India

An Insight Into The Changed Patent Regime & Protecting Your Pharmaceutical IP

Chid S. Iyer, SUGHRUE MION, PLLC, Washington DC ciyer@sughrue.com

V. Lakshmikumaran, LAKSHMIKUMARAN & SREEDHARAN, New Delhi, India
vlakshmi@lakshmisri.com

Mark Pohl, Pharmaceutical Patent Attorneys, LLC www.licensinglaw.net

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www.aplf.org

Agenda

- General Introduction
- Salient features of Indian economy
- History of Indian patent law
- Significant aspects of recently passed Patent Act
- Impact on contract manufacturing of pharmaceuticals
- Discussions

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India – its strengths

- ***A well diversified industrial base in all core industries.***
- ***A large & sophisticated financial architecture.***
- ***A robust capital market eqvt of over $ 200 billion***
- ***A balanced GDP composition***
  - *agriculture and industry contributing 25% each and rest services*
- ***Strong Knowledge-based industry***
  - *IT.*
  - *Biotechnology,*
  - *Pharmaceuticals.*
  - *Entertainment etc.*

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Quality of Manpower

- Major differentiating factor giving advantage in knowledge driven industries.
- Cutting edge research generating new knowledge.
- India gaining in both counts

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Advantage INDIA

- Over 3 million scientific & technical manpower
  - Over 0.8 million post graduates in science
  - Over 1 million graduate engineers
  - 0.4 million doctors and
  - 0.3 million graduates in agriculture and veterinary sciences.

- Second only to US in English speaking scientific manpower.
- Above factors provides significant advantages in
  - Drugs & Pharmaceuticals,
  - Biotechnology,
  - Information Technology,
  - Space Industry,
  - Speciality Chemicals and Petrochemicals, etc.

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Drugs and Pharmaceuticals

- Strength in IT, biology and synthetic chemistry fosters research services in drugs and pharmaceuticals, clinical trial services, data management, etc.
- Indian pharmaceutical industry is expected to grow from $ 6 billion in 2001 to $ 25 billion by 2010.
- Expertise is abundant in genomics, bio informatics, DNA technologies, clinical studies, genetically modified materials, Stem cell biology, molecular probes, genetic based vaccines, molecular taxonomy, etc.
- Indian investment expected to increase five fold from $ 2 billion to $ 10 billion during the decade in biotech

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Factors pushing drug development to India

- Emphasis on cutting cost of discovering drugs
- Large pharma companies vacating development and pre-clinical phases
- Small companies picking up the slack
  - large burn rates
- Possible to outsource

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Factors pulling drug development to India

- New product patent regime
- No longer possible for Indian pharma companies to “reverse engineer” drugs
- Success of “copycat” drugs will depend more on having good lawyers than on having good scientists

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History of Patents and impact on Pharma Industries

- 1911: The Indian Patents and Designs Act promulgated.
  - Product patent and Process patent in all fields
  - 1950s and 60s. MNCs dominate new formulations
- 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 items other than above) 14 years;
  - Process Patent 7 years.
- 1980s: MNC influence declines to some extent.
- 1990s: MNC influence further declines. Significant amount of indigenous production and export.

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History of Patents and impact on Pharma Industries

- 1995: WTO – TRIPS comes into effect.
- 1999-2002: TRIPS compliant laws-
  - the First Amendment in the Patents Act .
- 2002: Second Amendment –
  - India's Patents Law brought in line with TRIPs.
  - Patent term of 20 years for both product and process patents, 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: Ordnance passed introducing product patent in Medicines, Food and Agro-chemicals.
- Increasing R&D activity expected in post 2005 period.

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PATENTS (AMENDMENT) ACT, 2005

Presentation by

V. Lakshmikumaran
Lakshmikumaran & Sridharan
New Delhi 110 029
vlakshmi@lakshmisri.com

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TRIPS Article 27.1 Patentable Subject Matter

- Patents shall be available for any inventions
  - Whether Products or Processes
- In all fields of technology
- Provided
  - They are new [Novelty]
  - Involve an inventive step [Non-obviousness]
  - Capable of industrial application [Utility]
- Without Discrimination
  - As to place of invention
  - The field of technology
  - Whether products imported or locally produced

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Exclusions from Patentability

- **Article 27.2: Members may exclude:**
  - **Commercial exploitation necessary to protect**
    - ***Ordre public* or morality, including**
      - **Human, animal or plant life or health**
    - **Serious prejudice to environment.**
- **Article 27.3: May also exclude:**
  - **Diagnostic, therapeutic & surgical methods for the treatment of humans or animals; [Article 27.3(a)]**
  - **Plants and animals other than micro-organisms; [Article 27.3 (b)]**
  - **"Essentially biological processes" for the production of plants or animals. [Article 27.3(b)]**

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TRIPS Art 27.3(b)…

- **Protection of plant varieties shall be provided by:**
  - **Patents,**
  - **An effective sui-generis system, or**
  - **Any combination thereof.**

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Position 1995 - 2004

- Patents granted for
  - All products other than medicines, agro-chemicals and food
    - Patents granted for synergistic compositions
      - cosmetics
  - Mail Box provision for pharmaceutical substance
    - Will be taken up for examination from 1.1.2005
    - Exclusive Marketing Rights

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Position from 1.1.2005…

- All products and processes patentable
  - medicines for internal or external use of human or animal
  - substance used in diagnosis
  - intermediate chemical substances used in the preparation or manufacture of medicine or drug
  - fertilizers
  - insecticides, pesticides, fungicides, weedicides

Patentability

- Inventions should satisfy
  - Novelty/ New
  - Inventiveness/ Non-Obvious
  - Industrial Application/ Utility

    AND
  - Should not be covered by negative list

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What are not inventions – Section 3(d)…

"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or

the mere discovery of any new property or new use for a known substance or

of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant"

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What are not inventions – Section 3(d)…

Explanation to Sec. 3(d)

"Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

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What are not inventions – Method of treatment-S 3(i)

"any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products"

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What are not inventions..

- *Sec. 3(k)* Computer program *per se*

- *Sec. 3(j)*
  - Plants and parts of the plant
  - Animals and parts thereof
  - Essentially biological process

  However, micro-organisms are patentable subject matter

Patent Rights

- Protection from the date of publication of patent application
- Proceedings to enforce rights only on grant of patent
  - Damages/ profits for prior period infringement
- From date of grant
  - Patentee can seek injunction

Patent Rights…

- No retrospective protection to patents granted on basis of mail box applications
- In case person manufacturing patented product on 1.1.2005
  - No infringement action
  - Reasonable royalty
- TRIPS compliant??

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Patent Rights…

- Special provision for mail box applications (Grandfathering Clause)

- Section **11A(7)……** in respect of applications made under sub-section (2) of section 5, the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent, and no infringement proceedings shall be instituted against such enterprises.

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Compulsory Licensing

- To any third person after 3 years
  - if reasonable requirements of the public not satisfied
  - not available to the public at affordable price
  - not worked in India
- Patentee can apply for termination of license
  - Conditions for licensing no longer exist

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Compulsory Licensing …

- Revocation of patent
  - after two years from grant of first compulsory license if above conditions still not met
- Compulsory licensing also in case of
  - national emergency
  - extreme urgency
  - public non-commercial use
  - public health crisis
- Patentee entitled to reasonable payment on licensing

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Compulsory Licensing …

- Doha Declaration (Sec 92A amended) - Compulsory License for export of drugs to LDCs
  - Controller can grant license for
    - manufacture and export of patented pharmaceutical products to country having insufficient or no manufacturing capacity
  - if compulsory license or *notification or otherwise allowed by* importing country from India

Parallel Imports

- **Sec 107A(b)**
  - **Certain acts not to be considered as infringement.—**

    .....

    (b) importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as a infringement of patent rights.

Exceptions to Infringement

- Bolar like provisions (Sec 107A(a))
  - act of making, constructing, using , selling or importing of patented product for regulatory approvals
- Research Exemption (Sec 47)
  - experimental purpose, imparting of instructions to pupils
  - Not for commercial purpose

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India's New Patents Act Provides Opportunities

Pharmaceutical Patent Attorneys, LLC

How multi-national drug manufacturers can use India's new patents act to respond to global pressures

Overview

- Drug industry faces certain long-term pressures
- Aging world population assures demand
- Yet curtails price flexibility !
- Shift in business activity overseas
  - Curtails price flexibility
  - Can USA afford to continue to devote same amount of its wealth to pharmaceuticals?

Long-term goal

- Protect long-term profitability of pharmaceutical research and manufacturing industry
- Provide cost-effective medicines
- Earn profits to finance future scientific research

The Present Situation

- India has for a long time enjoyed an English style court system
- India has finally acceded to TRIPS, and has passed laws to again include drugs as patentable subject matter

Development up to present

- India has had a patent statute for a long time
- Statute was amended ca. 1970 to exclude drugs from patentable subject matter
- This allowed low-cost generic drugs to be supplied to India's large, poor population
- India-based drug manufacturing capability
  - CGMP compliant
  - Supplies much of the “non-regulated” world
  - Supplies much of regulated world

Potential Alternatives

- India based contract manufacturing
- Uneven legal enforcement history undermines value of IP
  - Product patents
  - Process patents
  - Trade Secrets
  - India based R&D (?)
  - India based CRO
  - ISO 9002-compliant IND statute
- **Development up to present**

Recommendation

- Identify where in process India may help
- Find India drug manufacturers
- Sort the more reputable manufacturers
- Open dialog for preliminary collaboration

Thank You

Questions?

Chid S. Iyer, SUGHRUE MION, PLLC, Washington DC ciyer@sughrue.com

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