

THE IP ACADEMY



Overview and comparison of data exclusivity legislation in Israel and in selected - OECD countries

International Standards Group

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Data Exclusivity Vs. Patents

Data exclusivity is based on a different type of trade-off: demanding that pharmaceutical companies provide data on the safety and efficacy of a new medicine in exchange for treating these data as a trade secret for a limited period

Two layers of protection of data exclusivity

Non-disclosure -

Authorities will keep the data secret and will not disclose it to third parties

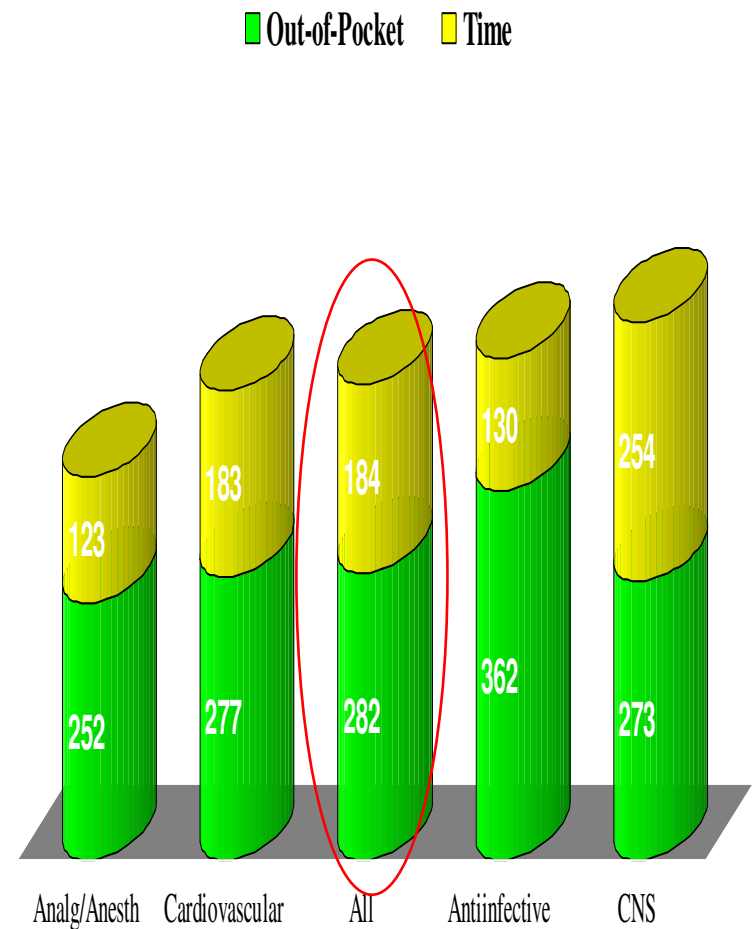
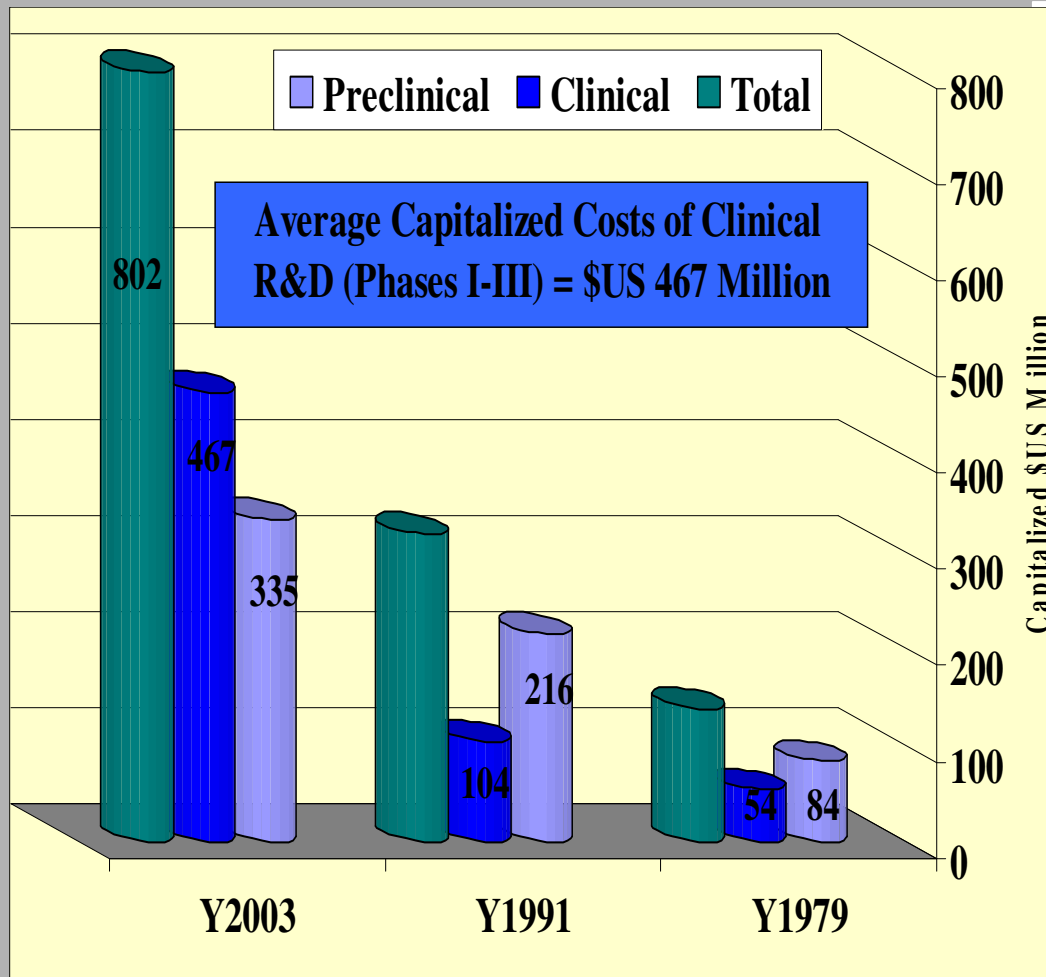


Non-use – during the exclusivity period the health authorities will not compare the submissions of a generic applicant (bio-equivalence tests) to the parallel results of the innovator for the purpose of approving the generic product

Market Power derives from the Huge costs associated with the creation of a pharmaceutical registration file

The Economic Significance of Data Exclusivity

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



Data Exclusivity (DE) as a Formula

Coverage - to which types of drugs data protection applies, mostly a distinction between: 1. Drugs that are based on a new active ingredient (NAI) such as new chemical or biological entity 2. 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 version 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 protected
Against: 1. Non disclosure (as explained above)
& 2. 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]

An additional term of protection for new indications - does a DE legislation provides an extra term of protection to new indications (new uses) of existing drugs.

OECD Countries – DE legislations

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)	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:	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”
		8 years		
		2 years	Non-disclosure	

OECD Countries – DE legislations

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 17 th , 2006 – 5 years	Non disclosure	None + 6 months to clinical trials relating to the use of the innovative drug in relevant pediatric populations
		As of June 17 th , 2006 - 8 years: 6 Years	Non-disclosure & Non-use	
		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	None

OECD Countries – DE legislations

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	None
S. Korea* - Article 26- 2 of the PAL; Article 5, Paragraph 11 of the KFDA Regulations Regarding the Safety and Efficacy Examination of Drug Products * Secondary source (IFPMA 2005)	NAI-based drugs	6 years for new drugs	Non-disclosure & Non-use	4 years for new indications


OECD Countries – DE legislations

Country	Coverage	Term of protection	Scope of protection	Term of protection for new indications
Japan*- Japanese Drug Regulation Article 18-3 *Secondary source (IFPMA 2005)	NAI-based drugs	6 years	Non disclosure & Non-use	None
Mexico – Articles 82-86bis – Trade Secrets – Industrial Property Law – June 1991(Amended 1997)	Not specified – By power of Article 82&83 – any information submitted to the authorities for the purpose of obtaining “license, permits authorization and registration”	Not specified	Non-Disclosure	Not specified


ISRAEL – The Bill - Art. 47C. of the Pharmacists' Ordinance [New Version]



Apply both to NAIs-based drugs and combination products (?)



Five years from the day of registration OR 5.5 years from date of product registration in the first recognized country (US, EU), whichever precedes. **DE FACTO LESS THEN FIVE YEARS OF MARKET EXCLUSIVITY SINCE ISRAEL RELIES ON FDA/EMEA REGISTRATION AND THERE IS A BUILT-IN DELAY OF MORE THEN xxxxx MOTNHS**



Do not apply the “non-use” principle - Article 47(D)(E) - generic companies can submit bioequivalence tests during the exclusivity period



No protection to new indications



Bill will commence in July 2005 and apply only to drugs not registered in the Preparations Register OR in a Recognized Country before the Commencement Day

United States - USC 355(c)(D)(ii & iii) - Federal Food, Drug, and Cosmetic Act of 1997, Chapter 5 - Drugs and Devices, Section 355, (Washington: FDA)
<http://www.fda.gov/opacom/laws/fdcaact/fdcaact5a.htm> -

EU - Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, Official Journal of the European Communities, (30 April 2004), L 136/34 -
http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/dir_2004_27/dir_2004_27_en.pdf

Canada - Food and Drug Act - Food and Drug Regulations, Division 8-New Drugs, C.08.004.1
http://www.he-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/legislation/e_e-drugs.pdf

Australia - Section 25A, Therapeutic Goods Act 1989 – (updated to Act No. 96 of 2006)
http://www.comlaw.gov.au/ComLaw/Legislation/ActCompilationLnsf/0/C44F0188DD3AFB41CA2571E2001EAC50/Sfile/TherapeuticGoods1989_WD02_Version2.pdf

New Zealand - Article 23.b&c Medicines Act – Protection of confidential supporting information about innovative medicines
http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes&jump=a1981-118

S. Korea - Articles 82-86bis – Trade Secrets – Industrial Property Law – June 1991 (Amended 1997)
http://www.wipo.int/clea/does_new/pdf/en/mx/mx016en.pdf