



## PERCEPTIONS vs REALITY

Facts and Figures on the Generic Industry

DCAT Week

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March 12, 2008



## Agenda

- History of Thomson Scientific, API Intelligence
- ANDA Trends
- Trends in Paragraph IV filings
- Availability of High-Quality API
- Trends in Regulatory Filings and FDA Inspections

## TS API Intelligence is the leading supplier of strategic competitive intelligence and product targeting systems to the generic industry

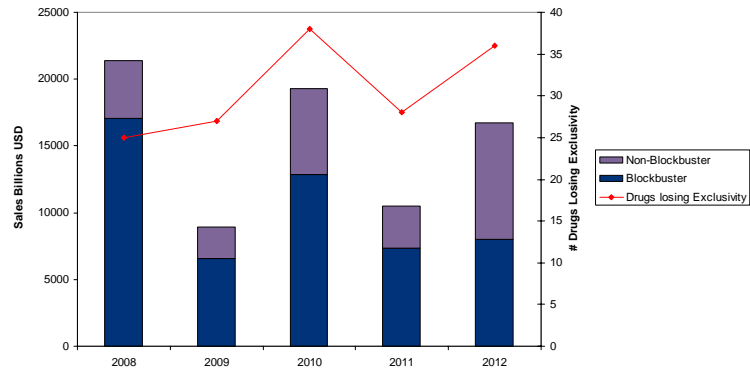
- Newport Strategies was founded in 1990 and acquired by Thomson Scientific in 2004
- Industry pioneer in research and analysis of how global API development drives competition in launched pharmaceutical products
- Horizon Global and Vision CI are used by professionals in
  - Product Targeting and Evaluation
  - Business Development & Licensing
  - Corporate Development and M&A
  - R&D, Market Research
  - Competitive and Business Intelligence
  - API Sourcing
- In use at more than 150 companies including 8 of the world's Top 10 innovators and 38 of the Top 50 generic companies

## What are the Combined US Sales of Products Losing Patent Protection in 2008?

1. \$0 - \$5 Billion
2. \$5 - \$10 Billion
3. \$10 - \$15 Billion
4. \$15 - \$20 Billion
- ★ 5. >\$20 Billion

### Generic Opportunities in the U.S.

- Over 150 products, including 20 blockbusters, with \$77 Billion in total branded drug sales in the US are coming off patent in the next 5 years

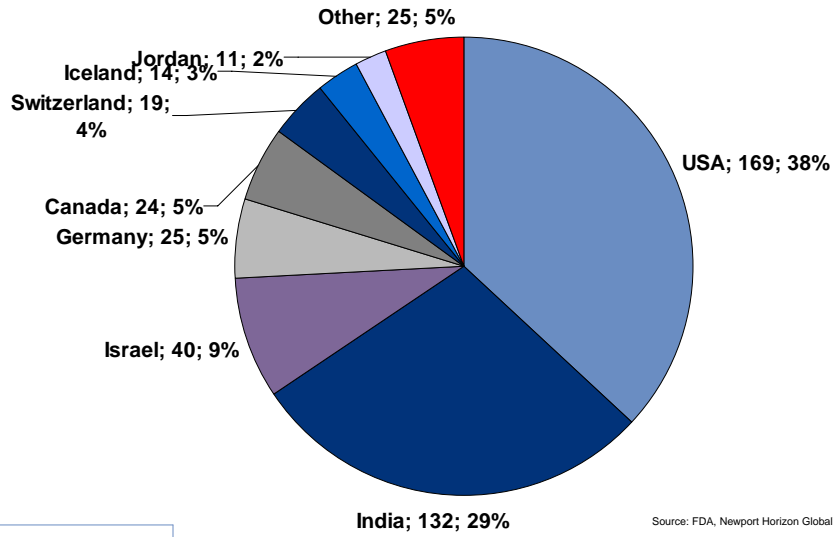


Source: Newport Horizon Global™

### What Country had the Most ANDA Approvals in 2007?

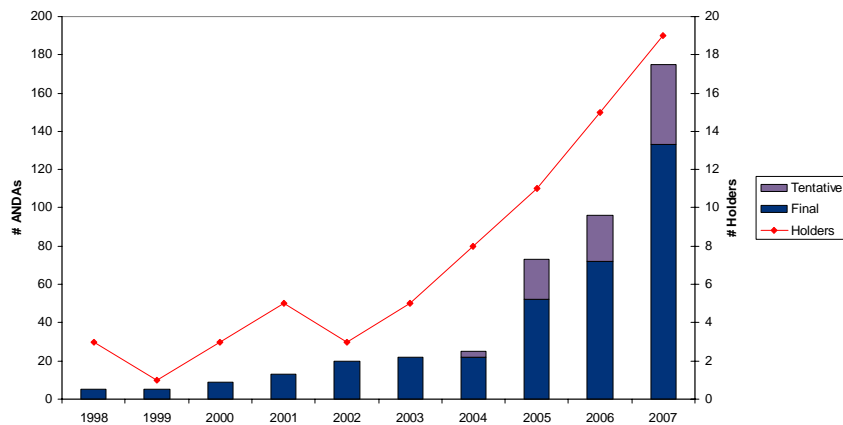
- GERMANY
- INDIA
- ★ USA
- CHINA
- ISRAEL

### 2007 Final ANDA Approvals by Country



Source: FDA, Newport Horizon Global™

### Total ANDA Approvals by Indian Generics



Source: Newport Horizon Global™

## Top 10 Companies by Number of Final ANDA Approvals: 1998 – 2007

Group	Country	Number
Teva Pharmaceutical Industries Ltd	Israel	427
Novartis AG	Switzerland	280
Apotex Inc	Canada	219
Ranbaxy Laboratories Ltd	India	180
Mylan Laboratories	USA	168
Barr Laboratories Inc	USA	121
Watson Pharmaceuticals Inc	USA	120
Vintage Pharmaceuticals Inc	USA	116
Taro Pharmaceutical USA Inc	Israel	115
Boehringer Ingelheim KG	Germany	113

Source: Newport Horizon Global™

## Major New Generic Launches - 2007

- Of the 29 products that witnessed first ANDA approval in 2007, 15 of them were considered blockbusters
- Some major new generic launches of 2007 include:
  - Ceterizine HCl
  - Carvedilol
  - Pantoprazole Sodium
  - Zolpidem Tartrate
  - Risedronate Sodium
  - Valacyclovir HCl

Source: FDA, Newport Horizon Global™

## Anticipated 2008 Generic Launches

- 25 products will lose patent protection in 2008 in the US and see generic competition
- Some anticipated generic launches of 2008 include:
  - Memantine HCl
  - Topiramate
  - Risperidone
  - Levetiracetam
  - Ropinirole HCl
  - Alfuzolin HCl
  - Eplerenone
  - Rocuronium Bromide

Source: FDA, Newport Horizon Global™

## How Many Unique Molecules/Combinations Received First ANDA filings with Paragraph IV Certification in 2007?

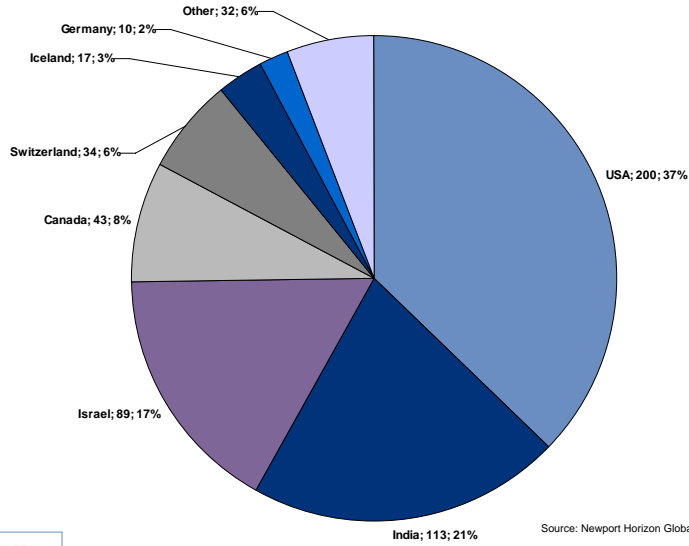
1. 0-10
2. 10-20
- ★ 3. 20-30
4. 30-40
5. >40

### Paragraph IV Patent Challenges - 2007

- 27 unique molecules or molecule combinations saw first Paragraph IV Patent challenge in 2007
- Some Examples (RLD):
  - Abilify
  - Boniva
  - Crestor
  - Opana
  - Strattera
  - Zanaflex

Source: Newport Horizon Global™

### Patent Challenges by Country



Source: Newport Horizon Global™

## Top 10 Companies by Number of Patent Challenges

Group	Country	Number
Teva Pharmaceutical Industries Ltd	Israel	78
Apotex Inc	Canada	36
Mylan Laboratories Inc	USA	35
Barr Laboratories Inc	USA	34
Novartis AG	Switzerland	31
Dr Reddy's Group	India	29
Ranbaxy Laboratories Ltd	India	26
Sun Pharmaceutical Industries Ltd	India	24
Watson Pharmaceuticals Inc	USA	20
Par Pharmaceutical Companies Inc	USA	19

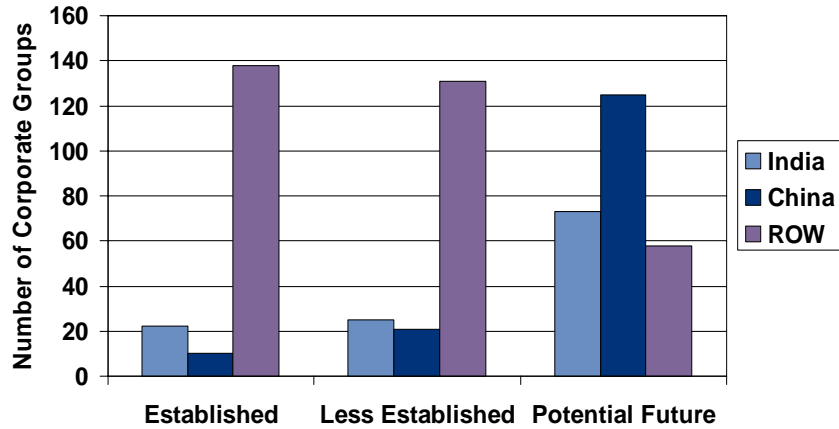
Source: Newport Horizon Global™

## Paragraph IV Patent Challenges - 2008

- There are 29 molecules with New Chemical Entity exclusivity expiring in 2009, so therefore are exposed to Paragraph IV Patent Challenge in 2008
- So far in 2008, 5 molecules (or combinations) have seen their first patent challenges
- Some major products that will likely see a Patent Challenge include:
  - Duloxetine HCl
  - Pregabalin
  - Tiotropium Bromide

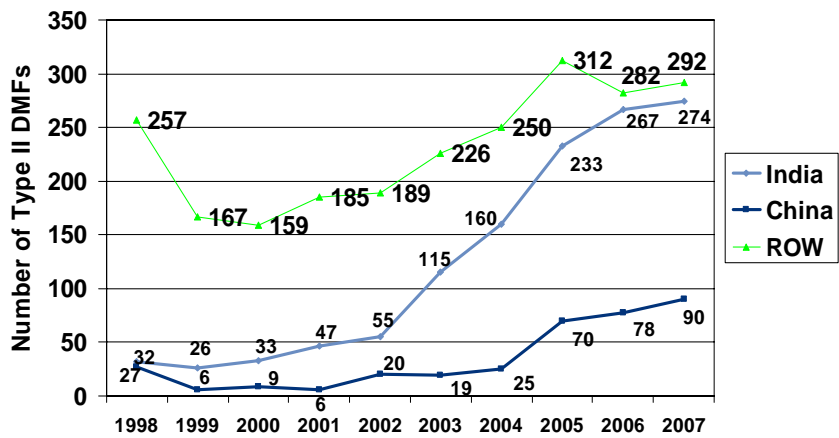
Source: FDA, Newport Horizon Global™, data as of 2/29/2008

### Availability of High-Quality API for India, China and Rest of World



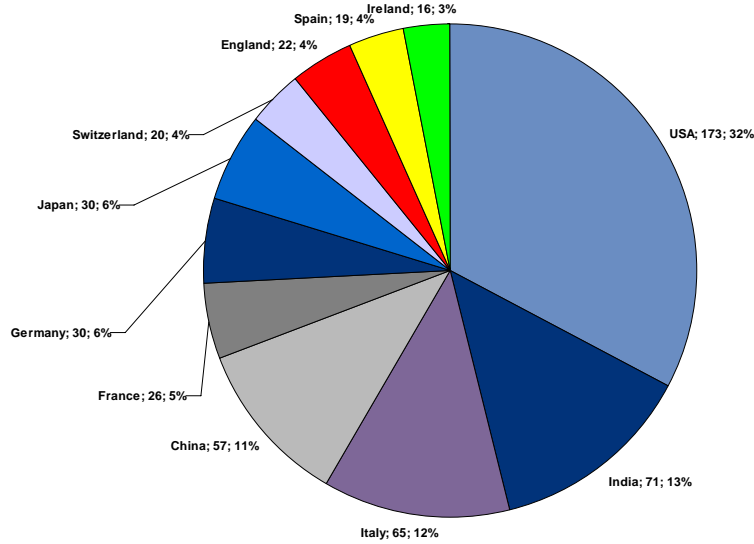
Source: Newport Horizon Global™

### US DMF Filings by Indian, Chinese and Rest of World API Manufacturers: 1998 - 2007



Source: Newport Horizon Global™

### Number of Plants Inspected by US FDA: 2001 – 2007



Source: Newport Horizon Global™



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Thank you!

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