INTRODUCTORY REMARKS : PATENT INFORMATION FOR DRUG RESEARCH, URDIP, PUNE

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Mr. R.R. Hirwani, Dr. R.A. Mashelkar, Mr. M. Waikar, participants in the seminar on Patent Information for Drug Research, Ladies and Gentleman,

I am delighted to be here today at URDIP and be part of this Workshop. The Workshop is timely and relevant. Drug research today is both a scientific as well as an intellectual property challenge. Without a deep understanding of both the scientific and legal content of a patent, no drug research can become successful.

Let me briefly explain. The US 400 $ billion a year drug industry is in serious trouble. The drug industry's expenditure on R&D was close to US $ 25 billion in 2000, yet less than fifteen drugs received approvals by FDA. Compare this with 1995, when 50 drugs were approved for a total R&D expenditure of 15 billion US $ and 1985 when 30 drugs were approved for a total R&D expenditure of 10 billion US $.

This drought of new discoveries is making the industry move from laboratory to Patent office and court room to protect its turf. The global drug industry, having gotten used to windfall profit is looking at every opportunity to extend its monopoly rights on drugs. It is believed that by 2007, close to 50 $ billion worth of drugs will go off product patent. Cheap generics, especially from low cost producing nations like India and China will compete for these markets. The Hatch – Waxman Act has lowered the entry barrier of generics in the US markets. It is therefore, only natural that major drug companies will do everything possible to block the entry of generics. The only way they can do it is by the creative use of the Patent Laws. Already the directions are clear. Patenting new cures for old drugs, patenting of chiral single isomer drugs and polymorphs, NDDS etc. Some of these will be innovation driven, but many will exploit the loopholes of the law.

If the Indian drug companies have to be competitive, we need to understand not only the scientific underpinnings of a patent, but also its legal implications. We need to have clear strategies as to how India may capture a fair share of the 50 billion US $ generic markets that will open up shortly. We have to take the battles to those territories where the stakes are high.

This will require new knowledge of science, technology and law. Scientists and business leaders of the Indian drug industry cannot shy away from this battle. The stakes are too high.

I do hope that the program that is laid for you brings you greater awareness of these issues that stare at us rather starkly today. Time is too short for us to prepare for the battle. Awareness of IPR related issue is the imperative need of the hour.