Lakshmi Kumaran & Sridharan ATTORNEYS

Intellectual Property and Public Health: Regional Perspectives

India

V. Lakshmikumaran, Managing Partner

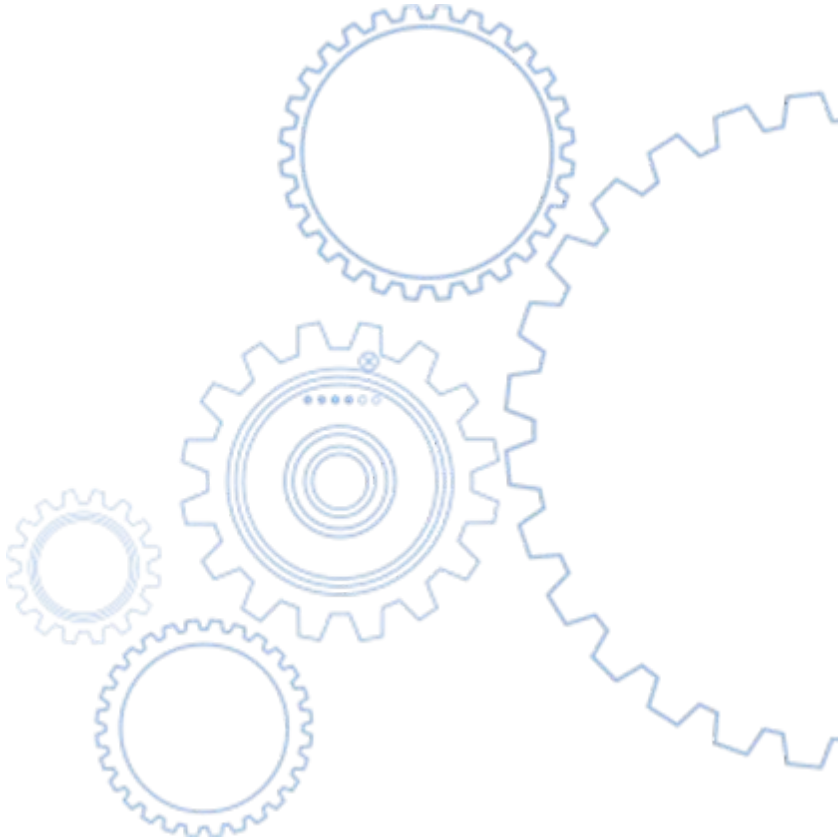
Scope

- Efforts against ‘evergreening’ of patents in the pharmaceutical sector;
- Policy Issues relating to exclusivity of clinical trial data;
- Compulsory licenses;
- Direct Drug Price Control Mechanism

Introduction and Importance

- Rich – poor divide getting steeper in many countries like India;
- Increased privatization (rising costs);
- Health insurance penetration not high in many developing countries
- Raging debate – IP v/s Access to Medicines
  - In the present state of affairs, solution cannot rest in extremes

Lakshmi Kumaran & Sridharan ATTORNEYS



1

Anti-‘Evergreening’ of Patents?

Anti-‘Evergreening’ of Patents?

Lakshmi Kumaran & Sridharan ATTORNEYS

“**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 ….

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.”

Explanation to Section 3(d).—For the purposes of this clause, 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.

Anti-'Evergreening' of Patents? ...Contd.

Lakshmi Kumaran & Sridharan ATTORNEYS

- Section 3(d) held constitutional by Indian Court
- IPAB ruled that mere increase in bio-availability is insufficient to overcome Section 3(d)
  - Decision under appeal before Supreme Court
- Section 3(d) concerned with IMPs (Incrementally modified products) and not New Chemical Entities (NCEs)
- Recently, Argentina and Philippines implemented similar provision; Thailand may follow suit

Lakshmi Kumaran & Sridharan ATTORNEYS

2

Data Exclusivity to Clinical Trial Data

Indian Situation

- Satwant Reddy Committee Report
  - Recommended 5 year exclusivity period (follow foot-steps of Hatch-Waxman Regime in USA)
  - Severe Opposition
- Indian vehemently opposed such a clause in the recent India-EU FTA negotiations.
- Generally seen by critics as unnecessary – merely an attempt to delay generic entry

The Issues

- Generics can currently use clinical data developed by innovators
  - Generics only need to prove bio-equivalence
  - **Saves duplication of data – improves overall social welfare by encouraging use of competitor resources to enable quicker and cheaper access to medicines**
  - Generics (being market players) will "enter at risk" only if "bad patents" are involved – a **market-driven mechanism** to force litigation and **weed out "bad patents"**

The Issues

…Contd.

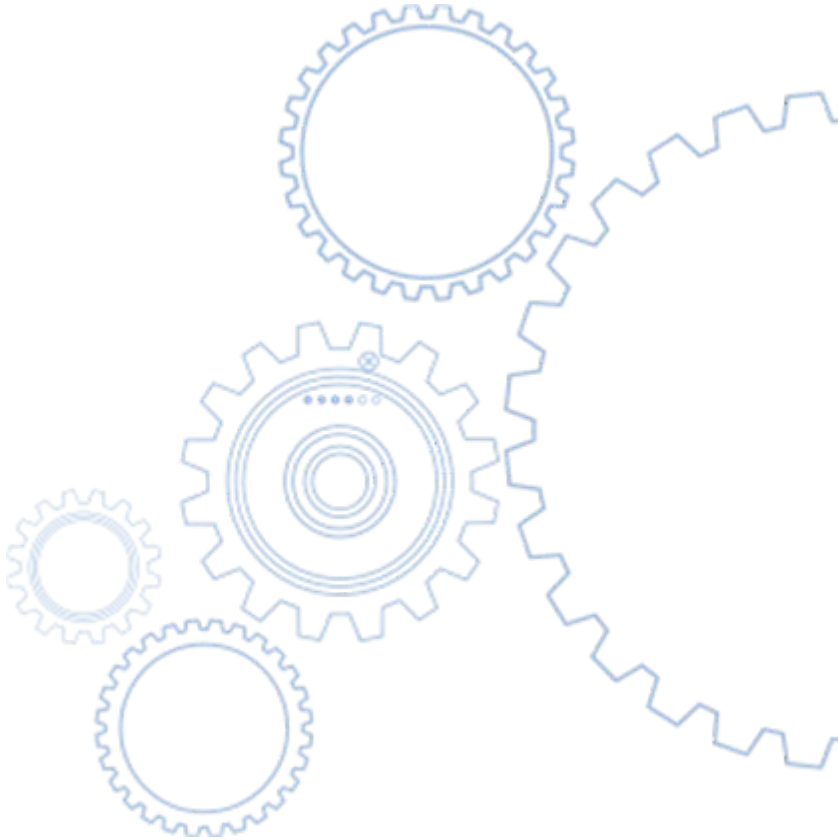
Lakshmi Kumaran & Sridharan ATTORNEYS

- Pro-Data exclusivity –
  - Time-lines in drug regulatory approval results cuts effective patent term to less than half at times
  - W/o data exclusivity – generics can compete even earlier in the patent term
  - Forces litigation – uncertainties, delays and costs;
  - Interim injunctions not easy – patentee may quickly lose significant market share and not recover costs
  - **Hence, patent system is inadequate; data exclusivity will delay generic entry w/n patent term**

Need for Balance

- Tough balancing act
  - Concerns regarding access to cheaper generics cannot be ignored in developing countries
  - Concerns about patent system being insufficient may be true in certain cases
- "One Size fits all" approach – inappropriate
  - Possible solution – more research on regulatory time-periods for specific therapeutic classes
  - Exclusivity periods could possibly be "therapeutic class" specific

Lakshmi Kumaran & Sridharan ATTORNEYS



3

Compulsory Licenses

Natco v. Bayer - Introduction

- First Indian decision (2012) – reasoned order
  - Under appeal
- Compulsory license granted by Patent Office to manufacture and sell sorafenib (Nexavar) –
  - Anti-cancer drug of Bayer (Kidney and Liver cancer)
  - Covered under Indian Patent No. 215758
  - Life-extending drug
- Proceedings completed within a year
- Recent report – US may challenge this in WTO

The Terms

- Non-Exclusive and Non-assignable
- Entire Patent term, but no license to import
- Quarterly payment of 6% royalty on net sales
- MRP at around INR 8900 (USD 200)
- Free supply to 600 needy patients / annum

The Terms

...Contd.

Lakshmi Kumaran & Sridharan ATTORNEYS

- Product specific: generic of Nexavar
- Indication-specific: only for treatment of Kidney and liver cancer
- Cannot engage in passing-off.

Natco v. Bayer – Reasons

- Demand for drug not met as authorized supply was enough only to meet the requirements of 2% of the patients

- Drug not available at an affordable price as required dosage is priced at approx. USD 65000 / annum

- Invention not worked in India as drug was only imported and not manufactured in India

Natco v. Bayer – Concerns

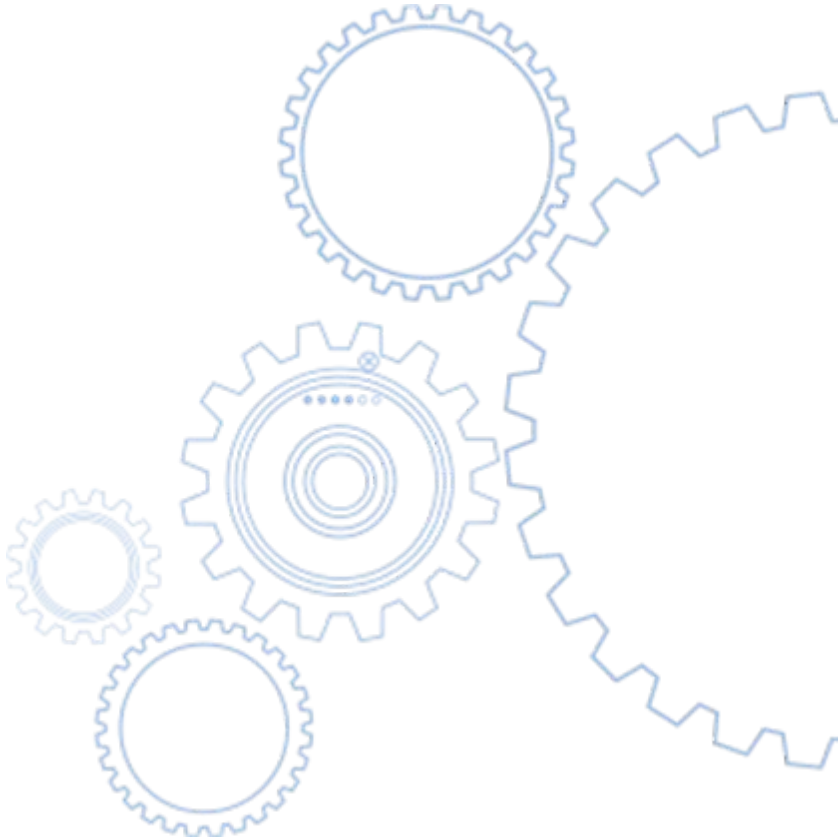
- Glaring difference in prices – drug to be supplied at 3% of patented drug price!?
- Patentee was unable to substantiate and economically justify its high prices – facts and evidence!?
- How would meeting requirements of public be judged if there were alternate drugs or methods of treatment available ?

Natco v. Bayer – Concerns …Contd.

Lakshmi Kumaran & Sridharan ATTORNEYS

- The slipper slope of “reasonably affordable price”
  - Patent Office held that “reasonably affordable price” is not about balancing the interests of the parties
- Effects of Compulsory License –
  - Volume of sales in market will significantly increase
  - **What if the 6% royalty on this volume is greater than or comparable to the earlier revenue of the patentee?**

Lakshmi Kumaran & Sridharan ATTORNEYS



4

Direct Drug Price Control

Direct Drug Price Control

- Limits pricing of listed drugs (e.g. Drug (Prices Control) Order, 1995 issued in India)
- As per an OECD Report 2004, price controls may reduces the revenue available for R&D by $18 billion to $27 billion annually
  - Therefore, access to “new” drugs is delayed

Direct Drug Price Control …Contd.

Lakshmi Kumaran & Sridharan ATTORNEYS

- But in global market, considering country-wise revenue v/s R&D revenue is not appropriate
  - Most statistically studies / evidence do not seem to consider the economics from a global perspective
- If compliance issues are addressed –
  - Seems to be a simplistic solution!?
  - TRIPs is silent.

Direct Drug Price Control …Contd.

Lakshmi Kumaran & Sridharan ATTORNEYS

- Draft Indian Policy of 2011
  - Decision to limit price based on “essentiality” of the drug – cover priority health needs of the country with regular re-assessments.
- Employ marked based principles for pricing –
  - Orphan drugs – price over volume;
  - Common drugs – volume over price.

Discussion

Lakshmi Kumaran & Sridharan

ATTORNEYS

About Us

New Delhi • Mumbai • Bengaluru • Chennai • Hyderabad • Ahmedabad • Pune

Lakshmi Kumaran & Sridharan ATTORNEYS

Lakshmi Kumaran & Sridharan

Lakshmi Kumaran & Sridharan (L&S) is an Indian law firm specializing in the areas of International Trade, Taxation, Intellectual Property and Corporate law.

Founded by V. Lakshmi Kumaran and V. Sridharan in 1985, the firm has eight offices across India in New Delhi, Mumbai, Chennai, Bengaluru, Hyderabad, Pune and Ahmedabad.

The firm is well-known for its high ethical standards, quality work and transparency in all business dealings. It supports its clients by providing litigation, dispute resolution and advisory services and compliance reviews across each of its divisions of Tax, International Trade, Intellectual Property and Corporate.

For more information, visit us at http://www.lslaw.in

Lakshmi Kumaran & Sridharan
ATTORNEYS

Contact Details

New Delhi
B-6/10, Safdarjung Enclave
New Delhi - 110 029
Phone - +91-11-4129 9811
E-mail - lsdel@lakshmisri.com

Bangalore
505-508, 5th Floor,
Brigade Plaza (North)
71/1, Subedar Chetram Road,
Anand Rao Circle
Bangalore - 560 009
Phone - +91-80-4171 7777
E-mail - lsblr@lakshmisri.com

Mumbai
401-404, Kakad Chamber
132, Dr. Annie Besant Road
Worli, Mumbai - 400 018
Phone - +91-22-2491 4382
E-mail - lsbom@lakshmisri.com

Hyderabad
Hastigiri, 5-9-163, Chapel Road
Opp. Methodist Church, Nampally
Hyderabad - 500 001
Phone - +91-11-4129 9811
E-mail - lshyd@lakshmisri.com

Ahmedabad
B-334, SAKAR-VIII,
Nehru Bridge Corner, Ashram Road,
Ahmedabad - 380 009001
Phone - +91-79-4001 4500
E-mail - lsahd@lakshmisri.com

Chennai
2, Wallace Garden, 2nd Street
Chennai - 600 006
Phone - +91-44-4396 1600
E-mail - lsmds@lakshmisri.com

Pune
Ebony Meeting Room
1st Floor, Apartment Section
Hyatt Regency
Weikfield IT Park, Nagar Road
Pune - 411 014, Maharashtra
Phone - +91-20-6641 1234
E-mail - lspune@lakshmisri.com

Lakshmi Kumaran & Sridharan

Thank you

For more information visit http://www.lslaw.in