also bound to bring with it an element of deterrence among the violators of IPRs, increasing their desire to seek licences from the rightful IP owners.

Presently, licensing exists through the vehicle of joint venture companies or subsidiaries of multinationals in India and the subject matter of most licensing contracts are trademarks or trade secrets. However, with an increase in the grant of patents, IPR licensing is bound to shift towards patent licensing. At present, where trademark licensing is concerned, the proprietors can receive up to 1% for domestic sales and 2% for exports. The relaxation of the government's policies for the outflow of foreign exchange would ensure the free flow of royalties from Indian licensees to foreign proprietors.

Another serious disincentive to commercialisation in India has been a lack of transparency in the accounting of royalties. This is a general problem, as illustrated by examples from the entertainment and book publishing world. Artists, authors and composers constantly complain about their works being exploited without their knowledge and about inaccurate statements of accounts and under-reporting by their publishers. While in the past, an artist would achieve a platinum album when 500,000 records were sold, today platinum is achieved even with a sale of 100,000 albums. This is primarily due to under reporting by music companies to the artists.

The opportunity to inspect and search company records and books of accounts exists under Indian laws. However, quite frequently the accounts are not properly audited and inspection and search would reflect negative sales or losses. In a regime like this, contractual provisions assume greater significance and should provide for various presumptions and terms such as minimum royalties.

Overall, however, despite the bottlenecks, commercialisation and licensing of IP will grow rapidly in the next few years due to increased use of IP, better and quicker enforcement and cleaner reporting mechanisms.



Pravin Anand senior partner,
Anand & Anand, New Delhi

has a broad, non-sector specific remit; another, focused on IT and telecoms technologies, includes a fee-based sharing agreement with Madras IIT (Indian Institute of Technology); and the third, the US\$30m biotech fund, is focused on mainstream and peripheral technologies.

Sarath Naru says: "We're interested in how publicly-funded research labs in the US and Europe have licensed out their inventions to the private sector – and we've been anticipating a similar trend here in India." In particular, he says, APIDC is interested in CSIR's life science and chemistry-focused laboratories to the extent that it is now in a formal agreement with a number of them. "We set up a working group with the directors of three of their key laboratories, and we meet every three months to review and shortlist promising technologies for development. Thus far, we've shortlisted five and will probably focus efforts on two of those at the moment," Naru explains.

Helping scientists come to market

Naru observes an increasingly commercial mindset amongst Indian inventors. But, he says, the commercialisation process, as it stands, is not always in their own best interests: "As members of academic institutions or publicly-funded laboratories, they are unable to participate in the equity." Publicly-funded institutions, Naru explains, retain ownership of IP, with the government maintaining a march-in right, similar in some ways to the equivalent under Bayh-Dole. "While modest mechanisms exist for them to share in the success of their inventions, they are usually neither very equitable nor motivating. I believe that these scientists should step out and take a crack at developing technologies themselves, instead of making do with 20%-30% of the royalty incomes, not all of which goes to them in any event," Naru adds.

He goes on to explain how various ways have been found of incentivising inventors: "There are two preferred structures that we pursue. One in IIT Madras, enables professors to create a charitable trust whose purpose is the furthering of technology in a given sector." The shareholding, Naru says, is held by the trust and the inventors are appointed as its trustees, thereby giving them some participation in the upside of the business. Another route, in use at the Indian Institute of Science (IISc), employs an intermediary organisation, constituted as a society, positioned between the company and the inventors. This society can hold shares and there is nothing to prevent the inventors from being the controllers of that society. "We're

now trying to engage with the CSIR to come up with a model that will work elsewhere. We have been studying a number of international models, including John Hopkins University in the US," Naru explains.

Elsewhere, the Society for Innovation and Development (SID) at IISc has overseen the development of a 45,000 square foot Entrepreneurship Centre, located adjacent to the IISc campus in Bangalore, where ideas in software development, embedded systems and electronics can be developed in conjunction with private industry houses. The SID's CEO, Professor S Mohan, told the *Times of India* in mid-May: "Scientists find it difficult to sell innovations to industry. We do it for them and also take care of technology transfer and IP rights."

Indian IPR – getting on track at last?

India's success in addressing IP enforcement will play a key part in the roll-out of technology commercialisation, by domestic and international companies. Until now, enforcement has been a source of real concern to investors, explaining why research centres have used India as a development centre only, preferring to commercialise IP outside the country.

Dr RA Mashelkar puts this in context: "The impact of techno-globalism in India so far indicates that access to highly-talented human capital is going to be the most important factor. The challenge is how to continue to tap the incredible dynamism of global R&D so that Indian institutions and companies can assume leadership in creating high-wage jobs and building new industries." Among other things, he continues, this will require government incentives and protection, in particular for protection of intellectual property to be extended to science-based high-tech inventions.

All change in 2005

Many predict that the IP landscape will change dramatically next year. Although process patents are already available, it is only in 2005 that India will meet its TRIPs obligation to provide for product patents. Having enacted the TRIPs-compliant Trademarks Act, Copyright Act and Designs Act during 1999-2002, the introduction of robust product patent protection legislation will be a crucial boost to the credibility of the Indian market.

A seasoned commentator on IP rights is Professor Prabuddha Ganguly, CEO of VISION-IPR, adjunct professor at the Institute of Technology, Bombay and formerly manager responsible for tech transfer and IPR at Hindustan Lever Ltd (Unilever's Indian subsidiary). He says: "The patent regime

created a contracted mindset about pharma innovations and their protection using the patent system. Efforts were directed towards the development of alternative cost-effective manufacturing processes for molecules already invented and patented in other countries. Lesser efforts were invested in Indian R&D towards developing new molecules or products."

The legal complications surrounding the recent grant of an exclusive marketing right (EMR) to Novartis India Ltd for its oncology drug Glivec have highlighted the need for clarity in the new amending patent legislation. That said, there have also been encouraging signs of government's commitment to addressing shortcomings. "It used to take five or six years to obtain a [process] patent in India. Now 120 new examiners have been hired and distributed between India's four patent offices. Patent examination reports have been issued for all pending patent applications," Professor Ganguly explains.

An upsurge of life-science activity

Once the amending legislation is in force, Professor Ganguly predicts that the approximately 4,000 product patent applications currently held in the so-called mailbox (ie, filed from 1st January 1995 but dormant pending full TRIPS compliance) will move into full-scale prosecution. There will be a rush by pharma and biotech multinationals and Indian companies to get these products out into what will be an increasingly competitive field. There will also be an upsurge of licensing activity, as foreign companies leverage the local resources of Indian companies for their own product distribution.

Acquisition activity will escalate, as Indian companies become increasingly attractive targets to foreign acquirers. By the same token, domestic mergers will increase, as companies with complementary assets and abilities identify benefits in consolidation. Rajeev Dalal is a director of transaction advisory services for Ernst & Young covering health sciences in India. He confirms that major foreign multinationals currently represented in India, with their brand rights licensed to Indian subsidiaries, and potential market entrants, are poised. "Those currently looking at acquisitions will be targeting Indian companies with the least number of patent infringements. Target companies with, say, 10% of their products infringing, will have their portfolios acquired outright – and their infringing products discarded," Dalal says. Although he agrees that 2005 represents a watershed for the Indian pharma and life sciences industries, Dalal is sceptical about the speed of change. "It depends on two things," he

says. "How effective the licensing monitoring process proves to be and, assuming it is effective, how quickly the Indian government introduces acceptable pricing controls."

Exactly what shape the new legislation will take, and when it will be enacted, remains unclear. Professor Ganguly does not expect TRIPS compliance to be top of the new government's agenda. "There will, in the short term, be more pressing economic requirements to be addressed. If no bill is in place by the time of the winter session, we should expect to see an ordinance announcing compliance from 1st January 2005," he says.

IAM urgently required

Other growth areas for next year will be IP litigation and, inevitably, IP valuation. The valuation process for patents is presently negligible but, with a predicted upsurge in corporate finance involving IP assets, this will rapidly become more prominent. More sophisticated IAM techniques, now almost non-existent, will probably develop as and when foreign companies begin their predicted acquisition spree.

For the moment, however, specialists like Professor Ganguly are in short supply. "As technology transfer began to develop in the IITs, in the CSIR and in the IISc, many of these organisations found that they lacked the infrastructure and expertise needed to develop the IP," he says. "This is largely because we lack adequate numbers of people trained in technology and IPR – that is to say, developing strong technologies and negotiating deals," he adds.

Three years ago, in the first such initiative nationwide, IIT Bombay hired Professor Ganguly to train its scientists in IPR and institute a formalised IPR policy. In its first 30 years, this IIT had filed just 25 patents in India – in the last 30 months it has filed 32. It is clear that many more such efforts will be needed if India is to continue to develop effectively as an innovation centre. ■

Council for Scientific and Industrial research (CSIR): patenting activity 1994-2004

CSIR tops the list of Patent Cooperation Treaty applicants from developing countries, sharing top-place in 2002 with Samsung Electronics Corp (with 184 filings: WIPO, Geneva). CSIR places ahead of the other most active Indian players – Ranbaxy Laboratories Ltd (56); Dr Reddy's Laboratories Ltd (19); Orchid Chemical and Pharmaceuticals Ltd (16); and Biocon India Ltd (10). For the year 2002-2003, CSIR accounted for 39.5% of all US patents granted to India (source: IPMD, CSIR)

Year	India		Foreign	
	Filed	Granted	Filed	Granted
1994-95	241	104	29	10
1995-96	260	106	58	14
1996-97	209	92	70	15
1997-98	264	155	94	24
1998-99	310	134	112	38
1999-00	377	112	199	35
2000-01	410	117	452	56
2001-02	410	341	580	86
2002-03	421	166	728	189
2003-04	405	181	486	194
Total	3307	1508	2808	661

Big-five CSIR laboratories based on their performance for 1999-2002 (patents filed and granted abroad)

- Central Institute of Medicinal and Aromatic Plants, Lucknow (CIMAP)
- Indian Institute of Chemical Technology, Hyderabad (IICT)
- National Chemical Laboratory, Pune (NCL)
- Central Drug Research Institute, Lucknow (CDRI)
- Indian Institute of Chemical Biology, Kolkata (IICB)