

Product Patents for Pharmaceuticals – the Challenges Ahead

**A Presentation made at a One-Day Seminar
on Patents Headband, India
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The Key Issues:-

◆ "Product" Patents

- New Chemical Entities: Does Art. 27 of TRIPS permit to draw a distinction between patentable and non-patentable 'products' – say a distinction among NCEs, new isomers, new intermediates etc.

Exclusion 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 License

- ◆ The wording of Sec. 84 (grounds for invoking CL provisions) is absolutely unclear. Anything can be read into it!!.
- ◆ India has an untested CL system. So it is highly likely that each CL would end up in a Court of Law. Good for lawyers!!!

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
- ◆ An amendment to the Drug & Cosmetics Act to provide 5 years of data exclusivity – is that the desirable proposition?

Concluding Remarks

- ◆ IP awareness is steadily increasing in India.
- ◆ The 40 years old system of limited term process patents for pharmaceutical products is almost abolished. The product patent regime will change the rule of the game in Indian pharmaceutical, agro-chemical and food industries
- ◆ Multinational Pharmaceutical Companies have started looking at the Indian market more seriously. The number of foreign patent filings in pharma is expected to increase considerably after January 1, 2005
- ◆ There are over 5000 patent applications in the Mail Box. Many of these applications are likely to lead to infringement actions.
- ◆ The number of foreign patent filings in pharma is expected to increase considerably after January 1, 2005

The Challenges Ahead.....

**Untested principles compulsory licenses –
availability & affordability of price**

**Tested patent prosecution strategies of
major pharmaceutical companies**

**Tested Patent Enforcement Strategies of
overseas pharmaceutical companies**

Lack of IP preparedness

Absence of a competent patent bar



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Thank You