

Presentation to Secretary - DoP

**Indian Pharmaceutical Industry
Threat to Survival and Growth**

by
D G Shah
Secretary General
Indian Pharmaceutical Alliance

Mumbai
21 July 2009

Indian Pharmaceutical Industry Threat to Survival and Growth

Outline of Presentation

- ❑ PCT Reforms – Global Patenting
- ❑ WIPO – New Agenda
- ❑ WHO/IMPACT – Action Plan for Counterfeit
- ❑ EAC Draft Report – Sealing India's Exports
- ❑ EU Customs – Barrier to Trade
- ❑ India's IPR Regime – Ugly Ground Reality
- ❑ Summing Up

PCT Reforms – Global Patenting

US Proposal for Comprehensive Reforms

- ❑ Comprehensive Revision of the International Patent System leading to a New Patent Cooperation Treaty, PCT II
- ❑ The PCT was specifically designed as a mechanism for reducing the overall workload of Patent Offices worldwide through the use of the International Reports either as the basis for grant or at least as the basis for an accelerated examination process
- ❑ The USPTO proposal aims at improving the International Patent System so that it would be readily used and accepted by National Offices

- Contd

3

PCT Reforms – Global Patenting

US Proposal for Comprehensive Reforms - Contd

- ❑ The USPTO has proposed developing a new PCT which would include:
 - Combining of International and National Processing
 - Search/Examination Collaboration Among Authorities
 - Allowing for the Submission of Prior Art by the Applicant, and
 - Allowing Third Party Submission for Prior Art
- ❑ Suggests Implementation of Patent Prosecution Highway as applicants enter the National Phase
- ❑ Applications receiving a positive report at the end of the International/National Processing by designated Patent Offices would essentially result in ***automatic patent grants in all Member States***
- ❑ Such a system should result in substantial long term savings for the National/Regional Offices through its collaboration, work sharing, and mutual exploitation allowing for the rapid resolution of International Patent Rights

PCT Reforms – Global Patenting

Implications

- Dilutes TRIPS Flexibilities
- Prevents Developing Countries from Learning Intricacies of IPRs
- Makes Developing Country Patent Laws Irrelevant
- Makes Their Patent Offices Redundant and Burdensome
- Makes Patent Challenge Almost Impossible

Do Not Empower Developing Countries

WIPO - New Agenda

- ❑ Move Away from Capacity Building Programmes
- ❑ Marginalize India's Role
 - Alienate India
 - Discredit India's Mission at Geneva
 - Use Indian Bureaucrats in WIPO Secretariat
 - Breach the Ranks of the Developing Country Groups
- ❑ Use Crumbs to Win Over Some Other Countries
- ❑ Focus on "Customer Satisfaction" to Steer Changes

WIPO - No Longer a Member Driven Organization

WHO/IMPACT - Action Plan for Counterfeit

Using Counterfeit to Block Exports

- ❑ IMPACT – An Initiative of IFPMA
- ❑ Gained Respectability by Positioning Within WHO
- ❑ Leveraging African Countries' Frustration to Advantage of IFPMA
- ❑ Misleading African Countries to Frame Laws that Treat Generic as Counterfeit
- ❑ Encouraging WCO, WIPO and ACTA to Create Barriers to Exports from India

Let Not WHO Compromise India's National Interest

EAC Draft Report – Sealing India's Exports

Spreading Beyond Kenya

- Spreading Kenya's Anti-Counterfeit Act to East African Community (EAC)
- Converting "Territorial" Rights into "Universal" Rights
- Will Treat Legitimate Generic as Counterfeit
- Direct Threat to India's Exports of Pharmaceuticals

Address Role of EC and IMPACT to Safeguard National Interests

EU Customs – Barrier to Trade

Protecting EU Industry

- Crude Manifestation of Protectionism
- Violative of TRIPS and GATT
- Destroying India's Brand Equity
- Creating Barrier to Access

Urgent Need for Government Intervention

India's IPR Regime – Ugly Ground Reality

Strategic Use of Judiciary by MNCs

- ❑ Efforts to Amend India's IPR Regime
- ❑ Back Door Introduction of TRIPS Plus IPR Eco System
- ❑ Government – A Silent Spectator and Non-responsive

Compromising Public Health and Access to Medicines

India's IPR Regime – Ugly Ground Reality

Linking Regulatory Approval to Patent Status

- ❑ A Device for Delaying Entry of Generics
- ❑ Exceeds India's Obligation under the TRIPS Agreement
- ❑ Inconsistent with Role of Drug Regulatory Authority (DRA)
- ❑ DRA Incompetent to Handle Intricacies of Patents
e.g. Glivec (Novartis); Tarceva (Roche)

***Why Should Government Take
Responsibility for Protection of Private Property Rights?***

India's IPR Regime – Ugly Ground Reality

Data Exclusivity (DE)

- ❑ Revival of “Endless Exercise” for TRIPS Plus IPR Regime
- ❑ “National Companies will Ask for DE in Two Years” is Misleading and Self-serving
- ❑ DE is a Substitute for “Weak” Patents
- ❑ It is an Incentive to Delay New Products in India
- ❑ India will be Put on a Slippery Slope

Government Ignoring Hard Evidence

Summing - Up

Protectionism is Universal

All Developed Countries Pursue Policies that Protect
Their Industries, Employment and Agriculture

Why Does India Shy Away from Protecting
Not Only its Industries
but
Also Public Health
and
Access to Affordable Medicines

Why Do We Not Protect Our Interests?

THANK YOU

dgshah@vision-india.com