

Impact of TRIPS Compliant IPR Regime on Pharmaceutical Industry in India

**Presentation at the Seminar on Patents
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TRIPS Compliance - The Key Issues

- Product Patent Regime
- Compulsory Licenses
- Patent Prosecution Issues – Evergreening
- Patent Opposition – post grant or pre-grant
- Data Exclusivity

Product Patents for 'medicine' and 'drug'

■ Patentability

- The dialectics between Sec. 2(1) (j) of the Patents Act, 1970 r/w Section 3 and Article 27 of the TRIPS Agreement

■ “Product” Patents

- New Chemical Entities: Does Art. 27 of TRIPS permit to draw a distinction between patentable and non-patentable ‘products’ – say a distinction between NCEs and its polymorphs or isomers

Exclusions from Patentability

■ Swiss-Type Claims

- Mere new use of known substances – With the addition of the word “mere” in Section 3(d), are we agreeing to allow ‘Swiss-type’ new use claims?

■ Diagnostic Methods

- Methods of diagnosis of humans and animals are apparently unpatentable under Section 3(d) – whether a distinction can be drawn between in vitro and in vivo methods of diagnosis

Compulsory Licences

- The wording of Sec. 84 (grounds for invoking CL provisions) is **absolutely unclear**. Anything can be read into it!!
 - "reasonable requirements of public not satisfied"
 - "invention not available at affordable prices"
 - "non-working"
- India has an untested CL system. It is likely that each CL would end up in a Court of Law.

Post-grant opposition

- Shifting the burden of proving the validity/invalidity of a patent to the public (18 months the application is already published)
- A third party representation mechanism whereby any third party can write to the Controller on the patentability of the claimed invention and/or the non-disclosure or wrongful disclosure of the source of a biological material in the application
- Opposition will be post-grant. Before 1 year from the date of grant. Will be heard by an Opposition Board – Question – Is it in violation of the principle that the Controller who grants the patent also hears an appeal against his own decision? Some people say YES. So the GoM is considering this.

Data Exclusivity

- Does the mandate under Art. 39(3) of TRIPS for protection of undisclosed test data against 'unfair commercial use' means 'business exclusivity'
- To what extent the 'protection of public' exception can be used to limit the abuse of data exclusivity
- What should be the term for Data Exclusivity – 5 years or even 10 years.

How TRIPS Compliance would impact the Pharma industry?

- TRIPS Compliance is going to change the way Pharma Companies do business in India
- TRIPS compliance will impact the entire spectrum of the industry – right from Drug Discovery to marketing pharmaceutical products
- Patent Clearance has to be a part of Formulation Development Programs
- Patent Prior Art Searches and Patentability Assessments will become part of Formulation development strategies
- Patent Conflict Clearance must precede Product Launch

Can you use patent as a marketing tool?

What would be a Physician's response if your sales personnel say that your product is a patented product?

Does it mean that there is R&D that has gone behind the Formulation Development?

Does it also mean that a Doctor would understand that the product is not a copy, it is innovated?

Will the Doctor prefer a patented formulation on grounds that patent stands for innovation?

Thank You
