

**Speech delivered at the 41<sup>st</sup> Foundation Memorial Lecture of Shriram Institute for Industrial Research, 28 April 2005**

The New IPR Regime: Converting a Challenge into an Opportunity

- (1) It is indeed a matter of great pride and privilege to deliver the 41<sup>st</sup> Foundation Memorial Lecture of Shriram Institute for Industrial Research. This lecture is in the memory of its founder Lala Shri Ram Ji. I deeply appreciate this opportunity to pay my own humble tributes to this great son of India.
  
- (2) We emphasise today that industrial enterprises should not only build financial capital but social, moral and ethical capital too. Lalaji did this in abundant measure as is evident from the fact that he established educational institutions, cultural institutions as well as several other bodies founded for public service. In this sense he was well ahead of his time.
  
- (3) His initiative to establish Sriram Institute of Industrial Research in 1950 is indicative of his deep commitment to indigenous R&D in industry. This institute has been developed into a unique institute, which has earned the respect of the industry as a trusted partner. This is the only self-supporting industrial research institute in India. Its business model is something that other institutes can emulate including my own CSIR. I would also like to congratulate the Institute for winning the INSME award for innovation. It is a great international honour bestowed on the institute for a unique innovation for rural women. This means that the institute has given equal emphasis to creating private good, public good and social good. I would like to convey my deepest appreciation of what this institute has

achieved so far. I wish it all the very best for the glorious journey ahead in the coming years.

(4) It was last month that India ushered in new IPR regime by passing the 3<sup>rd</sup> patent amendment bill. Against much speculation as to whether India would keep its commitment to modify its patent laws, India showed that it had the will to take up the challenge. I am going to focus my lecture on the challenges that lie ahead of us by analysing the deeper and wider consequences of this bill. Equally importantly, I will also highlight the opportunities that India can create for itself if it plays its cards right.

(5) Let me begin by emphasising that the issues of generation, valuation, protection and valorisation of intellectual property are becoming critically important all around the world. Why is this so? Firstly, we have the phenomenon of increasing dominance of the new knowledge economy over the old 'brick & mortar' economy. Generation and protection of new knowledge assumes importance in this context. Then there is the exponential growth of scientific knowledge. Then there is also the increasing demand for new forms of intellectual property protection as well as access to IP related information. Additionally, we have also to address the emerging complexities linked to IP in traditional knowledge, community knowledge and animate objects. All these pose a challenge in setting up the new 21<sup>st</sup> century IP agenda, especially for a country like India.

(6) We have to view IP in a broad context. IP will no longer be seen as a distinct or self-contained domain, but rather as an important and effective policy instrument that would be relevant to a wide range of

socio-economic, technological and political concerns. The development of skills and competence to manage IPR and leverage its influence will, therefore, need increasing focus.

(7) Historically, the intellectual property system has been divided into two main branches. One branch is concerned with industrial property. This deals with technological inventions providing new solutions to technical problems. These are registered as patents; utility models also known as 'petty patents' or 'utility innovations', trademarks for goods and services; commercial names and designations; industrial designs; geographical indications or indications of source and appellations of origin; and layout-designs of integrated circuits. The other branch deals with copyright and related rights, which protect literary and artistic expression or works of culture, which, in the broadest sense, relate to creative expression of ideas. Copyright provides protection to literary, musical, artistic, photographic and audiovisual works, computer programs, software, multimedia creations, etc. The protection of confidential business information of commercial value, often called 'trade secrets' is also an important and distinctive form of intellectual property. The protection of breeders rights in relation to new varieties of plants is another distinct form of intellectual property.

(8) The adoption of Trade Related Aspects of Intellectual Property Systems (TRIPS) Agreement has meant certain obligations on all countries, within which they have to circumscribe their laws. Any nation always needs a robust IP act. It should be designed to facilitate innovation, growth as well as development. In particular, TRIPS has entailed significant changes for the protection of pharmaceutical

products and processes. The Agreement not only made product patent protection binding to all member countries (article 27.1); it also strengthened, *inter alia*, process patents (articles 28 (b) and 34), narrowly defined the conditions for establishing exceptions to patent rights (article 30), and limited the possibility of applying especial modalities of compulsory licenses to pharmaceuticals (e.g. as provided for in Canada until 1993).

(9) India has continuously evolved its IP laws. Several amendments to the Copyright Act, creation of a new Trademark Act, a new Designs Act and amendments to the Patent Act show India's desire to change. New Acts have also been enacted covering semi-conductors and layout designs, which are of considerable importance to the electronic industry. Similarly, our plant variety protection Act and farmers rights Act will have impact on our agriculture and food industry. Geographical indications Act will protect the interests of groups in the different geographical areas in our country.

(10) Although intellectual property covers diverse aspects, it is the issue of patents that has attracted the greatest attention. Therefore, we need good patent laws in India. The first patent law in India was enacted in 1856. The Indian Patents and Designs Act was enacted in 1911. The need for a comprehensive law so as to ensure that patent rights are not worked to the detriment of the consumer or to the prejudice of trade or the industrial development of the country was felt as early as in 1948. After several attempts the bill introduced in the Parliament came on the Statute Book as the Patent Act 1970.

(11) India needed the 1970 Act, given our state of scientific, technological and industrial development at that time. This Act did not allow product patents in the field of drugs and pharmaceuticals, food and agriculture. Only process patents were allowed. This allowed India to use its undoubted prowess in process chemistry and engineering. I do not think we could have succeeded in having a drugs and pharmaceutical industry that we have today without the Patent Act of 1970. In 1950s, we were importing even formulations. Our industry developed a reputation of a robust industry. Thus, our pharmaceutical industry is one of the most developed amongst the developing countries thanks to this Act. However, the context decides the content. The context of 1970 was different. In 2005, the context is different. Therefore, change over to a new IPR regime was a must not only to meet our commitments under WTO but also to give a further fillip to our industrial development. The third patent amendment bill has attempted to do precisely this.

(12) The latest amendments have not been without concerns from different quarters. The first concern is about the rise of the prices of the drugs within India. We have been told that 97 percent of the drugs are off patent and none of the 354 drugs for 27 therapeutic areas in the essential medicines list are patented. So the prices for these are unlikely to rise. The same will not be the case, of course, for the new drugs that will enter the market.

(13) On April 23, 2001 the United Nations Commission on Human Rights called on governments to ensure the accessibility of pharmaceuticals and medical treatments used to treat pandemics such

as HIV/AIDS, as well as “their affordability for all,” in accordance with international law and international agreements. The resolution also calls on governments “to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties”.

(14) In this context, there is a concern about limiting the impact of the monopolies that will come in as a result of the enactment of the new Act. Here, one must understand the way licenses are issued. There are three types – namely voluntary, automatic and compulsory. The voluntary license is the result of a negotiated arrangement between the patent holder and any other party interested in commercialisation of the patent product. The patent holder gets a royalty payment and there is no state intervention. On the other hand, state intervention is needed in the case of automatic and compulsory licensing, which can be used by the Government in special circumstances. If AIDS poses the threat of a serious epidemic, then compulsory license can be issued, even if the drugs are under patent. Therefore, we can take care of such exigencies within India.

(15) But then what about other countries? Can we legally supply AIDS drugs for a country, which has no capacity to manufacture it? After all, it was CIPLA, an Indian company, who offered an antiretroviral cocktail of a triple therapy AIDS drug at \$ 350 for an year treatment, as against \$ 10,000 offered by multinationals. But this was before the patent amendment bill was passed. Can we do it now? The answer is in the affirmative. The amendment includes a provision to facilitate exports to such countries “with limited or no

manufacturing capacity". This means that other countries can also be helped by Indian manufacturers.

(16) 'Evergreening' is another issue that everyone is concerned about. A company, which holds the original patent, can add something in the composition or change the mixture and get another patent for a modified product. This is invariably done, when the patent is about to expire. The patent holders, in principle, develop different salts, mixtures, polymorphs, metabolites, hydrates, isomers and other derivatives of the same molecule and extend the life of the patent. Here, sometimes, the modifications can be trivial and may not meet the true threshold of an "innovative" step, which is so critical for the grant of a patent. What constitutes a real 'innovative' step? To address some of these and other related issues, the Government has formed a five-member expert committee under my chairmanship and we are looking into these issues. It will be ideal to have an approach, which while being TRIPS-compliant, is also one, which only admits truly inventive steps and scrupulously eliminates "evergreening".

(17) The issue of patents versus patients is a thorny issue. There is a Commission on Intellectual Property Rights, Innovation and Public Health, that has been set up by WHO. Ruth Dreifuss, the former President of Switzerland, is the chairperson. I am the Vice Chairperson. Our objective is to look at the issue of availability, affordability and access of drugs for the needy. The report will be submitted by the end of the year. We hope to throw some light on the way a balanced IP regime could be evolved to address this issue. What I wish to emphasise is that both nationally and internationally,

there is a deeper discussion of the issues connected with impact of patents on public health and we do.

(18) Let us now turn to the question of the challenge before our own drugs and pharma industry. As I said earlier, an importer of even the formulations in early 50s, our drugs and pharma industry has now become a net exporter. It survived so far without developing new molecules. Indeed, only fourteen new molecules were developed so far in the last forty years, out of which eleven have been from the CSIR system. But with the advent of the new patent regime, the strategies will have to change. I do strongly believe that the Indian industry can once again rise to the occasion just as it did in the 70s under the provisions of the Indian Patents Act 1970. Indian pharma industry, apart from pursuing novel synthetic routes to known molecules, must pursue basic research for patent-worthy inventions comprising new molecules. It will have to forge partnerships with national laboratories in a Team India spirit to surge ahead.

(19) Are we beginning to see this spirit? Yes, I do believe that we are seeing a great momentum. The drugs and pharma industry has increased its R&D spend by about 500% in the last four years. At least 10 companies have launched themselves into the new molecule discovery research. Reddy Laboratories and Ranbaxy were early leaders, but others are following rapidly. Four months ago, I was a witness to the opening of a new R&D Centre of Nicholas Piramal at Mumbai at the hands of our President. It is a world-class centre by all counts. I myself visited Torrent R&D in Vadodara and Sun Pharma R&D in Ahmedabad over the last three months. The enthusiasm and commitment was clearly visible. But mere enthusiasm is no substitute

for large investments. Therefore, there are doubts expressed, when one realises that a new molecule now takes 12 to 15 years and 1 to 1.5 billion dollars to enter the market. Our total national drug R&D spending is less than \$ 300 million. But a dollar goes a long way in India. Some drugs and pharma companies have said that they can cover the journey of molecule to market in about \$ 50 million to \$ 100 million. This does not look too far-fetched to me.

(20) We have talked about the momentum. But is there any evidence of promising leads or results coming in? Indeed they are. CSIR has designed a unique public-private partnership (PPP) called "New Millennium Technology Leadership Initiative" (NMITLI). It is the biggest public private partnership in post independent, India involving 65 private sector companies and 160 institutions and universities. It has a high emphasis on drugs and pharma R&D partnerships. Some of its successes are unique. Let us see an example.

(21) The last time a new molecule was discovered for a tuberculosis treatment was in 1963, when Rifampicin was introduced. The new breakthrough has come under the NMITLI programme. A new molecule, named as Sudoterb has been discovered, which shortens the treatment time from 6-8 months to 2 months. It is entering phase I clinical trials. This was a result of a partnership between Lupin and other institutions. There are other interesting leads too. We need more of this PPP. Government's initiative of a Rs.150 crore Drug Development Promotion Fund is again a step in the right direction.

(22) Let us now turn to the general strategies that the industry employs in patenting. Patents are important for companies and

research institutes for different reasons in a number of contexts. A recent survey done in the case of Swiss biotechnology industry showed that the motivation for patenting in decreasing order of importance is as follows:

- Protect our technology from imitation
- Prevent competitors from patenting and application activities
- Improve the technological image of one's company or institution
- Create a conducive climate for R&D cooperation
- Generate licensing income
- Improve inter-firm negotiations (cross licensing, joint ventures)
- Prevent patent infringement suits
- Acquire venture capital

As India learns the game, firms and institutions will have to understand the nuances of these strategies.

(23) In this context, the challenge is not for drug industry alone, it is for all industries. They must understand the fundamentals of the game of patenting described above. The knowledge based industry in India, such as the IT industry, biotechnology, microelectronics etc. will have to face new challenges in the new IPR regime. The IT industry has maintained an impressive growth rate and we have the dream of becoming an IT super-power. If this has to happen, then we will have to reduce the content of body shopping and move on to innovative IT products, which will need IP protection. Indian IT industry has not so far focussed on this, but will have to play an increasing attention to this aspect. The same is true of biotechnology. Indian biotechnology industry now has a turnover of \$ 1 billion, which is impressive. But we

have not seen any evidence of a spurt in creation of new IP barring a few exceptions. We need to accelerate this process.

(24) Again it is not industry alone. There is a responsibility on others too. Before we protect IP, we must generate IP, which is worth protecting. Our institutions, national laboratories and industrial R&D laboratories will have to gear up for this. Nurturing a strong innovation base through a balanced system of recognition and rewards is the need of the hour. We will have to invest liberally to enhance the skills and knowledge base of scientists, through structured in-house and external professional training programmes, some even abroad, on understanding, interpreting and analysing the techno-legal and business information contained in IP documents, and in drafting of IP documents. For this we need to avail the services of high-class national and foreign consultants and attorneys.

(25) For instance, skills in filing, reading and exploiting patents will be most crucial in the years to come. We must properly protect our inventions. We must fully understand the implications of the patents granted to our competitors. Many of the patents written by our professionals could be easily circumvented. Manpower planning for IPR protection needs priority. IPR must be made a compulsory subject matter in the law courses in the universities in India. Our graduates coming out of engineering and technology streams have no idea about IPR, and yet it is these young people, who will have to fight these emerging wars in the knowledge market.

(26) A number of patent training institutes will have to be set up. China has already set up 5000 patent training institutes! Judicious

management of patent information will require well-structured functioning of information creating centres, information documenters and retrievers, information users, IPR specialists and information technology experts.

(27) Monitoring national and international patents and other IP through access to on-line databases, to ensure effective protection and to ward off infringements and threats to India's IP portfolio will be crucial. Analysing and assessing techno-legal and business information and market intelligence to identify strategic alliances and to exploit potential uncovered niche areas of opportunities itself will give rise to new knowledge based business.

(28) Albert Einstein had once said "Imagination is more important than knowledge." Abraham Lincoln had said, "the patent system added the fuel of interest to the fire of genius." That is how the western world viewed IP. That is how US built its economy. We have been late beginners, but we have to catch up fast. In this context, I am happy to see CSIR showing the way. Ten years ago, CSIR secured only five to six US patents per year. Last year, they secured 196 US patents in one year! CSIR has been constantly in the top three positions amongst the top fifty PCT filing list brought out by World Intellectual Property Organization (WIPO) for the developing countries. CSIR has maintained a 30-40% share of the US patents granted to Indians in India. We need to spread this movement.

(29) A particularly big challenge is going to be for our academic institutions. When I look at University of California's performance. I find that it continuously garners around 400 to 500 US patents. It has

always been a leader amongst the US academic institutions. The biotech enterprises that have spun off over the years around University's Campus have created billions of dollars of market capitalisation and provided jobs for 80% of its graduates in life sciences. But while creating jobs and wealth, science has not suffered in the University. They boast of around 45 Nobel Prize winners too! They seem to understand the respective roles of Saraswati and Lakshmi and also manage to find a route from Saraswati to Lakshmi. Why are our academic institutions failing to do this?

(30) It is hard to estimate the loss of Indian intellectual property due to the inadvertent publication of usable knowledge in the last few decades in our academic institutions. We need to encourage the publication of R&D results in scientific papers only after careful consideration of the consequences on IP rights. Indeed, we need clearly articulated IP policies. We have seen seven policies emerge recently in University of Pune, IIT (Bombay) etc., but this is not enough. We need more aggressive movement on this front.

(31) There are other actors in the play too. In order to ensure that the Courts deliver judgements which meet the ends of justice there is a need for further exposure for those in the judiciary to deal with the evolving new developments in the intellectual Property field. In our country the delay in the Courts is a matter that is causing a great frustration to the patentee and as such it would be desirable to have the members of the judiciary exposed to the decisions and the guiding principles that emerge from them.

(32) There are special areas of concern to India, and that includes its rich traditional knowledge base, in particular its great strength in traditional medicine. Indeed, traditional medicine (TM) play a crucial role in health-care of serves the health needs of a vast majority of people in developing countries including India.

(33) The grant of patents on non-original innovations (particularly those linked to traditional medicines), which are based on what is already a part of the traditional knowledge of the developing world have been causing a great concern to the developing world. It was CSIR that challenged the US patent No.5,401,5041, which was granted for the would healing properties of turmeric. In a landmark judgement, the US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries.

(34) There was yet another case of revocation May 2000. The patent granted to W.R. Grace Company and US Department of Agriculture on Neem (EPO patent No.436257) by European Patent Office was squashed again on the same grounds that its use was known in India. Then followed another case. India filed a reexamination request for the patent on Basmati rice lines and grains (US Patent No.5,663,484 granted by the USPTO, and Ricetec Company from Texas decided to withdraw the specific claims challenged by India and also some additional claims.

(35) There is a problem on the grant of such patents linked to the indigenous knowledge of the developing world that needs to be addressed jointly by the developing and the developed world. To

mitigate this problem, steps have been taken to create a Traditional Knowledge Digital Library (TKDL) on traditional medicinal plants and systems. This has been done by CSIR in partnerships with Department of Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH). TKDL will also lead to a Traditional Knowledge Resource Classification (TKRC). Linking this to internationally accepted International Patent Classification (IPC) System will mean building the bridge between the knowledge contained in and old Sanskrit *Shloka* and the computer screen of a patent examiner in Washington! This will eliminate the problem of the grant of wrong patents since the Indian rights to that knowledge will be known to the examiner.

(36) Eventually the creation of TKDL in the developing world would serve a bigger purpose in providing and enhancing its innovation capacity. It could integrate widely scattered and distributed references on the traditional knowledge systems of the developing world in a retrievable form. It could act as a bridge between the traditional and modern knowledge systems. Availability of this knowledge in a retrievable form in many languages will give a major impetus to modern research in the developing world, as it itself can then get involved in innovative research on adding further value to this traditional knowledge; an example being the development of an allopathic medicine based on a traditional plant based therapeutic. Sustained efforts on the modernisation of the traditional knowledge systems in India will create higher awareness at national and international level and will establish a scientific approach that will ensure higher acceptability of these systems by practitioners of modern systems and public at large.

(37) An ideal regime of intellectual property rights strikes a balance between private incentives for innovators and the public interest of maximizing access to the fruits of innovation. This balance is reflected in article 27 of the 1948 Universal Declaration of Human Rights, which recognizes both that "Everyone has the right to the protection of the moral and material interest resulting from any scientific, literary or artistic production of which he is the author" and that "Everyone has the right to share in scientific advancement and its benefits". The burning question seems to be balancing the interest of the inventor and that of the society in an optimum way. India can show the way to the rest of the world as to how to achieve this balance.

(38) In a recent essay in the journal *Science*, I had referred to the Goldman Sachs study, where India is supposed to assume the position of a top economic power by 2050. But I had also predicted that if India plays its cards right, it can become a global knowledge production centre by 2020. For this to happen, our strategies on not only the generation of new knowledge, but also its protection and valorisation are going to play a critical role. Indian strategy has to evolve around bringing IP protection into mainstream of our endeavours in education, science and technology, legal and judicial systems, trade and economics, etc. This is the big challenge, which I am sure India will take on and convert it into a huge opportunity that awaits us as we begin our great journey at the dawn of this new century.