

» Patent Literature and Methodology: WHO Model List of Essential Medicines

International Technology
Transfer Institute

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- » Purpose
- » Background
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» Purpose of this Project

- Develop methodology to assess the patent status of medicines on the WHO EML.
- Generate a detailed report for the public on the present (2010) patent status of medicines that were on patent in 2003 and those medicines added to the Model List since 2003 by country and level of development.
- Analyze patent trends of Essential Medicines by the development status of countries.



» Limited Scope of Methodology

- Companies that do not file U.S. patent applications will fall outside the search parameters of this report
- Many national jurisdictions have not made their patent information easily accessible through electronic resources making it difficult to ascertain patent filing trends for emerging economies.
- Engaging patent professionals in these jurisdictions may be necessary to research records in national patent offices
- Not comprehensive outside of current standardized available patent databases
 - Low patent information for non-reporting jurisdictions
 - Additional patents may have been available for evaluation but without the necessary time within which to consider them, they may have not been considered.
- The team did not do claim interpretation and cannot guarantee that the patents discovered were evaluated at the level of expert scientific sophistication to determine validity.



» Disclaimer

- This is an educational report and is neither inclusive nor comprehensive.
- Not a Freedom-To-Operate Analysis. In other words, one should NOT feel free to produce a medicine in a country simply because this report did not discover patent activity there.



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Essential Medicines List (EML)

- Published by The World Health Organization
- What are Essential Medicines?
 - “Essential medicines are those that satisfy the priority health care needs of the population.”
 - Factors: Public Health Relevance, Evidence of Efficacy and Safety, and Comparative Cost Effectiveness
 - Essential Medicines List:
 - Guide for the development of national/institutional medicine lists
 - Tool for health equity
- Most current: March 2009, 16th Edition [Next Ed. March 2011]
 - Total Number of Medicines: 355 Medicines



Previous Assessment of EML

- “How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?”¹ -- Dr. Amir Attaran

– Dr. Attaran’s Methodology

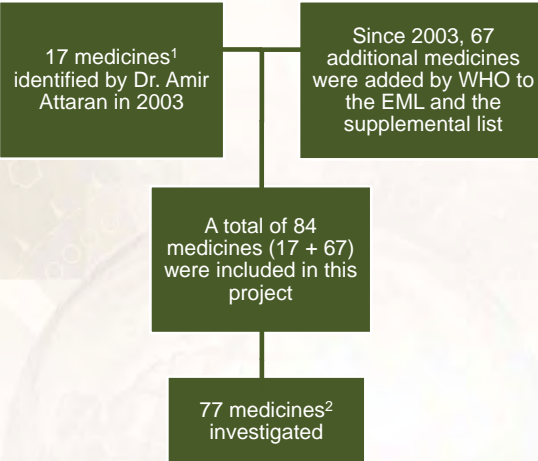


- This project covers Dr. Attaran’s researched medicines¹ and medicines added to the EML and Supplemental list since 2003.



¹ Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?* 23(3), *Health Affairs*, 155, 2004.

Medicines included in this Project



¹ Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?* 23(3), Health Affairs, 155, 2004.

² Seven medicines were removed due to their generalized nature. e.g. rehydration therapies and surfactants



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Basic Overview

Methodology for each medicine researched:

1. Find the expired or unexpired United States Base Patent
2. Find the expired or unexpired derivative patent(s) from the limited listings of US FDA Orange Book.¹
3. Collect the applications, grants, and other patent documents filed in foreign jurisdictions (i.e. patent families) related to the patents found above.
4. Generate world maps indicating patent filing trends.

¹ FDA requires reporting for the following patent types: medicine substance, polymorphs, formulation, composition, and method-of-use



1. Finding Base Patents

- What is a Base Patent?
 - Definition: The expired or unexpired patent for the active ingredient of the medicine.
- How to find a Base Patent:
 - Developed a decision tree protocol to systematically search various databases to efficiently find a base patent.
 - Examples of databases used: USPTO, Merck Index, FDA Orange Book



2. Finding Orange Book Patents

- What is the Orange Book?
 - A publication by the U.S. Food and Drug Administration (FDA)
 - Purpose: List all the medicine products approved by the FDA on the basis of safety and effectiveness in one place.
 - Also includes limited patent information
- Orange book information is available online



3. Finding Patent Families

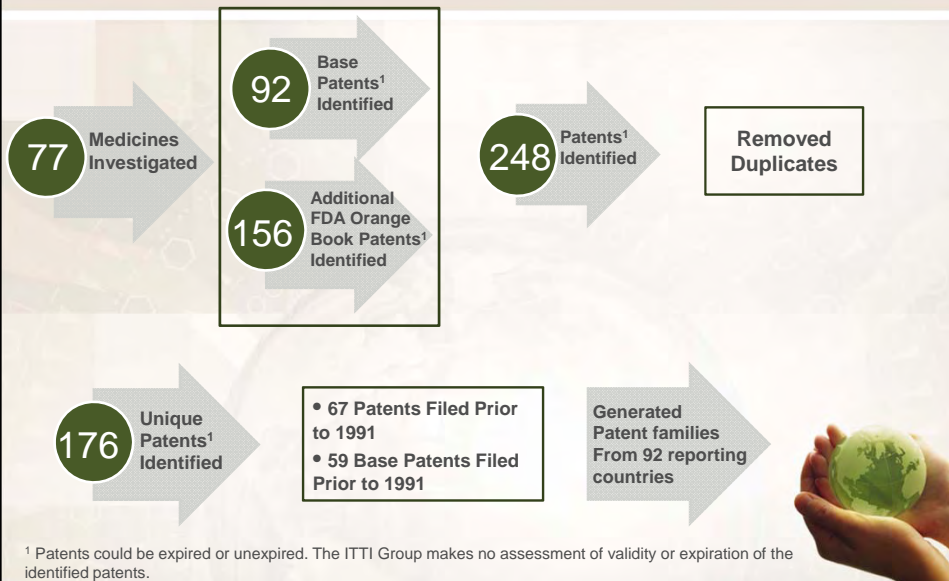
- What is a Patent Family?
 - Definition: A collection of expired or unexpired documents from different countries, including patents, applications, and other materials, that are associated with a single parent patent.
- Three sets of family data created for each patent:
 - Derwent World Patent Index (DWPI) Family
 - International Patent Document (INPADOC) Family
 - LexisNexis TotalPatent Family
- Scope of family coverage:
 - 92 countries
 - Remember: There is no “international patent.” Patents are specific by country.



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» Overview of Results





Example: Abacavir

Used to fight HIV infections in combination with at least two other antiretroviral medicines.

World Map Showing Abacavir Patent Filing Trends:



- 1 Base Patent
- 8 FDA Orange Patents
- 706 Family Documents
- 55 Reporting Countries



¹ Patents could be expired or unexpired. The ITTI Group makes no assessment of validity or expiration of the identified patents.

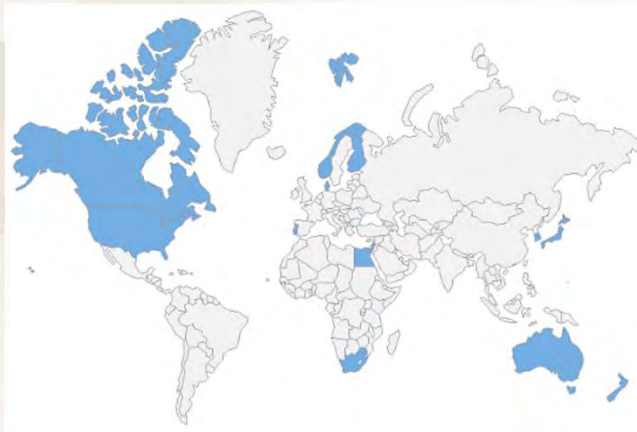
Geographic boundaries based on this map are not endorsed by authors or affiliates, and are merely used and presented for illustrative purposes.



Example: Stavudine

Used to fight HIV infections in combination with at least two other antiretroviral medicines

World Map Showing Stavudine Patent Filing Trends:



- 1 Base Patent
- 0 FDA Orange Patents
- 90 Family Documents
- 13 Reporting Countries



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Example: Stavudine

Used to fight HIV infections in combination with at least two other antiretroviral medicines

World Map Showing Stavudine Patent Filing Trends:



Example: Egypt

- Note family filing information from our analysis (country is flagged as possible patenting jurisdiction)
- Investigate INPADOC/WIPO Patent Family Legal Status
- Engage patent professional in Egypt to research records in national patent office.

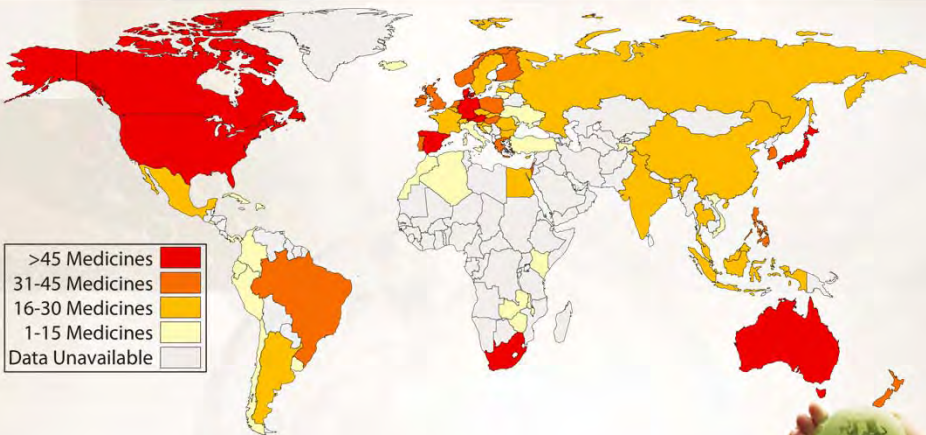


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Patent Filing Trends - Jurisdictional



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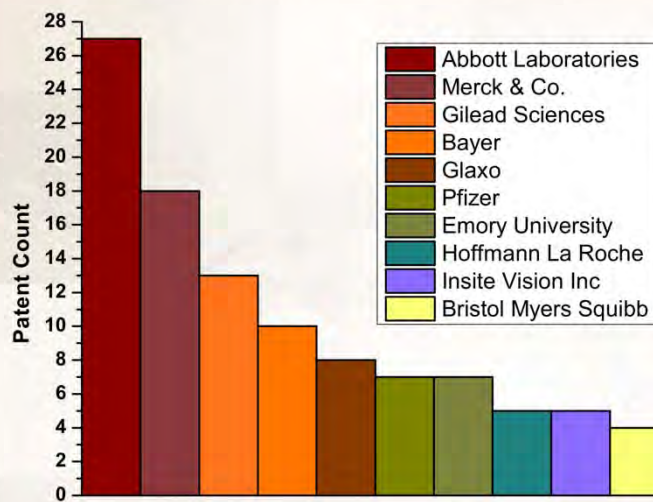
Patent Filing Trends – WHO Regions

WHO Region	Filings Per Region	Countries Per Region	Average Per Country
African Region	70	46	2
Eastern Mediterranean Region	30	21	1
European Region	992	53	19
Region of Americas	238	35	7
South East Asia Region	100	11	9
Western Pacific Region	318	27	12

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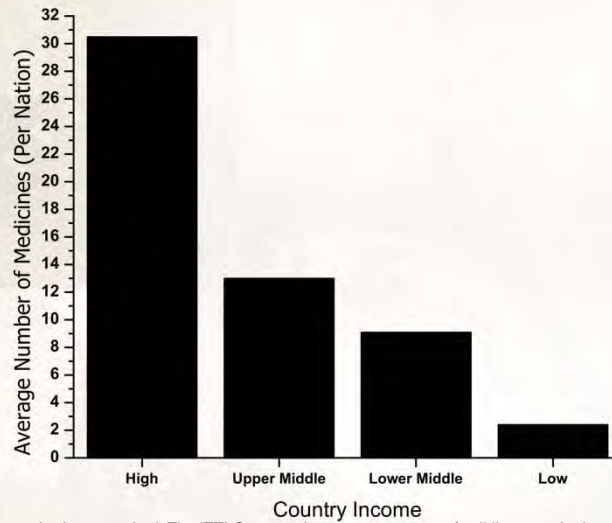
Top Companies



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Medicines vs. Income



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Thank You!!

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Identified patents after 1991

- Lamivudine + Nevirapine + Stavudine
 - **US20080241265A1**
- Stavudine
 - **US5130421A**
- Emtricitabine
 - **US5210085**
- Nevirapine
 - **US5366972A**
- Indinavir
 - **US5413999A**
- Nelfinavir
 - **US5484926A**
- Efavirenz
 - **US5519021A**
- Artemether
 - **US5677331A**
- Omeprazole
 - **US5693818A**
- Atazanavir
 - **US5849911A**
- Tenofovir
 - **US5922695A**
- Lamivudine
 - **US6180639B1**
- Medroxyprogesterone + Estradiol Cypionate
 - **US6495534B2**
- Emtricitabine + tenofovir
 - **WO2004064845A1**
- Efavirenz + Emtricitabine + tenofovir
 - **WO2006135933A2**



Consolidated Countries		Total Patent Countries		DWPI Countries		INPADOC Countries	
Code	Consolidated Country	Code	Total Patent Country	Code	DWPI Country	Code	INPADOC Country
AP	African Regional Intellectual Property Organization	OA	African Intellectual Property Organization	AP	ARIPO	AP	ARIPO
AR	Argentina	AP	African Regional Intellectual Property Organization	AR	Argentina	AR	Argentina
AT	Austria	DZ	Algeria	AU	Australia	AT	Austria
AU	Australia	AR	Argentina	AT	Austria	AU	Australia
BA	Bosnia and Herzegovina	AU	Australia	BE	Belgium	BA	Bosnia
BE	Belgium	AT	Austria	BR	Brazil	BE	Belgium
BG	Bulgaria	BY	Belarus	CA	Canada	BG	Bulgaria
BN	Brunei	BE	Belgium	CN	China	BR	Brazil
BO	Bolivia	BO	Bolivia	CZ	Czech Republic	BY	Belarus
BR	Brazil	BA	Bosnia and Herzegovina	CS	Czechoslovakia	CA	Canada
BY	Belarus	BR	Brazil	DK	Denmark	CH	Switzerland
CA	Canada	BN	Brunei	EP	European Patent Office	CL	Chile
CH	Switzerland	BG	Bulgaria	FI	Finland	CN	China
CL	Chile	CA	Canada	FR	France	CO	Colombia
CN	China	CL	Chile	DE	Germany	CR	Costa Rica
CO	Columbia	CN	China	DE	German	CS	Czechoslovakia
CR	Costa Rica	CO	Columbia	DD	German Dem. Rep.	CU	Cuba
CS	Czechoslovakia	CR	Costa Rica	HU	Hungary	CY	Cyprus
CU	Cuba	HR	Croatia	IN	India	CZ	Czech Republic
CY	Cyprus	CU	Cuba	IE	Ireland	DD	Germany (EX_GDR)
CZ	Czech Republic	CY	Cyprus	IL	Israel	DE	Germany
DD	East Germany	CZ	Czech Republic	IT	Italy	DK	Denmark
DE	Germany	CS	Czechoslovakia	JP	Japan	DO	Dominican Republic
DK	Denmark	DK	Denmark	KR	Rep. of Korea	DZ	Algeria



EA Eurasian Patent Office	EC Ecuador	NL Netherlands	EE Estonia
EG Ecuador	EG Egypt	NZ New Zealand	EG Egypt
EE Estonia	SV El Salvador	NO Norway	EP European Patent Office
EG Egypt	EE Estonia	WO Patent Cooperation Treaty	ES Spain
EP European Patent Office	EA Eurasian Patent Office	PH Philippines	FI Finland
ES Spain	EP European Patent Office	PT Portugal	FR France
FI Finland	FI Finland	RO Romania	GB United Kingdom
FR France	FR France	RU Russian Federation	GC Gulf Coop. Council
GB United Kingdom	DE Germany	SG Singapore	GR Greece
GC Gulf Cooperation Council	GR Greece	SK Slovakia	GT Guatemala
GR Greece	GT Guatemala	ZA South Africa	HK Hong Kong
GT Guatemala	GC Gulf Cooperation Council	SU Soviet Union	HR Croatia
HK Hong Kong	HN Honduras	ES Spain	HU Hungary
HN Honduras	HK Hong Kong	SE Sweden	ID Indonesia
HR Croatia	HU Hungary	CH Switzerland	IE Ireland
HU Hungary	IS Iceland	TW Taiwan	IL Israel
ID Indonesia	IN India	GB United Kingdom	IN India
IE Ireland	ID Indonesia	UK United Kingdom	IS Iceland
IL Israel	IE Ireland	US United States	IT Italy
IN India	IL Israel	PCT Patent Cooperation Treaty	JP Japan
IS Iceland	IT Italy		KE Kenya
IT Italy	JP Japan		KR Republic of Korea
JP Japan	KZ Kazakhstan		KZ Kazakhstan
KE Kenya	KE Kenya		LT Lithuania
KR South Korea	KR Korea, Republic of		LU Luxembourg
KZ Kazakhstan	LV Latvia		LV Latvia
LT Lithuania	LT Lithuania		MA Morocco
LU Luxembourg	LU Luxembourg		MC Monaco

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LV Latvia	MW Malawi	MD Moldova
MA Morocco	MY Malaysia	MN Mongolia
MC Monaco	MT Malta	MT Malta
MD Moldova	MX Mexico	MW Malawi
MM Mongolia	MD Moldova	MX Mexico
MT Malta	MC Monaco	MY Malaysia
MW Malawi	MN Mongolia	NI Nicaragua
MX Mexico	MA Morocco	NL Netherlands
MY Malaysia	NL Netherlands	NO Norway
NI Nicaragua	NZ New Zealand	NZ New Zealand
NL Netherlands	NI Nicaragua	OA OAPI
NO Norway	NO Norway	PA Panama
NZ New Zealand	PA Panama	PE Peru
OA African Intellectual Property Organization	PY Paraguay	PH Philippines
PA Panama	PE Peru	PL Poland
PCT Patent Cooperation Treaty	PH Philippines	PT Portugal
PE Peru	PL Poland	RO Romania
PH Philippines	PT Portugal	RU Russia
PL Poland	RO Romania	SE Sweden
PT Portugal	RU Russia	SG Singapore
PY Paraguay	SG Singapore	SI Slovenia
RO Romania	SK Slovak Republic	SK Slovakia
RU Russia	SI Slovenia	SM San Marino
SE Sweden	ZA South Africa	SU U.S.S.R.
SG Singapore	SU Soviet Union	SV El Salvador
SI Slovenia	ES Spain	TJ Tajikistan
SK Slovak Republic	SE Sweden	TR Turkey
SM San Marino	CH Switzerland	TW Taiwan
SU Soviet Union	TW Taiwan	UA Ukraine

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SV	El Salvador	TI	Tajikistan	US	U.S.A.
TH	Thailand	TH	Thailand	UY	Uruguay
TJ	Tajikistan	TT	Trinidad and Tobago	VN	Viet Nam
TR	Turkey	TR	Turkey	WO	W.I.P.O (P.C.T.)
TT	Trinidad and Tobago	UA	Ukraine	YU	Yugoslavia
TW	Taiwan+839	GB	United Kingdom	YU	SERBIA and MONTENEGRO
UA	Ukraine	US	United States	ZA	South Africa
UK	United Kingdom	UY	Uruguay	ZM	Zambia
US	United States	UZ	Uzbekistan	ZW	Zimbabwe
UY	Uruguay	VN	Vietnam		
UZ	Uzbekistan	WO	World Intellectual Property Organization		
VN	Vietnam	YU	Yugoslavia		
WO	World Intellectual Property Organization	ZM	Zambia		
YU	Yugoslavia	ZW	Zimbabwe		
ZA	South Africa				
ZM	Zambia				
ZW	Zimbabwe				

