

# Presentation to Health Secretary

## **TRIPS Article 39.3 & Data Exclusivity (Regulatory Data Protection)**

by  
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# TRIPS Article 39.3 & Data Exclusivity

## Outline of Presentation

- TRIPS Article 39.3 & Its Genesis
- Impact of Data Exclusivity
- Summing Up

# TRIPS Article 39.3 & Its Genesis

## Protection of Undisclosed Information Article 39.3

“Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

# TRIPS Article 39.3 & Its Genesis

## US Submission to Negotiating Group in 1987

- Introduced Concept of Trade Secrets
- Sought Prevention of Misappropriation by Unauthorised Use
- Provided Exception for Disclosure, if Disclosure did Not Impair Market

*Proposal for “Misappropriation Regime” and Not for Conferring Rights*

# TRIPS Article 39.3 & Its Genesis

## Subsequently Changed by Trilateral Business Communities

- Protection of Test Data
- Information Disclosed to Government Shall Not be Used Commercially Without the Consent of the Owner
- Information Disclosed as a Condition for Registration of a Product shall be for the Exclusive Use of the Registrant for a ***Reasonable Period from the Date of Approval***

# TRIPS Article 39.3 & Its Genesis

## Delegates Deferred with the Trilateral and Argued

- Trade Secret did not Constitute IP
- IP Requirement of Disclosure Can Not be Enforced on Trade Secret
- Fell Outside the Scope of the Negotiating Group
- However, Recognized Need for Protection of Know How, Under Relevant Laws

# TRIPS Article 39.3 & Its Genesis

## Text of Draft Submitted to Brussels Ministerial Conference in 1990

“Parties, when requiring as a condition of approving the marketing of pharmaceutical product or of a new agricultural chemical product, the submission of undisclosed tests or other data, the origination of which involves a considerable effort shall protect such data against unfair commercial use. Unless the Person submitting this information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, **generally no less than five years**, commensurate with the efforts involved in the origination of the data, their nature and the expenditure involved in their preparation. In addition parties shall protect such data against disclosure, except where necessary to protect the public” (emphasis added).

*The Final Text of the TRIPS Agreement Did Not Mention  
Period of Non-reliance*

# TRIPS Article 39.3 & Its Genesis

## Protection of Undisclosed Test Data

Member States' obligation is to protect "undisclosed test or other data" *submitted* to Regulatory Authority against "unfair commercial use"

It does not mean "Market Exclusivity"; and

Use of originator's data for regulatory approval is "not unfair commercial use."



# Impact of Data Exclusivity on Access

## Brand Industry Seeks Two Layers of Protection

- ❑ ***Non-disclosure:*** Authorities will keep the data secret and will not disclose it to third parties
- ❑ ***Non-use:*** Health Authorities will not compare the submissions of a generic applicant (bio-equivalence tests) to the parallel results of the innovator for the purpose of approving the generic product

*Non-use Exceeds Obligations Under TRIPS Article 39.3*

*Patent Protection Period was Raised to 20-Year  
to Cover Costs of Creating Data for Product Registration*

# Impact of Data Exclusivity on Access

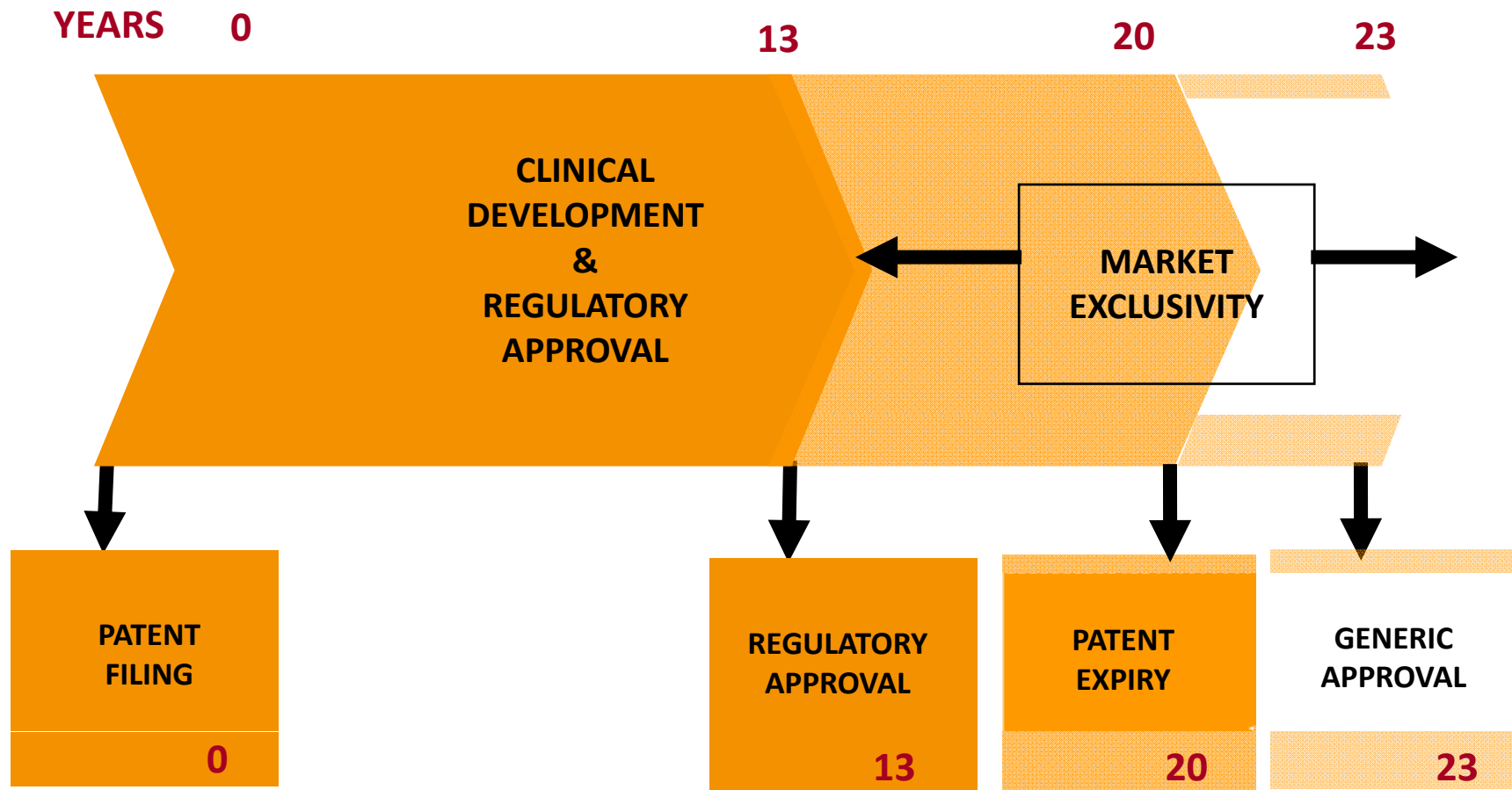
## Implications of Exceeding TRIPS Obligations

- ❑ Longer than 20-Year Market Monopoly
- ❑ Delay in Entry of Generics
- ❑ Protection to Weak Patents
- ❑ Tool for “Evergreening”/Dilution of Sec 3(d)
- ❑ Incentive to Delay Launch of New Products
- ❑ Offers Market Exclusivity to Pre-1995 Molecules

*Monopoly Beyond Patents*

# Impact of Data Exclusivity on Access

## Implications of 10-Year "Data Exclusivity"



# Impact of Data Exclusivity

## PhRMA "Special 301" Submissions

### India: Damage Estimate - 2003

CRA Study "conservatively estimates losses in India due to the absence of intellectual property protection at more than \$1.7 billion dollars annually."

### India: Damage Estimate - 2005

Damage estimate of \$1.7bn in 2001 was revised to \$ 3.5 bn in 2005 !

Patent Protection Damages	\$ 2.5 Bn
Data Protection Damages	<u>\$ 1.0 Bn</u>
Total Damage Estimate	<u><u>\$ 3.5 Bn</u></u>

*This Constitutes 78% of the Indian Market*

# Summing Up

## Recommendation by the WHO Commission\*

"A public health justification should be required for data protection rules going beyond what is required by the TRIPS Agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. **Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.**"

\* The WHO Commission on Intellectual Property Rights, Innovation and Public Health, Pg 126

# Summing Up

## Recommendation of the Parliamentary Standing Committee on Commerce\*

“Since the consequences of Data Exclusivity are quite serious, the Committee strongly recommend that the Government should not fall prey to such demands of MNCs. The Government must thwart such attempts, being made at the behest of certain vested interests. It should also guard against moves to enter into FTA with USA, as the developed countries, particularly the USA, are trying to bring in certain TRIPS Plus measures through Bilateral and Regional Agreements.”

\* Eighty Eighth Report on Patents and Trademarks Systems in India, New Delhi, October 2008, Rajya Sabha Secretariat

# Summing Up

## **Recommendation of the Report Published in Collaboration with Department of Essential Drugs and Medicines Policy of the WHO\***

“In sum, Article 39.3 – interpreted according to the ordinary meaning of the words used, in their context (notably Article 39.1) and taking into account the object and purpose of the Agreement as expressed in Articles 7 and 8 – does not require the granting of exclusive rights. The obligation that it imposes may be satisfied by other means, not specified in the Agreement.”

“Use by the government to assess the efficacy and toxicity of a pharmaceutical or agrochemical product is not a commercial use subject to Article 39.3. Granting marketing approval to a second entrant, based on the second product’s similarity to a previously approved first product, is not a proscribed “use” under Article 39.3.”

\*Correa CM, *Protection of data submitted for registration of pharmaceuticals:*

Implementing the standards of the TRIPS Agreement, South Centre, 2002 Geneva, 2002, p 45-46



# THANK YOU

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