

**The MHRD Chair on IPR  
National Law School of India University**

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**Keynote Address:  
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# **Broad Objectives**

- **Patent Law: Implementation of Sound Public Policy**
- **Conflicts Arising in Different Disciplines**
- **Resolution of Conflicts in US**
- **Comparison with India**
- **Ensure approval/disapproval based on correct premise of law/operation/facts**

# Public Policy

- **Historically: *Quid Pro Quo* for Disclosure**
  - **No longer the driver in many disciplines**
- **Now:**
  - Ensuring ideas reach market place/people**
  - Vs.**
  - Restraint on free flow of ideas**
- **Alternative View:**
  - Avoid free-riders if detrimental to broad interests**
  - Vs.**
  - Free flow of ideas**

# Ground View - US

- **Leadership in innovation and major initial market**
- **Vibrant business climate**
  - **Lead by independent intellectuals**
  - **Healthy mix of new/small/big/old businesses**
- **Strong tradition of ‘obviousness’ analysis**
  - **Developed by judges over several decades**
  - **Machinery in place to execute for decades**
- **Conviction towards strong patent protection**
  - **Pro-business commitment at every level**

# **Ground View - India**

- **Substantial population below poverty line**
- **Priority: Access to life-saving medicines for poor**
- **Influence of pre-independence experience**
- **Many rural areas still untouched by Internet**
  - **Exception: Cell phone**
- **Absence of strong product companies**
  - **many started/owned by families**

# **Ground View – India (Cont..)**

- **Patent Act the substantial authority on practice**
  - **Limit: Broad based experience on ‘obviousness’**
  - **Obviousness into the Act only in 2002**
- **Strong base of generics companies**
  - **Strong export markets**
- **Aspiring to be the next global power**
  - **Ambitious student base/middle-class**
- **Growing inclination to integrate with global economy**

# Predictable Arts

- **Includes hardware, software, communications, web**
- **Low barrier to copy/reproduce independently**
- **Low capital requirements**
- **Limited or Non-existent regulatory requirements**
  - **Patent term 20 years from earliest priority**
  - **US: Minor adjustments for delays**
- **Software: difficult to design without infringement**

# Predictable Arts – US View

- **Patents integral to evolution of start-up businesses**
  - **Required by founders and investors**
  - **Often only protection against big businesses**
- **Established businesses require it**
  - **Clarity with departing employees**
  - **Necessary to thwart copying**
  - **NPEs: Often considered a ‘nuisance’**
  - **Litigation/licensing accepted as a necessary evil**



# Predictable Arts – US View (Cont...)

- **Software rooted patents consistently allowed/upheld**
  - **Technology centric innovations patent eligible**
- **AIA Changes**
  - **Patent ineligible: tax strategies**
  - **Unchanged: Damages computation & Injunction**
- **Rationale for patent support**
  - **Without patents, none may work as hard**

# Unpredictable Arts

- **Definition: “Not certain to occur”**
- **Does solution for common cold merit patent?**
  - **How about for HIV?**
  - **What about various aspects in between?**
- **Capital intensive and long cycles**
- **Highly regulated for public safety**
- **EVERGREENING a concern!**

# What Evergreening is NOT!

<http://www.letstalkip.com/patent-evergreening-strategy>

**“Patent evergreening is a strategy mostly adopted by pharma companies. In this strategy, the pharma companies that have patent rights that are about to expire, try to renew their patent in order to keep that particular patent alive and make more money out of it. There are many strategies that they can adopt such as filing new patent applications with minor changes, substituting chemicals with new chemicals that would have similar effect and so on. Pharma companies adopt these strategies on highly valuable patents that provide huge profit margins. These companies intend to prolong the life of a patent further than 20 years in order to gain profits for a very long time. ...” (Emphasis Added)**

# **Expiration – Antithesis of Evergreening**

- **20 year presumptive term not changed as a matter of law**
  - **Efforts to ensure ‘close’ to that duration**
- **First Patent for Plain pencil vs. later one with erasor**
  - **Plain Pencil Patent = Filed 2005; Expires = 2025**
  - **Erasor pencil patent = filed 2010; Expires = 2030**
  - **2025 onwards: no patent restriction on plain pencils**
  - **2030 onwards: no restriction on erasor pencil as well**
- **Legally incorrect to say evergreening occurs by filing patents for improvement when a product is covered by single patent**

# Evergreening: Multiple Patents

<http://www.egagenerics.com/gen-evergrn.htm>

**Evergreening, in one common form, occurs when the brand-name manufacturer literally “stockpiles” patent protection by obtaining separate 20-year patents on multiple attributes of a single product. These patents can cover everything from aspects of the manufacturing process to tablet colour, or even a chemical produced by the body when the drug is ingested and metabolised by the patient.**

# Evergreening: Multiple Patents (Cont...)

- **First patent requires enabling + best mode disclosure**
  - **That much in public domain (FTO) for use upon expiry**
- **First patent published in 18 months**
  - **That information is prior art for later patents**
  - **Prior art from other areas additive in patentability**
- **Fairness factors**
  - **If base technology is fundamental, marginal ‘later covering term’ for improvements not unfair**
  - **Base technology in public domain during ‘later covering term’**

# **Evergreening: Continuation Practice**

**[http://ipmall.info/hosted\\_resources/crs/R40917\\_091113.pdf](http://ipmall.info/hosted_resources/crs/R40917_091113.pdf)**

**“Some observers believe that the availability of so-called continuation applications at the U.S. Patent and Trademark Office (USPTO) may promote evergreening practices.”**

**-No evergreening under US Practice since 1995 amendment changing patent term to 20 years from filing date**

# Evergreening: New Use

<http://spicyipindia.blogspot.com/2011/11/section-3d-equivalent-in-offing-for.html>

**For example, the Bristol Myers AIDS drug Atazanavir originally patented in 1997 was further patented in 2005 in respect of further medical uses and again in 2008 on the formulation itself. It is believed that if the evergreening patent is granted, it could extend the validity of the Atazanavir patent to 2028 from 2017, and in the process block attempts by others to manufacture generic versions. (Emphasis Added)**



# Evergreening: New Use (Cont...)

- **Blocking Dates**
  - **Up to 2017: Original Atazanavir**
  - **Up to 2025: New use**
  - **Up to 2028: formulation**
  
- **Fairness factor**
  - **6 years to uncover the new use!**
  
- **Basic patent law internally fair!**
  - **if you accept limited duration monopoly**

# Evergreening Vs. Incremental Patents

- **‘Incremental’ is the Norm in unpredictable arts**
- **Patent eligibility constrained by ‘obviousness’**
- **Section 3(d) of India Patent Act**
  - **Superfluous/improper provision OR**
  - **Lawful standard for obviousness**

# **Pharma Industry: US Regulations**

- **Originator invents a new molecule entity (NME)**
- **Data exclusivity for a limited term**
- **Extensive clinical trials before FDA approval**
- **Formulation developed in parallel**
- **Minimum patent term guaranteed if approved**
- **Generics company files an ANDA application**
  - **No clinical trials requirement**
  - **Litigation if generic drug covered by a patent**
  - **Experimental use exception**

# **Understanding the Stakeholders**

- **Stakeholders – Innovator company, generics company, affording consumer, non-affording consumer**
- **Patent or none, a government choice that is made**
  - **Benefit to innovator company if patent grant**
  - **Windfall to generics maker otherwise**
- **Affording consumer: Prefers enhanced choice**
- **Non-affording Consumer: Does the higher probability of availability justify the short term deprivation? Or should someone step up to bear the cost?**

**THANK YOU!**

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