

# **CHALLENGING TRIPS: THE ROLE OF PATENT OPPOSITIONS**

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## TYPES OF PATENT OPPOSITION

### **Pre-grant**

- Observations/comments
- Pre-grant opposition

### **Post Grant**

- Post grant opposition
- Re-examination

## TRIPS ON PATENT OPPOSITIONS

Articles 62.4, 62.5:

(Articles 41.2. and 3)

Observations/ Comment	Pre-grant Opposition	Post-grant Opposition
Brazil	Bangladesh	Brazil
Colombia	Belize	India
China	Bolivia	Iran
El Salvador	Chile	Pakistan
Indonesia	Egypt	South Korea
Venezuela	Guatemala	Ukraine
	India	
	Israel	
	Jordan	
	Pakistan	
	Thailand	

## INDIA - 2005 IMPLEMENTATION

Patent (Amendment) Bill:

- Patentability criteria - section 3d efficacy standard
- Negotiating for a patent opposition system

## IN PRACTICE

Challenges:

- Lack of transparency
- Access to patent documents
- Clarity of rules

## IMPACT

- Successful oppositions - continued access
- Voluntary licenses/application withdrawals
- Increased participation in the patent system
- A double edged sword for local industry?
- Ripple effect? Brazil, China, Colombia, Egypt, Pakistan, Philippines

## DECISIONS

- 58 decisions on pharmaceutical patents (Sep 2010)
- Top players (based on decisions to date):

### **Opponents**

Cipla (20)

Ranbaxy (9)

Torrent (9)

Natco (6)

Sun (4)

### **Applicants**

Novartis (9)

Gilead (6)

Astrazeneca (6)

Pfizer/Roche (4 each)

Eli Lilly, Tibotec and Wockhardt (3 each)

## INTERPLAY WITH PATENTABILITY CRITERIA

Out of the 58 decisions:

- 72.5% of decisions resulted in refusal/revocation
- 57% rejected under s3d (21% granted despite s3d raised)
- 66% rejected under inventive step
- 26% rejected under s3e (admixture)

# CONCERNS

- Delays
- Serial oppositions
- Too few oppositions
- Serial divisional patents

## LOOKING FORWARD

- Pre-grant/post-grant?
- WIPO PCT observation system
- FTAs
- Patent Prosecution Highway
- Company take-overs