



## Observations from Pharma

Indian Patent Enforcement in the Chemical Arts

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London, 26/9/11

a Novartis company

# The Indian Pharmaceutical sector: Overview

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- India is a world player in the pharmaceutical market:
  - 2009: India supplied 1.3% (by value) and 8% (by volume) of the world market ;
  - 2010: Top 3rd worldwide by volume supplying 10% of world volume and top14th by value (1.5%).
- Pre-2005:
  - US\$7.3 bn (finished products: domestic consumption plus exports);
  - Indian pharma supplied 70% of bulk drugs and 80% of formulations in the Indian market; largely self sufficient;
  - Domestic market: Fragmented; many market segments eg pure generics, branded generics, formulations etc and highly competitive

# 2005: Amendments to Patent law

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- Some concerns expressed pre-2005 changes:
  - Indian pharmaceutical companies would be replaced or acquired by large international MNCs;
  - Signaled the end of low priced medicines in India and internationally (eg developing countries relying on India for the generic drug supplies);
  - Lack of innovative edge in Indian companies to compete effectively with MNCs and big pharma.

# 2005: Amendments to Patent law

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- Position post-2005:
  - M&As; joint ventures; takeovers and greater presence and activity from MNCs in India;
  - Drug pricing:
    - Legislative changes did not affect patented drugs pre-1995. This category together with drugs coming off patent as at 2005, accounted for 90% of the products on the Indian market in 2005;
    - Patented drugs-post 1995: this will be dictated by challenges made to patent registrations; approach adopted by IPAB and Indian Courts; role played by grant of interim injunctions/remedies;
    - Potential role for Compulsory Licensing;
    - Potential role for competition authorities/regulators

# 2005: Amendments to Patent law

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- Indian pharma companies have successfully effected structural changes to meet with the new challenges eg:
  - Shift of focus to international stage: Evidenced by :
    - larger concentrations of FDA approved manufacturing plants;
    - a significantly higher number of drug applications to the FDA;
    - acquisitions of companies by Indian pharma in foreign markets
  
  - Shift of focus to R&D/product innovation either independently and/or through joint ventures/partnerships with foreign pharma:
    - Expenditure by Indian Pharma on R&D:  
2000: 1.9%, US\$73.6m (of sales); 2011: Average R&D expenditure by top Indian pharma companies: is close to 7.5-8 %.

# 2005: Amendments to Patent law

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- New opportunities have arisen for Indian companies: outsourced manufacturing; CROs; outsourced/collaborative R&D; clinical trials
  - Foreign firms /investment attracted by:
    - competitive lower costs structures offered by Indian based companies (around 1/8 th of the R&D spend which companies would incur in the West and 1/5 th of manufacturing costs);
    - the availability of professionally qualified talent pool at a cheaper cost;
    - large domestic market;
    - A more secure IP registration and enforcement regime in comparison to China;
    - fewer language barriers

# Life cycle of a new Pharmaceutical

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- Broadly, this spans three distinct periods:
  - The R&D phase up to market launch
    - Includes patent application, clinical trials, regulatory approvals for new pharmaceuticals
  - Period between a successful launch and loss of exclusivity
    - Protected by patent and data exclusivity;
    - Originator recoups R&D investment and significant profits achieved;
    - Extensive manufacturing and marketing/promotion by patentee;
    - Exclusive licensing for certain jurisdictions.
    - Where patent is weak: oppositions to grant; actions seeking revocation of patent. Procedure differs from jurisdiction to jurisdiction.
    - Towards the end of patent/data exclusivity periods: applications by generics for marketing approvals

# Life cycle of a new Pharmaceutical

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- The period following loss of exclusivity:
  - Generic entry and increased competition
  - Impact on pricing and loss of market share for patentee
  - Life cycle management strategies implemented by patentee: patent clusters; “evergreening”)
  - Possible infringement of follow-on/secondary patents

# Challenges: Patent Enforcement

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- The right litigation team
- Speedy and efficient resolution of disputes
- Other challenges:
  - Patent-Regulatory linkage
  - Data exclusivity
  - Compulsory Licensing
- Competition law landscape

# The right team

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- The team:
  - In house counsel
  - In house and external patent attorneys,
  - Internal and independent experts
  - External lawyers
  - Counsel.
- Sector knowledge:
  - Success dependent on each party having a keen understanding of how the pharmaceutical sector operates and the using this knowledge to devise the right prosecution & litigation strategy.
  - An element of presenting sector issues/difference to decision makers & the nuances of commercial realities in the pharma industry
  - Impact of interim injunctive relief on patentee and generics and adequacy of damages

# The right team

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- Local knowledge
  - Knowing your Judge
  - Particular local legal provisions: eg Article 21 of Indian constitution and impact on decisions; other non-IP related procedures or laws to achieve end objectives

# Resolution of disputes

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- Delays in grant of patents; pre-grant opposition process; lack of clarity concerning process and legislative interpretation
- Enforcement: Delays in Court process:
  - complicated by technical nature of patent disputes
    - Ability of courts may have powers to appoint technical experts to assist with such issues: differs in each jurisdiction
  - quality and ability of judges/judicial arbiters;
    - Training for judges on IP laws/issues
    - Include sector focus training?
  - Consequent impact on commercial reality:
    - Uncertainty with consequent impact on growth and further development of industry.
- Fast tracking patent disputes

# Other Challenges

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- Patent Regulatory link:
  - Bayer v DCGI & Cipla case:
    - Issue raised by Bayer: the Drug Controller General of India (DCGI) be required to consider the patent status of sorafenib tosylate (Nexavar), and refuse approval to any generic version of the drug.
    - High Court and the Supreme Court held against Bayer
  
- Data Exclusivity:
  - Arguments on behalf of patentee/originator:
    - Should be given sufficient time to recoup investment related to preparing quality, efficacy and safety data and compensate for delays in regulatory process which may have eaten into the patent protection period

# Data Exclusivity

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- Arguments on behalf of generics; advocates for public interest right to cheaper but safe medicines
  - Generics do not rely directly on data supplied by originators as such data is usually never released directly to third parties; applications are approved on the basis of development data supplied by the generics to show bioequivalence.
- India has no data exclusivity provisions
- Challenge for India: whether such provisions should be introduced
- Role for Compulsory Licensing

# Competition Issues

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- EU: Pharmaceutical Sector enquiries and consequent investigations
- Balancing IPRs with market access to cheaper generic rights
- Approach to market consolidation:
  - Pre-2005: the Indian market was very fragmented
  - Post-2005: with increased competition from MNCs, there may be greater impetus for consolidation resulting in decreased competition and higher prices.

# Conclusion

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- India is a major world player in the world pharmaceutical sector
  - Offers a large domestic market and cost effective platform for international players
  - Offers an attractive environment for foreign investment in the pharmaceutical sector
- Patent enforcement is central to the pharma industry and developments in this field will be keenly observed and will dictate the commercial decisions made by both domestic and international companies.