

IP and FTAs: Significant Issues in Current Negotiations and their Relation to US IP Laws

Workshop on IP, FTAs, and Sustainable Development

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Today's Agenda

- I. FTAs as tools for Maximizing Profits
- II. TRIPS PLUS; “US PLUS = Health – MINUS” (beyond the flexibilities)
- III. Harmonization Efforts
- IV. US Patent Reform
- V. US: Unreliable Trade Partner?



I. FTAs as tools for Maximizing Profits

- These agreements are about **Money!**



- Using trade agreements as tools to change the laws of countries
- While traditionally trade agreements have sought to open new markets to competition and lower prices, IP agreements do exactly the opposite.



I. FTAs as tools for Maximizing Profits

- US Exports of Pharmaceuticals

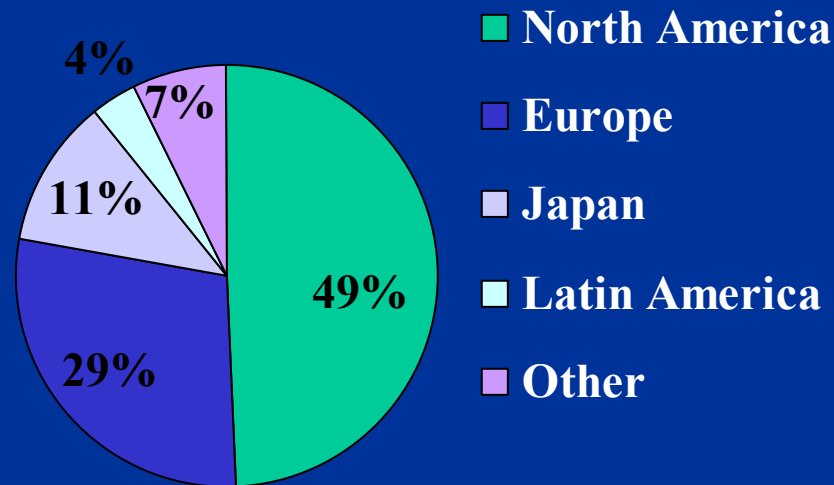
1997: \$6 billion

2004: \$19 billion



I. FTAs as Tools for Maximizing Profits

World Pharmaceutical Sales 2003



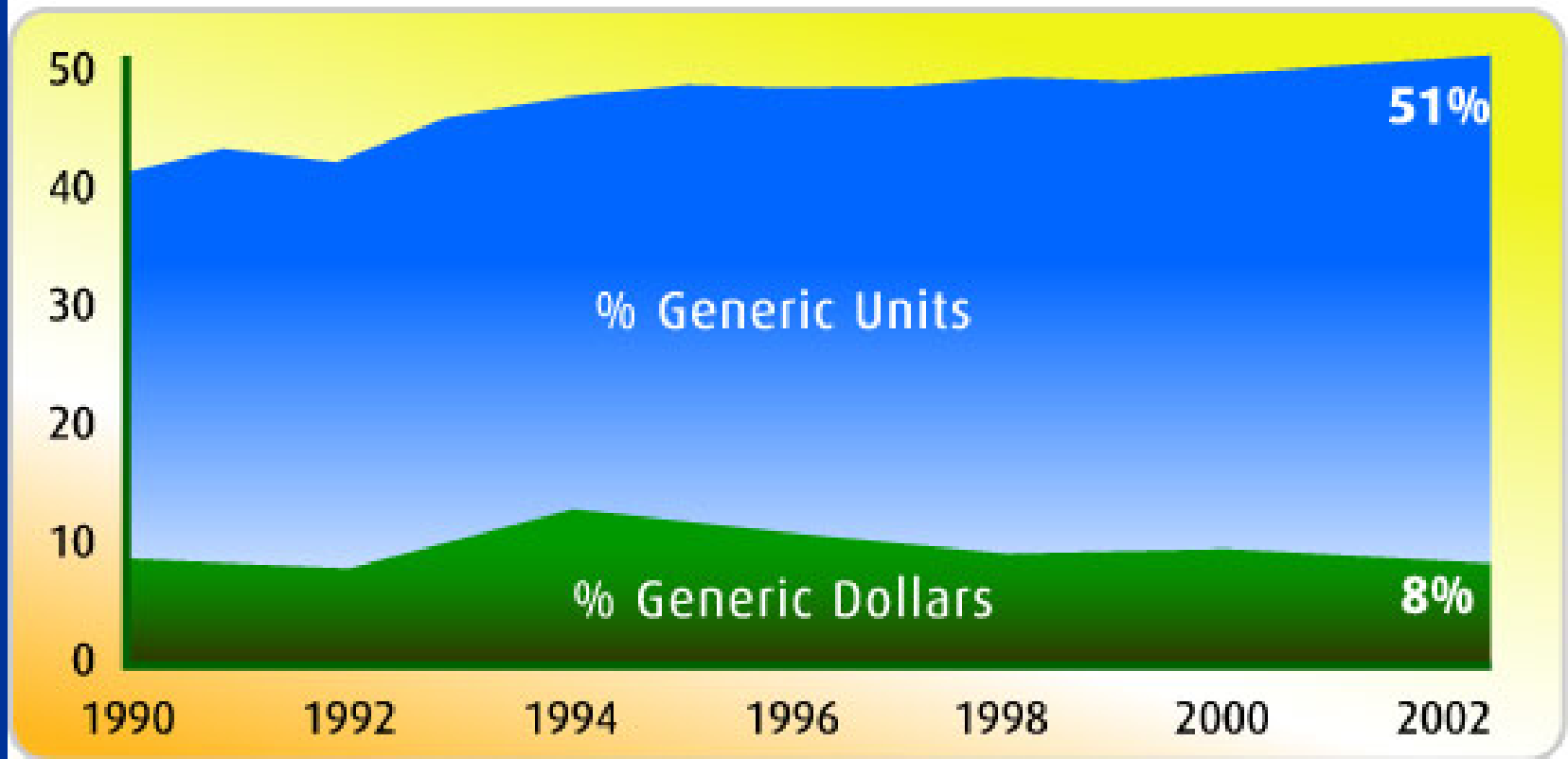
Total Sales: \$467.9 bn

Source: IMS



I. FTAs as Tools for Maximizing Profits

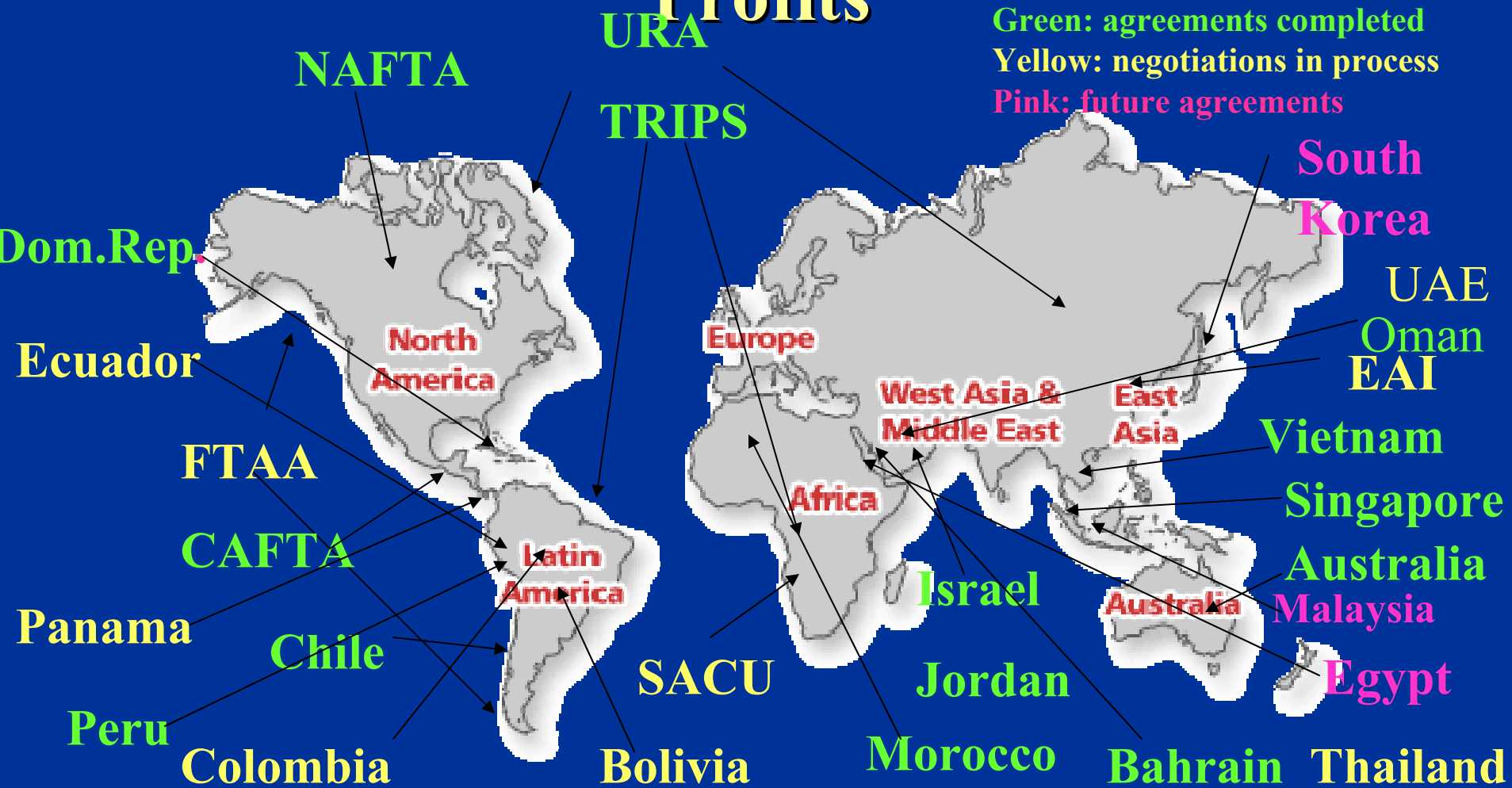
In 2002 Generic Drugs Represented:



Source: GPhA



I. FTAs as tools for Maximizing Profits





II. TRIPS +; US + = Health -

Provision	WTO	US	FTAs
Bolar	Allowed (WTO: EU- Canada, 2000)	Required US Code (35 USC § 271(e)(I)) X provision (21 USC § 382)	Only allowed but not required X problem
Patent Ext. Sanitary Agency	Not included	Only for NCE; max 5y; max 14 (35 USC § 156)	Not limited to NCE; no caps





II. TRIPS +; US + = Health -

Provision	WTO	US	FTAs
Patent Ext. PTO	No provision	Allowed (35USC § 154)	Trigger time 2/4 or 3/5
Market Exclusivity	No provision; Art. 39.3 non disclosure	5 years NCE; 3 years for new clinical investigation (21 USC § 355)	<u>At least</u> - 5 years; -New ph. products; -similar prod.; -Add. 3 yr new clinical information -Consecutively -“Undisclosed” dropped! -Require vs. permit





II. TRIPS +; US + = Health -

Provision	WTO	US	FTAs
Linkage	No provision	Yes (21 USC § 355 (j)(2)(A)(vii))	More restricted than in US - All Patents - No need patent holder to file law suit
Disclosure of a Patented Invention	No provision	Best Mode required (35 USC § 112)	Dropped! Conditional in Peru FTA



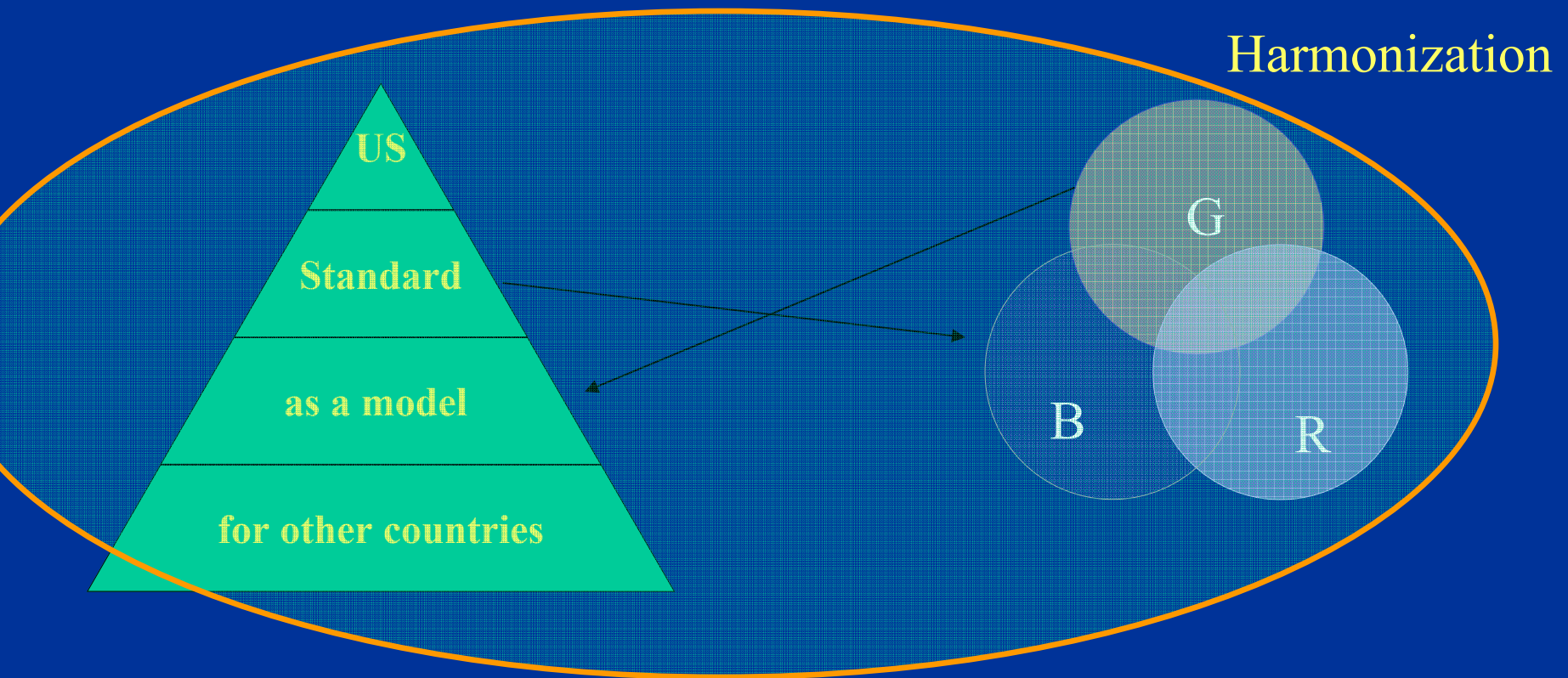
III. Harmonization

- Global Negotiations
- Regional Negotiations
- Bilateral Negotiations



III. Harmonization

Interaction between domestic and international strategy



III. Harmonization

- WIPO (Standing Committee on the Law of Patents-SCP)
- USPTO with other Patent Offices from developed countries



IV. US Patent Reform

HR 2795:

- Drops “best mode” from US legislation;
- Changes the standards for inequitable conduct

Senator Hatch (Sept.2005): It “is one of the most significant IP issues currently in Congress”. Its goals are:

- Goal 1: Increasing patent quality;
- Goal 2: Increasing international harmonization;
- Goal 3: Decreasing unwarranted or abusive patent litigation.



US: Unreliable Trade Partner?

- TRIPS Implementation: US pressured other nations not to implement TRIPS flexibilities
- TPA/Respect for Doha Declaration: USTR negotiated multiple restrictions of flexibilities
- US track record: it is becoming an unreliable trading partner. This has led to increasing opposition to trade agreements



Conclusion



- I. FTAs have become tools to maximize profits by extending monopolies.
- II. FTAs: lack of balance between rights of patent holders and those of consumers.
- III. General objective: change laws in US partners to increase patent holders' power.
- IV. Ultimate objective: change US patent law increasing monopoly power also in largest global pharmaceutical market.



Thank you!

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