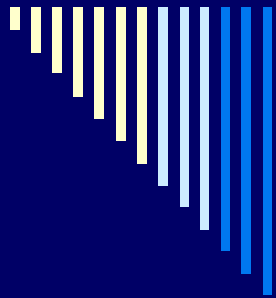



Presentation before CIPIH of the WHO

By
Yogin Majmudar
President
**INDIAN DRUG MANUFACTURERS'
ASSOCIATION**

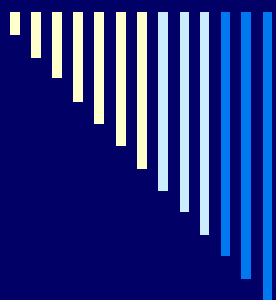


New Delhi
4 November 2004



Progress of Pharma Industry in India

- **1911: The Indian Patents and Designs Act promulgated. Product patent and Process patent in all fields**
- **1950s: Formulations. MNC Dominance**
- **1960s: Formulations. MNC Dominance continues. Some indigenous companies start work on Formulations from imported bulk drugs.**
- **1970s: Patents Act 1970 comes into force in 1972. Medicines, Food and Agro-chemicals removed from product patent (and put under process patent). Term of patent -Product Patent (for all other items) 14 years; Process Patent 7 years. Indigenous industry starts manufacturing bulk drugs.**
- **1980s: MNC influence declines to some extent. Growth of indigenous production of bulk drugs as well as formulations.**
- **1990s: MNC influence further declines. Significant amount of indigenous production and export.**



Progress of Pharma Industry in India

- ❑ **1995: WTO – TRIPS comes into effect.**
- ❑ **1999-2002: TRIPS compliant EMR law- the First Amendment in the Patents Act .**
- ❑ **2002: Second Amendment - Our Patents Law brought in line with TRIPs. Patent term 20 years for both product and process patents, national treatment, change in burden of proof etc.**
- ❑ **Medicines, Food and Agro-chemicals to continue to be under Process patenting till 31 Dec 2004. (Product patent in all other areas continues)**
- ❑ **1-1-2005: Deadline for introducing product patent in Medicines, Food and Agro-chemicals. The legislative procedure on this work has started and the Bill is to be introduced in Parliament in December 2004.**
- ❑ **Increasing R&D activity expected in post 2005 period.**

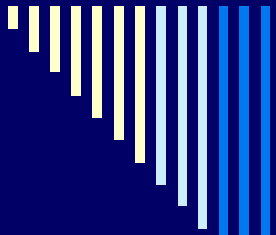


Achievements (India) - Industry Contribution

	<u>1960-61</u>	<u>2000-01</u>
Life Expectancy (yrs.)	41	65.39
Birth rate (per 1000)	41.7	25.8
Death Rate (per 1000)	23	8.5
Infant Mortality per 1000)	146	68

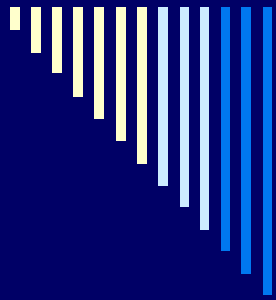
Introduction of Process Patent in 1970 spurred the development of the domestic pharmaceutical industry.

- ✓ Abundant availability of medicines at reasonable prices
- ✓ International quality
- ✓ Self reliant in formulations and most bulk drugs
- ✓ Improvement in Health Indicators



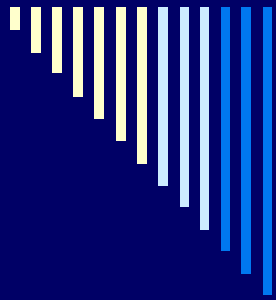
About IDMA

- ❑ Founded in 1961, IDMA is the oldest Association of indigenous drug manufacturers in the organized sector.
- ❑ Has over 570 members comprising of large, medium and small companies (bulk drug manufacturers as well as Formulation manufacturers).
- ❑ Members' Indian Market share: approx 85% in bulk drugs approx 75% in formulations
- ❑ Indian Pharma exports at Rs. 14,000 Crores (over \$ 2.5 billion) - growing at over 21%. IDMA Members' share: 90% of India's Pharma exports
- ❑ A professional and scientific body.
- ❑ Publishes a weekly *IDMA Bulletin* and a monthly scientific and technical journal *Indian Drugs* and other publications.
- ❑ Recognized by the Government as the 'Voice of the People'.



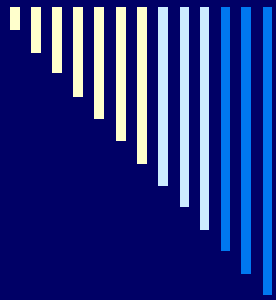
India –Weaknesses on the Emerging IPR front

- The objectives of human welfare and public health not fully taken care of.
- Under pressure from the MNCs and powerful countries, India has made a compromise in its Patents Law – important areas e.g. patentability, parallel imports, CL and Government's powers considerably weakened.
- Flexibilities available under TRIPs or Doha are not fully utilized.
- There is pressure to accept TRIPs plus measures. (e.g. Data Exclusivity)



India Diseases Profile and Health Policy (2002)

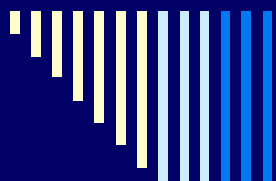
- ❑ Diseases such as Malaria and TB are on a rise.
- ❑ HIV/AIDs a new threat.
- ❑ Water Borne diseases such as Gastroenteritis, Cholera, hepatitis etc also prevalent.
- ❑ New lifestyle diseases, e.g. diabetes, cardiac diseases, etc. are on an increase.
- ❑ Nutrient deficiency particularly among children and women high.
- ❑ Health Policy (2002) Goals include tackling above.



Overview

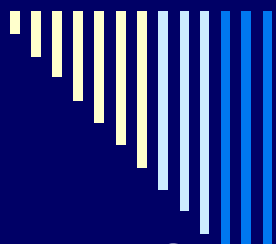
- Human welfare being the goal, WHO should persuade WTO to agree to remove distortions.
- To show that the patent system distorts the pricing mechanism of drugs. Trade barriers enhance price by 20-40%. Patents push up prices 400 to 1000%
- Suggestions for reducing the huge gap between price and the marginal cost created by the Patent system.
- Best option - Enhancing public funding for research & public-private partnership.
- Other models of funding and incentives discussed
- Tech. Transfer to developing countries not taking place.

TRIPS review to make it more equitable is urgently necessary.



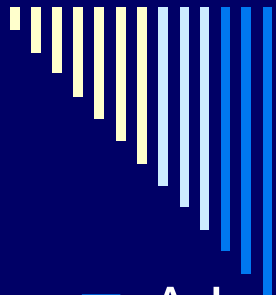
Objectives of the WHO

- ***The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being...*** - Preamble to the WHO Constitution
- **“Health and human rights has been designated as a cross-cutting activity in WHO. Ethics, Trade, Human Rights and Law (ETH) within Sustainable Development and Healthy Environments (SDE) is the focal point within the Organization for human rights.**
- **“WHO is actively strengthening its role in providing technical, intellectual and political leadership in the field of health and human rights. The main objectives are to:**
 - **strengthen WHO's capacity to integrate a human rights-based approach in its work**
 - **support governments to integrate a human rights-based approach in health development**
 - **advance the right to health in international law and international development processes**



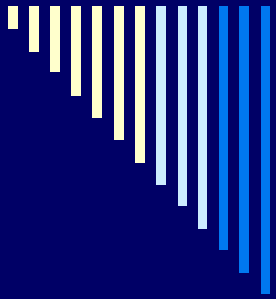
Implications of TRIPs (effects of a strong product patent law)

- ❑ Creates distortions in market and local economic development.
- ❑ Enhances price by 400% to 1000% or more compared to Trade Barriers which do it by 20-40% only.
- ❑ Leads to unnecessary marketing expenditure
- ❑ Qualitative improvement of existing drugs ignored. Duplicative drug research promoted.
- ❑ Neglect of drugs which do not promise good profits such as orphan drugs or drugs for poor man's diseases.
- ❑ Researchers tend to conceal unfavourable findings which may affect public health.



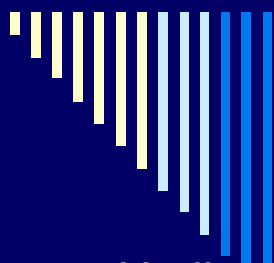
Patent Matters - What we expect

- A balanced approach – that the rights of patent holders are reasonably protected and at the same time, the public interest is fully safeguarded.
- No ever-greening of patents is to be accepted.
- The likely abuse of the patent monopoly should be prevented.
- Traditional Knowledge of India must be protected
- Powers of the Government should not be eroded.



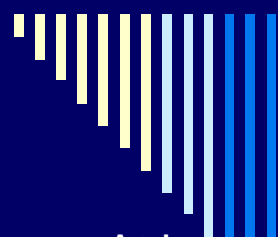
Patent Matters - What we expect

- ❑ Compulsory licencing should be liberalized on payment of royalty.
- ❑ TRIPS Plus demands e.g. Data Exclusivity should not be accepted.
- ❑ No by-passing or superceding of the TRIPS Agreement through FTAs and Regional Agreements be allowed.
- ❑ **We are not against limited patent harmonization**
BUT
 - There should be a clear recognition that one size cannot and does not fit all.
 - In the interest of developing countries the pace of harmonization should be slowed down,
 - Acceptance of International Search and Examination results should be optional ;
 - Enforcement harmonization should be put on hold till SPLT is not agreed to by all.



TRIPS and R&D in India

- Until 1970 – negligible R&D as MNCs mainly confined R&D to home country
- From 1970 – 90 – Process Research and Clinical trials by Indian companies
- 1990's – First time Basic Research by some Indian companies
- Currently more than 150 companies engaged in some type of R&D including Novel Drug Delivery systems
- Post 2005 many more Indian Companies aided by National Laboratories expected to enter into all fields of R&D including Basic Research
- Patents held by India in the world (all sectors) are mere 0.6% in year 2000. The reason is not absence of Product Patent as Product Patent existed in areas other than Pharma, Food and Agrochemicals.
- The reasons probably are : very small capital base, low level of economic growth because of faulty economic policies, prevalence of inspector-permit Raj, absence of institutions for higher learning and Research, etc. etc. The result is that R&D in all fields in India is inadequate.



R&D, Patents and Price Paid By Consumers

From “The Truth About Drug Companies: How They Deceive Us And What To Do About It” by Marcia Angell (a Prof in Harvard Medical School)

- At least a third of the drugs are discovered by Universities and sold to drug companies for a small royalty. Drug companies, however, make huge profits.
- Example - Cancer drug Taxol discovered by NIH, sold to Bristol Myers Squibb (BMS) for only 0.5% royalty. However, BMS sells Taxol to public at \$20,000 a year, which is more than 20 times the manufacturing cost.
- Me-too drugs – minor variations of old molecules which most probably were discovered by Universities and Government funded research (tax payers’ money). Drug companies make small variations and sell them as new inventions. Examples - 6 Cholesterol reducing Statin drugs, 9 ACE inhibitors for Hyper Tension.
- Top ten US Drug companies make more profit than the rest of the Fortune 500 Companies combined.
- Top U.S. drug makers spend 2.5 times more on marketing than R&D. Then, why blame R&D for prices?
- Cost of invention is claimed to be \$802 million per drug, which is pure cost manipulation. They are looking at a tiny number of most costly drugs. Most drugs do not fall in this category. Firstly, most are minor variations which does not involve this huge amount, Two, tax deductions and tax credits given are not counted, and Three, ‘Opportunity cost’ (what they could have made in other investments- a notional figure) added to double the cost.

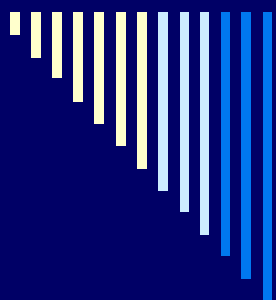


Drug Prices (India)

- Experience all over the world is that the cost of patented medicines is always high and that of generic medicine low. Examples - Ciprofloxacin 10s Rupees 29 in India (generic price), 424 in Pakistan (patented price) and 393 in Indonesia (patented price)
 - Ziduvudine Rs 58 (India) 313.47 (Pakistan) and 393 (Indonesia)
 - Simvastatin Rs 25 (India), 283 (Pak), 187 (Indonesia).

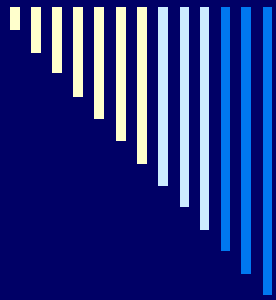
- Another Example – Ciprofloxacin. Bayer reduced price by 70% at the height of the Anthrax scare in 2001 when US Govt. threatened for granting CL. Year 2001 was the 18th year of the patent on Ciprofloxacin (Expired 2003). **Does it not mean that by selling at three times the right price all these years, they overcharged the American people?**

- The truth is that the MNCs charge **'WHAT THE MARKET CAN BEAR'** and **not 'WHAT IS REASONABLE'**



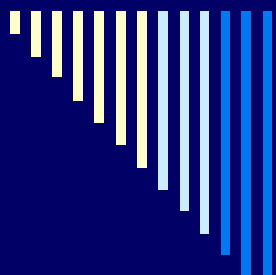
Post 2005 Access to Drugs (India)

- Access to medicines particularly the high cost patented drugs would go down in the post 2005 India
- Even the price of the 2nd best alternative drug (generic) would also go up in sympathy with the price of the patented drug.
- Doctors are likely to prescribe the best medicine (mostly patented) even in case of less serious patients who can be cured by lower potency older drugs (generic) to enhance their reputation. Cost is no consideration.
- The problem in India is very crucial because there is no social security system. The majority of our population is unprotected from the vagaries of life.



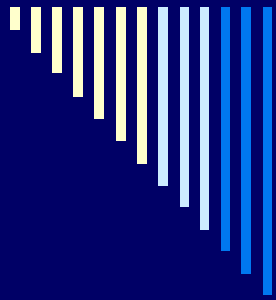
Options on Funding – R & D

- Government (public) funding and Joint Public-Private funding should be encouraged.
- International (UN, WHO) support in funding should be encouraged.
- Government buying inventions and paying royalty – i) at a Fixed Royalty, or at a Royalty dependent on sale or popularity of the drug or ‘rated quality of life improvement ((Aidon Hollis 2004)’.
- Government buying the required drug patent through auction system and places it in public domain (Kremer 1998)



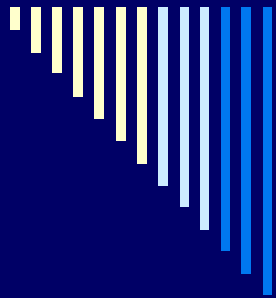
Conclusion - WHO and WTO (TRIPS) should come to an understanding as follows

- TRIPS Review as provided in TRIPS Agreement be undertaken to address the problems of developing countries. The objectives should be Human Rights, Welfare and Public Health.
- Patent term of 20 years is too long. It should be reduced to 15 and there should be no extensions on any ground.
- The tilt in favour of the patent holder (which are usually from developed countries) be corrected.
- Increasing use be made of safeguards available in TRIPS, Doha Declaration on Public Health and also on the Agreement on S&D.



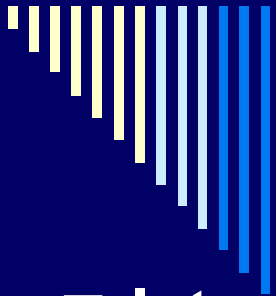
Conclusion - WHO and WTO (TRIPS) should come to an understanding as follows

- There should be a balance between the rights and obligations of the patent holder. At present, the TRIPS is tilted in favour of the rights of the Patent-holder (usually from developed countries) ignoring the needs of the developing countries.
- The Patent laws of the member countries should be aimed at protecting public interest and promoting public welfare.
- While reasonable remuneration is acceptable, the patent holder (usually a corporation) should not profiteer.
- Compulsory Licences should be issued freely. Generous royalty may be allowed in such cases.



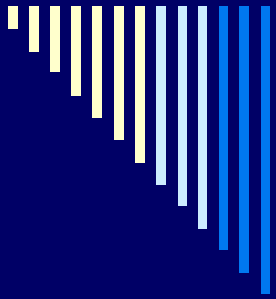
Conclusion- WHO and WTO (TRIPS) should come to an understanding

- To ensure that the prices of drugs particularly the essential drugs are reasonable and that the medicines are affordable for the public, keeping in view the economic status of the society.
- Special care to be taken in case of Developing countries and LDCs.
- International funding be organized for R&D for diseases of tropical and developing countries.



Conclusion- WHO and WTO (TRIPS) should come to an understanding

- International funding for improving access to medicines for poorer section of society.**
- Differential Pricing (already being practiced in a limited fashion) be accepted as a viable way to address this problem.**
- Patent Harmonization (by WIPO) on US lines is unwarranted. If individual countries flexibilities are taken away, it will retard progress and increase health problems. Therefore, Patent Harmonization be stayed till the effects of the new TRIPs regime is thoroughly studied.**



Thank You

Indian Drug Manufacturers' Association delegation:

- 1) Shri Yogin Majmudar, President, IDMA**
- 2) Shri Gajanan Wakankar, Exec. Director, IDMA**