Pharmaceutical Patents in India

Pravin Anand,
AIPPI Paris
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Outline

• **Procedural and Strategy issues**
  – Where and when?
  – Options?
  – Evidence?
  – Trial Design
  – What to expect

• **Substantive Law issues**
  – Anticipation Obviousness and 3(d)
  – Amendments
  – Suppression and Public Interest
The Indian Patent Office and its branches

Each office has its own territorial jurisdiction for receiving

- national (Domestic) applications,
- international application under PCT
- national phase applications under PCT
- design applications (H.O.)

Jurisdiction for foreign applicants depends upon the address of service

Each of the Patent Office is empowered to deal with all sections of Patent Act
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Top Indian Patent filing companies

Others include: Torrent, Cadila, Cipla, Matrix Labs, Nicholas Piramal, Biocon, Glenmark, Hetro – new delivery systems, processes and formulations
# Top Patent recipients in 2004

## US

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What are not inventions - **Section 3(d)**

- Mere discovery of a new form of a known substance...unless...enhancement of known efficacy...
  - Explanation: Salts, Ethers, Esters, Polymorphs, metabolites...and other derivatives...shall be considered same substance unless they differ **significantly in properties with regard to efficacy**
3(d)

- Efficacy – Novartis Glivec decision (under Appeal) – interprets as therapeutic
  - Dorland Medical Dictionary – therapeutic is curative
  - Not defined technically – must have common meaning
  - Properties with regard to efficacy – Roche Valcyte – bioavailability allows oral admin
3(d)

• **Second Medical use** – mere discovery of new use of a known substance – Not Allowed

• **Enantiomers** – Roche Valcyte case – under appeal

• **Crystalline Forms** – Polymorph B – Roche Erlotinib Hydrochloride – only process claims allowed (Cadilla vs Ind Swift)
3(d)

- **Prodrugs and metabolites** – Roche Valcyte
- **Sustained release Forms** - allowed
- **Regiments, Dosages** – BMS Entecavir – low dosage formulation (BMS vs Ranbaxy)
3(d)

- Minimal efficacy data in Specification
- May not be available on filing date
- Attempt to introduce data through amendment (Glaverbel case)
- File data with evidence in Pre or post grant oppositions
- Person of ordinary skill in the art
Courts

- Supreme Court
- 23 high courts
- Over 500 district courts
- Unitary system
- Statutory and common law
  - Trade secrets, phishing, meta tagging, spamming etc all covered by common law
Where and When and Options

• High Courts – in order of preference
  – Delhi, Madras, Calcutta and Bombay,
• When – Earliest eg BMS vs Hetero
• Options – patents Ex parte rare
  – Cease and Desist – get full defence
  – Disadvantage – filing of cancellation before IPAB
• Simultaneous proceedings –
  – Infringement and counterclaim – Post grant
  – Post grant and Rectification
Evidence

- Product purchased examined investigated – best
- Sometimes – cannot wait
- Pharma – RTI information re DCGI approval (Don’t annoy DCGI – arms length enquiry)
- Export information
Trial Design

• Witnesses –
  – Novartis IPAB – avoid employees as sole witness
  – On Obviousness and S 3(d) – get independent experts
  – Expense: May develop Indian expert team
  – If overseas witness record before commissioners (3 day cross)
  – Inventor – good knowledge but too emotional
Evidence - scope

• Explain Chemistry (Drug Design)
• Prior Art (prosecution History elsewhere)
• Efficacy (properties and their effect)
• User experience
• Commercial Success
• Public Interest
  – Investments in invention
  – Public Access Programmes
Burden of Proof and Estoppel

• Burden in Pre and Post grant
• Burden in invalidation proceedings
• Burden in a Suit for infringement
• Estoppel – study patents of the opponent or defendant for concessions or admissions
Expectation

• Exparte injunctions rare – BMS, Philips VCD, Philips DVD (Anton Pillar only)
• Interim injunctions rare (Roche vs Cipla and TVS vs Bajaj)
• Time – Suit 2 to 3 years – could be faster – 4 month orders
• Cost – USD 20 to 100,000
• Damages – high probability
2005 – the year of Damages

- Time Magazine - 16 lakhs
- Microsoft – USD 280,000
- Cartier 24 lakhs
- Nasscom 16 lakhs (Phishing)
- Himalaya Drug 17 lakhs
- About 55 cases since
Anticipation

• Disclosure and enablement in a single prior art document
• Clear, Sufficient details to enable person of ordinary skills to practice the invention
• Identifying by name, a molecule necessary
• Selection Patents
  – S 91
  – Novartis IPAB
Suppression and Public interest

• Suppression – state more not less
• Public Interest –
  – Pricing issues
  – Investments on drug discovery
  – Patient access programmes
  – Donation camps, workshops to create awareness, government information
Recent cases

• Infringement cases
  – Ram Kumar vs Samsung (customs recordal)
  – Bajaj vs TVS
  – Roche vs Cipla

• Pre grants
  – Novartis, Gilead, Boehringer, Abraxis, Teva

• Post grants
  – Roche Valcyte

• Writs
  – Bayer and Syngenta (Linking argument)
Compulsory License

Pfizer vs Natco
Roche vs Natco
Discussion paper by DIPP
Conclusion

• Infringement complicated
  – Ex parte rare – don’t waste too much time on interim
  – Other forums (IPAB or Patent office)
  – Defendants look at world failure so bring success from other forums
  – Demystify the science (eg drug discovery)
  – Counter attack defendants for suppression, admissions estoppel etc
  – Pharma too political – add Indian public interest dimension

• Strengths – Speed of trial and Damages and Press that should be moulded