

PATENT LAW AND POLICY UNDERPINNINGS

For: LES + iHIPP Forum

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DISCLAIMER! NOT LEGAL ADVISE!!

Objectives

- **Policy**
 - Justifications/not
 - Popular misconceptions in India
 - Defending the patent system in India
 - Reduce extent of disagreement
- **Drivers for enforcement/licensing**
 - The markets
 - The legal infrastructure
- **Nitty-gritty from experience**
 - Section 39 permissions
 - Annual working statements
 - Patentable subject matter issues

My Background

- 1981-85: BE, Computer Engineering, Andhra University
- 1985-87: MS, Computer Science, Michigan State University
- 1988-92: Intel, Networking Engineer
- 1992-94: Intel, Patent Engineer
- 1994-95: Cirrus Logic, Patent Engineer
- 1995-96: Robert Platt Bell & Associates, Patent Engineer
- 1996-97: Sterne Kessler Goldstein & Fox, Patent Attorney
- 1997-2000: Sole Proprietor, California Law firm
- 2000-Present: Sole Proprietor, India Patent Operation
- Registrations: USPTO, IPO, California (inactive), Virginia (Expired), D.C (Active)

Policy: Justification

- **Starting point and journey**
 - Law is implementation of sound public policy
- **In medieval days**
 - *Quid pro quo* for disclosure
 - Not justified in this information age
 - open source models for software/ gene sequencing
- **Modern Justification**
 - enhanced possibility of product/service reaching market
Vs. (balancing)
Restraint on efficiencies with free flow/usage of ideas
 - same logic for unpredictable and predictable arts

Policy: Predictable vs. Unpredictable arts

- **Differences**

- certainty of getting there
- market models
 - Huge upfront investments in drug discovery
- regulatory structures
- patent law application
 - written description requirement (is it there in India?)

Policy: Software

- **Undercutting data points**
 - no uncertainty
 - industry tracks the ‘functional needs’
 - how better are they identified than other industries
 - Is patent incentive really needed?
- **Supporting data points**
 - role of creative mental effort
 - Amazon 1-click patent
 - substantial differences exist in same functional products
 - fundamental to start-up culture in silicon valley
 - inevitable for large companies as well
 - see credentials of extreme opponents
 - from core product industry?
 - visibility into innovation process?
 - Failure to be market viable due to others patents?
 - Leaders in the driver markets want it

Policy: Pharma

- **Typical Indian positions**

- 'access' driven
- colonial past
- Fear
 - Of Unknown
 - Developed countries
- obligations under international treaties

- **The stake holders**

- patentee pharma company (leader)
- few others who could have gotten there later (runners up)
- generics players
- affording consumers
- poor people of India (majority)

Policy: Pharma (Cont)

- **Patentee vs. Runners up**

- incentive to accelerate

Vs

Preclusion of access to independently developed products

- factor in the uncertainty of discovery

- **Patentee vs. Generic players**

- patent grant vs. No grant is still a government choice
- windfall to one of the two parties for respective choice
- Government policy **NOT** for benefitting generic players

Policy: Pharma (Cont)

- **Patentee vs. Affording consumers**
 - good for except those who want everything free!
 - increasing choices 'close to death'
- **Poor man viewpoint**
 - 10-15 years delay fine if enhanced probability of solution
 - patent OK if my brothers/posterity have cheap benefit?
 - Role of charity/government
 - The practicalities of Indian system
 - Can doctor's conduct be eventually controlled
 - Will there be higher costs for generics drugs
- **Clearly not a battle of \equiv vs Ψ**

Policy: Popular Misconceptions

- **Misconception: Scope of patent can be understood by reading abstract**
- **Misconception: Patents take away from public domain what pre-exists**
 - NEVER
 - Patent invalid as a matter of law if attempted
- **Misconception: Patents on useless technologies**
 - no issues if really useless
- **Patent as an instrument for ever-greening (extended monopoly)**
 - extremely overstated
 - reality: close to non-existent
 - monopoly beyond patent term of first patent for unobvious improvements only
 - EVEN in this case public free to use subject matter of first patent

Policy: Ever-greening concerns

On one blog it is stated (appears common misconception):

As many of you know, while "evergreening" has a healthy overtone in an "environmental" context, it connotes a rather sick practice in the "pharmaceutical" context, referring as it does to the practice of extending patent monopolies by effectuating mere modifications of existing drugs, where such modifications do not deliver any significant health benefits to the public.

Policy: Ever-greening concerns (Cont)

My Enquiry:

I thought all national laws were consistent in the following, contrary to the above statement.

Assume someone filed for a patent in 2000 for basic drug B, and then filed for a modification B-mod in 2005. Any patent granted for drug B would be effective only upto 2020, while any patent granted for drug B-mod would be effective upto 2025.

With or without a patent for B-mod, no national patent law permits extension of monopolistic rights for basic drug B beyond 2020. In other words, either the patentee of B or any others, would NOT have a patent monopoly right on drug B after 2020, including in the duration 2020-2025.

If a company/anyone somehow tries to cover drug B using the patent for B-mod, the patent covering B-mod would be plain invalid.

To the extent B-mod is useless, no harm is there to anyone since it is a restriction on useless stuff that would not be used any way.

Policy: Ever-greening concerns (Cont)

The response:

You're right in a way, since evergreening is coming to be used (wrongly) to refer to the entire gamut of undeserved pharma patents.

However, in its narrow and perhaps proper avatar, it rings technically true in certain contexts. Consider the prilosec vs nexium example and you'll understand why. Although the patent expired, Astra's marketing might had ensured that the later **undeserved patented version (nexium) came to be prescribed by most doctors.** **So the cheaper generic off patent Prilosec version was not effectively available to the consumer.**

Policy: Ever-greening concerns (Cont)

- **Prilosec vs. Nexium facts**

- Basic Prilosec patent expiring circa 2001
- Basic Nexium expiring circa 2015

- **Facts**

- Law: NO patent restriction on selling Prilosec from 2000
- From 2000-2014 patent rights on only Nexium
- No evergreening of the patented Prilosec
- Is Nexium composition obvious over Prilosec
 - Prilosec is R-isomer + S-isomer (enantiomer)
 - Nexium is one of the S-isomer
 - How prevalent was trying an isomer of a compound as a new drug?
 - Unexpected results
 - Reduced side effects
 - Gets into the bloodstream more efficiently than Prilosec
 - Nexium better for erosive esophagitis
 - Prilosec only for heartburn

Policy: Ever-greening concerns (Cont)

- **Popularity of Nexium vs. Generics of original Prilosec NOT a patent issue**
 - *Marketing/advertisements*
 - *Control of channels*
 - *Need for better competition/MRTP laws*
- ***Was patent granted for combination of Prilosec and antibiotic?***
 - *How do you counsel?*
 - *Opportunity to recognise problem*
 - *Was the bacteria (Helicobacter pylori) present independent of treatment w/ Prilosec*

OR

Did the bacteria pre-exist independent of treatment w/ Prilosec

 - *How to think about obviousness*
 - *One was not prevented to sell Prilosec and antibiotics as separate components*
 - *What if someone else discovered the bacteria (when)*

Policy: The Recommended Direction

- **Define obviousness to avoid undesirable results**
 - More flexible approach required
 - written description
 - combinations

- **Fortunately in a position where pain lags that in other countries**
 - US in the forefront of pain
 - India role: reduce transaction cost in IP
 - Number of transactions

Policy: The Recommended Direction

- **What is incremental vs. Innovation**
 - Guidance from terminal disclaimer
 - Patent of addition

- **Integrate more into the global economy**
 - cost/education advantage
 - the culture
 - Free markets help the hard-working/focussed lot

Drivers of Enhanced Patent Activity in India

- **Market**
- **Patent office**
- **Court/enforcement regimes**

Drivers: Market

- **Volumes of products at higher margins increasing**
 - Consumer
 - Manufacturing infrastructure
 - Components
- **Pharma will open the doors for litigation/licensing**
 - Product patents
 - Some Indian companies in forefront of innovation
- **Broader dynamics**
 - Value at the bottom of pyramid
 - Reverse innovation
 - Enhanced trade across nations
 - Reverse brain drain

Drivers: Patent Law/Office

- **Initially**

- more of registration in many art areas (like many patent offices)
- vigilant public to oppose
- not so well reasoned rejections
- secretive process

- **Obviousness**

- introduced into statute recently
- case law alludes to it in 1950s
- legislature tries to define by specific sections
 - Section 3(d)

- **Evolving to**

- transparent organization/processes
- more scale
 - CSIR for hiring

Drivers: Patent Law/Office (Cont)

- **Appeals board**
 - Very concerned about 'due process'
 - Written record being forced
- **Key challenge**
 - Examining the claim
 - obviousness definition
- **Probably will be forced for more external help**
 - Shri Kurian making great strides in administrative front

Nitty-gritty: Section 39 permissions

- **Get started soon**
 - request fax confirmation of orders
- **Extent of information submitted**
 - IPO guidance: “minimum 1000 words or complete specification”
 - Soon after disclosure to confirm material represents claim 1
 - Use Wiki/general info if needed
- **In case of emergency**
 - use sub-section 3?
 - “(3) This section shall not apply in relation to an invention for which an application for protection has first been filed in a country outside India by a person resident outside India.”
 - “not inventions” under section 3

Nitty-gritty: Annual working statements

- **The challenges**
 - what if operative in multiple products
 - how to value them
 - who do we get this information from
 - client comfort!!!
- **The legal constraints**
 - no filing: fine
 - false information: imprisonment
 - incomplete information:?
 - not working: compulsory license

Nitty-gritty: Annual working statements (Cont)

- **Pitfalls – inadvertent admissions**
 - “software”
 - value declaration
 - tax consequences
 - damages calculation in other jurisdictions
- **Managing the transactions**
 - Not readily available; will provide information on further enquiry
 - identify products in which generally embodied
 - looked to disclosure statements/other records
 - public requirement met at reasonable cost?
 - Balancing of market demand, as understood, and global corporate priorities
 - Products in general technology space available

Nitty-gritty: Patentable subject matter

- **Software program per se**
 - add hardware into claims
 - proactive definition of terms in the specification
 - Quote European law, pointing out not controlling

- **More by legislative efforts**
 - difficult to foresee the different market dynamics
 - section 3(d)

THANK YOU!!!