Protection of Test Data - Policy and Legal Choices: Empirical Analysis of National Models

LIFE SCIENCES SYMPOSIUM:

INTELLECTUAL PROPERTY AND LIFE SCIENCES REGULATION

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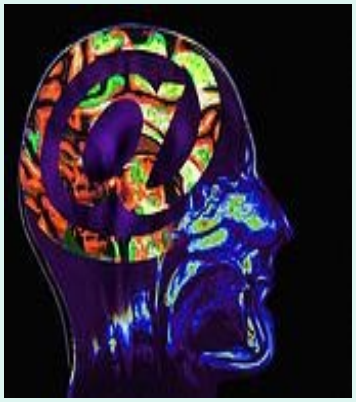
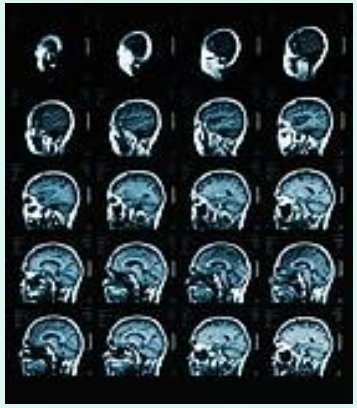




Test data, data protection, data exclusivity….

A new form of intellectual property (less than 25 years old (first introduced in the US in 1984)

A NON standardized form of intellectual property – different scope, terms, form and strength of protection

Subject to serious debates, but also to some confusion….

Rising regulatory and economic significance – globally!

Subject matter of test data

Data that is generated, gathered and submitted by pharmaceutical companies to regulatory authorities (such as the US Food and Drug Administration (FDA) and the European Agency for Evaluation of Medicinal Products (EMEA), for the purpose of obtaining marketing approval for new drugs

Process of "test data" (http://www.fda.gov/fdac/special/testtubetopatient/drugreview.html)

- **Pre-clinical phase – (lab & animals studies, pharmacokinetics, chemistry test**
- **Phase I tests – in a small number of healthy volunteers (<100)**
- **Phase II tests – "Placebo-controlled trials" – (100<>500) – safety and efficacy of the drug + side effects (proof of concept)**
- **Phase III tests – RCT (randomized, placebo-controlled trials), large scale trials in multiple locations in different countries (1000<>5000) – statistical validity of safety and efficacy of the drugs**
- **New Drug Application – submission to the regulatory authority**
- **Regulatory review (for example by FDA or EMEA) – marketing approval (or not)**
- **Post marketing studies**

Patents Vs. test data protection

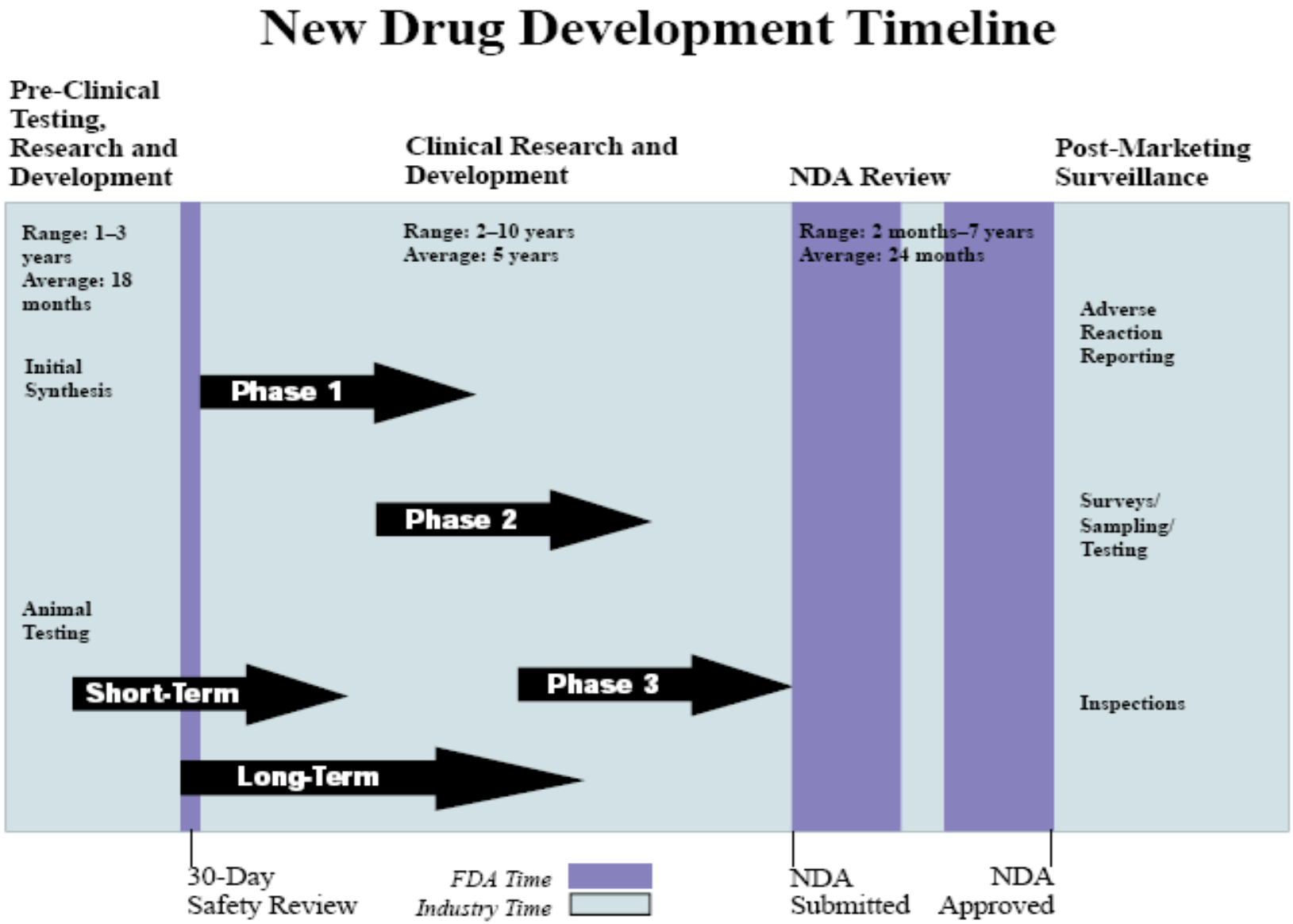
Patents

Market exclusivity derives from the **LEGAL** right of the patent owner to prevent others from using the subject matter of the patent without his/her consent

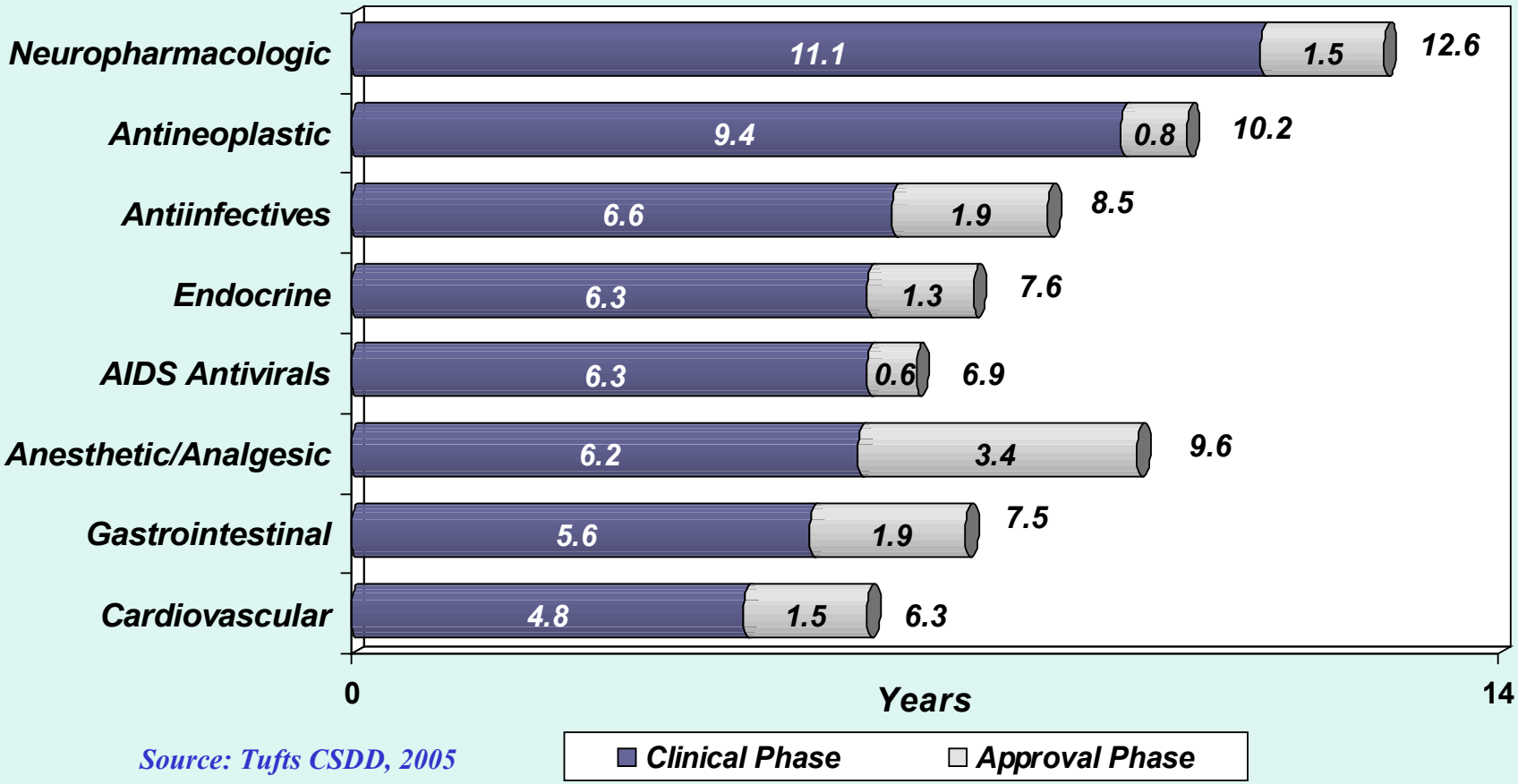
Test data

Market Power derives from the **COST & TIME** associated with the creation of a pharmaceutical registration file

FDA stats: drug development periods are very long

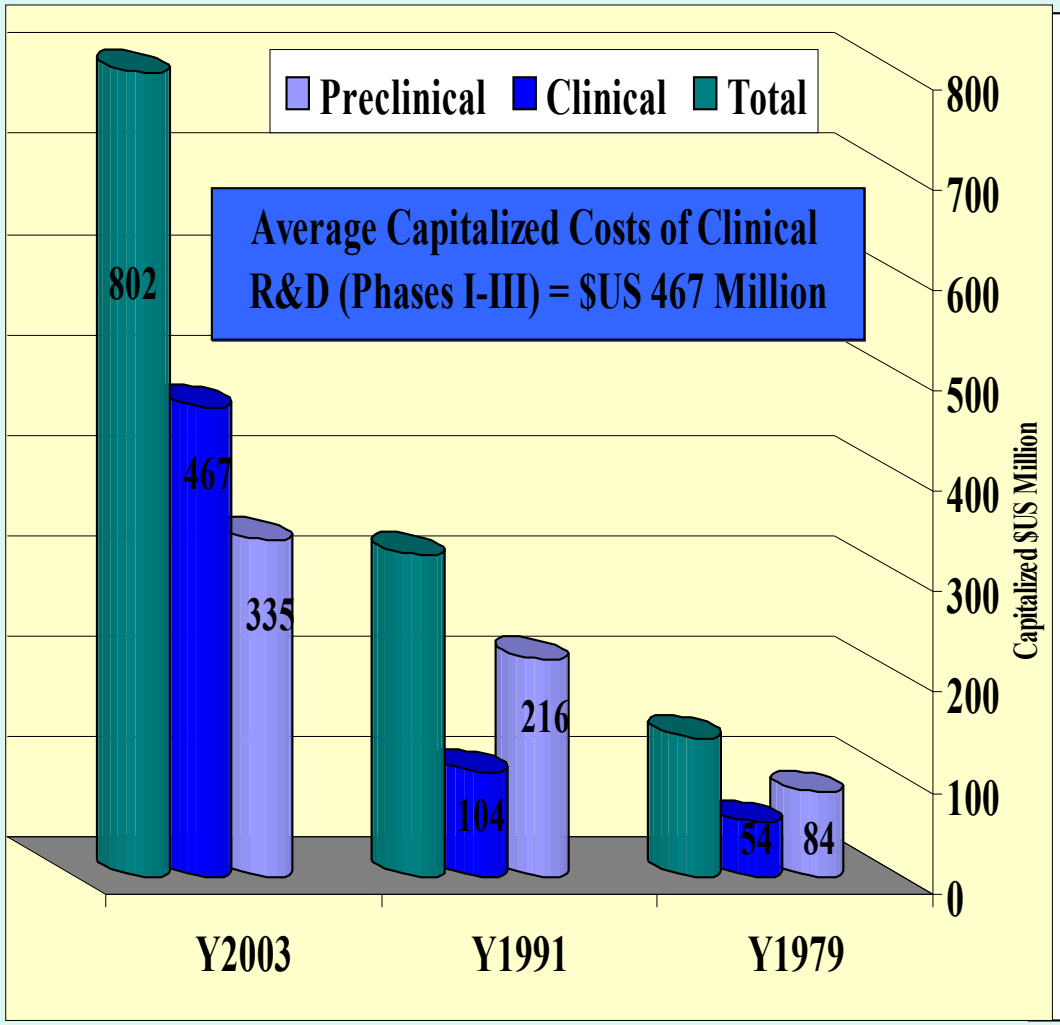


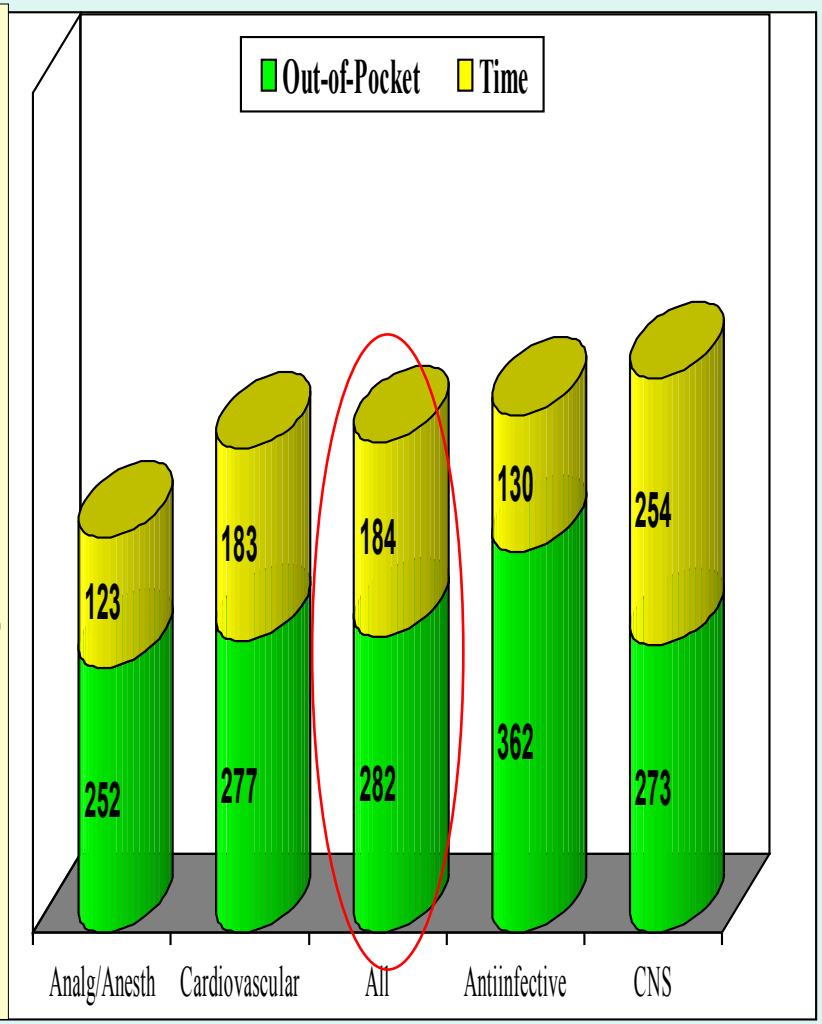
Clinical and approval times – vary across therapeutic classes, 2002-04



Source: Tufts CSDD, 2005

Trends in capitalized preclinical, clinical and total cost per approved new drug





Sources: Dimasi, Hansen and Grabowski, October 2002; Grabowski, December 2003;

The (debated) layers of data exclusivity

Non-disclosure - ensure that regulatory authorities treat the test data as a **TRADE SECRET** – do not disclose it to rival companies (usually generic companies)

Non-use (non reliance) – defines a period during which 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

Protection of test data as policy formula

Coverage - to which types of drugs test data protection applies, mostly a distinction between: Drugs that are based on a new active ingredient (NAI) such as new chemical or biological entity and New drugs based on combination of existing NAIs, which require additional clinical data

Term of protection - the number of years that will elapse before a generic drug can be introduced to the market. [Note: De facto marketing exclusivity of an original drug is not only influenced by the term of protection but also by the scope of protection]

Scope of protection - mostly if the registration file (dossier) is **only** protected against non disclosure (as explained above) **or also subject to a period of non-use** [in other words, whether a generic applicant can submit bioequivalence test to the health authorities prior to the expiration of the term of protection]

Additional term of protection for new indications - does a test data legislation provides an extra term of protection to new indications (new uses) of existing drugs

Test data legislation – developed countries

Country	Coverage	Term of protection	Scope of protection	Term of protection for new indications
United States Federal Food, Drug, and Cosmetic Act of 1997 - USC 355(c)(D)(ii & iii)	New Active Ingredient (NAI)-based drugs + Combination Products	5 years	Non-disclosure & Non-use	3 years for a new indication for which the innovator submit reports of new clinical investigations essential to the approval of the application
European Union Article 10 of Directive 2004/27/EC	NAI-based drugs + Combination Products	8+2 formula: 8 years	Non-disclosure & Non-use	1 year for new indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison"
		2 years	Non-disclosure	

Test data legislation – developed countries

Country	Coverage	Term of protection	Scope of protection	Term of protection for new indications
Canada - Food and Drug Act, Food and Drug Regulations, Division 8-New Drugs, C.08.004.1	NAI-based drugs	Up to June 17th , 2006 – 5 years	Non disclosure	No
		As of June 17th , 2006 - 8 years: 6 Years	Non-disclosure & Non-use	+ 6 months to clinical trials relating to the use of The innovative drug in relevant pediatric Populations
		2 Years	Non-disclosure	
Australia- Section 25A of Australia Therapeutic Goods Act 1989 – (updated to Act No. 96 of 2006)	NAI-based drugs	5 Years	Non-disclosure & Non-use	No

Test data legislation – developed countries

Country	Coverage	Term of protection	Scope of protection	Term of protection for new indications
New Zealand - Article 23.b&c Medicines Act – Protection of confidential supporting information about innovative medicines	NAI-based drugs	5 years	Non disclosure (but with some notable exceptions) & Non-use	No
Japan- Japanese Drug Regulation Article 18-3 (source IFPMA 2005)	NAI-based drugs	6 years	Non disclosure & Non-use	None
Singapore – Medicines (amendment) Act of 1998; New Sections 19A and 19B	NAI-Based drugs	5 years	Non disclosure & Non-use	No

Test data legislation – developing countries

Country	Coverage	Term of protection	Scope of protection	Term of protection for new indications
China - Drug Administration Law Art. 31	NAI based drugs	6 years	Non Disclosure	No
S. Korea - S. Korea - Article 26-2 & 30.1 the Pharmaceutical Affairs Law (PAL) &	NAI-based drugs	6 years for new drugs	Non-disclosure & Non-use	4 years for new indications
Taiwan – Pharmaceutical Affairs Law, Article 40-1 and 40-2	NAI-based drugs	5 years	First 3 years Non-disclosure & Non-use Remaining 2 years only non Disclosure	No
India	NCE Drugs	Not Specified	Dr. Satwant Reddy's Report to Indian govt Suggests for Non-disclosure	No

Test data legislation – developing countries

Country	Coverage	Term of protection	Scope of protection	Term of protection for new indications
Jordan – Unfair Competition Law, Art. 8	NAI based drugs	5 years	Non Disclosure	3 years
Morocco – US-Morocco FTA Art. 15.10	NAI based Drugs	5 years	Non Disclosure & Non Use	3 years
Bahrain – US-Bahrain FTA, Art. 14.9	NAI Based Drugs	5 years	Non Disclosure & Non use	3 years

Test data legislation – developing countries

Country	Coverage	Term of protection	Scope of protection	Term of protection for new indications
Chile – Chilean Industrial Property Law, Article.89 And US-Chile-FTA Art. 17.10	NAI Based drugs	5 years	Non Disclosure	No
Brazil – Protection Against Unfair Competition, Art. 195	NAI Based drugs	Not Specified	Not Clear	No
Philippines Republican Act no 3720,Section 11	NAI Based Drugs	Not Specified	(treated as trade secret) Non Disclosure	No

Test data legislation – international treaties

Country	Coverage	Term of protection	Scope of protection	Term of protection for new indications
NAFTA Article 1711	NCE-based drugs	Minimum 5 years, but with ***LINKAGE*** [in case in which the approval of a product in one country is dependent upon the marketing approval of that product in another country (a "reference country")]	Non-disclosure & Non reliance (though with some internal inconsistencies	No protection
TRIPs Article 39.3	NCE-based drugs	Period not specified	Non-disclosure Unclear about Non-reliance	No protection

Test data legislation – international treaties

Country	Coverage	Term of protection	Scope of protection	Term of protection for New indications
CAFTA Article 15:10	NAI-based drugs	Minimum 5 years, but with a ***STOPWATCH*** [no more than five years should elapse between the date of product registration in a reference country and the date of product registration in the granting country	Non-disclosure Non-reliance - but less explicit and subject to interpretation	No
Andean Pact (Bolivia, Colombia, Ecuador and Peru) Article 266 of Decision 486	NAI-based drugs	Minimum 5 years	Non Disclosure	No

Too many theoretical speculation too little data…

Market exclusivity – How many drugs in a given country are sensitive to test data protection in terms of the exclusivity period? In other words in which cases would the exclusivity of test data protection extend beyond the term of patent protection?

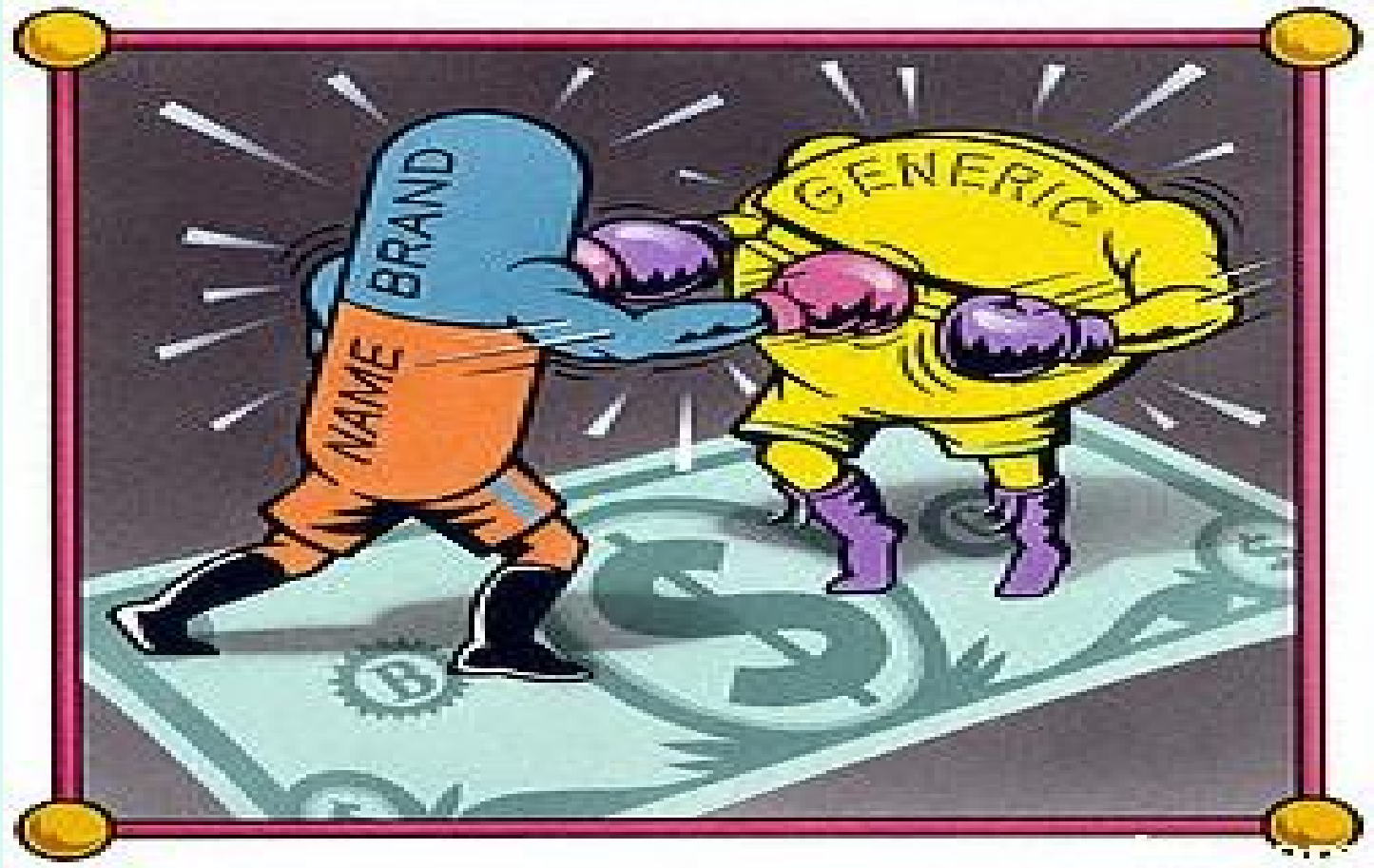
Protection – How many drugs rely on test data protection as their primary mode of IP protection (for example Taxol…)

Prices - What are the implications in terms of the costs of drugs as a result of test data legislation in a given country (will prices increase?)

Access - How many drugs are not registered in a given country due to the lack of test data protection, what are the implications for public access?

Investments in clinical research - What is the link between test data protection in a given country and investments in clinical trials in the healthcare centers in that country

The debate continues…



Thank you for your time!

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