

# Meds Pall THE MEDICINES PATENTS AND LICENCES DATABASE

www.medspal.org



### THE MEDICINES PATENT POOL

**Created in 2010** as first voluntary licensing and patent pooling mechanism in public health

To increase access to new treatments for HIV through licensing of patented medicines

#### And facilitate innovation

e.g. new fixed dose combinations and paediatric formulations

In 2015, expanded mandate to **Hepatitis C** and **Tuberculosis** 

In 2018, decision to expand to **other patented essential medicines** 



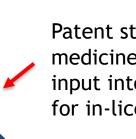
MPP's activities in HIV, HCV and TB are funded by:





#### WHY DID WE START COLLECTING PATENT DATA?





Patent status of medicines is one key input into prioritization for in-licensing



Facilitate access to affordable medicines for people in LMICs



Approach patent holders





Facilitate development of needed formulations

Negotiate public health oriented licences



Sub-license to generics





- In order to prioritize medicines for in-licensing, the MPP set out to collect patent status data on HIV medicines from LMICs
- Through national patent searches and the support of WIPO and many patent offices the MPP managed to obtain information for a large number of LMICs
- Many requests for data from public health stakeholders convinced MPP to make data public



#### MAKING PATENT DATA PUBLIC

April 2011: launch of the MPP Patent Status
Database, an enhanced worksheet including 24 HIV medicines in 88 countries



October 2016: launch of
MedsPaL as the most
comprehensive source of
information on the patent and
licensing status of medicines for
HIV, TB, hepatitis C and other
patented essential medicines in
low- and middle-income
countries





#### INITIAL FEEDBACK FROM STAKEHOLDERS



"The Medicines Patent Pool's Patent Status Database for Selected HIV Medicines takes an invaluable step towards furthering access to treatment of HIV/AIDS amassing information from numerous patent registries and jurisdictions into an easily navigable resource available to the public"

"The Medicines Patent Pool database is an essential impartial reference source for Global Fund Principal Recipients to understand the patent status of ARVs in their country - and it should be further expanded to include more countries."





"In the midst of a current patent regime that is at times not so transparent, this database is a great and valuable tool for players in the field, and one we regularly check as part of our procedures for determining a patent status. [It] ultimately allow[s] us to focus more of our energy into the actual delivery of HIV medicines to the ones who need it."

"The patent status database is an incredibly useful resource as it provides the most comprehensive pool of the available information on patent statuses, and combines this into one easy to use search engine."





### WHY DO WE NEED MEDSPAL?

## KEY QUESTION: IS MEDICINE "X" PATENTED IN COUNTRY "Y"?

Example: Lopinavir



#### LOPINAVIR BASIC COMPOUND PATENT



#### United States Patent [19]

Sham et al.

54]	RETROVIRAL PROTEASE INHIBITING	
	COMPOUNDS	

[75] Inventors: Hing Leung Sham, Mundelein; Daniel W. Norbeck, Crystal Lake; Xiaoqi Chen, Libertyville; David A. Betebenner, Gurnee, all of Ill.

[73] Assignee: Abbott Laboratories, Abbott Park, Ill.

[21] Appl. No.: 08/753,201

Nov. 21, 1996 Filed:

#### Related U.S. Application Data

[63] Continuation-in-part of application No. 08/572,226, Dec. 13, 1995, abandoned.

A61K 31/535; C07D 239/10 [52] U.S. Cl. ...... ..... 514/274; 514/211; 514/218; 514/228.8; 514/256; 514/376; 514/377;

514/392; 540/488; 540/492; 544/88; 544/97; 544/316; 544/332; 548/229; 548/233; 548/324.1; 548/331.5

548/233, 324.1, 331.5; 544/88, 316, 97, 332; 540/488, 492; 514/211, 218, 228.8,

274, 376, 392, 256, 377

#### [56] References Cited

#### U.S. PATENT DOCUMENTS

5,142,056	8/1992	Kempf et al.	 546/265
5,354,866	10/1994	Kempf et al.	 546/265
5,541,206	7/1996	Kempf et al.	 514/365

#### FOREIGN PATENT DOCUMENTS

0005689 11/1979 European Pat. Off. .

5,914,332 [11] Patent Number:

Date of Patent: Jun. 22, 1999

0342541 11/1989 European Pat. Off. . 365992 5/1990 European Pat. Off. . European Pat. Off. . 0428849 5/1991 1/1994 European Pat. Off. . 0580402 8910752 11/1989 WIPO .

4/1993

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#### WIPO . OTHER PUBLICATIONS

Scholz, et al., J. of Med. Chem. 37 3079-3089 (1994). Jindrich et al., Collect Czech. Chem. Commun 58 (7) 1645-1667 (1993).

Y. Becker et al., J. Org. Chem., vol. 45, (1980), pp. 2145-2151.

H. Takechi et al., Chem. Pharm. Bull., vol. 34, No. 8 (1986), pp. 3142-3152.

A. Smith et al., J. Am. Chem. Soc., vol. 117, (1995), pp. 11113-11123.

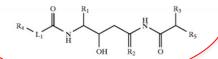
J. Vacca et al., Bioorg. Med. Chem. Lett., vol. 4, (1994), pp.

R. Randad et al., Bioorg. Med. Chem. Lett., vol. 4, (1994), pp. 1247-1252.

Primary Examiner-Richard L. Raymond Attorney, Agent, or Firm Steven R. Crowley

ABSTRACT

A compound of the formula:



is disclosed as an HIV protease inhibitor. Methods and compositions for inhibiting an HIV infection are also disclosed.

#### 17 Claims, No Drawings

**PCT** 

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: WO 97/21683 (11) International Publication Number: C07D 233/32, 239/10, 239/22, 207/40, A1 (43) International Publication Date: 19 June 1997 (19.06.97) 207/26, 241/08, 263/22, A61K 31/415 (81) Designated States: CA, JP, MX, European patent (AT, BE, (21) International Application Number: PCT/US96/19394 CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, (22) International Filing Date: 6 December 1996 (06.12.96)

(30) Priority Data:

08/572,226 13 December 1995 (13.12.95) US 21 November 1996 (21.11.96) 08/754,687

(71) Applicant: ABBOTT LABORATORIES [US/US]; CHAD 0377/AP6D-2, 100 Abbott Park Road, Abbott Park, IL 60064-3500 (US),

(72) Inventors: SHAM, Hing, Leung; 212 Knightsbridge Drive, Mundelein, IL 60060 (US). STEWART, Kent, D.; 4715 Kings Way North, Gurnee, IL 60031 (US). KEMPF, Dale, J.; 256 Tyler, Libertyville, IL 60048 (US).

(74) Agents: CROWLEY, Steven, R. et al.; Abbott Laboratories, CHAD 0377/AP6D-2, 100 Abbott Park Road, Abbott Park, IL 60064-3500 (US).

Published

With international search report.

(54) Title: RETROVIRAL PROTEASE INHIBITING COMPOUNDS

(57) Abstract

Inhibitors of HIV protease are provided. When bound to HIV protease, the inhibitors are characterized by a unique three-dimensional conformation and orientation relative to the S1, S1', S2, S2', S3, and S3' subsites of the protease. Pharmaceutical compositions containing the inhibitors and methods of treating HIV infection are also provided.

> Priority date: 1995 Filing date: 1996





Search
"Lopinavir" in
abstract of US
granted
patents

Hits: 21

Earliest date: 2001

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Searching US Patent Collection					
Results of Search in US Patent Collecti ABST/lopinavir: 21 patents. Hits 1 through 21 out of 21	on db for:				
Jump To					
Refine Search ABST/lopinavir					

20 6.864.369 T Crystalline pharmaceutical 21 6.608.198 T Crystalline pharmaceutical

Title 1 9.782.409 ■ Treatment of cancer and benign proliferative disorders 2 9.713.622 Schedules for administering combination therapies useful for treating persons afflicted with the human immunodeficiency virus (HIV) 3 9.532.979 Compositions of lopinavir and ritonavir 4 9.370,578 Dosage form comprising lopinavir and ritonavir 5 9.198.912 Tschedules for administering combination therapies useful for treating persons afflicted with the human immunodeficiency virus (HIV) 6 9.174.944 Tervstalline lopinavir/surfactant adducts 7 8.895.051 ■ Flavoring systems for pharmaceutical compositions and methods of making such compositions 8 8.796.451 Crystalline pharmaceutical 9 8.501,219 Flavoring systems for pharmaceutical compositions and methods of making such compositions 10 8,445,506 Polymorphs of lopinavir 11 8.236.991 Process for the preparation of substantially pure (2S,3S,5S)-5-amino-2-N,N-dibenzylamino-3-hydroxy-1.6-diphenylhexane 12 8.058.433 Crystalline pharmaceutical 13 7,906.629 T Protease inhibitor conjugates and antibodies useful in immunoassay 14 7.649.085 Saguinavir conjugates and antibodies useful in immunoassay 15 7.615.542 Dioxolane thymine and combinations for use against 3TC/AZT resistant strains of HIV 16 7,569.678 Protease inhibitor conjugates and antibodies useful in immunoassay 17 7.482.437 T Protease inhibitor conjugates and antibodies useful in immunoassay 18 7.193.065 Protease inhibitor conjugates and antibodies useful in immunoassay 19 6.911.214 T Flavoring systems for pharmaceutical compositions and methods of making such compositions





#### **US PATENT & TRADEMARK OFFICE**

PATENT APPLICATION FULL TEXT AND IMAGE DATABASE

 Help
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 PTDLs

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Search
"Lopinavir" in
published
applications

Hits: 4305

	Searci	hing	App	FTI	Datai	base
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Results of Search in AppFT Database for: Lopinavir: 4305 applications. Hits 1 through 50 out of 4305

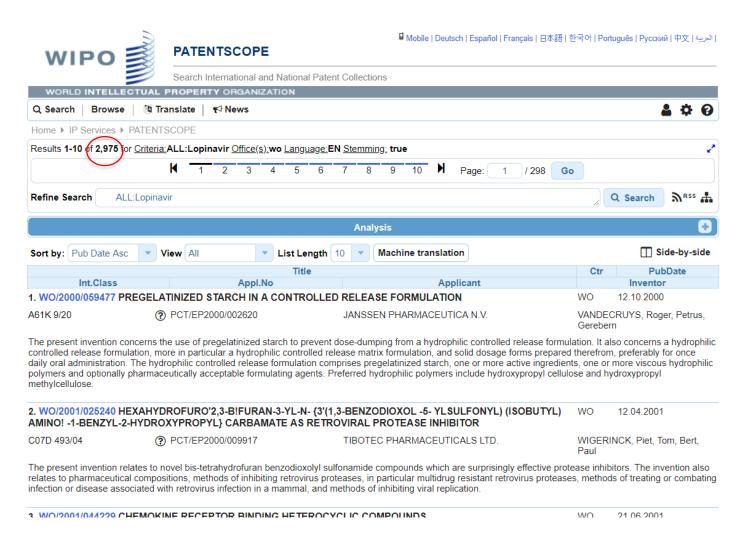
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Refine Search Lopinavir	

#### PUB. APP. Title

- 1 20180334732 COMPOSITIONS AND METHODS FOR HIV QUASI-SPECIES EXCISION FROM HIV-1-INFECTED PATIENTS
- 2 20180334430 ARYLSULFANYL COMPOUNDS AND COMPOSITIONS FOR DELIVERING ACTIVE AGENTS
- 3 20180333411 METHODS OF TREATMENT
- 4 20180333410 METHOD OF TREATING A PATIENT WITH A CYP3A4 SUBSTRATE DRUG
- 5 <u>201803333409</u> <u>METHOD OF TREATING A PATIENT WITH A CYP3A4 SUBSTRATE DRUG</u>
- 6 20180333362 Pulsed extended-pulsed and extended-pulsed pulsed drug delivery systems
- 7 20180333296 DRUG DELIVERY IMPLANTS AS INTRAOCULAR DRUG DEPOTS AND METHODS OF USING SAME
- 8 <u>20180327834</u> METHODS AND SYSTEMS FOR GENETIC ANALYSIS
- 9 20180327725 TATk-CDKL5 Fusion Proteins, Compositions, Formulations, And Use Thereof
- 10 20180327411 INDOLE AHR INHIBITORS AND USES THEREOF
- 11 20180326018 ALKALINE PHOSPHATASE FORMULATIONS
- 12 20180325927 Amido-Substituted Pyridotriazine Derivatives Useful As HIV Integrase Inhibitors
- 13 20180325926 Spirocyclic Pyridotriazine Derivatives Useful As HIV Integrase Inhibitors
- 14 <u>20180325889</u> <u>IMMUNOREGULATORY AGENTS</u>



### Search "Lopinavir" in all searchable fields



Hits: 2975 Earliest date: 2000



### Search "Lopinavir" in the field "abstract"



Acesso à informação



Instituto Nacional da

#### Propriedade Industrial

Ministério do Desenvolvimento, Indústria e Comércio Exterior

Consulta à Base de Dados do INPI

[ Início | Ajuda? ]

» Consultar por: Base Patentes | Finalizar Sessão

#### **RESULTADO DA PESQUISA** (29/11/2018 às 11:35:49)

#### Pesquisa por:

Resumo: 'LOPINAVIR' \

Foram encontrados 6 processos que satisfazem à pesquisa. Mostrando página 1 de 1.

orani cheomadays o p	occosos que	Sadisfazerii a pesquisa. Mostrando pagina 2 de 2.	
Pedido —	Depósito	Título	IPC
BR 11 2015 028644 5		COMPOSIÇÕES DE CENICRIVIROC E MÉTODOS DE CRIAÇÃO E USO DO MESMO	A61K 31/55
PI 1103593-5	10/0//2011	REFERIDO COMPOSTO E USO DO MESMO	C07D 277/20
PI 0714265-0	10/08/2007	COMPOSIÇÃO ORAL SÓLIDA, PROCESSO PARA PREPARAR UMA COMPOSIÇÃO ORAL SÓLIDA, USO DE UMA COMPOSIÇÃO E MÉTODO PARA TRATAR HIV	A61K 31/427
PI 0317113-2	08/12/2003	DE HIV	A61K 31/70
PI 0108433-0	04/09/2001	TAIS COMPOSIÇOES	A61K 31/425
PI 0109433-5	21/03/2001	SUBSTÂNCIA FARMACÊUTICA CRISTALINA	C07D 239/00

Páginas de Resultados:

1

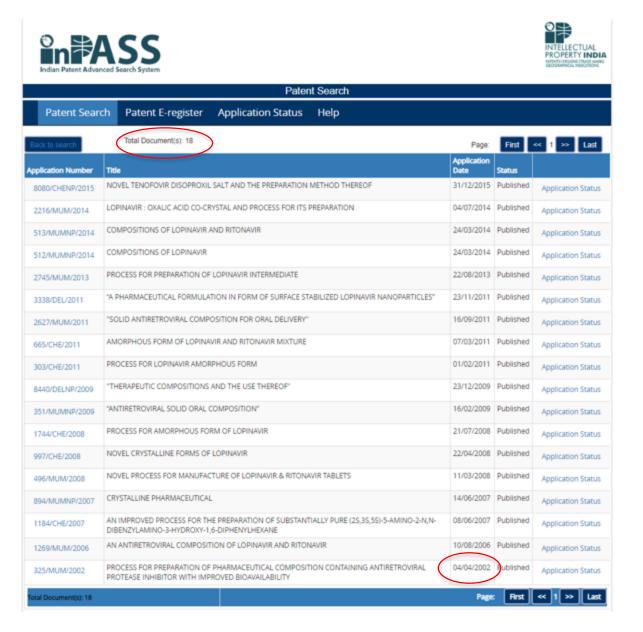


#### **INDIA**

Search
"Lopinavir" in
the field
"abstract"

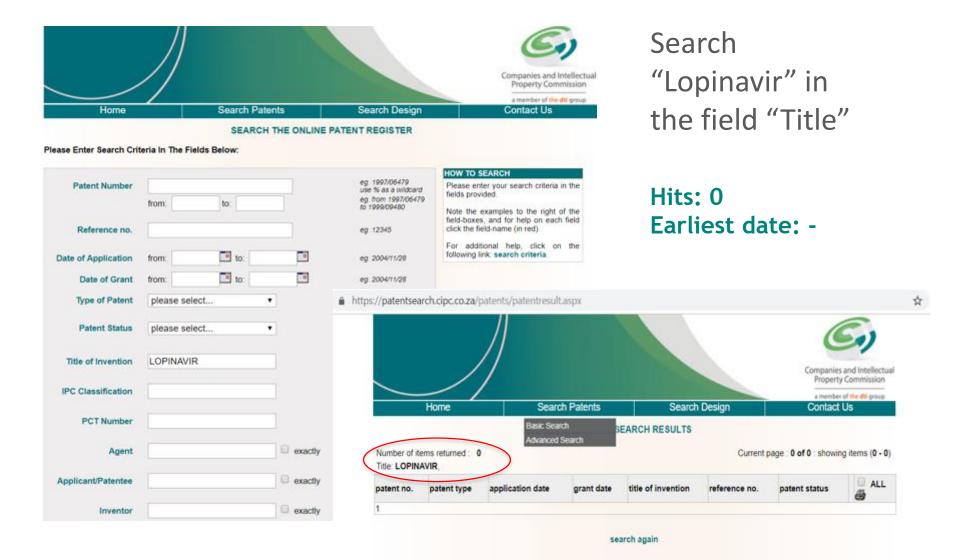
**Hits: 18** 

Earliest date: 2002





#### **SOUTH AFRICA**





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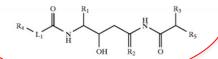
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Primary Examiner-Richard L. Raymond Attorney, Agent, or Firm Steven R. Crowley

ABSTRACT

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is disclosed as an HIV protease inhibitor. Methods and compositions for inhibiting an HIV infection are also disclosed.

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(51) International Patent Classification 6: WO 97/21683 (11) International Publication Number: C07D 233/32, 239/10, 239/22, 207/40, A1 (43) International Publication Date: 19 June 1997 (19.06.97) 207/26, 241/08, 263/22, A61K 31/415 (81) Designated States: CA, JP, MX, European patent (AT, BE, (21) International Application Number: PCT/US96/19394 CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, (22) International Filing Date: 6 December 1996 (06.12.96)

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> Priority date: 1995 Filing date: 1996



### MEDSPAL CONTENT





## MedsPal THE MEDICINES PATENTS AND LICENCES DATABASE

MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in low- and middle-income countries. For more detailed and up-to-date information on a given patent application, MedsPaL users are encouraged to contact the national patent office or consult legal counsel.

Additional information and disclaimer

### www.medspal.org



Patent status data from over **110** lowand middle-income countries



Data exclusivity information from 15 countries



Covering approx. 70 medicines (over 130 formulations).



Information on all relevant licences in LMICs

## medicines patent pool

#### PATENT DATA IN MEDSPAL

**Medicines** for the treatment of HIV, hepatitis C and tuberculosis that are (or were) included in WHO treatment guidelines and expanded to include patented medicines on the **WHO Essential Medicines List** (**Total: 70 medicines, over 130 formulations**)

Over 210 patent families were identified and included in MedsPaL based on disclosures by patent holders to the USFDA Orange Book and Health Canada Patent Registry and supplemented with patent families disclosed in licences and in patent landscapes of reputable organizations (e.g. WHO).

MedsPaL includes patent status data on over 6,000 national patents or patent applications



### PATENT SEARCHES IN MEDSPAL







SIGN UP FOR UPDATES

## MedsPaL

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Additional information and disclaimer





### **EXAMPLE – SEARCH RESULTS**



Coun	try	Product Name(s)	Patent Description	Patent Status	Patent Application Date (dd/mm/yyyy)	Patent Application Number	Publication / Grant Number(s)	Expected Expiry Date (dd/mm/yyyy)
8	Argentina	Bedaquiline 100 mg	Bedaquiline fumarate salt	Rejected	05/12/2007	ARP070105442	AR064149A1	
			Bedaquiline to treat MDR TB	Withdrawn	27/05/2005	ARP050102200	AR049127A1	
			Bedaquiline to treat latent TB	Withdrawn	09/12/2005	ARP050105140	AR051790A1	
			Bedaquiline compounds family	Granted	24/07/2003	ARP030102655	AR040673A1	24/07/2023
	South Africa	Bedaquiline 100 mg	Bedaquiline compounds family	Granted	24/01/2005	ZA200500680	ZA200500680B	18/07/2023
			Bedaquiline to treat MDR TB	Granted	27/11/2006	ZA200609899	ZA200609899B	24/05/2025
		Bedaquiline to treat latent TB	Granted	22/06/2007	ZA200705160	ZA200705160B	08/12/2025	
			Bedaquiline process	Granted	26/11/2007	ZA200710150	ZA200710150B	22/05/2026
			Bedaquiline fumarate salt	Granted	04/06/2009	ZA200903907	ZA200903907B	03/12/2027



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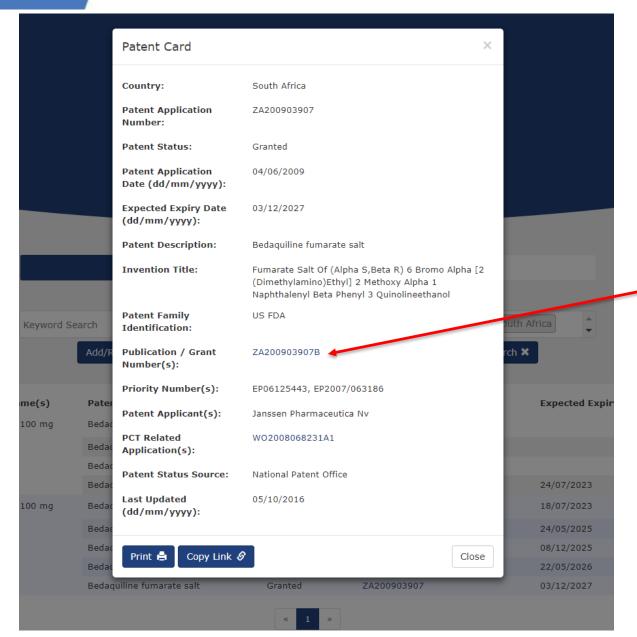
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		Bedaquiline to treat latent TB	Granted	22/06/2007	ZA200705160	ZA200705160B	08/12/2025
		Bedaquiline process	Granted	26/11/2007	ZA200710150	ZA200710150B	22/05/2026
		Bedaquiline fumarate salt	Granted	04/06/2009	ZA200903907	ZA200903907B	03/12/2027



#### **EXAMPLE – PATENT CARD**



Link, if available, to ESPACENET, the EPO database that provides patent information (in many cases including legal status) for 103 countries, including 51 LMICs.



#### **SEARCHING FOR LOPINAVIR IN MEDSPAL**





#### **SEARCHING FOR LOPINAVIR IN MEDSPAL**





### LICENCE INFORMATION IN MEDSPAL



#### INFORMATION ON LICENCES INCLUDED

### **Types of Licences**

Licences negotiated by the Medicines Patent Pool

Bilateral licences between originators and generics

Commitments not to enforce patents on a given product

Compulsory licences

### Information in MedsPaL

Full information on the licences incl. links to summaries and full text

Information on countries, products, licensees (where public or provided by patent holder for public disclosure)

Information on countries and products

Based on publicly available information





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Additional information and disclaimer

	SEARCH VIEW		MA	AP VIEW	
daclatasvir	3	× Daclatasvir 30 mg	Å ×In	dia × South Africa	^ ~
A	Add/Remove Columns 🌣	Export Patent Data 生	Share This Search 🔗	Clear Search 🗙	

Showing result 1 out of 1 total results

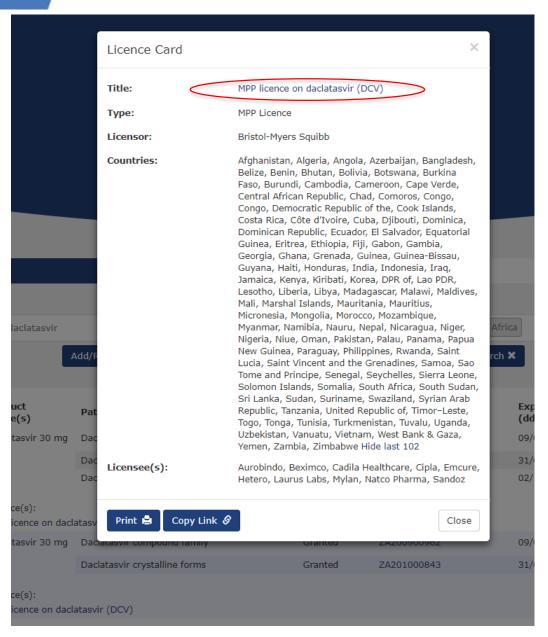
Count	ry	Product Name(s)	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date (dd/mm/yyyy)
•	India	Daclatasvir 30 mg	Daclatasvir compound family	Filed	IN853/DELNP/09	09/08/2027
			Daclatasvir crystalline forms	Filed	IN806/DELNP/2010	31/07/2028
			Daclatasvir intermediate manufacturing process	Filed	IN3999/CHENP/2012	02/11/2030
		Licence(s):  MPP licence on daclatasvir (DCV)				
	South Africa	Daclatasvir 30 mg	Daclatasvir compound family	Granted	ZA200900962	09/08/2027
			Daclatasvir crystalline forms	Granted	ZA201000843	31/07/2028

Licence(s):

MPP licence on daclatasvir (DCV)



#### **EXAMPLE – LICENCE CARD**





## LICENCE SUMMARIES AND FULL TEXT OF MPP LICENCES

From the licence card, users can access further information on MPP licences

This includes a summary of key features and full text of MPP licences

Links to information about other licences also included where available

#### DACLATASVIR (DAC)

COMPANY: BRISTOL-MYERS SQUIBB DATE: NOVEMBER 2015



In November 2015, the MPP announced a licensing agreement with Bristol-Myers Squibb covering the direct-acting antiviral (DAA) drug, daclatasvir (DAC), and its combinations. The agreement allows generic manufacture of the hepatitis C treatment for sale in **at least 112 countries** that together are home to 65.4% of people living with HCV in low- and middle-income countries.



LICENCE AGREEMENT



SUBLICENCE AGREEMENT - FORM



EATURES



SS



CHAIRMAN'S SUMMARY



ADVISORY GROUP REPORT



COUNTRY LIST



ADDITIONAL INFORMATION



## LICENCE SUMMARIES AND FULL TEXT OF MPP LICENCES

From the licence card, users can access further information on MPP licences

This includes a summary of key features and full text of MPP licences

Links to information about other licences also included where available

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- SUBLICENCE AGREEMENT - FORM





ADVISORY GROUP REPORT







TRY ADDITIONAL
T INFORMATION



## DATA EXCLUSIVITY INFORMATION IN MEDSPAL



## HOW IS INFORMATION ON DATA EXCLUSIVITY OBTAINED?

- Data exclusivity: Some LMICs have adopted regulations providing for data exclusivity (DE) in relation to the submission of pharmaceutical test data to regulatory authorities for approval of new medicines
- Data on MedsPaL: data from 15 countries has been collected for HIV, TB and HCV medicines with expiry dates and will be supplemented further as data is gathered
- Source of data: National regulatory authorities (sometimes aided by patent offices or local experts)



### **EXAMPLE - DATA EXCLUSIVITY**

SIGN UP FOR UPDATES



### MedsPaL

MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in low- and middle-income countries. For more detailed and up-to-date information on a given patent application, MedsPaL users are

Additional information and disclaimer

encouraged to contact the national patent office or consult legal counsel.

Showing result 1 out of 1

Country	Product Name(s)	Patent Description	Patent Status	<b>Patent Application Number</b>	Expected Expiry Date (dd/mm/yyyy)
Ukraine	ine Darunavir/Cobicistat 800/150 mg	Cobicistat compound	Granted	UA2008014338	06/07/2027
		Cobicistat compound	Granted	UA200909677	22/02/2028
		Cobicistat tablets	Granted	UA2010014398	01/05/2029
		Cobicistat tablets	Granted	UA2011010569	04/02/2030
		Cobicistat intermediates	Granted	UA2011011540	01/04/2030
		Darunavir compound	Not Filed		

Data Exclusivity:

Test data exclusivity until 15/09/2021

Licence(s):

Bilateral licences on COBI MPP licence on cobicistat (COBI)



### **MAP VIEW - NEW FEATURE**



### MedsPaL

MedsPaL provides information on the patent and licensing status of selected HIV, hepatitis C, tuberculosis and other patented essential medicines in low- and middle-income countries. For more detailed and up-to-date information on a given patent application, MedsPaL users are encouraged to contact the national patent office or consult legal counsel.

Additional information and disclaimer





#### HIGHLIGHT COUNTRIES ON THE MAP

- With at least one patent granted/filed
- With at least one compound patent granted/filed
- Included in licence(s)

Select a country to see patent(s)/patent application(s)



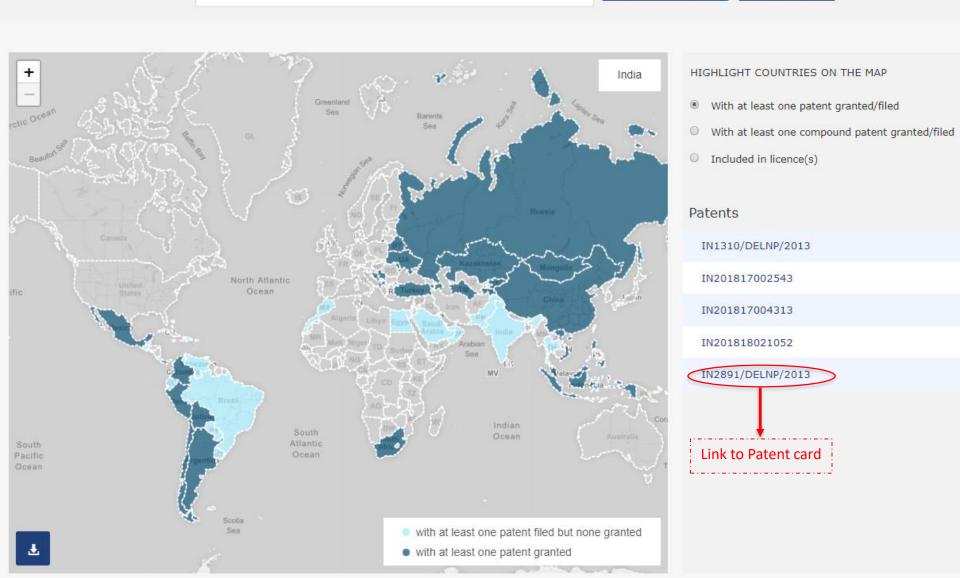
### **MAP VIEW- PATENT INFORMATION**

Select a product to display related patent or licence information per country directly on the map.

Glecaprevir/Pibrentasvir 100/40 mg

Share This Search 8

Clear search \*





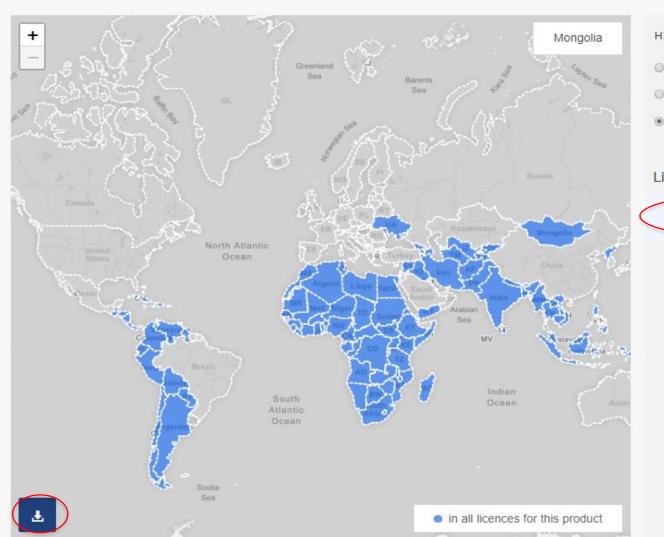
#### **MAP VIEW – LICENCE INFORMATION**

Select a product to display related patent or licence information per country directly on the map.

Dolutegravir 10 mg

Share This Search 8

Clear search X



#### HIGHLIGHT COUNTRIES ON THE MAP

- With at least one patent granted/filed
- With at least one compound patent granted/filed
- Included in licence(s)

#### Licences

MPP licence on paediatric formulations of dolutegravir (DTG)

Link to Licence card



### **UPDATES**



## HOW IS NATIONAL/REGIONAL PATENT DATA OBTAINED?

Automatic data feeds from Esp@acenet



National patent collections on PatentScope



- Patent holder disclosures
  - MPP licences, Pat-INFORMED, disclosures to patent offices
- National / Regional Patent Offices
  - On-line searches, direct communications with patent office, local experts
  - MOUs with patent offices



### MOUS WITH NATIONAL/REGIONAL PATENT OFFICES











**ARIPO** 

**El Salvador** 

**South Africa** 

**EPO** 

Chile











**Argentina** 

**Ecuador** 

**Brazil** 

**Uruguay** 

**Dominican Republic** 

The MPP looks forward to expanding its network of collaborating patent offices



### MOUS WITH NATIONAL/REGIONAL PATENT OFFICES

- Commitment to collaborate in undertaking a small number of patent searches on essential medicines (approximately 30 searches a year per patent office)
- To verify the legal status of the patents or patent applications and the expected expiry date
- Agreement that information can be included in MedsPaL with a disclaimer inviting users to contact the patent office if they need further information on a given patent



The MPP's HIV, TB and hepatitis C activities are fully funded by:





### THANK YOU

@MEDSPATENTPOOL
WWW.MEDICINESPATENTPOOL.ORG
WWW.MEDSPAL.ORG

Eburrone@medicinespatentpool.org