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A. Introduction:

- The first Indian Patent Law was enacted in 1856 as Act VI.
- Patent Designs and Protection Act came in 1872
- Protection of Inventions Act came in 1883 and continued upto 1970.
- In 1970 Product Patent Law was abolished for Pharmaceuticals to encourage domestic generic industry and make the prices of Pharmaceuticals more affordable.
- With the help of reverse engineering the domestic Pharmaceutical Industry started growing very fast by piggy-back riding on the inventions of the innovators across the world.
- The economic reforms started in early 1990.
- India signed WTO effective 1st January 1995.
- After a transition period of 10 years, the Patents (Amendment) Act 2005 was enacted bringing back Product Patent Regime in India, once again, and ushering a new paradigm.

B. India's Presence:

- Currently, India is engaged in medium levels of research:
 - NDDS
 - Contract Research
 - Specialised Generics
 - Biogenerics
 - New Chemical Entities (NCEs) – the ultimate aim

C. Research done by Indian Companies:

- 8 major companies engaged in research in India are:
 - Ranbaxy
 - Dr. Reddy's
 - Glenmark
 - Wockhardt
 - Zydus Cadila
 - Piramal Healthcare
 - Lupin
 - Biocon

- All put together, they have 21 NCEs in pre-clinical stages, 7 in Phase I, 16 in Phase II and 2 in Phase III.

- It is expected that by the year 2015, India will launch about 3 NCEs with sales around 500 Mn. U.S.\$.

- Adoption of advanced biological and chemical techniques such as:
 - Gene sequencing
 - Proteomics
 - Genomics
 - Structure based product designare currently being done on a very small scale in India.

D. Patent Applications:

- In 2005-2006, 24,505 applications were filed with Indian Patent Office.

- Patents granted – 4,380 (18%).

- Drugs – 9% of all applications. Areas: CNS, Immunological Disorders and Cancer Therapy.

- Of 4380 patents granted, 11% were drugs and 1% biotechnology patents.

- Backlog substantial – 25,000 applications.

E. R&D Funding Structure:

- In developed countries, 2% of GDP spent on R&D.
- In India, it is currently 0.6% of GDP stated to be 2% by 2011.
- R&D spend of major pharmaceutical companies in India stands at about 7-8% (495.2 Mn. U.S.\$) of total revenues with a growth of 26%.
- Total spend in U.S. Pharmaceutical Industry in 2005 was 52.2 Bn. U.S.\$, approximately 19% of total industry.

F. Talent Supply:

- For Life Sciences Industry, 674,000 available candidates, 101,000 i.e. 15% are suitable.
- The same number is 10% in China (available 543, suitable 54).
- Therefore, it indicates for Life Sciences Industry available talent in India is more than China.

G. Patent Examiners**H. Patent Infrastructure****I. Patent Data Management****J. Issues with Research-based Pharmaceutical Industry**